Analysis of measures geared to the sustainable use of biocidal products

FINAL REPORT

070307/2013/668685/ETU/ENV.A.3

EUROPEAN COMMISSION

Directorate-General for Health and Food Safety
Directorate DDG2.E – Safety of the food chain
Unit SANTE.DDG2.E.3 - Pesticides and Biocides

Contact: Mr Christophe Kusendila

E-mail: christophe.kusendila@ec.europa.eu

European Commission
B-1049 Brussels

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Milieu Ltd, Chaussee de Charlerloi 112, B-1060 Brussels, tel: 32 2 506 1000; e-mail: josephine.armstrong@milieu.be; web address: www.milieu.be.

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EXECUTIVE SUMMARY

The overall objective of the study is to provide the European Commission with information on how the application of the BPR contributes to the sustainable use of biocides, to feed into the European Commission's report to the European Parliament and the Council, which is to be provided by 18 July 2015. This shall include information on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to human and animal health and the environment by biocidal products.

While the BPR does include a number of provisions addressing the use phase, it does not specifically regulate the use phase. However, to an extent the sustainable use of biocides is already addressed during the active substance approval and product authorisation processes. The following aspects of the BPR are thus considered to contribute to the sustainable use of biocidal products:

- The approval of an active substance, in particular the exclusion criteria and the substitution principle, which prohibits and substitutes the substances of most concern;
- The authorisation scheme for biocidal products, for the authorisation and the use of products where risks are controlled;
- The simplified authorisation procedure under Chapter V of the BPR; and
- The provisions on research and development, providing better supervision of those activities; and

The study involved stakeholder consultation and follow-up interviews with Member State competent authorities, companies and industry associations, and non-governmental organisations in order to obtain information on the measures taken with regard to the sustainable use of biocidal products, and views on further measures that could be adopted. Legal and technical analysis was also undertaken as part of the study.

Overall 114 responses were received to the questionnaires issued to industry stakeholders, and non-governmental organisations. Of these 114 responses, 4 responded simply that the questionnaire was not relevant to their operations since they only manufactured an active substance and were not responsible for placing a biocidal product on the market. The remaining 110 responses are made up of 104 responses from companies and industry associations, and six responses from non-governmental organisations. 21 Member States responded to the questionnaire for competent authorities.

Based on the responses received from stakeholders and further analysis, the report draws together the information on the various aspects set out in Article 18 of the BPR and makes recommendations as to further measures to be adopted.

Monitoring

Monitoring of the use of biocidal products is required as data is currently lacking and very little information is collected at present across the Member States. The information provided by Member States on data collected indicates that very few of them collect data on the use of biocidal products. Of those that do, the data collected is limited as covers data on the placing on the market of biocidal products (i.e. sales data), rather than actual use. There are currently no available IT tools in the Member States, which could be developed for use across the EU-28 in order to monitor the use of biocidal products. The SIMMBAD tool used in France, is the most advanced system of data collection, but its functionality has to a large part been superseded by the European Chemicals Agency (ECHA) IT tool, the Register for Biocidal Products (R4BP).

It therefore appears that the R4BP would be the most appropriate way at the EU level to promote harmonised monitoring of the use of biocidal products. The following recommendations regarding monitoring are made:

1. As a first step, authorisation holders should be required to provide data on the annual amounts of biocidal products placed on the market in each Member State. There is adequate provision under Article 68(1) BPR for competent authorities to request that records of biocidal products placed on the market be made available. This information should therefore be requested by each Member State from authorisation holders;

2. The Commission could investigate with ECHA the possibility of extending the functionality of R4BP in order that it serves as an EU-wide tool for the collection of data. If considered appropriate, an individual module could be included to allow for the direct submission of information on use. .

3. In order to collect data on use of biocidal products, a reporting requirement could be imposed on professional users. .

Additional measures to reduce risk

As to whether additional measures are needed to reduce the risks associated with biocidal products, especially in specific areas, the study concluded that the risks are already appropriately addressed by the use restrictions under the conditions of approval of the active substance and authorisation of the biocidal product. Any additional exposure risk arises from the poor application of recommended control measures. Additional measures to ensure the proper application of identified risk mitigation measures, consist mainly of measures to increase the dissemination of information to the end-user, education and training. Other measures on the development of best practices are also recommended.

Training and certification

The key measures to reduce the risks from the use of biocidal products are training and certification. Whilst it is not considered appropriate to extend the scope of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides (the Sustainable Use Directive) to biocidal products, due to the number and diverse nature of biocidal products, the provisions of this Directive on training and certification are also relevant for biocidal products. It is therefore recommended that the principles of integrated pest management (IPM) should be adapted to specific biocidal product types, as part of the development of best practices for that product type and thereafter incorporated within a training scheme and certification for biocidal products.

Training is a key measure to ensure the sustainable use of biocidal products. In approximately half of the Member States, a system of certified training is more or less in place, in addition to other forms of training operated internally by companies. It is recommended that this could be harmonised at the EU level, by introducing a requirement for all professional users and distributors of biocidal products to have access to appropriate training, to establish certification systems, and designate the areas of activity that should be covered. Based on a review of existing certification systems in Member States, this aspect is already well advanced in most of them in the field of disinfection and pest control, and will be aided by the development of the CEN 16636 standard for pest management services. A certification scheme should also be considered for wood preservation products and antifouling products. A phased approach to the introduction of training requirements for all professional users should be adopted according to product type as required.

IPM and best practices

In addition to the inclusion of IPM principles and best practice documentation as part of a training and certification scheme, a number of options could be used to encourage the dissemination of best practice and to ensure compliance with these. The following recommendations are made:

1. Link with product authorisation – the product authorisation could refer to the relevant guidance/best practice documents;

2. Voluntary standards - company or industry voluntary standards should include adherence to guidance/best practice documentation where appropriate;

3. Best available techniques reference documents (BREFs) – future BREFs could refer to guidance/best practice documents on the sustainable use of biocides in that sector.

4. Where there is a need to develop further guidance/best practice for an activity or for the use of individual product types, the Commission could look to establish specific working groups for the industry sectors concerned, or support industry initiatives on this. The creation of working groups and framework for the development of BREFs could serve as an example for EU-wide collaboration on the development of best practices for sustainable use of biocides.

5. In the absence of a formal legal requirement to establish national action plans for the sustainable use of biocidal products, the Commission could seek to support initiatives taken at the Member State level to develop strategies on the sustainable use of biocides which incorporate best practices.

Information and awareness-raising

With regard to information and awareness-raising, Member States are already required to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use under Article 17(5) BPR. However, further measures are required to ensure that information is reaching the end-user. The following recommendations are therefore made:

1. To make information accessible to all users, it is recommended that the Commission considers establishing a website which acts as a database of all available guidance and other information on the sustainable use of biocidal products.

2. Awareness raising campaigns for general consumers of biocidal products should be carried out at EU and national level.

3. Depending on the needs identified by follow-up measures, targeted campaigns should be implemented, if necessary.

4. Information websites or other means should be used to inform the consumer, e.g. quick response codes providing link to manufacturers website or mobile phone applications providing more information on the product. In-store leaflets summarising the critical steps for use of the product, and for the protection of man and the environment, could also be produced .

Annual fees for biocidal products

Member States should consider levying annual fees which are proportional to the degree of risk of the biocidal product, payable by the authorisation holder, in order to

encourage the placing on the market and the sustainable use of biocidal products. This is referred to within guidance produced by the European Commission but could be further encouraged at the EU level, through amendments to Regulation (EU) No 564/2013 on the fees and charges payable to ECHA, following its review.

Tools to stimulate innovation and the development of new products

The analysis of the criteria under Regulation (EC) No 66/2010 on the EU Eco-label, and the criteria applied by other national eco-label schemes in Germany and Norway, show that biocidal products are not suitable for an eco-label.

Schemes other than an eco-label that highlight the environmental and public health profile of biocidal products were also generally considered not to be suitable for biocidal products. However, a number of voluntary schemes do exist across the EU which highlight the environmental and public health profile of particular products. In each case these have been developed by industry, where individual companies have developed a process to assist them in making internal decisions over the choice of raw materials. These schemes play a useful part in the development of products that have a better environmental and public health profile and help stimulate innovation in this regard.

Initiatives by industry associations such as the International Association for Soaps, Detergents and Maintenance Products Charter for Sustainable Cleaning are also considered particularly useful and therefore the development of a similar approach to other groups of biocidal products should be encouraged.

With regard to steps that could be taken on an EU-wide level to highlight products which have a better environmental and public health profile, the Viennese Database for Disinfectants in Austria could serve as an example, and be developed further at an EU-level in order to provide a tool for the selection of products that have a lower impact on the environment and human health. Using the information available in R4BP, the European Commission/ECHA could develop an EU-wide version of the database, for each product type.

Finally, with regard to the advertising restrictions set out in Article 72 BPR, it is proposed that the BPR could be amended so as to include an exemption to the advertising restrictions for those products authorised by the simplified authorisation procedure. Use of the term ‘natural’ should however remain prohibited.

SOMMAIRE EXECUTIF

L'objectif global de l'étude est de fournir à la Commission européenne des informations sur la façon dont l'application du RPB contribue à l'utilisation durable des biocides, afin d'alimenter le rapport de la Commission européenne au Parlement européen et au Conseil, qui doit être fourni d'ici au 18 juillet 2015 . Ce rapport doit inclure des informations sur la nécessité d'introduire des mesures supplémentaires, en particulier pour les utilisateurs professionnels, afin de réduire les risques posés par les produits biocides pour la santé humaine, la santé animale et pour l'environnement.

Alors que le RPB inclut déjà un certain nombre de dispositions concernant la phase d'utilisation, il ne réglemente pas spécifiquement cette phase. Cependant, dans une certaine mesure, l'utilisation durable des biocides est déjà adressée dans le cadre des processus d'approbation des substances actives et d'autorisation des produits. Les aspects suivants du RPB sont ainsi considérés comme permettant de contribuer à une utilisation durable des produits biocides :

- L'approbation d'une substance active , notamment sur les critères d'exclusion et de substitution visant à interdire et substituer les substances les plus préoccupantes;
- Le régime d'autorisation des produits biocides, visant à l'autorisation et l'utilisation de produits dont les risques sont maîtrisés;
- La procédure d'autorisation simplifiée en vertu du chapitre V du RPB; et puis
- Les dispositions sur la recherche et le développement, prévoyant un meilleur encadrement de ces activités.

L'étude a comporté une consultation des parties prenantes et des entrevues de suivi avec les autorités compétentes des États membres, les entreprises et fédérations industrielles et des organisations non-gouvernementales afin d'obtenir des informations sur les mesures prises à l'égard de l'utilisation durable des produits biocides, et de recueillir des avis sur les nouvelles mesures qui pourraient être adoptées. Une analyse juridique et technique a également été entreprise dans le cadre de cette'étude.

Un total de 114 réponses aux questionnaires envoyés aux intervenants de l'industrie et des organisations non-gouvernementales ont été reçues. Parmi ces 114 réponses, quatre ont répondu simplement que le questionnaire n'était pas pertinent à leurs activités car celles-ci n'impliquaient que la fabrication d'une substance active sans inclure la responsabilité de mettre sur le marché un produit biocide. Les 110 réponses restantes sont constituées de 104 réponses des entreprises et des fédérations industrielles, et six réponses des organisations non-gouvernementales. 21 Etats membres ont répondu au questionnaire destiné aux autorités compétentes.

Sur la base des réponses reçues par les parties prenantes et d'une analyse plus approfondie, ce rapport rassemble les informations sur les différents aspects énoncés à l'Article 18 du RPB et formule des recommandations sur d'autres mesures à adopter.

Suivi

Le suivi de l'utilisation des produits biocides est nécessaire car les données font actuellement défaut et très peu d'informations sont collectées à l'heure actuelle dans les États membres. Les informations fournies par les États membres sur les données recueillies indiquent que très peu d'entre eux collectent des données sur l'utilisation des produits biocides.Parmi ceux qui le font, les données recueillies sont limitées en ce qu'elles ne couvrent que les données sur la mise sur le marché des produits biocides (ie.données sur les ventes), plutôt que sur leur utilisation réelle. Il n'existe pas d'outils informatiques dans les États membres qui pourraient être développés pour une utilisation

dans toute l'Union (UE-28) dans le but de surveiller l'utilisation des produits biocides. L'outil SIMMBAD utilisé en France, est le système le plus avancé de collecte des données, maisses fonctionnalités ont dans une grande partie été remplacées par l'outil informatique de l'Agence européenne des produits chimiques ('ECHA') : le registre des produits biocides ('R4BP'Il apparaît donc que le R4BP serait le moyen le plus approprié au niveau de l'UE pour promouvoir une surveillance harmonisée de l'utilisation des produits biocides. Les recommandations suivantes concernant la surveillance sont faites:

1. Dans un premier temps, les détenteurs d'autorisation devraient être tenus de fournir des données sur les quantités annuelles de produits biocides mises sur le marché dans chaque État membre. L'Article 68(1) du RPB est une base appropriée à ce titre, permettant aux autorités compétentes de demander que les relevés de produits biocides mis sur le marché soient rendus disponibles. Cette information devrait donc être demandée par chaque État membre aux titulaires d'autorisations;

2. La Commission pourrait examiner avec l'ECHA la possibilité d'étendre les fonctionnalités du R4BP afin qu'il puisse servir d'outil pour la collecte de données à l'échelle de l'Union. Si cela est jugé approprié, un module individuel pourrait être inclus pour permettre la soumission directe de renseignements sur l'utilisation des produits biocides.

3. Afin de recueillir des données sur l'utilisation des produits biocides, une obligation de déclaration déclaration pourrait être imposée aux utilisateurs professionnels.

Des mesures supplémentaires pour réduire les risques

Quant à savoir si mesures supplémentaires sont nécessaires pour réduire les risques liés aux produits biocides, en particulier dans des domaines spécifiques, il'étude a conclu que les risques sont déjà traités de façon appropriée par les restrictions d'utilisations prévues dans les conditions d'approbation de substances actives ou d'autorisation des produits biocides. Tout risque additionnel d'exposition provient de la mauvaise application des mesures de contrôle recommandées. Les mesures additionnelles pour assurer la bonne application des mesures identifiées d'atténuation des risques consistent essentiellement de mesures augmentant la diffusion des informations à l'utilisateur final, l'éducation et la formation. D'autres mesures concernant le développement des meilleures pratiques sont également recommandées.

Formation et certification

Les principales mesures pour réduire les risques liés à l'utilisation des produits biocides sont la formation et la certification.. S'il n'est pas jugé approprié d'étendre le champ d'application de la Directive 2009/128/CE établissant un cadre d'action communautaire pour parvenir à une utilisation durable des pesticides ('Directive sur l'utilisation durable') aux produits biocides, en raison du nombre et de la nature diverse des produits biocides, les dispositions de formation et de certification de cette Directive sont aussi pertinents pour les produits biocides. Il est donc recommandé que les principes de la lutte intégrée contre les ennemis des cultures soient adaptés à des types de produits biocides spécifiques dans le cadre de l'élaboration de meilleures pratiques par types de produits, et par la suite incorporés dans un programme de formation et de certification pour les produits biocides.

La formation est une mesure clé pour assurer l'utilisation durable des produits . Dans environ la moitié des États membres, un système de formation certifiée est plus ou moins en place, s'ajoutant à d'autres formes de formation interne des entreprises . Une harmonisation au niveau européen pourrait être recommandée par l'introduction de l'obligation pour tous les utilisateurs professionnels et les distributeurs de produits

biocides d'avoir accès à une formation appropriée, de mettre en place des systèmes de certification, et la désignation des domaines d'activités qui devraient être ainsi couverts . D'après un examen des systèmes de certification en vigueur dans les États membres, cet aspect est déjà bien avancé dans la plupart d'entre eux pour le domaine de la désinfection et de contrôle des nuisibles , et sera facilité par le développement de la norme CEN 16636 pour les services de gestion des nuisibles. Un système de certification devrait également être envisagé pour les produits de préservation du bois et des produits antisalissures. Une approche progressive de l'introduction d'exigences de formation pour tous les utilisateurs professionnels devrait être adoptée selon le type de produit en fonction des besoins.

Contrôle intégré des nuisibles et meilleures pratiques

En plus de l'inclusion des principes de contrôle intégré des nuisibles et de documents sur les meilleures pratiques dans le cadre d'un programme de formation et de certification, un certain nombre d'options pourraient être utilisées pour encourager la diffusion des meilleures pratiques et pour en garantir le respect. Les recommandations suivantes sont faites:

1. Lien avec l'autorisation du produit - l'autorisation du produit pourrait faire référence au documents d'orientation / de meilleures pratiques , et

2. Normes volontaires - les normes volontaires de l'entreprise ou de l'industrie devraient inclure l'adhésion aux documents d'orientation / de meilleures pratiques le cas échéant;

3. Documents de référence sur les meilleures techniques disponibles ('documents de référence MTD') - des documents de référence MTD futurs pourraient faire référence aux documents d'orientation / de meilleures pratiques sur l'utilisation durable des biocides dans ce secteur.

4. Lorsqu'il est nécessaire d'élaborer de nouveaux documents d'orientation / de meilleures pratiques pour une activité ou bien pour l'utilisation de différents types de produits, la Commission pourrait chercher à établir des groupes de travail spécifiques pour les secteurs de l'industrie concernés, ou soutenir les initiatives de l'industrie à ce sujet. La création de groupes de travail et le cadre pour le développement des documents de référence MTD pourraient servir d'exemple pour une collaboration de l'Union sur le développement de meilleures pratiques pour l'utilisation durable des biocides.

5. En l'absence d'une obligation légale formelle sur l'établissement de plans d'action nationaux pour l'utilisation durable des produits biocides, la Commission pourrait viser à soutenir les initiatives prises au niveau des États membres pour l'élaboration de stratégies sur l'utilisation durable des biocides qui intègrent les meilleures pratiques.

Information et sensibilisation

En ce qui concerne l'information et la sensibilisation, les États membres sont déjà tenus de fournir au public des informations appropriées sur les avantages et les risques associés aux produits biocides et les moyens de réduire leur utilisation en vertu de l'article 17(5) du RPB. Cependant, d'autres mesures sont nécessaires pour s'assurer que l'information atteigne l'utilisateur final. Les recommandations suivantes sont donc faites:

1. Pour rendre l'information accessible à tous les utilisateurs, il est recommandé que la Commission considère la création d'un site-web qui serait une base de données

de tous les conseils et autres renseignements disponibles sur l'utilisation durable des produits biocides.

2. Des campagnes de sensibilisation destinées aux consommateurs des produits biocides devraient être menées au niveau européen et national.

3. En fonction des besoins identifiés par les mesures de suivi, des campagnes ciblées devraient être mises en place, le cas échéantDes sites d'informations ou d'autres moyens devraient être utilisés pour informer le consommateur, par exemple, des codes QR fournissant un lien vers le site des fabricants ou des applications de téléphonie mobile fournissant plus d'informations sur le produit. Des dépliants disponibles en magasin et résumant les mesures critiques pour la bonne utilisation, et pour la protection de l'homme et de l'environnement pourraient également être produits.

Redevances annuelles sur les produits biocides

Les États membres devraient envisager la perception de redevances annuelles proportionnelles au degré de risque du produit biocide, à payer par les détenteurs des autorisations, afin d'encourager la mise sur le marché et l'utilisation durable des produits biocides. Cet élément est mentionné dans la note explicative de la Commission européenne, mais pourrait encore être encouragé au niveau de l'Union, grâce à des modifications du Règlement (UE) n° 564/2013 sur les droits et taxes exigibles par l'ECHA, à la suite de sa révision.

Outils pour stimuler l'innovation et le développement de nouveaux produits

L'analyse des critères en vertu du Règlement (CE) n° 66/2010 sur le label écologique (Eco-label) européen, et des critères appliqués par d'autres systèmes de label national en Allemagne et en Norvège, montrent que les produits biocides ne sont pas adaptés à un label écologique.

D'autres régimes alternatifs à un label écologique, mettant en évidence le profil sanitaire et environnemental des produits biocides, ont également été généralement considérés comme n'étant pas appropriés pour les produits biocides. Cependant, un certain nombre de régimes volontaires existent bel et bien dans l'Union, qui mettent en évidence le profil sanitaire et environnemental des produits particuliers. Dans chaque cas, ils ont été mis au point par l'industrie, les entreprises individuelles ayant élaboré un processus les aidant à prendre des décisions internes sur le choix des matières premières. Ces régimes jouent un rôle utile dans le développement de produits qui ont un meilleur profil sanitaire et environnemental, et aident à stimuler l'innovation dans ce domaine.

Les initiatives prises par des fédérations industrielles, comme la Charte pour le nettoyage durable de l'Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien, sont également considérées comme particulièrement utiles. Ainsi, le développement d'une approche similaire à d'autres groupes de produits biocides devrait être encouragé.

En ce qui concerne les mesures qui pourraient être prises au niveau de l'Union pour mettre en évidence les produits qui ont un meilleur profil sanitaire et environnemental, la base de données Viennoise pour les désinfectants pourrait servir d'exemple , et être davantage développé au niveau européen afin de fournir un outil de sélection des produits qui ont un impact moindre sur la santé humaine et l'environnement . En utilisant l'information disponible dans le R4BP, la Commission européenne / l'ECHA pourrait développer une version à l'échelle européenne de la base de données, pour chaque type de produit.

Enfin, en ce qui concerne les restrictions de publicité énoncées à l'article 72 du RPB, il est proposé que le RPB puisse être modifié de manière à inclure une exemption des restrictions pour les produits autorisés par la procédure d'autorisation simplifiée. L'utilisation du terme ‘naturel’ devrait être interdit.

ABBREVIATIONS USED

AA	Annual average
ACGIH	American Conference of Industrial Hygienists
A.I.S.E	The International Association for Soaps, Detergents and Maintenance Products
BAT	Best available techniques
BPC	Biocidal Products Committee
BPR	Biocidal Products Regulation
BREF	BAT reference document
CA	Competent Authority
CAR	Competent authority assessment report
CAS	Chemical Abstracts Service
CEFIC	European Chemical Industry Council
CEN	European Committee for Standardisation
CLP	Classification, labelling and packaging
CRRU	Campaign for responsible rodenticide use
CTGB	Board for the authorisation of plant protection products and biocides
DG	Directorate General
DIN	German Institute for Standardisation
EBPF	European Biocidal Products Forum
EC	European Community
ECHA	European Chemicals Agency
EQS	Environmental Quality Standard
ESD	Emission scenario document
EU	European Union
EUR	Euro
GHG	Greenhouse gas
HACCP	Hazard analysis and critical control points

HSE	Health and Safety Executive (UK)
IPM	Integrated Pest Management
IPPC	Integrated pollution prevention and control
ISO	International Organisation for Standardisation
IUCLID	International Uniform Chemical Information Database
MAC	Maximum average concentration
MRL	Maximum Residue Level
MS	Member State
MWF	Metal working fluid
NACE	Nomenclature of Economic Activities
NAP	National Action Plan
NGO	Non-governmental Organisation
OECD	Organisation for Economic Co-operation and Development
OELV	Occupational Exposure Limit Value
PAR	Product assessment report
PBT	Persistent, bioaccumulative and toxic substances
PPE	Personal protective equipment
PPP	Plant Protection Products
PPPR	Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market
PT	Product Type
R4BP	Register for biocidal products
REACH	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RKI	Robert Koch Institute
RMM	Risk mitigation measures
SDS	Safety data sheet
SGAR	Second generation anticoagulant rodenticide
SME	Small and medium-sized enterprises
SPC	Summary of product characteristics

STP	Sewage treatment plant
vPvB	Very persistent and very bioaccumulative substances
WFD	Water Framework Directive
WHO	World Health Organisation

1 INTRODUCTION

1.1 Background to the study

Directive 98/8/EC of the European Parliament and of the Council on the placing on the market of biocidal products[1] (Biocidal Products Directive) entered into force on 14 May 1998 and was to be transposed by Member States within two years of its entry into force[2]. The Directive set out for the first time a process of authorisation and placing on the market of biocidal products in the Member States, provided for the mutual recognition of authorisations within the Community and established a list of active substances at the Community level which could be used in biocidal products. Under the Directive, Member States were to ensure the authorisation, classification, labelling, packaging and proper use of biocidal products, which included measures necessary to keep the use of biocidal products to a minimum as well as an obligation to ensure that their use in the workplace is in compliance with the directives on health and safety protection for workers[3].

The Biocidal Products Directive was repealed and replaced by Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (BPR)[4] with effect from 1 September 2013.

Prior to the introduction of the BPR, the Sixth Environmental Action Programme, which covered the period from 2002 to 2012, called for the development of a thematic strategy with the objective of minimising risk to human health and environmental degradation from pesticide use. In view of this, in 2006 the Commission put forward *A Thematic Strategy on the Sustainable Use of Pesticides*[5]. This was accompanied by a proposal for a Framework Directive on the sustainable use of pesticides[6], which was adopted as Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides (Sustainable Use Directive).

The Sustainable Use Directive was adopted in parallel with Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (PPPR). This was to ensure that the widely recognised gap under the previous EU legislation on plant protection products concerning the "use" phase could be addressed. The new PPPR rules concerning the authorisation process is complemented by the Sustainable Use Directive's provisions regulating the use phase of plant protection products. However, while biocidal products are included in the definition of "pesticides"[7], the Sustainable Use Directive only regulates plant protection products at present[8]. Although recital 2 of the Directive states that it is anticipated that the scope of the Directive will be extended to cover biocidal products, a concrete deadline for a revision of the Directive is only set out in Article 4(3) of the Directive in relation to the implementation of national targets adopted under National Action Plans (NAPs) to reduce risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides.

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123/1, 24.4.98.
[2] Directive 98/8/EC, Article 34(1).
[3] Directive 98/8/EC, Article 3(7).
[4] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167/1, 27.6.2012.
[5] COM(2006) 372 final.
[6] COM(2006) 373 final.
[7] Directive 2009/128/EC, Article 3(10).
[8] Directive 2009/128/EC, Article 2(1).

There has been an ongoing debate about the best ways to address the use phase of biocides including the various regulatory options. A 2008 study (*Assessing the Impact of the Revision of Directive 98/8/EC concerning the Placing of Biocidal Products on the Market*) considered three options to address the use phase of biocides[9]:

- Biocides could be included in a future revision of the Sustainable Use Directive
- Biocidal Products Directive could include provisions on the use phase of biocides
- An independent framework on the use phase of biocides could be created.

During the revision of the Biocidal Products Directive therefore, calls were made for the proposed BPR to cover the use phase of biocidal products. However, as with the Biocidal Products Directive, the focus remained on the authorisation of biocidal products, and while the BPR does include a few provisions addressing the use phase, it does not regulate the use phase systematically. The BPR defines "use" as follows:

'use' means all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the Union.[10]

This definition of "use" focuses on the product and the steps leading up to its application. This is in accordance with the aim of the BPR, which is to address the risk (acceptable/non-acceptable) for a biocidal substance, based on the product (properties and toxicity) and its application (exposure). The BPR thus places the major obligation on the person placing the biocidal product on the market, and not on the actual user.

During discussions leading up to the adoption of the BPR, calls were made for a framework directive on the use phase of biocidal products which should include provisions for NAPs, integrated pest management, risk reduction measures and the promotion of alternatives. However, by way of compromise, Article 18 of the BPR was included, which requires the Commission to provide a report on how the BPR contributes to the sustainable use of biocidal products, and if appropriate, to submit a proposal for the adoption of legislation on the sustainable use of biocidal products.

It should be noted that the Biocidal Products Directive provided for a 10-year transitional period to allow the completion of the review of the active substances used in biocidal products that were already on the market when the Directive came into force on 14 May 2000. The transitional period was later extended from 14 May 2010 to 14 May 2014 (amendment of Article 16 of the Directive) and more recently to 31 December 2024[11]. Examination of all existing active substances used in biocidal products will only be finalised by 31 December 2024 and therefore some have argued that it is premature to consider whether additional measures focusing on the use phase are needed at this stage in order to foster sustainable use.

However, in accordance with Article 18 of the BPR, the Commission shall present to the Council and the European Parliament a report on how the BPR contributes to a sustainable use of biocidal products, including on the need to introduce additional measures, in particular for professional users.

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[9] 2008 RPA, Hydrotox and Milieu *Study on Assessing the Impact of the Revision of Directive 98/8/EC concerning the Placing of Biocidal Products on the Market*, p. 172.
[10] Regulation (EU) No 528/2012, Article 3(k).
[11] Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances.

1.2 Objectives of the study

The overall objective of the study is to provide the European Commission with information on how the application of the BPR contributes to the sustainable use of biocides, to feed into the Commission's report to the European Parliament and the Council, which is to be provided by 18 July 2015 under Article 18 of the BPR. This shall include information on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to human and animal health and the environment by biocidal products.

Article 18 - Measures geared to the sustainable use of biocidal products

By 18 July 2015 the Commission shall, on the basis of experience gained with the application of this Regulation, submit to the European Parliament and the Council a report on how this Regulation is contributing to the sustainable use of biocidal products, including on the need to introduce additional measures, in particular for professional users, to reduce the risks posed to human health, animal health and the environment by biocidal products. That report shall, inter alia, examine:

(a) the promotion of best practices as a means of reducing the use of biocidal products to a minimum;

(b) the most effective approaches for monitoring the use of biocidal products;

(c) the development and application of integrated pest management principles with respect to the use of biocidal products;

(d) the risks posed by the use of biocidal products in specific areas such as schools, workplaces, kindergartens, public spaces, geriatric care centres or in the vicinity of surface water or groundwater and whether additional measures are needed to address those risks;

(e) the role that improved performance of the equipment used for applying biocidal products could play in sustainable use.

On basis of that report, the Commission shall, if appropriate, submit a proposal for adoption in accordance with the ordinary legislative procedure.

Tasks 1 to 5 (set out in chapters 3 to 7) cover each of the specific elements that are to be included in the report to the European Parliament and the Council under Article 18(a) to (e) of the BPR:

- Task 1: Provide an overview of the promotion of best practices as a means of reducing the use of biocidal products to a minimum – Article 18(a);
- Task 2: Identify whether need for additional provisions regulating professional users;
- Task 3: Investigate and make recommendations for the most effective approaches for monitoring the use of biocidal products – Article 18(b);
- Task 4: Specify the risks posed by the use of biocidal products in specific areas and whether addition measures are required to address those risks – Article 18(d); and
- Task 5: Examine the relevance of integrated pest management principles for biocidal products and the role that improved performance of the equipment used for applying biocidal products could play in sustainable use – Article 18(c) and (e).

Thereafter, chapters 8 to 10 provides an analysis of the tools that could be used to stimulate innovation and the development of new products to decrease the environmental and human health impact of biocidal products, based on the following tasks:

- Task 6: Investigate the possibility to attribute an eco-label to biocidal products;

- Task 7: Provide an overview of voluntary schemes that are used to highlight those products and uses that have a better environmental and human health profile, and suggest other approaches or tools; and
- Task 8: Analyse whether it is appropriate to revise Article 72 of the BPR on advertising.

1.3 Product types covered by the study

In accordance with Article 2(1) of the BPR, the BPR applies to biocidal products and treated articles. A list of the types of biocidal products covered by the BPR and their description is set out in Annex V of the BPR. The study therefore covers the following product types:

- Main Group 1: Disinfectants
  - PT 1 - Human hygiene
  - PT 2 - Disinfectants and algaecides not intended for direct application to humans or animals
  - PT 3 - Veterinary hygiene
  - PT 4 - Food and feed area
  - PT 5 - Drinking water
- Main Group 2: Preservatives
  - PT 6 - Preservatives for products during storage
  - PT 7 - Film preservatives
  - PT 8 - Wood preservatives
  - PT 9 - Fibre, leather, rubber and polymerised materials preservatives
  - PT 10 - Construction material preservatives
  - PT 11 - Preservatives for liquid-cooling and processing systems
  - PT 12 - Slimicides
  - PT 13 - Working or cutting fluid preservatives
- Main Group 3: Pest Control
  - PT 14 - Rodenticides
  - PT 15 - Avicides
  - PT 16 - Molluscicides, vermicides and products to control other vertebrates
  - PT 17 - Piscicides
  - PT 18 - Insecticides, acaricides and products to control other arthropods
  - PT 19 - Repellents and attractants
  - PT 20 - Control of other vertebrates
- Main Group 4: Other biocidal products
  - PT 21 - Antifouling products
  - PT 22 - Embalming and taxidermist fluids

However, as noted above, the review of the active substances used in biocidal products that were already on the market is ongoing and examination of all existing active substances used in biocidal products will only be finalised by 31 December 2024. Only once an active substance has gone through the review programme, can a product then be authorised. The current focus of the Commission, Member States and the European Chemicals Agency (ECHA) is therefore on substance approval and product authorisation.

The only products therefore for which proactive concrete actions concerning sustainable use could be taken are wood preservatives (PT 8) and rodenticides (PT 14). The Commission is also currently looking at insecticides (PT 18), repellents and attractants (PT 19) and anti-fouling products (PT 21). It was felt that it was too early to focus on disinfectants (main group 1) since only a few active substances have been approved to date. PT 8, PT 14, PT 18, PT 19 and PT 21 would be the first products for which concrete actions on sustainable use could be taken.

1.4 Methodology of the study

The following methodological tools were used throughout the study:

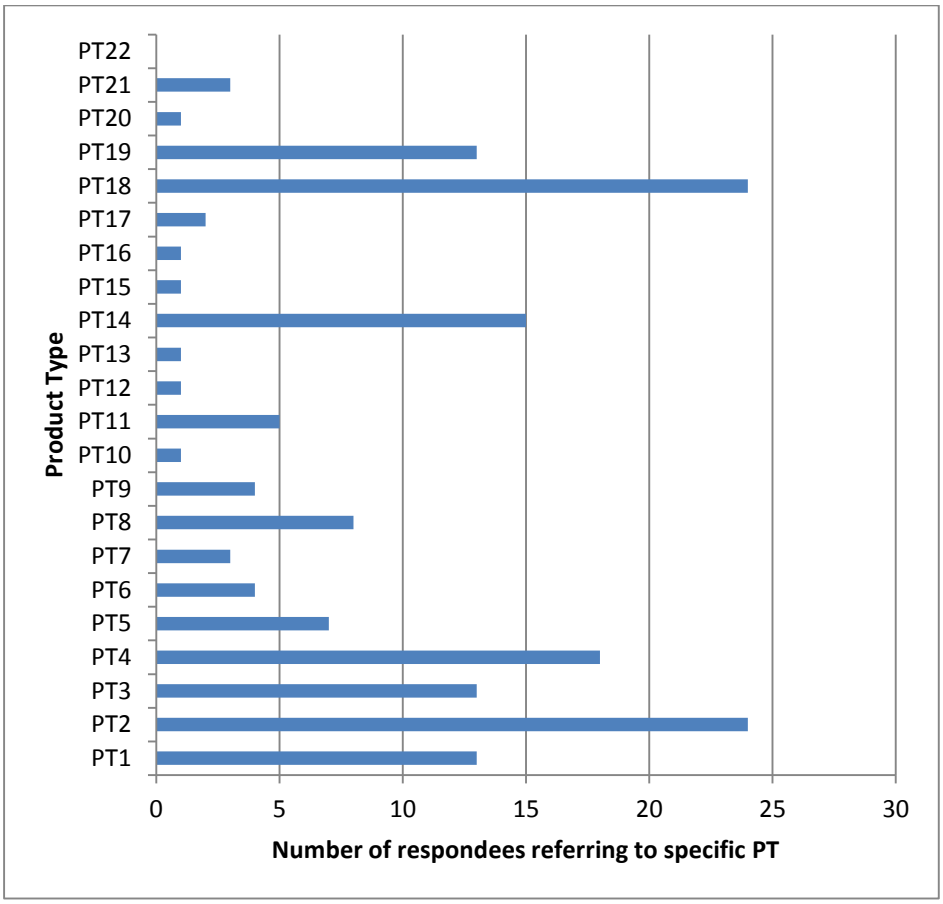
- Desk-based research - Initial desk-based research was carried out to identify relevant information to be reviewed during the first part of the work, in particular in relation to Task 1 on best practices, Task 3 on monitoring approaches and Task 5 on integrated pest management, and also to inform the development of the questionnaire. The results of the desk-top study are reported on in each respective section of the report, where relevant to the task.

- Questionnaire to Member States, Industry and NGOs - The questionnaires are provided at Annex I. The questionnaires for Member States, industry and non-governmental organisations (NGO's) were issued to stakeholders on 4 April 2014. Stakeholders were asked to reply by 30 April 2014. Approximately 1800 companies, retailers and industry associations were contacted by the Commission by email and asked to complete the questionnaire. However, due to a low response rate this was extended until 21 May 2014.

Overall 114 responses were received to the questionnaires issued to industry stakeholders, and NGO's. Of these 114 responses, 4 responded simply that the questionnaire was not relevant to their operations since they only manufactured an active substance and were not responsible for placing a biocidal product on the market, and therefore did not include any information other than their name and contact details. The remaining 110 responses are made up of 104 responses from companies and industry associations, and six responses from NGO's.

Respondents	Number of responses received
Member States	21
Companies and industry associations	104
NGO's	6
Questionnaire not relevant	4
TOTAL	**135**

48 industry respondents did not specify which product types they dealt with. Based on the information received from the remaining 56 industry respondents, the table below show the number of industry respondents that referred to each product type:



- Follow-up interviews with key Member State officials as well as key EU and other industry; associations, NGOs and experts, where necessary - Following receipt of all Member State responses and completion of the initial analysis of all responses, follow-up interviews were conducted by phone with selected stakeholders, in order to clarify a particular response or to obtain further information on a particular point/issue raised in the response. This was used to help deepen the analysis regarding issues and trends identified through the review of the responses to the questionnaires.

- Review of information on toxicological analysis – As part of tasks 2 and 4, in order to identify whether there may be a need to introduce additional measures to reduce the risks, in particular to professional users of biocides, or to address exposure risks in specific areas, our technical experts carried out a review of available information on the main uses and types of application for biocidal products, the risk mitigation measures applied and control measures applied, based on the available safety data sheets (SDS), competent authority assessment reports (CARs), emission scenario documents (ESDs) Inclusion Directives, product leaflets and literature and research studies.

- Legal and policy analysis - This covered in particular the identification of the control measures that are applied in order to address the exposure risks, namely those arising under a number of pieces of EU health and safety legislation, in particular Directives 89/391/EEC, 98/24/EC, 2000/54/EC and 2004/37/EC, EU chemicals legislation and EU water legislation, namely the Water Framework Directive 2000/60/EC. As part of task 6, legal analysis of the Eco-label Regulation was also carried out in order to identify what criteria will require to be met in order to comply with the requirements of the Eco-label Regulation.

2 EXISTING PROVISIONS OF THE BPR THAT CONTRIBUTE TO SUSTAINABLE USE

2.1 Introduction

Article 18 of the BPR concerning "measures geared to the sustainable use of biocidal products" requires the Commission to report to the European Parliament and the Council on how the BPR is contributing to the sustainable use of biocidal products. This is to be based on experience gained with the application of the BPR. Therefore, before considering whether further measures need to be introduced to reduce the risks posed to human health, animal health and the environment, by biocidal products, the existing provisions of the BPR should be analysed.

As noted in the introduction, while the BPR does include a few provisions addressing the use phase, it does not specifically regulate the use phase. However, to an extent the sustainable use of biocides is already addressed during the active substance approval and product authorisation processes. For example, provisions to limit the use of a product to professional users only or to prohibit specific application scenarios of the products are included in order to promote the safe, correct and sustainable use of biocidal products for the environment and human health.

2.2 Consultation responses

Information on the application of the BPR was sought as part of the stakeholder consultation, where Member State authorities, industry and NGO's were asked the following question:

- Based on your experience with the application of the Biocidal Products Regulation (authorisation process), how does the BPR contribute to the sustainable use of biocidal products?

Of the 21 Member States that responded, five Member States felt that they either did not have enough experience of the authorisation procedure yet, or that it was too early in the adoption of BPR to assess the contribution or effectiveness of the new product authorisation requirements under the BPR. In particular, it was commented that the provisions concerning treated articles were too new to assess. In some Member States, discussions on the sustainable use of biocides had only recently come to the forefront, while in others such as Germany and Denmark, action has been taken to establish specific national strategies on the sustainable use of biocidal products.

16 Member States felt that the application of the BPR had contributed in some way to the sustainable use of biocidal products. Within their responses, reference was made to the following aspects of the BPR which were considered to contribute to the sustainable use of biocidal products:

- The approval of an active substance, in particular the exclusion criteria and the substitution principle, which prohibits and substitutes the substances of most concern;
- The authorisation scheme for biocidal products, for the authorisation and the use of products where risks are controlled;
- The simplified authorisation procedure under Chapter V of the BPR; and
- The provisions on research and development, providing better supervision of those activities..

From the responses received from NGO's, one NGO also commented that it was too early in the application of the BPR to assess how it contributes to the sustainable use of

biocidal products, and another referred to the low level of knowledge of the BPR in civil society as well as amongst manufacturers and retailers. Another two NGO's commented that the BPR should in theory help to reduce the consumption of biocidal products. The remaining responses from NGOs largely focused on the provisions on use of biocidal products under Article 17(5) BPR and are therefore dealt with below.

Of the responses from industry, approximately a third (36 respondents) either left the question blank or commented that they did not have enough experience of the authorisation process under the BPR to say whether or not it contributes to the sustainable use of biocidal products. The remaining industry respondents were split between those that felt that the BPR authorisation process does contribute to the sustainable use of biocidal products and those that felt that it does not. Of those that felt that the BPR does contribute to the sustainable use of biocidal products, most respondents referred to the benefit of taking the most hazardous substances of the market, the risk assessment process carried out as part of the active substance approval and biocidal product authorisation and the simplified authorisation procedure which encourages the development of low risk biocidal products. These are therefore discussed further in the relevant sections below.

Of the industry respondents that felt that the BPR does not contribute to the sustainable use of biocidal products, the main issues raised concerned the high costs involved in bringing a biocidal product to market and the decrease in the number of products available, which are discussed below. In addition to the two related issues of costs and availability of products on the market, industry respondents also raised a number of other criticisms of the BPR in terms of its contribution to the sustainable use of biocidal products. One respondent commented that there is a lack of guidance and specific advice on sustainable use under the BPR since it only gives general advice on 'proper use' under Article 17(5) BPR. Another respondent commented that there is duplication in assessment since an assessment of emissions is required as part of the application for product authorisation, despite emissions from installations already being considered under other regimes for example under the Industrial Emissions Directive. Finally, it was stated that the BPR does not contribute to the sustainable use of biocidal products since authorisation focuses purely on evaluating the risks of the active substance and biocidal product and does not promote the use of biocides with a better carbon footprint or take into consideration other factors such as whether risk mitigation measures (RMM) are creating the need for multiple applications and thus additional site visits, more fuel usage etc.

2.2.1 Approval of an active substance

In accordance with Article 5(1) of the BPR, the evaluating competent authority should first check that the active substance does not meet the exclusion criteria, in which case it would not be approved. The objective of the exclusion criteria is to ensure that the most hazardous active substances are phased out. Based on the exclusion criteria, carcinogens, mutagens and reprotoxic substances category 1A or 1B according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures[12] (CLP Regulation), endocrine disruptors, persistent, bioaccumulative and toxic (PBT) substances, or very persistent and very bioaccumulative (vPvB) substances will not be approved. Thereafter an active substance can only be approved if at least one biocidal product containing the active substance is expected to meet the criteria for authorisation of a biocidal product.

[12] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008

The process of approval of an active substance therefore serves to remove the most hazardous biocidal active substances, by prohibiting them from being approved and from entering the market.

For those products that are already on the market when the Biocidal Products Directive came into force in 2000, provision was made for a 10-year transitional period to allow the completion of the review of the active substances used in biocidal products that were already on the market. The review programme is ongoing and examination of all existing active substances used in biocidal products will only be finalised by 31 December 2024. The most recent list of active substances included in the review programme is set out in Annex II to the Commission Delegated Regulation (EU) No 1062/2014[13]. Through the review programme, active substances that are not supported under the BPR will be removed from the market, which also contributes to the sustainable use of biocidal products.

As part of the approval process, the evaluating competent authority should also consider whether the active substance is a candidate for substitution under Article 10 of the BPR. This provision aims to identify substances of particular concern to public health or the environment and to ensure that over time these substances are phased-out and replaced by better alternatives. Where an active substance is identified as a candidate for substitution during the approval procedure, the approval of that active substance can only be granted for the shorter period of up to seven years, instead of 10 years and biocidal products containing that active substance will have to be subject to a comparative assessment at the time of authorisation and can only be authorised if there are no better alternatives. This seeks to ensure that substances of concern are phased out and encourages the development of alternatives.

Finally, the approval of an active substance will be restricted to those product types for which relevant data have been submitted as part of the application and will set out the specifications and conditions that it is to comply with. Taking a recent example, Commission Implementing Regulation (EU) No 945/2013[14] approved cypermethrin as an existing active substance for use in biocidal products for product type 8, subject to the specifications and conditions set out in the Annex to the Regulation. In the case of cypermethrin, the following conditions apply:

- The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.
- Authorisations are subject to the following conditions:
  (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
  (2) Appropriate risk mitigation measures shall be taken to protect the soil and aquatic compartments. In particular:
  (a) Labels and, where provided, safety data sheets of products authorised shall indicate that industrial application shall be conducted within a contained area or on impermeable hard standing with bunding, that freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil or water, and that any losses from the application of the product shall be collected for reuse or disposal.

[13] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council, OJ L 294, 10.10.2014
[14] Commission Implementing Regulation (EU) No 945/2013 of 2 October 2013 to approve cypermethrin as an existing active substance for use in biocidal products for product-type 8, OJ L 261/23, 3.10.2013

(b) Products shall not be authorised for industrial treatment by dipping or spraying of wood that will be exposed to weathering, unless data is submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures.
(c) Products shall not be authorised for treatment of outdoor constructions near or above water, or for treatment of wood that will be used for outdoor constructions near or above water, unless data is submitted to demonstrate that the product will not present unacceptable risks, if necessary by the application of appropriate mitigation measures.

By including provisions to limit the use of a product to industrial or professional users only, by prohibiting specific application scenarios of the products, and by requiring that appropriate risk mitigation measures are taken, the conditions of approval of an active substance promote the safe, correct and sustainable use of biocidal products for the environment and health.

In Member State responses to the stakeholder consultation, it was indicated that as a result of the process of approval of active substances under the BPR (and previously under the Biocidal Products Directive), many active substances have been phased out and more information is now available on both the active substances and biocidal products due to the review procedure and new data on exposure having been generated. The availability of new information has increased the quality of information that can be passed down the supply chain to the user, as well as providing an improved evidence base on which experts can make recommendations for safe use, or for products posing an unacceptable risk to be removed from the market. Reference was made specifically to the product assessment reports (PAR) and summary of product characteristics (SPC), though one Member State felt that this information should be further distributed to the public using different media, such as additional awareness raising campaigns for the general public as well as specific training for users.

While it is still relatively early stages in the application of the BPR, a number of Member States as well as one NGO specifically referred to the exclusion criteria and the requirement for a comparative assessment where a substance is identified as a candidate for substitution during the approval process, as being two aspects of the BPR that contribute to the sustainable use of biocidal products. Through this, information is gathered regarding alternatives in accordance with Article 10(3) BPR and a comparative assessment of biocidal products is carried out in accordance with Article 23 BPR. This serves as a means of reducing the use of high-risk biocidal products and highlighting alternatives. This will therefore contribute to the promotion of products with less impact on health and environment in the long term.

A number of industry respondents also indicated that the BPR contributes to the sustainable use of biocidal products by significantly reducing the number of available active substances, thereby ensuring that only those which present the most sustainable profile will remain in future. However, the limited number of available active substances on the market now, and the costs associated with bringing new products to the market were also stated to be the two main hurdles to development of sustainable solutions, and are discussed under authorisation below.

2.2.2 Authorisation of a biocidal product

For an authorisation to be granted, the active substances must be included in Annex I or approved for the relevant product-type and meet any conditions specified for those active substances as well as the criteria (Article 4(1) BPR) for authorisation of a biocidal product:

i) the biocidal product is sufficiently effective;
ii) the biocidal product has no unacceptable effects on the target organisms, in

particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;

iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;

iv) the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the
   - the fate and distribution of the biocidal product in the environment,
   - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
   - the impact of the biocidal product on non-target organisms,
   - the impact of the biocidal product on biodiversity and the ecosystem.

In order to ensure a high and harmonised level of protection of human health, animal health and the environment, any risks arising from the use of a biocidal product are to be identified, and a risk assessment carried out to determine the acceptability of otherwise of the risks identified. The competent authorities will use the data submitted in support of an application for authorisation of a biocidal product by carrying out a risk assessment based on the proposed use. A risk assessment of the active substance(s) present in the biocidal product is always required, and additional risk assessments are to be carried out on any substance of concern present in the biocidal product. The risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issue. The assessment shall also take account of how any 'treated articles' treated with or containing the product may be used and disposed of and the possibility of cumulative or synergistic effects.

Biocidal products are to be used in compliance with the terms and conditions of the authorisation, which stipulates the terms and conditions relating to the making available on the market and use of the biocidal product and includes a summary of the biocidal product characteristics. The summary of the biocidal product characteristics is to include the following information:

1) qualitative and quantitative composition in terms of the active substances and non-active substances, knowledge of which is essential for the proper use of biocidal products;
2) hazard and precautionary statements;
3) product-type and, where relevant, an exact description of the authorised use;
4) target harmful organisms;
5) application doses and instructions for use;
6) categories of users;
7) particulars of likely direct or indirect adverse effects and first aid instructions and emergency measures to protect the environment;
8) instructions for safe disposal of the product and its packaging;
9) conditions of storage and shelf-life of the biocidal product under normal conditions of storage;
10) where relevant, other information about the biocidal product.

Compliance with the conditions of authorisation, in particular the authorised use, application doses, and instructions for use, therefore plays a large part in the sustainable use of biocidal products as aims to ensure the safe, correct and sustainable use of biocidal products for the environment and health.

In Member State responses to the stakeholder consultation, it was indicated that the authorisation process under the BPR contributes to the sustainable use of biocidal products as includes an assessment of safe and adequate use and limits the use of the

most dangerous (environment, human health) biocides, focuses on finding alternatives for them, replacing them with more suitable low risk biocides. The authorisations therefore may restrict the uses to the ones that are confirmed as efficient, preventing the use of inefficient products that may trigger resistance. The use of biocidal products by the general public may also be restricted, preventing the use of such products in cases where the application would not be appropriate. The authorisation procedure also allows the competent authorities to request that the resistance of a product is monitored. Hazardous characteristics of the active substances and products are reviewed and accordingly proper labelling of the products is established.

One Member State felt that the authorisation process only contributes to the sustainable use of biocidal products where an appropriate restriction is placed on the product during the authorisation process and where it has an integrated product management (IPM) implication, providing the example of the use instructions for rodenticides which specify a targeted pulse baiting technique rather than continuous all-year-round baiting.

Almost all of industry respondents that indicated that the BPR does contribute to the sustainable use of biocidal products referred to the benefits of the authorisation procedure in removing dangerous products from the market (through the exclusion and substitution criteria) and ensuring that those products authorised to be placed on the market have gone through a thorough risk assessment. The BPR includes a systematic risk assessment of each use according to very conservative models and the resulting RMM are largely sufficient to ensure that biocides are use sustainably. The authorisation process under the BPR is believed to contribute to the sustainable use of biocidal products as it assesses the product's safety (human health and the environment) and efficacy. Due to the risk assessment process there is confidence that the recommended uses do not pose unacceptable risk for users and/or the environment if they are used in accordance to recommendations.

It was also stated that the BPR contributes to the sustainable use of biocidal products by encouraging the minimum level of application of products. By requiring efficacy testing at these minimum levels and clear instructions for use, it encourages consumers to use only what is required to combat the pest problem they face. Efficacy testing is a source of information for proper amount to be used to assure protection against certain organisms and therefore a number of industry respondents also felt that the BPR authorisation process defines better dosing concentrations of biocidal products which helps to avoid overdosing. Reference was made to the example of RMM applied to rodenticides, where as a result of the BPR, RMMs for the use of rodenticides across the whole of the EU have to be put in place so that there are clear minimum standards of use.

Finally, reference was made to the benefits of increased data and improved transparency under the BPR, which also play a part in the sustainable use of biocidal products.

A number of drawbacks under the authorisation procedure were however also noted.

One Member State referred to duplication in the authorisation procedure due to the number of products on the market and authorisation holders not always knowing the composition of a product. This results in the multiplication of the same biocidal product on the market and if the same product is applied under different names, this may weaken the perceived responsibility of the authorisation holder. Another Member State also referred to problems resulting from the number of biocidal products on the market and these being exempt from authorisation due to the active substance still being under review. It should be noted however that this will resolve itself over time once the review programme is completed and the requirement for those active substances not supported under the BPR to be removed from the market.

Another shortcoming identified by a Member State was the limited emphasis on efficacy. As a non-effective biocide is a superfluous biocide, it felt that the requirements for proof of efficacy should be stronger (also during active substance approval) to make sure that only effective active substances and biocidal products are being used. In relation to treated articles, the possibility not to approve treated articles where the biocidal treatment is not effective is not available.

From an industry perspective, the main issues raised concerned the high costs involved in bringing a biocidal product to market and the decrease in the number of products available.

On costs, a number of industry respondents indicated that research and development is limited due to the high costs of authorisation. As this is both expensive and time consuming (both internally for the dossier preparation and data gathering, and waiting for authorisation once a dossier has been submitted) this prevents any interim improvements to biocidal products that could include the reduction in the levels of biocides. In most cases the costs for approval of an active substance are too high for SME's, leaving only the larger companies with the financial resources to take forward applications for approval. Furthermore, given the fact that the BPR data requirements are all 'up front' costs this will create a barrier to innovation. Costs to generate data for a new active from scratch are purported to be in the region of €6-9 million. This effectively closes the door to novel technologies as the investment is simply too high to take them to the market in an effective way. The costs involved are so high that no business or venture capitalist will take such a high risk of investment for so little gain. Given the size of the biocides industry and limited profit margins compared to similar applications such as pesticides, there is very little market incentive to develop new products which could result in novel, potentially benign, biocides with excellent efficacy. The high compliance costs, very conservative risk assessments and the lack of clarity around comparative assessment (where applicable) provide increasing unpredictability and reduced commitment to new product development thus leading to fewer products on the market as products have to remain economically viable.

One industry respondent commented that already the Biocidal Products Directive resulted in a decrease of products available, since around 75% of the active ingredients available in 2000 have disappeared from the market and this is continuing under the BPR. In response to this comment it should be noted that among the 75% of active substances removed from the market are numerous old-fashioned or obsolete active substances, as well as a number of high risk or non-efficient active substances, some of which are restricted by legislation other than the Biocidal Products Directive or BPR. The number of active substance identified during the first phase of the Biocidal Products Directive should not be compared with the number of active substances that are actually needed, and industry should instead identify what active substances are not supported, yet which they would like to use continuously.

The reduction in the number of available active substances with which to formulate biocidal products also makes innovation in the market more difficult and therefore reduces the opportunity for development of sustainable solutions. One respondent specifically commented that the BPR will have a potentially negative impact on the availability of in-can preservatives for water-based mixtures. This may lead to shorter storage time for many water based products and therefore potential waste of products. Another industry respondent raised concerns that no new biocides will be found for antifouling paints and therefore industry will be required to use a limited number of biocides over the next decade. If active substances which are effective as antifoulants are removed from the market, this will impact on greenhouse gas (GHG) emissions and transfer of evasive species. The sustainable use of biocides for antifouling products therefore has to include consideration of the impact on the environment of both GHG and transfer of invasive species. The removal of active substances from the market makes it

difficult to find effective products and causes difficulties in maintaining certain important products for the control of pests.

Finally, on the availability of products, one industry respondent commented that the practical implementation of the BPR only seems to assess sustainability from the perspective of how, and how much, product is used and does not consider the broader aspects of the costs associated with the BPR. To be a true model of sustainable use the BPR needs to give more consideration to the impact that the RMMs have on the sustainability of the biocides industry and the biocide users concerned.

2.2.3 Simplified authorisation procedure

One of the measures introduced under the BPR to encourage the use of products that are less harmful for the environment, human and animal health is the simplified authorisation procedure. The simplified authorisation procedure is based on the principle that once the eligible product is authorised in one Member State it can then be freely circulated within the Union provided that the other Member States are notified and have no objections to placing the product on the market.

Under Article 25 of the BPR, an application for authorisation may be made under the simplified authorisation procedure if the biocidal product is an 'eligible biocidal product'. A biocidal product is eligible if all the following conditions are met:

a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;
b) the biocidal product does not contain any substance of concern;
c) the biocidal product does not contain any nanomaterials;
d) the biocidal product is sufficiently effective; and
e) the handling of the biocidal product and its intended use do not require personal protective equipment.

As stated above most Member States felt that the authorisation process under the BPR contributes to the sustainable use of biocidal products, and in particular referred to the simplified procedure for low risk products. Moreover, the simplified authorisation procedure facilitates the promotion of products that have less impact on health and environment in the long term. This was also reflected by a number of industry respondents, who referred to Annex I and the simplified authorisation procedure being a relevant tool for sustainable use of biocidal products.

2.2.4 Mutual recognition

Mutual recognition is the process that allows for the harmonisation of product authorisations between Member States. If the holder of an authorisation wishes to extend the national product authorisation to other Member State markets, it can apply to those Member States for mutual recognition. Chapter VII of the BPR sets out the procedures for mutual recognition, which can be sought either in sequence or in parallel.

A number of Member States highlighted the benefits of the mutual recognition process. One Member State highlighted that through the mutual recognition process they can access information on the active substance for the relevant product type and the evaluation process prior to authorisation. They can also obtain information from the active substance evaluation and recommendations that are useful to pass on to consumers. Another Member State highlighted that the mutual recognition in parallel required every concerned Member State to complete the evaluation in parallel. All concerned Member States therefore see what the others have written. This is a useful exchange of information from which they can learn about the approach taken in another Member State, which results in discussion and exchange of information and increased awareness between national authorities. As some Member States have good solutions,

others can learn from these and use them in their Member State. This therefore also benefits industry as can lead to more consistency across the EU.

2.2.5 Research and development

By way of derogation from the requirement for authorisation under the BPR, an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal product or a non-approved active substances intended exclusively for use in a biocidal product may take place under the conditions set out in Article 56 of the BPR.

Where the experiment or test may involve, or result in, release of the biocidal product into the environment, the person intending to carry out the experiment or test must first notify the competent authority of the Member State in which the experiment or test will be carried out. Where an opinion has not been received from the competent authority within 45 days of the notification, the experiment or test may take place. If the experiments or tests could have harmful effects, whether immediate or delayed, on the health of humans, particularly of vulnerable groups, or animals, or any unacceptable adverse effect on humans, animals or the environment, the relevant competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences.

A number of stakeholders highlighted the benefits of this notification procedure to encourage development of more sustainable products. One respondent indicated that it would be helpful to have a temporary and quick form of authorisation to place products for research and development trials on the market, beyond what is already foreseen in Article 56 BPR. Technical innovations on biocidal products in terms of special formulation technologies, where performance of biocides can be optimised and negative impact on the environment can be reduced should be encouraged as this results in a reduction of the overall amounts of biocides that are needed are reduced.

2.2.6 Provisions on 'use'

As noted in the introduction, while the BPR does not regulate the use phase systematically, it does include a few provisions addressing the use phase. Under Article 17(5) of the BPR, biocidal products are to be used in compliance with both the terms and conditions of the authorisation and the labelling and packaging requirements. As noted above, this can contribute to the sustainable use of biocidal products. Article 17(5) goes on to provide that 'proper use' is to "involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken". Article 17(5) also provides that Member States are to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use. One Member State indicated that the provision on 'proper use' is important, but should be further elaborated. One NGO commented that the terms "proper use" and "minimum necessary" in Article 17(5) BPR are not clearly defined and the term "use" in the title of the BPR is not considered appropriately in the text of the Regulation, therefore further measures are required.

One Member State commented that as the BPR focuses on the product authorisation process, consideration is not given to alternatives to biocides or preventative measures that could be used. There is therefore a need to look beyond product authorisation and consider best practice. Legislation is therefore required on the sustainable use of biocides, to ensure that measures for the minimisation of biocides, control on sales, best practices, equipment, unnecessary uses, treated articles, training schemes etc. are applied. This view was also reflected in the responses from NGOs. One NGO commented that at this stage the BPR does not contribute to the sustainable use of biocidal products as it does not consider the need for EU-harmonised standards regarding training,

application equipment, education, certification, monitoring, reporting or other requirements such as the implementation of IPM principles or use restriction in sensitive areas. In addition the BPR does not set any harmonised indicators for sustainable use such as the monitoring and publication of market and use data. The need for further provisions on 'use' was therefore emphasised in the responses received from NGOs. Two NGOs commented that a legal instrument for the use phase of biocidal products is necessary in order to provide an EU harmonised framework comparable to the Sustainable Use Directive for pesticides.

2.3 Conclusion

It is clear therefore that while not specifically addressing the use phase of a biocidal product, the BPR does include a number of provisions which contribute to the sustainable use of biocidal products. These will therefore be considered where relevant in subsequent chapters when drawing conclusions on the need for further measures to reduce the risks posed to human health, animal health and the environment by biocidal products. At the same time, provisions of the BPR that discourage the development of sustainable solutions should also be considered, for example, whether changes are required to the provisions on fees for authorisation of biocidal products.

3 BEST PRACTICES IN REDUCING THE USE OF BIOCIDAL PRODUCTS TO A MINIMUM

3.1 Introduction

Article 18 of the BPR concerning "measures geared to the sustainable use of biocidal products" requires the report to the European Parliament and the Council on how the BPR is contributing to the sustainable use of biocidal products, to examine amongst other issues the promotion of best practices as a means of reducing the use of biocidal products to a minimum.

A number of previous studies have been carried out on the sustainable use of biocides, namely the '*Study towards the development and dissemination of best practice on sustainable use of biocidal products*'[15]. The study followed up on the options presented in an earlier study on the '*Assessment of different options to address risks from the use phase of biocides*'[16], which aimed to identify the appropriate measures and legal instruments that would ensure the sustainable use of biocidal products, and looked at what could be done to further control and/or reduce the risks associated with the use of biocides. This earlier study therefore identified the available data on the risks posed by the use of biocides, the possible measures to reduce the risks and the environmental, social and economic impacts of the identified risk reduction measures. Data and information on the use of biocides and associated risks was however limited and difficult to identify at this stage. The study on the '*Assessment of different options to address risks from the use phase of biocides'* was therefore largely based on responses received to a questionnaire sent to Member State competent authorities by the European Commission in 2008, which sought information on the measures in use in Member States to reduce the risk of biocides. The questionnaire included seven categories of question covering training and certification of users, inspection of application equipment, monitoring and reporting, general data on the use of biocidal products, restriction on the use of biocidal products, transposition of IPM, and additional measures to reduce risk. The conclusions from an expert workshop held in Brussels on 23 April 2008 which looked at the suitability of additional measures, were also taken into account[17]. The study further assessed three measures identified: training and certification of professional users; certification and inspection of application equipment; and long-term good practice and prevention.

Following up on this, the more recent '*Study towards the development and dissemination of best practice on sustainable use of biocidal products*', therefore aimed to identify existing best practices that had been developed by the competent authorities of Member States or by industry (stakeholders) for the 23 biocidal product types identified in Directive 98/8/EC concerning the placing of biocidal products on the market, in order to ensure sustainable use of biocidal products. To this end, it looked at the approaches towards best practices on the use of biocidal products that had been developed at the Member State level, best practices that had been developed and promoted by industry and the ways in which the concept of best practices could be adapted and used at the Community level. The final report was published in 2010.

[15] Milieu, Study towards the development and dissemination of best practice on sustainable use of biocidal products, Final Report, October 2010, available at http://ec.europa.eu/environment/chemicals/biocides_history/pdf/Biocides%20best%20pactices%20for%20sustainable%20use.pdf

[16] COWI, Assessment of different options to address risks from the use phase of biocides, Final Report, March 2009, available at http://ec.europa.eu/environment/ppps/pdf/final_report0309.pdf

[17] Conclusions from the expert workshop, 23 April 2008, available at http://ec.europa.eu/environment/chemicals/biocides_history/pdf/conclusions_workshop230408.pdf

Based on an analysis of the information gathered, including current actions to promote best practices at EU level as well as the activities reviewed in other sectors, the study identified a set of possible policy options for the European Commission to consider in terms of how the concept of best practices could be adapted and used at the Community level. In total, 14 options were proposed, 12 of which did not require changes to EU legislation. The options were categorised in terms of the main stages in the development and promotion of best practice documents: development, dissemination (including training) and monitoring/evaluation and an estimate of the costs of the options was also developed. Of the 14 options proposed, the following five options were identified which could strengthen the development of best practice.

Option	Benefits
Options to strengthen the development of best practice (without legislative changes)	
Option 1: EU-funded background research (per project per year)	Increased knowledge of the impacts of biocides on target organisms, the environment and human health; A basis to prioritise any further action; and Provision of the knowledge required to improve best practice on sustainable use of biocides use.
Option 2: EU-level procurement process to develop guidelines	Increased availability of best practice; and Standardisation and harmonisation of best practice across EU.
Option 3: National best practice transferred to EU-level	Making existing best practice guidance more widely available, by translating it into a range of EU languages; and Encouraging harmonisation of best practice across EU.
Option 4: Best practice developed by stakeholders through standardisation process	Wider availability of best practice guidance, via the communication networks of CEN and national standards authorities; and Standardised best practice across EU.
Option 5: Addressing biocides within the BREFs under IPPC	Integration of biocides best practice into EU wide guidance for major industrial operations (i.e. all relevant guidance in one place); Enhanced focus on best practice use of biocides by enforcement authorities; and Standardised best practice across EU.

As a result of this report, a wealth of information on guidance documents and other examples of best practice has already been collated in the past four years. This task therefore focuses on recent developments and guidance on the sustainable use of biocidal products produced in the last three years, and in particular best practices for PT 8, PT 18 and PT 19.

3.2 Best practice on the sustainable use of biocides

At this juncture it is worth first considering what we mean by "sustainable use" in order to be able to identify best practices for sustainable use.

It is recognised that sustainable use highly depends on the choices taken by the individual operator at the various decision points, and therefore that a number of definitions may exist. However, throughout the study, the definition set out in the '*Study towards the development and dissemination of best practice on sustainable use of biocidal products*' carried out for DG Environment in 2010 has been used as the basis for identifying best practices for the sustainable use of biocides.

"Sustainable use" is a broader concept that considers the use of biocides in general, along with the overall risks posed by all biocidal product use, and aims at the overall least impact on human health and the environment. It considers the three pillars of sustainability (economic, social, environmental) at the various points when decisions are taken concerning how to achieve the desired objective of preventing or controlling the growth of harmful organisms or of materials preservation, etc. Thus it goes beyond acceptable risk to seek any additional opportunities for further risk reductions that can be achieved while ensuring effective action against harmful organisms. This provides a further margin for ensuring least possible impacts on health and environment; it may also lead to cost savings, thereby addressing the economic pillar of sustainable use as well.

Further clarification of the term 'best practice' is also required. During the 'study towards the development and dissemination of best practice on sustainable use of biocidal products' a number of elements were identified regarding what constitutes 'best practices' for reducing the use of biocidal products to a minimum. The following key elements were identified:

- Going beyond existing EU regulatory controls, in this case the BPR;
- Balanced consideration of economic, social and environmental aspects; and
- Reducing risks from the use of biocides by minimising and/or eliminating exposure, including use of less harmful, including non-chemical alternatives.

On this basis, the following criteria have been used for selecting potential best practices:

Criterion: Best Practice	Sub-criteria
Scope	Focus on the use phase of biocidal products.
Ambition	Measure seeks to reduce risk.
	Measure seeks to promote technical understanding and detailed best practice.
Development	Involvement of stakeholders in development.
Wider applicability	Potential for expansion to EU as a whole.

Best practice on the sustainable use of biocides is therefore not concerned just with the authorisation process, but rather focuses on the use phase of biocidal products. However, it should be noted that 'sustainable use' does not necessarily mean reducing the use of biocidal products to a minimum in all cases, but about using biocidal products when necessary and in the correct amounts, having considered means of prevention and other non-chemical methods of control available.

In particular the fourth criterion of 'wider applicability' is important when considering what actions should be taken at an EU level, and what steps can be taken to encourage the wider dissemination and to promote best practices across the EU.

3.3 Consultation responses

As part of the questionnaire to Member State authorities, industry and NGOs, stakeholders were asked whether they had developed or were aware of any guidance or other documents (e.g., information mechanisms, industry standards etc.) on the use of biocides that they considered as best practice.

Only documents produced since 2010 were considered so as not to duplicate the work carried out in the previous '*Study towards the development and dissemination of best practice on sustainable use of biocidal products*'. Thereafter, the documents were categorised into the following categories of information:

- Guidance and other best practice documents
- Industry standards (e.g. CEN, ISO and national standardisation bodies)
- Economic incentives, including fee-based approaches
- Regulatory mechanisms, including binding standards
- Information mechanisms for the general public
- Other information mechanisms for professionals and businesses

A list of documents, divided according to the above categories is provided in Annex II. While this still produced a large number of documents particularly in the case of the first category, one example from each of the categories is reviewed in more detail below. However, where the documents covered are relevant to specific tasks, for example Task 5 on the application of integrated pest management principles with respect to the use of biocidal products, these are also discussed further in the Chapters that follow.

3.3.1 Guidance and other best practice documents

The 'Guidelines on Best Practice in the Use of Rodenticide Bait as Biocides in the EU' was selected as an example of best practice as has been developed by an industry association, the European Biocidal Products Forum (EBPF) of the European Chemical Industry Council (CEFIC), in consultation with stakeholders. Focusing on the use of rodenticide baits, authorised under PT 14, the guidelines consider the use phase and measures to reduce risk. Developed by an EU industry association, the guidelines clearly have potential to be applied across the EU, and also were intended to act as a template for the development of best practice documents for other types of biocidal products.

EBPF 'Guideline on Best Practice in the Use of Rodenticide Baits as Biocides in the EU'

Within EBPF's publication on the 'Sustainable use of rodenticides as biocides in the EU' (2011), the EBPF proposed that a working group should be set up, in consultation with appropriate experts from the European Commission, Member State Competent Authorities, universities and industry, to construct a new best practice guideline document for PT 14 use in the EU. This was to go beyond the description of the risk mitigation measures for anticoagulants used as rodenticides, set out in the European Commission's document from 2009 (CA-May09_Doc.6.3c) and consider IPM approaches to rodent pest management, specific mitigation measures for the active substances, and data recording, amongst other aspects.

The EBPF therefore published its 'Guideline on Best Practice in the Use of Rodenticide Baits as Biocides in the EU' in September 2013, which is intended to give guidance to professional people working in rodent control in urban and rural areas and set out sensible precautions to ensure safe and effective use of rodenticides. It should be noted that the guidance specifically covers the effective and safe application of rodenticide baits, rather than general guidance on rodent control. Applicable to PT 14, the document provides Best Practice guidance, and therefore advises on how to monitor for the presence of rodent infestations without the permanent application of rodenticide baits, discusses alternatives to rodenticides, provides practical guidance to be followed in different circumstances of rodenticide use, and describes what to do before, during and after rodenticide application. The guidance document also directs the reader to sources of information on anticoagulant resistance and how to manage it, and provides links to further information on rodent control, that is available from other organisations and authorities.
http://www.rrac.info/content/uploads/CEFIC-EBPF-RWG-Guideline-Best-Practice-for-Rodenticide-Use-FINAL-S-.pdf

3.3.2 Industry standards

In considering the sustainable use of biocidal products across the EU, EU harmonisation in terms of training and certification of professional users is a key aspect of applying integrated pest management principles to the use of biocidal products. The development of a CEN standard for pest management services therefore serves as an example of best practice, as applies at the EU level, has been developed in consultation with stakeholders (European Standard Institutes), focuses on the use phase in the delivery of pest management services and seeks to reduce risk as sets out the requirements and competences to be met by professional providers of pest management services in order to protect public health, and the environment.

EN 16636 – Pest Management Services

The activities of disinfestation and the control of insects, rodents, other vertebrates and micro-organisms has developed as a service over the years and is now commonly referred to the Pest Management industry (NACE Code 8129 A). The provision of pest control services is subject to a number of EU Directives and Regulations. In recognition of the need to develop a common standard throughout Europe, prEN 16636:2013 was prepared by Technical Committee CEN/TC 404 "Project Committee – Services of pest management companies". Following peer review by 17 European Standard Institutes, the draft standard received 100% approval at the end of 2014 and was officially launched in March 2015.

EN 16636 specifies the requirements and competences to be met by professional providers of pest management services in order to protect public health, assets and the environment. It applies to those responsible for delivering pest management services, including in the assessment, prevention, consultancy and execution of the relevant control procedures. EN 16636 does not apply to field crop protection or routing cleaning and disinfection associated with regular contract cleaning services.

Compliance with EN 16636 will enable pest management providers to demonstrate that they have the necessary competence and know-how to deliver pest management services, they have a management system to ensure a consistent level of quality, they systematically minimise risks for clients and the public and that they systematically minimise potential negative impacts on the environment and animal welfare.

It should be noted that examples of industry accreditation, ecological standards or other voluntary labelling schemes are provided in Chapter 9, which considers voluntary schemes that are used to highlight the profile of biocidal products and their use from an environmental and public health perspective. In particular the International Association for Soaps, Detergents and Maintenance Products (A.I.S.E) Charter for Sustainable Cleaning is cited as an example of best practice for the soaps, detergents and maintenance products industry.

3.3.3 Economic incentives

In addition to being asked whether they had developed or were aware of any guidance or other documents (e.g., information mechanisms, industry standards etc.) on the use of biocides that they considered as best practice, Member States were asked to provide information on any economic incentives in place in their country to encourage the sustainable use of biocides.

Of 21 Member States that responded to the questionnaire, only four Member States indicated that a fee-based approach was taken to the regulation of biocidal products in their country, as set out below. Certain elements of the fees applicable in France and Germany are also noted below.

MS	Fee-based approach
Austria	Under the future Austrian fee-Regulation, the fees for the simplified authorisation procedure according to Article 25 BPR are to be significantly lower than for a normal authorisation procedure. The simplified authorisation procedure is applicable if a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex; b) the biocidal product does not contain any substance of concern; c) the biocidal product does not contain any nanomaterials; d) the biocidal product is sufficiently effective; and e) the handling of the biocidal product do not require personal protective equipment. The fee-Regulation will be applied at the national level.
Belgium	Belgium already has an authorisation scheme in place for all biocides for which the active substance is taken up in the review program. All authorisation holders have to pay, at the beginning of each year, an annual fee of which the amount depends on i) the annual quantity of biocide placed on the Belgian market in the previous year and ii) the score assigned to the product (this varies in accordance with the hazard categories assigned to the product and is given at the stage of product authorisation or notification act). This measure applies at the national level.
France	In order for a biocidal product to be placed on the market in France, the fee for the permit ranges from EUR 500 to EUR 165,000. This wide range depends on the circumstances of the authorisation. For instance, when a product is sought to be authorised for the first time in the EU it is subject to the highest fee, whilst the fee will be considerably less if the product has already been recognised and tested elsewhere in the EU. The presence/absence of "substances of concern"

MS	Fee-based approach
	shall be taken into account in the calculation of the authorisation fee.
Germany	Under the ChemKostV[18], reduced fees are applied for the simplified procedure. Article 3 also states that a fee reduction or a fee waiver may be granted when there is a particular public interest in the marketing of the substance or biocidal product and the applicant cannot expect a reasonable economic benefit, when considering the fees and development effort.
Luxembourg	In Luxembourg, a fee-based approach is currently being introduced under Project de loi 6689. Art. 7 of the draft law, as submitted by the Government last year, sets out the fees for introducing biocidal products on the market. There is a maximum fee of EUR 300,000 for an application for authorisation of biocidal products and EUR 400,000 for an application for product type. Depending on the expertise required, these amounts may be increased to reflect the real cost. A 10-60% deduction applies for SMEs. In case of refusal of the authorisation, 50% may be reimbursed upon request. As the fees structure will be based on the Commission's Guidance document CA-DEC12-Doc.5.1.b-Final, the presence/absence of "substances of concern" shall be taken into account in the calculation of the authorisation fee.
Sweden	Sweden has a pesticides tax ("Bekämpningsmedel skatt") the intention of which was to reduce the use of biocides when the tax was first imposed. However, due to the increase in the cost of pesticides, the tax has lost its effect as is so minimal in comparison to the cost of dossiers and applications for authorisation. In addition, the tax depends only on the amount of active substance sold, and does not vary due to the hazardous nature of the active substance.

Article 80 of the BPR gives the Commission power to adopt an implementing Regulation specifying the fees payable to ECHA. Regulation (EU) No 564/2013 on the fees and charges payable to ECHA[19] was therefore adopted. The Commission was to review the fees and charges provided for under the Regulation at the latest by 1 January 2015.

The evaluating competent authorities may also charge a fee associated with their work. Article 80(2) of the BPR provides that Member States shall directly charge applicants fees for services that they provide with respect to the procedures under the BPR, including the services undertaken by Member States' competent authorities when acting as evaluating competent authority. Member States are to set and publish the amount of fees payable to their competent authorities.

To assist in developing a harmonised structure of fees, the Commission issued 'Guidance concerning a Harmonised Structure of Fees'[20] in 2012 in order to advise Member States on possible fee structures and relative amounts, taking into account existing national practices. Section 4 of the guidance sets out an indicative approach for a harmonised structure for the main tasks and services provided by the Member States under the BPR. In relation to the flat fees payable for biocidal products, the amount payable depends on whether the application is for product authorisation or product authorisation according to the simplified procedure, and in case whether the application relates to a single product, a single product where the product and use are identical to the reference product assessed for the active substance approval or for a biocidal product family.

This therefore allows Member States to differentiate the level of fee applied to the product authorisation according to whether the application is for national authorisation or under the simplified authorisation procedure, as is applied in Germany and will be introduced in the new fee-Regulation in Austria. The Commission guidance also refers to top-up fees, where for example the amount is based on whether the application includes a substance of concern or would require a specific assessment with a view to making a

[18] http://www.gesetze-im-internet.de/chemkostv_1994/BJNR211800994.html
[19] Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products, OJ L 167, 19.6.2013, at page 17.
[20] European Commission, 'Guidance concerning a Harmonised Structure of Fees', CA-Dec12-Doc.5.1.b-Final

recommendation regarding the establishment of maximum residue levels, as is the case with the fee structure applied (or to be applied) in France and Luxembourg.

Article 80(2) of the BPR also provides that Member States may levy annual fees with respect to biocidal products made available on their markets. The Commission guidance states that this could either be set at the same level for all products, could be a percentage of the value of the sale of each biocidal product during the preceding year, or "the annual fee could also be proportional to the degree of risk of the biocidal product, as for instance reflected in the number of R-phrases on its labelling. The higher the degree of risk, the higher the fee would be."

The only example found of where such a differentiation is made based on the risk of the biocidal product, is the annual contribution which requires to be paid in Belgium.

Belgium – Annual contribution

In addition to the fees that may be charged by the competent authorities for the work it carries out within the scope of the BPR, Article 80(2) of the BPR provides that Member States may levy annual fees with respect to biocidal products made available on their markets. The Commission guidance states that this could either be set at the same level for all products, could be a percentage of the value of the sale of each biocidal product during the preceding year, or could be proportional to the degree of risk of the biocidal product.

In Belgium, all authorisation holders have to pay, at the beginning of each year, an annual fee, the amount of which depends on i) the annual quantity of biocide placed on the Belgian market in the previous year (authorisation holders must declare the quantities before 31 January each year) and ii) the score assigned to the product (this varies in accordance with the hazard categories assigned to the product and is given at the stage of product authorisation or notification act). This measure applies at the national level.

Under Article 7 of the Royal Decree of 13 November 2011 setting the fees and contributions payable to the Budgetary fund for Raw Materials and Products, at the stage of authorisation, a biocidal product will receive a score which corresponds to hazard points calculated according to the risk/hazard phrases (R/H phrase). The number of points assigned to a product depends on the classification of the biocidal product according to the hazard categories set out in the table below, based on the risk phrases that are mentioned in the product authorisation or the summary of product characteristics. It should be noted that the table is not adapted to the Regulation (EC) no. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as the calculation is still based on the phrases used in the product documentation. The phrases are used to identify the risk categories. The points of a particular hazard category may be charged only once. If a biocidal product covers numerous categories, the points of these hazard categories will be added, with the exception of categories no. 9, 14 and 19, which shall not be added, in which case the category with the highest number of points will be charged.

No.	Hazard category	Phrases	Points
1	Explosive	1, 2, 3	2
2	Oxidising	7, 8, 9	1
3	Highly flammable	12	2
4	Highly flammable	11, 15, 17	1.5
5	Flammable	10	1
6	Corrosive	34, 35	2
7	Irritant	36, 37, 38, 41	1
8	Sensitising	42, 43	1
9	Harmful by short term exposure	20, 21 or 22 (to the extent not in combination with 48), 65, 68 in combination with 20, 21 or 22	1
10	Harmful by long-term exposure	48 in combination with 20, 21 or 22	1
11	Harmful (c)	40	1
12	Harmful (M)	68	1
13	Harmful (R)	62, 63	1
14	Toxic by short term exposure	23, 24 or 25 (to the extent not in combination with 48), 29, 31, 39 in combination with 23, 24 or 25	2
15	Toxic by long-term exposure	48 in combination with 23, 24 or 25	2
16	Toxic (C)	45, 49	2
17	Toxic (M)	46	2
18	Toxic (R)	60, 61	2

19	Very toxic by short term exposure	26, 27, 28, 32, 39 in combination with 26, 27 or 28	3
20	Dangerous for the environment	50, 50/53, 51/53, 59	2

3.3.4 Regulatory mechanisms

The main regulatory mechanisms identified either relate to a number of measures taken by Member States to prohibit or restrict the use of biocides in specific areas (these are considered further in Chapter 6, which considers the risks posed by the use of biocidal products in specific areas) or to certification schemes, such as the French Certibiocide scheme or certification schemes which apply to specific product types, which are considered further in Chapter 7 on the application of integrated pest management principles to the use of biocidal products. In addition, one Member State referred to the overall prohibition of use of biocidal products by amateurs where they are restricted to "professional use" only.

3.3.5 Information mechanisms

The Danish 'THINK' campaign was selected as an example of an information mechanism, which acts as a mechanism for dissemination of best practice as is intended to raise awareness of biocides generally, but also specifically to provide the consumer with knowledge about what biocides are, and how to use them correctly without harming people or the environment, thereby providing advice on measures to reduce risk during the use phase of biocidal product. The campaign included both a website and a mobile phone app which provides information on how to prevent the presence of a particular pest through practical measures, non-chemical means of control, and information of the use of biocides to kill the organism.

Danish 'THINK' campaign

The most recent in a line of campaigns launched by the Danish Environmental Protection Agency is the campaign called "hverdagsgifte". The term "hverdagsgifte" means "every day poisons" and was chosen to replace the term biocides, as a more explanatory term. The campaign, which uses the slogan "Think"…before you use everyday products containing poison", is intended to raise awareness of biocides in general as toxic compounds, and also provide the consumer with knowledge about what biocides are, and how to use them correctly without harming people or the environment.

The campaign includes a website, a music video as well as an app for mobiles, computers and tablets. The website (www.hverdagsgifte.dk (in Danish)) provides information on household poisons (biocides) as well as products that often contain household poisons, how to use biocides safely, and how to dispose of them in a responsible manner. Furthermore, the Danish Ministry of the Environment website (www.mst.dk) offers advice on how to avoid using household poisons and use another solution instead. The campaign includes a YouTube music video with the Danish actor Nikolaj Kopernikus, and a musical track entitled "poison".

The campaign also included a new app for smartphones (www.bekaemp.dk) which allows you to select whether it is a problem with mammals, snails, algae, fungi and bacteria, or insects, ticks and mites that you wish to deal with. Each individual section of the app for that category of pest provides information on how to prevent the presence of that pest through practical measures, non-chemical means of control, and lastly information of the use of biocides to kill the organism. In such cases, it is made clear that you must read the label and follow directions on the use of the biocide. Links are also provided to where further information can be found. In addition, the Danish Ministry of the Environment website (www.mim.dk) offers advice on how to avoid using biocides and alternative solutions.

http://eng.mst.dk/topics/biocides/think-before-you-use-everyday-products-containing-poison/

Whilst the Danish 'THINK' campaign obviously targets the Danish consumer, similar initiatives could be adopted in other Member States. The responses to the consultation did identify a number of Member State authority websites as well as information leaflets provided by industry associations, competent authorities and NGO's. For example, a website of the German Federal Environment Agency provides information to the general

public about physical, chemical and other measures as alternatives for the use of biocidal products or for minimisation of their use. The focus lies on the description of preventive measures. A short description of habitats, biology and risks from common pests is presented. Available best practices are also referred to. The web-portal is continuously extended and shall also include an English version in future[21].

It may be advisable therefore to have one central hub for information on biocidal products, where leaflets and other information mechanisms could also be translated into different EU languages in order to improve distribution across the EU. It is therefore recommended that the Commission considers establishing a website which acts as a database of all available guidance and other information on the sustainable use of biocidal products.

3.4 Measures used for the promotion of best practices

While there is a variety of best practice documents relating to different product types, in recent years these have largely been developed by industry/industry associations, such as CEPE's guidance on 'Personal Health Protection during Application of Antifouling Paint' or A.I.S.E's 'Tips for Sustainable Use of Biocides by Professionals'. Member States have indicated that further guidance on the sustainable use of biocidal products would be helpful, particularly given that due to a lack of resources they are unable to develop guidance themselves.

A number of Member States are however looking to develop their own strategies for the sustainable use of biocidal products. In particular, the German Federal Environment Agency issued a position paper setting out a 'Proposal for a concerted European approach towards a sustainable use' in December 2014, which includes a list of possible actions at the national level. Whilst it is recognised that these do not replace the need for a collective European solution to the sustainable use of biocidal products, it is stated that this could help to encourage other national authorities that want to take a leading role in the sustainable use of biocides to take action. Indeed, the Danish Environmental Protection Agency is currently undertaking a study on solutions and tools for sustainable use of biocides, with a view to developing a Danish strategy on the sustainable use of biocides. Where possible, the Commission could seek to support such initiatives at the Member State level and facilitate further developments in best practice across the EU.

For those product types for which guidance on sustainable use and other best practice documents are available, there are a number of means by which to promote compliance with best practices. These could potentially include the following measures:

1) that compliance with guidance/best practice documentation is made a condition of authorisation;
2) that the label and instructions for use on the product refer to the relevant guidance/best practice documentation;
3) that compliance with guidance/best practice documentation is part of a stewardship or certification scheme for the individual product type;
4) that compliance with guidance/best practice documentation is part of an industry standard, for example as required under the A.I.S.E Charter for Sustainable Cleaning; or
5) that compliance with guidance/best practice documentation forms part of a Best Available Techniques Reference Document (BREF) developed for the sector.

The first and second options require the competent authority to stipulate these requirements within the conditions of authorisation. However, there is no guarantee of

[21] www.biozid.info

compliance by the authorisation holder with best practice, particularly since they are not the end-user, and these options therefore rely on the correct application of user instructions by the end-user.

The third option is therefore more feasible as involves initial approval/accreditation and ongoing checks on compliance with the scheme. For example, this is the approach being adopted in the UK in relation to the authorisation of rodenticides, where compliance with a proposed industry stewardship scheme will be required as a condition of authorisation of anticoagulant rodenticides. Best practice guidelines on the safe use of the product, compiled by the industry body are included in the scheme and the labelling of the product is to contain the phrase 'For supply to and use only by professional users holding certification demonstrating that they have been trained according to the UK second generation anticoagulant rodenticide (SGAR) stewardship programme requirements.' Further details of the UK SGARs stewardship scheme are provided in the table below:

Second Generation Anticoagulant Rodenticide (SGAR) Stewardship Regime

The Campaign for Responsible Rodenticide Use (CRRU), an industry-funded organisation, designed a code of conduct aimed at the reduction of exposure of wildlife to rodenticides based on seven principles: 1) always have a planned approach; 2) always record the quantity of bait used and where it is placed; 3) always use enough baiting points; 4) always collect and dispose of rodent bodies; 5) never leave bait exposed to non-target animals and birds; 6) never fail to inspect bait regularly; and 7) never leave bait down at the end of treatment. Several pest control companies in the UK were 'CRRU supporters' and applied this scheme (www.thinkwildlife.org/) for rodenticides generally.

Following the risk assessments of Second Generation Anticoagulant Rodenticides (SGARs) carried out within the framework of the BPR by the Health and Safety Executive (HSE) as competent authority for the regulation of biocides in the UK, it was shown that due to the potential impact that SGARs can have on the environment and non-target species, SGARs would require to be restricted to indoor use only. However, given the significant benefits that SGARs bring to the protection of public health, animal welfare and the environment, industry was invited to develop proposals for the effective stewardship of SGARs. Where the risks associated with the use of SGARs would be reduced through implementation of a stewardship scheme, this would allow HSE to proceed with the authorisation of SGARs. The CRRU was therefore invited to co-ordinate the development of a stewardship scheme for SGARs.

Building on the earlier work of the CRRU, four Sector Groups were established to develop the stewardship scheme: professional pest control (including local authorities), farming, game keeping and suppliers (including amateur use), under the coordination of the CRRU. A designated Oversight Group was also established, made up of HSE, Defra and officials from the Department of Health. Each sector group therefore drew up plans for a range of stewardship measures and for monitoring their benefits, as set out in the individual sector group documents.

Proposals for the SGARs stewardship scheme for all four sectors were submitted to the HSE in 2014, and by the Autumn, it was announced that the stewardship scheme would go ahead, with the details of implementation and timing to be determined at a later date. In the meantime, product authorisations for SGARs were put on hold and consultation was carried out (until end January 2015) with a view to authorising the first products for outdoor use under the stewardship scheme in early 2015. HSE intend to authorise anticoagulant rodenticides for sale and professional use under the terms of the proposed industry stewardship scheme, adherence to which will be set as a condition of authorisation. This would also include a requirement that labels contain the phrase 'For supply to and use only by professional users holding certification demonstrating that they have been trained according to the UK second generation anticoagulant rodenticide (SGAR) stewardship programme requirements.'

Included in the stewardship proposals are Best Practice Guidelines compiled by CRRU for rodent control and the safe use of rodenticides by professional users. These take into account all the different literature available within the industry, and are to be applied across all Sector Groups in order to reaffirm best practice by all professional users. The Best Practice Guidelines also highlight that SGARs should be the final choice of control method, and that they are not the only solution to a problem as there are existing alternatives such as trapping and the use of aluminium phosphide.

The SGARs stewardship scheme also covers training and continuing professional development (CPD) with specified training levels to be obtained and proof of competence checks in place. Monitoring is also an important factor of the SGARs stewardship scheme. Three key areas of monitoring have been proposed which include monitoring SGAR residues in barn owls, monitoring the breeding pairs of barn owls and a KAP (knowledge, attitude and practices) survey in relation to SGAR use.

While the SGARs stewardship scheme is voluntary, almost all suppliers of SGAR products have signed up as

members of the CRRU. Through membership of the CRRU, members will be audited annually for compliance with the SGARs stewardship scheme.

http://pestcontrolnews.com/uk-second-generation-anticoagulant-rodenticides-sgars-stewardship-regime-proposals/

While the UK SGARs stewardship scheme is a voluntary initiative, compliance with the scheme is the only way in which companies will receive authorisation for the outdoor use of SGARs. A similar approach has also been taken in the Netherlands. Following consultation with sector organisations of pest controllers, the Dutch authorities have indicated that under specific conditions, outdoor use of rodenticides as part of IPM and with certification of the users may still be possible.

The fourth option would require that compliance with guidance/best practice documentation is part of an industry standard. For example, under the A.I.S.E Charter for Sustainable Cleaning, over 200 companies within the European soaps, detergents and maintenance products industry have joined the scheme which promotes a common approach to sustainability practice. Regular updates to the Charter ensure that it continues to offer the most advances sustainability assurance scheme for promoting best practice within the industry. Following the latest update to the Charter, a new product dimension is included where companies are required to comply with new advanced sustainability profiles for product categories, which are defined on the basis of best use information amongst other factors. The Charter also benefits from external verification and checks to ensure ongoing compliance and requires companies to report annually on sustainability. The A.I.S.E Charter for Sustainable Cleaning is discussed further in Chapter 9 on voluntary schemes used to highlight the environmental and public health profile of biocidal products.

Finally, the fifth option would require that compliance with guidance/best practice documentation forms part of a BREF developed for the sector. Under Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control)[22] (IPPC) several BREFs have been developed for different sectors[23]. In this context, BAT means the most effective and advanced stage in the development of activities and their methods of operation which are economically and technically suitable to prevent or reduce emissions to the environment. Annex I of the Industrial Emissions Directive refers to threshold production values in terms of capacities or outputs of selected industrial activities for which the BREFs are obligatory. Although these BREFs have no legally binding status, they are often referred to by the relevant authorities when defining BAT and limit values for discharges and emissions.

The following BREFs cover the use of biocides in the respective sectors, directly or indirectly:

BREF	Date	PT	Product threshold (examples)
Intensive Rearing of Poultry and Pigs	07.2003	3, 18	40000 places for poultry, 2000 for pigs > 30 kg, 750 for sows
Slaughterhouses and Animals By-products Industries	05.2005	4	Carcass production 50 t/day, animal raw materials 75 t/day
Food, Drink and Milk Industries	08.2006	4	300 t/day vegetable raw materials. 200 t milk per day

[22] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast), OJ L 334, 17.12.2010
[23] http://eippcb.jrc.ec.europa.eu/reference/

BREF	Date	PT	Product threshold (examples)
Surface Treatment using Organic Solvents	08.2007	8, 21	15 t/annum solvent for coating of wooden surfaces
Wood preservation with Chemicals	Review started	8	75 m^3/day
Textiles Industry	07.2003	9	10 t/day pre-treatment or dyeing of textile fibres or textiles
Tanning of Hides and Skins	02.2003	9	12 t/day finished products
Industrial Cooling Systems	12.2001	11	Energy industry 50 MW thermal input
Pulp and Paper Industry	12.2001	12	20 t/day paper or card board
Emissions from Storage	07.2006	-	10 t/day hazardous waste

The development or revision of BREFs is carried out by technical working groups which are established by the Commission and consist of 40 to 100 technical experts representing Member States, industry, and NGOs. The individual names of the working groups are kept confidential. The European IPPC Bureau organises the work, strengthens the exchange of information, makes a scientific and technical analysis of the information exchanged, proposes compromise solutions on issues when views of technical working group members differ, and writes the BREF. The procedure includes a few plenary or sub-group meetings, visits to installations, and submission of draft BREFs for comments. The information exchange in particular addresses the performance of installations and techniques in terms of emissions, the associated reference conditions, the consumption and nature of raw materials, water consumption, use of energy, and generation of waste for identifying best available and emerging techniques (Article 13 of the Industrial Emissions Directive). For this, a Guidance document on the collection of data, drawing up of BREFs, and on their quality assurance has been established (Commission Implementing Decision 2012/119/EU[24]). Once finalised each BREF is presented to DG Environment at the information exchange forum.

The platform for information exchange could be used for developing best practice documents for biocides use from industrial sectors. However, considering biocides in BREF documents would require a shift in BREF development because (with a few exceptions such as the BREF on cooling systems), these do not relate to specific substances but focus on emission control as a whole. For example, the BREF on "Intensive Rearing of Poultry and Pigs" covers the application area of PT 3 disinfectants. In the draft of the revised BREF it is stated that the use of evaluated cleaning agents and disinfectants could reduce the harmfulness of the waste water[25]. While the use of disinfectants for veterinary hygiene purposes usually is combined with cleaning and pest control of insects (PT 18) and rodents (PT 14) no details for the sustainable use of these biocidal products is given in the document. The use of biocides could be included in a general guidance of good housekeeping which is only shortly mentioned in the BREF. Providing more details about the selection criteria for biocides into the BREFs is one option to promote a sustainable use of biocides. The risks for professional user resulting from the use of chemicals such as biocides are not covered at all by the Industrial Emissions Directive.

[24] Commission Implementing Decision of 10 February 2012 laying down rules concerning guidance on the collection of data and on the drawing up of BAT reference documents and on their quality assurance referred to in Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions, OJ L 63, 2.3.2012

[25] http://eippcb.jrc.es/reference/

3.5 Conclusions

In conclusion, a great number and variety of documents on best practice for the sustainable use of biocidal products, including guidance, industry standards, regulations on fees, regulatory mechanisms, and information mechanisms for the public, professionals and business, have been produced in the last few years. However, in order to ensure a harmonised approach to the sustainable use of biocidal products across the EU, the key issue is how to ensure dissemination of best practice and adherence to the principles of sustainable use of biocidal products.

For those product types where best practice documents on the sustainable use of biocidal products are available, a number of options to promote compliance with these have been identified. However, with the exception of rodenticides where a lot of work has already been carried out in developing best practice documents and research into appropriate risk mitigation measures, there is a need to develop further guidance/best practice for individual product types.

The following recommendations are made:

1) Link with product authorisation – the product authorisation could refer to the relevant guidance/best practice documents;

2) Certification and training - for those product types for which a certification or training scheme is made mandatory as a condition of authorisation (see Recommendations in Chapter 7 on the application of integrated pest management principles to biocidal products), compliance with guidance/best practice documentation should form part of the requirements for certification;

3) Voluntary standards - company or industry voluntary standards should include adherence to guidance/best practice documentation where appropriate;

4) Best available techniques reference documents (BREFs) –future BREFs, for example the current review of the BREF on wood preservation with chemicals, could refer to guidance/best practice documents on the sustainable use of biocides in that sector.

5) Where there is a need to develop further guidance/best practice for an activity or for the use of individual product types, the Commission could look to establish specific working groups for the industry sectors concerned, or support industry initiatives on this. The creation of working groups and framework for the development of BREFs could serve as an example for EU-wide collaboration on the development of best practices for sustainable use of biocides.

6) To make information accessible to all users, it is recommended that the Commission considers establishing a website which acts as a database of all available guidance and other information on the sustainable use of biocidal products.

7) Member States should consider levying annual fees which are proportional to the degree of risk of the biocidal product, payable by the authorisation holder, in order to encourage the sustainable use of biocidal products. This is referred to within guidance produced by the European Commission but could be further encouraged at the EU level, through amendments to Regulation (EU) No 564/2013 on the fees and charges payable to ECHA, following its review.

4 ADDITIONAL MEASURES TO REDUCE RISKS

4.1 Introduction

Under Article 18 of the BPR, the need to introduce additional measures to reduce the risks posed to human health, animal health and the environment by biocidal products is to be considered as part of the report to the European Parliament and the Council on how the BPR contributes to the sustainable use of biocidal products. In particular, this is to include analysis of whether additional measures are required for professional users. The need to introduce additional measures is therefore considered for both professional users and the general consumer, where a product is authorised for use by the general public.

In each case the focus of this Chapter is to identify the potential exposure and risks posed to human health for the end-user of a biocidal product. Risks posed to the environment by the use of biocidal products in specific areas, such as the water environment, are considered separately in Chapter 6.

As a first step, the meaning of "professional users" should be clarified. While "professional users" are all those persons involved in the application of biocidal products in a professional context, the level of training and the information requirements differ considerably and some professional users may even not be aware that they use a biocidal product. Thus, an analysis of the different user categories is required.

4.2 Meaning of professional users

The BPR does not provide a clear definition of the different user categories. According to the data requirements of active substances (Title 1) or microorganisms (Title 2) the applicant must indicate the user "e.g. industrial, trained professional, professional or general public (non-professional)".

The Sustainable Use Directive distinguishes between professional users who use pesticides in the course of their professional activities (including operators, technicians, employers and self-employed people, both in the farming and other sectors) and non-professional users who in general do not have the same level of education and training.

Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals[26] (REACH) defines the "downstream user" as any natural or legal person other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture in the course of his industrial or professional activities. The distributor or a consumer is not a downstream user. The REACH guidance on occupational exposure estimation makes a distinction between the manufacturing, formulation, industrial use and professional use stages of the life cycle of a substance when considering occupational exposure. Industrial use covers the application of the substance, mixture/product in an industrial process, while professional use covers the application of mixtures/products in skilled trade premises. If it is unclear whether a use best fits professional or industrial use, the category "professional use" should be assumed[27].

[26] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC, OJ L 396, 30.12.2006

[27] ECHA 2012.Guidance on information requirements and chemical safety assessment Chapter R.14: Occupational exposure estimation. Version: 2.1 November 2012

Several other Directives or implementing Regulations for the approval of active substances require the restriction of use to "specifically trained professionals" or "adequately trained professionals" (fumigations such as Sulfuryl fluoride, Aluminium phosphide, Hydrogen cyanide PT 8 and or PT14). Others actives are restricted to professional use or industrial operators[28].

4.3 Different user categories

For the purposes of this study, 'professional users' are those persons involved in the application of biocidal products in a professional context, and therefore does not include those dealing with the production of the biocide in the manufacturing process, or consumers who use biocidal products in a private environment/personal capacity. However, while the application of biocidal products within a professional environment will largely be carried out within a workplace, the professional use of biocidal products can also occur outside designated workplaces, in a non-structured manner. Consideration should therefore be given to the different user categories.

From 2008 till 2012 there was an attempt by the Competent Authorities to reach a common understanding of the different user categories. In a consultation carried out there was a broad consensus that there is a need for harmonising the definition of the user categories in order to avoid misunderstanding during product authorisation. However the proposal to introduce the new terms "trained–professionals" and "industrial user" in the BPR was not accepted by all Competent Authorities[29].

The Guidance on information requirements provides the following attributions of user categories[30]:

- Industrial user: user involved in manufacturing, handling and/or packaging of actives or products at industrial sites.
- Trained professional user: professional user using end-products outside industry with a licence.
- Professional user: professional user using end-products outside industry.
- Non-professional user: member of the general public at a workplace or at home (consumer).

The rational for defining industrial user as a distinct user category is that in-house training of personnel and surveillance of industrial plants by authorities usually has a high level. All installations subjected under the Industrial Emissions Directive 2010/75/EU the former Integrated Pollution Prevention and Control Directive) must be operated according to a written authorisation (permit). Companies are obliged to apply "best available techniques", that means "the most effective and advanced stage in the development of activities and their methods of operation which indicates the practical suitability of particular techniques for providing the basis for emission limit values and other permit conditions designed to prevent and, where that is not practicable, to reduce emissions and the impact on the environment as a whole." These are described in Best Available Technique Reference Documents (BREFs). Thus, one option for defining "industrial use" is to refer to Directive 2010/75/EU.

A common synonym for 'trained professional user' is "specifically trained professional user". Optionally, the different level of training could be considered by referring to "qualified professional user" where the biocide specific training takes less than one week

[28] Gartiser, S., Jäger, I.: Efficiency and practicability of risk mitigation measures for biocidal products - wood preservatives and insecticides. Final report FKZ 3709 65 402, UBA-Texte Nr. 01/2011.
[29] CA 2008. User categories – consultations. PA&MRFG-Nov08-Doc.5a.
[30] ECHA 2013a. Guidance on information requirements. Version 1.0 July 2013
http://www.echa.europa.eu/documents/10162/15623299/biocides_guidance_information_requirements_en.pdf

without any test and reserve the term "trained professional user" to those who receive longer training and prove their knowledge in tests.

The term "professional user" might be interpreted in two different ways: it might be used as unspecific term for all people using biocidal products in a professional context with and without a qualification or it might be used as a generic term for the professional subgroups "professional user without specific qualification" and "trained professional user";

Non-professional user: member of the general public at a workplace or at home (consumer). This definition gives room for misunderstanding because previously all users at the workplace have been considered as "professional user". It is suggested to use the term "professional user without qualification" for this subgroup.

The following are examples of the use(r) categories given: preservatives for liquid-cooling and processing systems are used by professionals, avicides and piscicides are used by professional users other than industrial, and disinfectants for water beds are mainly used by non-professionals.

In the context of this task we use the term "professional user" to refer to all people using biocidal products in a professional context with or without a qualification, therefore incorporating the categories of professional users and trained professional users set out above. This does not therefore cover "industrial users" who use biocidal products in the manufacturing process. Separately, consideration is also given to whether additional measures need to be introduced to reduce the risks posed to "non-professional" users, who use biocidal products in a private environment/personal capacity, i.e., general consumers.

4.4 Questionnaire responses

As part of the stakeholder consultation, Member States were asked the following questions:

- Does your authority apply a specific definition of 'professional user'? Who do you regard as professional users for each product type?
- Does your country operate a scheme for the certification of professional users?

From the responses received it can be seen that the two questions are very much interlinked and in many cases, a definition of "professional user" arises as a result of there being a certification scheme or other training requirement in place in that Member State.

Of the 21 Member States that responded, only four indicated that they did not apply a definition of "professional user". From the 17 Member States that indicated that they do apply a definition of "professional user", overall, the responses can be split into those countries that apply a general definition, those countries that apply a definition based on a general scheme of certification or training in operation, and those countries that impose requirements for specific product types.

MS	General definition
Bulgaria	Under the Law of protection from the harmful impact of the chemical substances and mixtures, a "professional user" is any Bulgarian or foreign individual or corporate body, which is registered under the Commercial Law or under his national legislation or who exercises free-lance practice in the sense of the Law on Taxes on The Income of Natural Persons, who uses and/or places on the market dangerous chemical substances and mixtures." This definition concerns professional users of chemicals, including biocides.
Finland	In Finland, the term professional user is used in the national biocide authorisation system to mean persons who need to use certain biocidal products in their profession. More specific definitions, linked to certification schemes are however used for specific product types (see table on specific PT below).
Germany	A professional user is between 18-65 years of age and uses the product during the whole time or parts of his 8-h-working-shift. He is subject to national occupational laws but does not necessarily have more knowledge or motivation concerning the safe use of a biocide and/or correct use of PPE than a consumer. Examples include nurses, pool attendants, cleaners (PT1-5), farmers, horticulturists, conservationist, caretakers, pest controllers (PT14-20), ship owners, taxidermists, pathologists (PT21-22). In addition, a differentiation is made between the professional user and the trained professional user (see below).
Hungary	Under ministerial decree No 44/2000 (XII.27) on detailed provisions for procedures and activities connected to hazardous materials and mixtures, a person who deals with hazardous materials/mixtures in connection with his/her occupation or who employs workers dealing with hazardous materials/mixtures is classified as a professional user.
Ireland	The term "professional" is used in a general sense to mean those people employed to carry out an activity where biocidal products are used, e.g. farmers, fishermen, janitors. However, professional users of biocidal products are differentiated when appropriate, such as where there needs to be specific or specialised training such as where fumigants are used or where the work is carried out in an industrial setting with numerous technical/operation controls.
Luxembourg	A professional user is any person, intermittently using biocidal products in the context of his professional activity, where those products are indispensable to the exercise of his professional activity, having sufficient knowledge about the safe handling of chemicals including the implementation of appropriate personal protective equipment. The category of "trained professional" user also exits (professional users specialised in the use of pesticides, i.e. pest control specialists).
Slovenia	In Slovenia, the definition of professional user from guidance documents for the assessment of biocidal active substances and biocidal products is used. A professional user in Slovenia is therefore an industrial user or other professional user.
Sweden	In Sweden, anyone who is covered by the provisions of the Swedish workers protection legislation is regarded as a professional user. More specific definitions, linked to certification schemes are however used for specific product types (see below).
United Kingdom	A professional user is any person using a biocidal product as part of their work activity, regardless of the location. For some policy or legal purposes a further distinction might sometimes be made between 'industrial' workers in industrial locations such as factories or other industrial locations and other 'professionals' who might be operating in a non-industrial, public, or domestic environment.

As noted in the table above, in Germany a general definition of 'professional user' applies. However, in addition, a differentiation is made between professional users and trained professional user. This provides a useful example of where the different user categories are applied.

In Germany, the professional user applies biocidal products in the frame of his occupational activity and has no additional qualification for the appropriate use of biocidal products. The trained professional user applies biocidal products in the frame of his occupational activity and has special qualifications for the appropriate use of biocidal products that are listed in the authorisation certificate. The types of additional qualifications that may be required include a certificate of competence in accordance with the German Hazardous Substances Ordinance, or under other legal regulations, or specific experience gained from attending training courses.

For example, for the authorisation of rodenticides, the following user categories apply:

- Specialised professional user – this is a professional user with a certificate of competence according to the German Hazardous Substances Ordinance, Annex 1, No. 3;
- Licensed professional user – this is a professional user with competence according to the German Ordinance Governing Specialist Qualifications in Plant Protection or under §4 of the Protection of Animals Act in combination with a certification of training or a professional user that has specific experience following participation in a training course on behaviour, biology and habits of rodents, the legal base for the control of rats and mice, rodent control (following the best practice code for the application of baits to control rodents including integrated pest management and resistance management), the mode of action of rodenticides (anticoagulants in particular), rodenticides as hazardous substances and risks for human health and the environment during application and appropriate risk mitigation measures (especially to avoid primary and secondary poisoning of non-target animals, risks of PBT-/vPvB-substances), application techniques / procedure and documentation, and the behaviour of rats in sewers.;
- Non-specialised / Non-licensed professionals.

The following Member States have in place certification schemes, which are used to set out the parameters of those regarded as 'professional' users:

MS	General certification scheme or training requirements
Austria	While "professional user" is not defined under the Austrian Act on Biocidal Products, the special profession of a "biocide controller" is a regulated trade under Art.94 of the Austrian Trade Act.
France	In France a "professional user" is a holder of an individual certificate granted in accordance with the Decree of 9 October 2013 concerning the conditions for the exercise of the activity of professional user and distributor of certain types of biocidal products (Certibiocide scheme).
Estonia	The Estonian Biocides Act defines 'professional user' as a person who has an appropriate qualification and who uses biocides, which are authorised for professional use, in the course of their professional or business activities. Professional users should have a relevant certificate or evidence of education and training in relevant areas, as administered by the Estonian Qualifications Authority. In addition, those who provide pest control services, must have a qualification certificate, following training and examination by the "Union of Estonian Disinfection and Pest Control Enterprises".
Hungary	Professional users must have a membership of the national Council of Hungarian Paramedical Professionals (for PT. 14, 18 and 19).
Malta	Professional users are those that handle and use biocides as part of their work, following either in-house training or completion of a recognised training course.

As can be seen from the example of Estonia above, in some cases product specific certification schemes operate in addition to a general certification scheme. Alternatively, in other Member States which have no general certification scheme, specific training requirements and/or certification have been introduced for specific products, primarily in the area of pest control.

MS	Product specific definition and certification requirements
Bulgaria	The National centre of infectious and parasitic diseases (NCIPD) is responsible for certification of operators carrying out disinfection and pest control activities of persons and entities acting as specialised companies and organisations engaged in these activities.
Croatia	According to the Law on communicable diseases and Veterinary Law, companies working in the area of disinfection and pest control and in veterinary hygiene should have a licence for their professional activities.

MS	Product specific definition and certification requirements
Denmark	In Denmark, rat control officers have to be certified by the Danish Nature Agency to control rats (not mice) using rodenticides (PT14). PT8 and other PT's trained professionals have to have a gassing certificate to be allowed to control pests using gassing.
Finland	Under the national authorisation for antifouling substances (PT21), professional users are people painting and repairing boats/ships in dry docks and shipyards. Certain AF-products can only be used by professionals. According to the Finnish Chemical Act (599/2013), pest control operators (PCO) must have completed a qualification on the use of biocidal products intended for pest control (PT14 and PT18) and be included within the register of PCOs to be maintained by TUKES by the end of 2016. The education and qualification events were planned to start during the second half of 2014. Other professions using insecticides and rodenticides such as farmers, caretakers etc. are considered as professional users without professional training.
Greece	Professional users of PT14, PT18 and PT19 under the competence of the Ministry of Rural Development and Food must be authorised by the Ministry on the basis of their University Degree and the specific knowledge gained during their studies.
Latvia	Requirements are in place for professional users, which provide disinfectant, disinfectant and anti-rodent services. The certificate of disinfector is issued in accordance with the Regulation on requirements regarding disinfection and pest control services.
Netherlands	In the Netherlands, there is a Certified Pest Animal Management scheme, operated by the NVPB, the trade association of pest management companies. Companies that can demonstrate that they meet the standard can be accredited by independent accredited certification bodies.
Spain	In Spain, there is a definition of professional users for PT 2, 3, 4, 14, 18 and 19 as well as a definition for training professional users. The certification of professional users depends on the activity, with those responsible for the design of the treatment required to hold a specific certificate of professional qualification, having carried out associated training of 540 hours. A worker who applies the biocidal product is required to hold a specific certificate of professional qualification, having undertaken 370 hours of associated training.
Sweden	In Sweden, two types of licence (So and SoX) are required under the Environment Code (1998:808) for professional users working with measures against vermin and pests and for professional users working with gases to treat vermin and pests. The Swedish Work Environment Authority also requires a licence for other activities (AV), for example use of wood preservatives and antifouling products, and provides training courses for wood impregnation industries, which includes knowledge in occupational safety and risks for the environment.

Finally, while there is no definition of a "professional user" in Belgium, the applicant for authorisation has to indicate if his product is intended for professional or public use (or both). Biocides for which public use is excluded, and/or for which there is an obligation to wear PPE (more than gloves), are classified as "class A". Biocides of class A can only be sold or used by registered sellers and authorised users. There are specific training and storage requirements for these products. Biocides for fumigation can also only be sold or used by specially authorised sellers or users. They have to prove that their knowledge and condition of use of the products are legally defined. In 2015 class A will be replaced by a closed circuit. All sellers and users will have to register their sales and uses. Afterwards, specific conditions of use and/or training will be defined per product or per product type.

These approaches to the certification of professional users and training schemes for different classes of users of biocidal products is considered further in Chapter 7, on the application of IPM principles under the Sustainable Use Directive to biocidal products.

4.4.1 Key areas of exposure risks

Exposure assessment is the evaluation of potential exposure to man and the environment. Exposure assessment in a workplace depends on information about that workplace and workforce and the use (handling, patterns of use and disposal) of products on-site.

Those placing on the market biocidal products, as with any other chemicals, are required to provide sufficient and appropriate information to ensure that those using or handling

their products are not at risk should exposure to the products occur. At the point of placing on the market, the data necessary for the identification and classification of a biocidal product will be generated and available with respect to it toxicological, ecotoxicological and physico-chemical properties, whether this relates to the product as a mixture or to the individual ingredients (actives ingredients and other components) which go to make up the biocidal product as supplied to users.

For professional users the risks from exposure will need to include and be based on specific information, some of which will be provided to them via the supplier of the biocidal product e.g. SDS and label and where required or available other product data specifications which can include manufacturer's instructions and recommendations regarding for example use, storage, actions in case of an emergency and/or disposal.

In effect an exposure assessment will contribute to the overall risk assessment of a product and thus assist in the determination of the level of control measures deemed to be appropriate so as to adequately protect the professional user should exposure occur. This level of exposure assessment is an integral part of risk assessment.

Such an exposure assessment therefore will need to consider the biocidal product, including its physical form, and the quantity, frequency and duration of use of the biocidal product. Additionally the exposure assessment will need to consider the potential route of exposure, e.g.

- inhalation;
- ingestion;
- dermal contact;
- intradermal;
- via mucous membranes

The potential route of exposure when linked to the physical form of the biocidal product will then assist in establishing the particular points of potential entry into/onto the body, which when considered in conjunction with possible physiological interactions, ergonomics and pattern of use can then contribute to the establishment of relevant and appropriate control measures for those workers using the biocidal product i.e. professional users.

Overall, for an exposure assessment, the predominant exposure determinants and events include, the likelihood of exposure happening, the frequency, the amount of exposure (taking account of duration of exposure), the variability of exposure and tasks involved, the route of exposure, the population exposed (including any possible 'vulnerable' workers (and the nature of the vulnerability), together with the adequacy and potential failure of engineering controls, personal protection measures (including respiratory protection, where relevant) and work practices and procedures.

4.4.2 Consultation responses

As can be seen above, some Member States have taken additional measures to restrict the use of biocidal products to professional users and require professional users to undergo specific education or training as part of a certification programme. In order to assess whether additional measures are required for professional users at the EU level, further information is required on any additional risks to professional users which are not already addressed by existing controls under EU health and safety and chemicals legislation. Within the questionnaire sent to stakeholders, Member States and industry were therefore asked the following questions:

- Are you aware of any exposure risks for professional users of a particular biocidal product (those involved in the application of biocides in a professional context), that are not adequately covered by risk mitigation measures set out in existing

health and safety (such as the requirement for personal protection equipment) and chemicals legislation (as set out in the safety data sheet)?
- Are you aware of any emergency/incident/accident or more importantly 'near-miss' scenario/dangerous occurrence which could have potentially caused exposure to professional users and/or others?

The majority of Member States (16) answered that they were not aware of any exposure risks for professional users of a biocidal product that were not adequately covered by risk mitigation measures set out in existing health and safety and chemicals legislation.

Four Member States indicated that they were aware of exposure risks. The responses covered the following specific product types:

PT	Use	Application	Exposure risk
PT2	Swimming pool disinfectants		Chlorine gas
PT7 & PT10	Preservative in paints, other coatings and construction materials	Production phase	Carbendazim (mutagen cat.1B) is included in the EU Review Programme and products containing carbendazim are authorised as PT 7 and PT10 preservatives, applied in the production of paints, other coatings and construction materials. Carbendazim is applied in these products in concentrations lower than those which lead to its reporting in the SDS and to classification of the final product as mutagens. Professional users therefore may not know about this substance and the genotoxic risk, which may be non-threshold. The paints, adhesives and construction materials may also pose a risk of secondary exposure (e.g. in scraping of old paint).
PT 8, 14 & 18	Control of rodents, insects, fungi etc	Gassing	Inhalation of toxic substances
14	Control of rats	Foam, blocks, pills etc.	Primarily dermal exposure

In response to exposure risk identified above for preservatives in paints, other coatings and construction materials under product types 7 and 10, it should be noted that Article 58(2) of the BPR requires that 'all active substances contained in the biocidal products' need to be approved or included in Annex I, and that a label on a treated article is to include the name of all active substances contained in the biocidal products. Where carbendazim is authorised for use in a preservative, which is applied in the production of paints, the labelling of the product should alert professional users to the presence of this active substance, and the need for any appropriate control measures.

The other three exposure risks identified, of exposure to chlorine gas following the disinfection of swimming pools, and dermal exposure or inhalation following the application of rodenticides is dealt with through the application of appropriate risk mitigation measures. Those working in these environments must be fully trained, supervised and protected against potential exposure to chlorine gas or rodenticides. Risk assessment and appropriate control measures must be performed and implemented at all times for all workers concerned. In addition, the amount of active substances present in the rodenticide product is relatively low and when and if handled in accordance with all safety requirements and any chemical agents control measures specified, then on a risk assessment the use of these products by the workers can be safe.

In relation to the examples cited of exposure risks, each of these should be adequately controlled either through the existing provisions of the BPR (requiring the active

substances present in a biocidal product to be listed on the label of a treated article) or controlled through the application of appropriate risk mitigation measures.

One Member State however responded that there was an exposure risk in relation to all product types since the use of personal protective equipment (PPE) as a RMM strongly depends on the qualification and motivation of the user. This however relates to the poor application or non-application of existing available RMM rather than there being an exposure risk that was not adequately covered by existing health and safety and chemicals legislation.

From 104 industry respondents, 85 (83%) were not aware of any exposure risks for professional users of the product type that they deal with that are not adequately covered by existing RMM, 10 did not provide an answer or stated that the question was not applicable, while nine answered that there were exposure risks for professional users of the product type that they deal with. The table below sets out the product type, use, application and exposure risk identified:

PT	Use	Application	Exposure risk
PT2	Algaecide	Directly in treated water	Security gloves and glasses
PT3	Disinfectant of animal housings & transport	Spraying	You may have release to water, soil etc. It may be necessary to put restrictions on the label in order to ensure safe use
PT4	Surface disinfection		Product strong oxidant. Inhalation may cause pulmonary edema. Prolonged exposure may cause lung damage, chronic bronchitis. Repeated and prolonged skin contact may cause dermatiiti. Possible long-term effects as a result of bleaching of hair.
PT4	Disinfection in slaughterhouses	Spraying	You may have residues of the chemicals in the meat.
PT6	Fuel tank protection	Directly in treated water	Security gloves and glasses
PT6			Sensitization against e.g. MIT (Methylisothiazolinone) is almost unavoidable
PT8	Professional and industrial use	Dipping and deluging	Skin, eyes
PT14	Rodenticide	Bait	Skin contact
PT17	Piscicide	Into water	Very limited when using closed systems or provided users are following instructions for personal protection when spraying into the water. Dosage and concentration is very low.
PT18	Insecticide	Distemper	Skin contact
Calcium dihydroxide	Disinfectants	Public areas, health. Hygiene biocidal products Veterinary hygiene	H315 Causes skin irritation. H318 Causes serious eye damage. H335 May cause respiratory irritation
Calcium oxide	Disinfectants	Public areas, health. Hygiene biocidal products Veterinary hygiene	H315 Causes skin irritation. H318 Causes serious eye damage. H335 May cause respiratory irritation

Each of these exposure risks are considered at the stage of the approval of the active substance or authorisation of the biocidal product. For example, a number of the Inclusion Directives for PTs 8, 18 and 19 include the following condition:

When assessing, in accordance with Article 5 and Annex VI, the application for authorisation of a product, Member States shall assess those use/exposure scenarios and/or populations that have not been representatively addressed in the Community level risk assessment and that may be exposed to the product. When granting product authorisation, Member States shall assess the risks and subsequently ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks. Product authorisation can only be granted where the application demonstrates that risks can be reduced to acceptable levels.

In some cases the active substance approval will already specify the necessary measures or specific conditions to be applied in order to mitigate any identified risks. The types of conditions that typically appear in the conditions of approval of an active substance for PT 18 are set out below:

PT 18 – conditions of approval

User group

For a number of active substances that have been approved for use in PT 18 to date, the conditions of approval specify that Member States are to ensure that when authorising a product, the product may only be sold to and used by professionals trained to use it. In some cases, products for professional use are only to be supplied in the form of ready-to-use products. Where the product is to be authorised for amateur uses, only ready-to-use products are to be authorised. In a number of approvals, it is also stated that the Union level risk assessment did not address all potential uses such as use by non-professionals, and therefore, where relevant, use by non-professionals should be assessed as part of the application for authorisation of a product.

Worker Protection

Member States are to ensure that authorisations are subject to the following conditions:

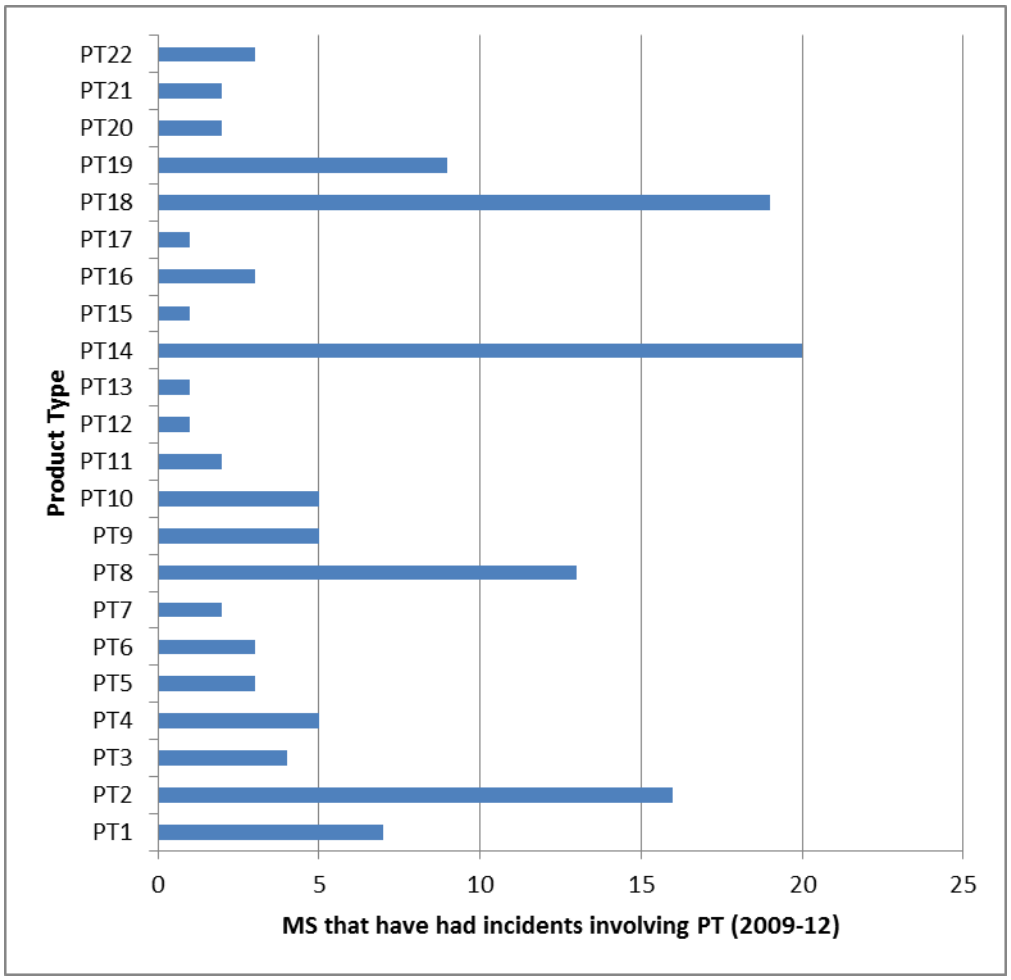
- Safe working practices and safe systems of work must be in place to ensure minimum risk, including the availability of personal protective equipment if necessary.
- Appropriate measures shall be taken to protect bystanders, such as exclusion from the treatment area during fumigation.
- Labels and/or safety-data sheets of products shall indicate that, prior to fumigation of any enclosure, all food items must be removed.
- In view of the risks identified for operators, appropriate risk mitigation measures must be applied. Those include, amongst others, the use of appropriate personal and respiratory protective equipment, the use of applicators and the presentation of the product in a form designed to reduce the exposure of operators to an acceptable level. For indoor use, those include also the protection of operators and workers during fumigation (including the establishment of a supervised exclusion zone), the protection of workers at re-entry (after fumigation period) and the protection of bystanders against leaking of gas.
- Products authorised for industrial or professional use (for example by spraying) shall be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial or professional users can be reduced to an acceptable level by other means and safe operational procedures and appropriate organisational measures shall be established.

4.4.3 Emergency incidents

With regard to emergency incident or accidents that had occurred which could have potentially caused exposure to professional users and/or others, half of the Member States that responded to the questionnaire were aware of some sort of incident or 'near-miss' scenario which could have potentially caused exposure to professional users and/or others. Five Member States referred to specific incidents that had arisen in their Member State concerning the misuse of insecticides, fumigants (aluminium phosphide and sulfuryl fluoride), antifungal chemicals, and rodenticides.

A number of Member States also referred to the requirement to keep a record of all injuries, incidents of poisoning, fumigations etc. As part of the study we therefore reviewed the composite reports prepared by the European Commission in accordance with Article 24 of the BPD (now Article 65 of the BPR), the latest of which covers the period from December 2009 to November 2012. Under Article 24 of the BPD Member States were required to report to the European Commission every three years on any poisonings involving biocidal products, following which the Commission would prepare a composite report. By that period, all Member States had appointed specific bodies responsible for collecting information on biocidal products in accordance with Article 23 of the BPD and making available this information in cases of suspected poisonings.

The report notes that based on the information received it is not possible to draw a detailed graph about the number of poisonings and the product types involved as it is not always clear whether these are linked to biocidal products, plant protection products, detergents, or products containing dangerous chemical substances in general. However, based on the product types involved, the number of Member States that have referred to one more incidents involving that product type are summarised in the graph below:



This shows that between 2009 and 2012, 20 Member States have had reports of incidents involving PT 14, 19 involving PT 18, 16 involving PT 2 and 13 involving PT 8.

The report also noted that the majority of poisonings are related to the professional or household use of disinfectants, insecticides and rodenticides. Repellents and wood preservatives are also frequently mentioned as are the active substances bromadiolone,

brodifacoum, difenacoum, permethrin, pyrethrins and pyrethroids, sodium hypochlorite, organophosphates and carbamates.

Information from particular Member States showed that the largest percentage of cases concerned exposure to disinfectants, with France stating that the highest number of cases of exposure arose in relation to food and feed area disinfectants (PT 4). The categories of biocides most often involved are PT 1, PT 2, PT 4, and PT 18, which included 14 cases of death associated with exposure to preparations of disinfectants within these PTs. In Italy, exposure to disinfectants (PT 1 to PT 4) accounted for 49% of cases, while exposure to pest control (PT 14, PT 16, PT 18 and PT 19) accounted for 46% of cases of poisoning. In Spain, 40.9% of cases of human poisonings were by disinfectants, of which 37.5% were related to bleach, hypochlorite and other acids and chlorine releasers and 4% to repellents.

4.5 Risk mitigation measures

In addition to the conditions specified in the approval of an active substance, appropriate risk mitigation measures will be specified at the stage of authorisation of the biocidal product. Industry respondents were asked to provide information on the use, application, and any risk mitigation measures applied to the main products that are manufactured, imported and/or used. Examples of the risk mitigation measures applied for most of the product types are provided below:

PT	Use	Application	Risk mitigation measures
1	Skin disinfection Hand sanitiser	Wipes or product applied directly to skin, e.g. gels.	Instructions on label Contact time exposure, use of PPE Safety data sheet (SDS)
2	Surface & equipment disinfectant	Disinfection of surfaces, materials, equipment etc., laundry disinfection, swimming pools.	Use of cleaning protocol prior to disinfection. Risk assessment. Control of dosing & dispensing to limit amount of concentrated product. Use in fully automated closed system. Use of gloves & PPE to minimise exposure. Labelling, instructions for use and SDS. Limited to professional use only & provision of training.
3	Veterinary hygiene	Disinfection of materials & surfaces for housing or transportation of animals.	Use of cleaning protocol prior to disinfection. Control of dosing & dispensing to limit amount of concentrated product. Use of gloves, protective suit & other PPE to minimise exposure. Labelling & SDS Training of professional users.
4	Disinfection of food and feed areas	Disinfection of surfaces & equipment.	Use of cleaning protocol prior to disinfection. CIP system or central cleaning station. Control of dosing & dispensing to limit amount of concentrated product as well as period of application. Use of gloves & PPE to minimise exposure. Labelling, instructions for use & SDS. Training of professional users.
5	Drinking water disinfection	Automatic application into water system	Training of professional users. Labelling, instructions for use & SDS. Use of PPE.
6	Incorporation into industrial products & in-can preservation	Manual or automated dosing in products. Paint.	Internal risk assessment. Limited to professional (industrial) use only. Training of professional users. Control of quantities by automated dosing. Use of PPE
7	Film preservation. Paints, coatings,	Dosing during manufacturing. Paint.	Limited to professional (industrial) use only. Automated dosing. Use of PPE

PT	Use	Application	Risk mitigation measures
	plaster.		Labelling, instructions for use & SDS.
8	Wood preservation or impregnation	Surface treatment - brush, spray or dip.	Use restricted to outdoor use for wooden structures. Labelling, instructions for use & SDS. Use of PPE
9	Textile protection Polymers & coatings	Dosage during manufacture. Lacquer, fibres, sealants & silicones	Automated dosing. Use of PPE.
10	Preservation of construction materials	Undiluted spray	Use of PPE.
11	Water treatment processes	Manual or automated dosing.	Internal risk assessment. Limited to professional use only. Training of professional users. Labelling, instructions for use & SDS. Automated dosing. Use of PPE.
12	Slimicides	Manual or automated dosing.	Internal risk assessment. Limited to professional use only. Training of professional users. Labelling, instructions for use & SDS. Automated dosing. Use of PPE.
13	Working or cutting fluid preservatives	Automated dosing.	Automated dosing. Use of PPE.
14	Rodenticide	Baits, fumigation	Risk assessment. Implementation of IPM system. Labelling, instructions for use & SDS. Training & best practice documentation. Restriction on area of use. Application rate. Ready to use pre-packs. Use of PPE.
15	N/A	N/A	N/A
16	N/A	N/A	N/A
17	Piscicide	To water.	
18	Insecticide	Sprays, gels, dry powder, aerosols, bait stations, fumigation, fogging.	Risk assessment. Use of cleaning protocol prior to use. Control of dosing & period of application. Labelling, instructions for use & SDS. Limited to professional use only. Restrictions on area of use (nurseries, schools etc). Use of PPE. Training of professional users.
19	Insect repellent	To human skin. Sprays, gels.	Labelling, instructions for use & SDS. Only to be used outdoors or in ventilated areas. Limited number of applications per day.
20	N/A	N/A	N/A
21	Antifouling	Airless spray, brush, roller.	Limited to professional use only. Use of PPE.
22	N/A	N/A	N/A

No responses were received regarding products in product types 15, 16, 20 and 22. For the remaining product types, this is not a comprehensive list of the risk mitigation measures applied, but rather example of the measures referred to within industry

responses. Therefore, while labelling, instructions for use and the provision of a SDS are not referred to in each case, these would of course be relevant to every product type. However, this highlights the main types of risk mitigation measures applied.

In order to identify potential exposure risks to professional users of biocidal products, the information from stakeholders on use, application and risk mitigation measures, coupled with information available on the use and applications for each product type based on a literature review and data from available SDS is set out in Annex III for each product type. Product types 8, 18, 19 and 21 are covered in more detail as part of the analysis under Chapter 6. In each case, a typical composition, use and health effects is presented for the product type, and a number of issues noted regarding the use of the product. Where relevant, reference is also made to the application of control measures stemming from EU health and safety legislation, which is described in more detail below.

4.6 Review of control measures

Where the products are used in a workplace environment, EU legislation on worker health and safety will apply. In accordance with Article 2(3) of the BPR, the BPR applies "without prejudice" to a number of pieces of EU health and safety legislation, in particular Directives 89/391/EEC (Framework Directive on the introduction of measures to encourage improvements in the safety and health of workers at work), 98/24/EC (on the protection of the health and safety of workers from the risks related to chemical agents at work), 2000/54/EC (on the protection of workers from risks related to exposure to biological agents at work) and 2004/37/EC (on the protection of workers from the risks related to exposure to carcinogens or mutagens at work).

The key requirements of each of the above Directives are set out below:

Key requirements of Directive 89/391/EEC (Framework Directive)	
Conduct a risk assessment Article 6(3)	The Directive requires that the risks to the safety and health of workers are evaluated.
Ensuring internal and/or external preventive and protective services Article 7	The Directive requires that one or more workers are designated to carry out activities related to the protection and prevention of occupational risks for the undertaking and/or establishment. If such protective and preventive measures cannot be organized for lack of competent personnel in the undertaking and/or establishment, the Directive requires that competent external services or persons are enlisted.
Information for workers Article 10	The Directive requires that workers and/or their representatives receive all the necessary information concerning any safety and health risks, as well as protective and preventive measures taken. Also workers must be informed of measures taken in regards to first-aid, fire-fighting and evacuation.
Training of workers Article 12	The Directive requires that each worker receives adequate safety and health training, in particular in the form of information and instructions.
Making available health surveillance Article 14	The Directive requires that workers receive health surveillance appropriate to the health and safety risks they incur at work.
Worker consultation and participation Article 11 and Article 6(3)	The Directive requires that workers and/or their representatives are consulted and can take part in discussion on all questions relating to health and safety at work, as well as when new technologies are planned and introduced.
Measures	The Directive requires a number of measures aimed at the avoidance and reduction of occupational risks.
Employer cooperation Article 6(4)	The Directive requires that, where several undertakings share a work place, the employers cooperate in implementing the safety, health and occupational hygiene provisions, coordinate their actions in matters of protection and prevention of occupational risks, and inform one another and their respective workers and/or workers' representatives of these risks.

Key requirements of Directive 89/391/EEC (Framework Directive)	
Emergency measures Article 8(1)	The Directive requires that necessary measures for first aid, fire-fighting and evacuation of workers are taken, and that any necessary contacts with external services, particular as regards first aid, emergency medical care, rescue work and fire-fighting, are arranged.

Key requirements of Directive 98/42/EC on chemical agents	
Conduct a risk assessment Article 4	The Directive requires a risk assessment to be carried out. In case of activities involving exposure to several hazardous chemical agents, the risk must be assessed taking into all chemical agents in combination.
Worker information Article 8	The employer must ensure that workers are provided with data obtained from the risk assessments, information on the hazardous chemical agents occurring in the workplace (e.g. relevant occupational exposure limit values) and the safety data sheet.
Worker training Article 8	The employer must ensure that workers are provided with training and information on appropriate precautions and actions to be taken
Worker consultation and participation Article 11	Consultation and participation of workers and/or their representatives shall take place in accordance with the Framework Directive.
Health surveillance Article 10	The employer shall provide health surveillance of workers for whom the results of the assessment of the hazardous chemical agents reveal a risk to health. Individual health and exposure records shall be made and kept up-to-date and contain a summary of the results of health surveillance and of any monitoring data representative of the exposure of the individual. Copies must be supplied on request to the authorities
Prohibition Article 9	Prohibition of the production, manufacture or use of chemicals listed in Annex III
Substitution Article 6(2)	Employer shall avoid the use of hazardous chemical agents by replacing them.
Exposure limit values and biological limit values Article 6(5)	Where binding limit values have been set by the Commission or where indicative limit values have been set by the Commission and hence binding values set by MS, the employer – in the event that these limit values are exceeded - must take steps to remedy this situation by providing preventive and protective measures.
Design systems & organise work to reduce risk Article 6(2)	Risk to the health and safety of workers involving hazardous chemical agents must be eliminated or reduced to a minimum by, inter alia, the design and organisation of systems of work at the workplace; the provision of suitable equipment and maintenance procedures.
Storage, handling, and segregation of incompatible chemical agents Article 6(6)	The employer must take technical and or organisational measures (e.g. storage, handling, and segregation of incompatible chemical agents) to prevent the presence at the workplace of hazardous concentrations of inflammable substances or hazardous quantities of chemically unstable substances, or avoid the presence of ignition sources and mitigate the detrimental effects to the health and safety of workers in the event of a fire or explosion due to the ignition of inflammable substances. The employer must take measures to provide sufficient control of plant, equipment and machinery or provision of explosion suppression equipment or explosion pressure relief arrangements.
Establish procedures & communication systems for accidents, incidents & emergencies Article 7	The employer must establish procedures and communication systems, which can be put into effect when an accident, incident or emergency occurs related to the presence of hazardous chemical agents at the workplace.

Key requirements of Directive 2000/54/EC on biological agents	
Conduct a risk assessment Article 3	The Directive requires that the nature, degree and duration of workers' possible exposure to biological agents must be determined in order to assess the risk to health or safety and to lay down the measures to be taken. The employer must supply the authorities with the information used for the assessment, if the authority requests that. The risk assessment must be conducted on the basis of all available information, including information specified in Article 3(3).
Worker information Articles 9 and 10	The Directive requires (9) information to workers on a) potential risks to health, b) precautions to be taken to prevent exposure, c) hygiene requirements, d) wearing and use of protective equipment and clothing, e) steps to be taken by workers in case of incidents and to prevent incidents. In addition, the Directive requires (Article 10) that the workers get information in these particular cases on the procedure to be followed in the case of a serious accident or incident involving the handling of a biological agent, or in the case of handling a group 4 biological agent, any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and/or illness, if they are on a list of workers exposed to group 3 and/or group 4 biological agents, and when a safety and health document is made available to the competent authority.
Worker training Article 9	The Directive requires that workers are trained concerning the same areas as mentioned for worker information (a-e).
Worker consultation & participation Article 12	The Directive requires that consultation and participation takes place in accordance with the requirement of the Framework Directive.
Health surveillance Article 14	The Directive requires that arrangements are established by MS for carrying out relevant health surveillance for workers with a risk to health or safety according to the risk assessment.
Substitution Article 5	The Directive requires that the use of a harmful biological agent is avoided if the nature of the activity permits it. The harmful agent should be replaced by an agent which is not dangerous or is less dangerous to workers' health.
Introduce measures based on results of risk assessment Article 6	The Directive requires that workers' exposure is prevented and, where that is not technically practicable, that the risk of exposure is reduced to as low a level as necessary to protect adequately the health and safety. In reducing the exposure a list of measures must be applied in the light of the results of the risk assessment.
Hygiene & individual protection Article 8	The Directive requires that appropriate measures are taken to ensure good hygiene and individual protection of the workers in the case of all activities for which there is a risk to the health or safety of workers due to work with biological agents.

Key requirements of Directive 2004/37/EC on carcinogens and mutagens	
Conduct a risk assessment (Article 3)	Employers must determine the risk of exposure to carcinogens or mutagens and the nature, degree and duration of workers' exposure, and assess the risks to the workers' health or safety and lay down the measures to be taken to remedy this risk. This assessment must be renewed regularly and in any event when any change occurs in the conditions, which may affect workers' exposure to carcinogens or mutagens. Information on the assessment must be supplied to the authorities. Employers must pay particular attention to any effects concerning the health or safety of workers at particular risk and take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens or mutagens.
Exposure limit values (Article 5(4))	Exposure shall not exceed the limit value of a carcinogen as set out in Annex III
Replacement (Article 4)	Employers must reduce the use of a carcinogen or mutagen at the place of work, in particular by replacing it, if technically possible, by a substance, preparation or process, which is not dangerous or is less dangerous to workers' health or safety.
Worker information (Article 12)	Appropriate measures shall be taken to ensure that: (a) workers and/or workers' representatives have access to information regarding the consequences for workers' safety and health of the selection, wearing and use of protective clothing and equipment and the measures determined by the employer regarding foreseen exposure; (b) workers and/or workers' representatives are informed as quickly as possible of abnormal exposures of the causes thereof and of the measures taken or to be taken

Key requirements of Directive 2004/37/EC on carcinogens and mutagens	
	to rectify the situation; (c) the employer keeps an up-to-date list of the workers engaged in the activities for which a risk exists, indicating the exposure to which they have been subjected; (d) the doctor and/or the competent authority who have responsibility for health and safety at work have access to the above-mentioned list; (e) each worker has access to the information on the list which relates to him personally;
Training (Article 11)	Workers must receive sufficient and appropriate training on potential risks to health and precaution to be taken to prevent exposure
Worker consultation & participation	Consultation and participation of workers and/or their representatives in connection with matters covered by this Directive shall take place in accordance with Article 11 of Directive 89/391/EEC.
Health surveillance (Article 14)	Worker are to be able to undergo, if appropriate, relevant health surveillance prior to exposure, and at regular intervals thereafter. Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens or mutagens, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

A number of the risk mitigation measures applied to the product categories above therefore stem from the requirements set out in the above EU legislation on worker health and safety, in particular Directive 98/42/EC on chemical agents. Each of the worker health and safety Directives include requirements to carry out a risk assessment (including assessing the risk of chemicals in combination), to provide workers with data obtained from the risk assessments, information on the hazardous chemical agents occurring in the workplace (e.g. relevant occupational exposure limit values) and the safety data sheet, and to provide information and training to workers on appropriate precautions and actions to be taken to be taken to prevent exposure and the wearing and use of protective equipment and clothing, amongst other issues. The employer must also establish procedures and communication systems, which can be put into effect when an accident, incident or emergency occurs related to the presence of hazardous chemical agents at the workplace. These requirements are taken into consideration in the review of information on the use, application and health effects of each of the product types, as set out in Annex III.

In addition to the requirements of the relevant health and safety legislation, the information available through the SDS under REACH is also taken into account in consideration of each of the product types. The general requirements of REACH Annex II indicate that the information provided in the SDS shall meet the requirements set out in Directive 98/42/EC on chemical agents. The SDS should therefore enable the employer to assess the risk to the health and safety of workers of the substances covered in the SDS. The risk should then be addressed for the handling and storage of the substances in accordance with Article 5 of Directive 98/42/EC. Moreover, the information on exposure control under REACH can be used for the risk assessment carried out by the employer under Directive 98/42/EC. Information available through REACH also assists with the risk assessment required under Directive 2004/37/EC on carcinogens and mutagens.

4.7 The need for additional measures?

Having identified the control measures which apply under existing EU health and safety and chemicals legislation, and outlined the types of risk mitigation measures applied following authorisation of a biocidal product, consideration was given to whether there were any remaining gaps in addressing the exposure risks from the use of the biocidal product that would justify a need for further measures.

To assist in identifying whether the existing control measures give sufficient protection to professional users of biocidal products, as part of the stakeholder consultation, Member States and industry were asked the following question:

- Do you consider that there is a gap in the existing risk mitigation measures aimed at the protection of professional users, or does the exposure risk arise as a result of the poor application of existing available risk mitigation measures?

In response to whether any exposure risk identified arises as a result of gap in the existing risk mitigation measures aimed at the protection of professional users, or as a result of the poor application of existing available risk mitigation measures, five Member States responded that there was both a gap in existing RMM and that the exposure risk was as a result of the poor application of existing RMM. An additional two Member States referred only to the poor application of existing RMM. It should be noted that a number of Member State commented on this point despite having indicated that they were not aware of any exposure risks to professional users.

The reasons cited for there being a gap in the existing RMM which could potentially result in an exposure risk to professional users included the following:

- the ongoing process of the evaluation of existing active substances;
- the failure of producers to specify proper RMM in an SDS;
- the lack of consideration of and failure to recommend engineering and technical RMM (e.g. dosing system, special packaging, spraying devices with controlled droplet size, closed systems etc.);
- the quality of instructions provided.

However, with the exception of the reference to the ongoing evaluation of existing active substances, the other reasons provided related to the failure to communicate RMM or provide adequate instructions concerning their use rather than there being an actual lack of appropriate RMM that could be applied. This therefore relates to the quality of the information that is being passed down the supply chain and risk communication and risk perception, rather than there being a gap in the existing RMM. Measures for improved dissemination of information and awareness-raising as suggested by the Sustainable Use Directive are therefore considered in Chapter 7. In addition, even where reference was made to there being gaps in existing RMM, in most cases it was felt that the main issue lay with the poor application of existing RMM or failure to read the use instructions. One Member State commented that the "poor application" of PPE is well known as there are numerous possible errors in choice and application due to low qualification and motivation of the user.

As part of the stakeholder consultation, industry and NGOs were also asked whether they consider that additional measures are required to reduce risks to professional users of particular biocidal products.

From 104 industry respondents, 75 (72%) did not consider that additional measures are required to reduce the risks to professional users, 18 (17%) did not provide an answer or stated that the question was not applicable, while 11 (11%) answered that additional measures were required to reduce the risks to professional users.

The following suggestions to reduce the risk to professional users were made by industry:

Definition of professional users

- The definition of 'professional users' should be better defined in order to ensure that only users who have the correct level of training, competence and knowledge and have an ability to assess a biocidal application are allowed to apply biocides;
- The definition of "professional" should not relate to the businesses activity but the users competence/level of training;

Training

- The use of biocides should be restricted to trained and qualified professional users.
- There should be a mandatory training requirement for all professional users to a recognised minimum EU standard. A specific training module should be made available for outdoor use.
- Risk mitigation measures as mentioned in the label are considered sufficient for the professional user with risk awareness. However professional users should be trained on how to understand the SDS and exposure scenarios.

Safety Data Sheet

- The safety information contained in the safety sheets of each product should contain the same information in each language (unified form in all EU)

With the exception of one NGO which did not comment, and another that did not deal with risks to professional users, the remaining four were of the view that additional measures were required to reduce risks to professional users. The following suggestions were made as to how risks to professional users could be reduced:

- Effective substitution, ban and restriction of highly hazardous active ingredients e.g. carcinogenic, mutagenic or endocrine disrupting substances,
- Prohibition of online sales of biocidal products;
- Mandatory and appropriate training and education of users and distributors;
- Training should only be carried out by officially accredited and licensed institutions (and include training on subjects such as IPM principles, biocide-free alternatives, preventive measures etc.) and require to be regularly updated;
- EU wide harmonisation of qualification and certification criteria;
- Independent advisory services should be provided;
- Awareness raising campaigns for professional users and for the supply chain, including distributors, retailers; and
- Implement EU-harmonised guidelines / requirements for the quality and high-level risk reduction standards of application equipment, the intervals of inspections of the equipment, training certificates for user.

The issue of training therefore features largely in both the responses from industry and NGOs. The suggestions set out above are considered further in Chapter 7 on the application of integrated pest management principles and a number of recommendations made regarding training and information.

4.8 Case study

In addition to covering the general product categories and applications for each product type, one specific case study example of a biocidal product used in a particular application, to demonstrate the exposure risks and control measures for that specific product. The product known as 'Bleach', containing sodium hypochlorite, was selected, as covers the range of issues and information required by professional users (and others), which may not currently be disseminated to all or understood by users when received, whether it relates to the risks to health, to storage, use, disposal and/or during transport of the product, containing sodium hypochlorite.

The case study is set out in Annex IV.

The case-study concluded that professional users of disinfectant can be exposed to these chemicals while using them for work activities. However where professional users are employed in settings such as manufacturing, large food and beverage production facilities, hospitals, i.e. workplaces with a formalised structure, management systems, supervision capabilities etc., together with fixed engineering controls and readily available prevention/control measures and personal protective equipment, then those professional users can work safely with such chemical in accordance with the requirements and specifications set out in existing worker protection legislation.

However notwithstanding those professional users above, there are many other professional users who are not so well protected by virtue of their circumstances of work and whether or not they have been trained/informed or whether their employers are fully informed of employers' responsibilities to all their workers, including the materials and equipment required to be used on-site for the purpose of work activities. For example, the primary focus for a school is education and the children being educated therein. However also present are cleaners, janitors, caretakers and probably, on a more casual basis, persons employed for specific tasks which arise e.g. drain clearage, pluming related issues etc. These workers are entitled and should be protected to the same degree, and in accordance with the same worker protection legislation as those working in manufacturing and industrial sectors. However the message is not getting through to (a) these employers, and (b) the professional users themselves (especially if self-employed).

Finally, by law manufactures of chemical have a responsibility regarding the chemicals they produce and place on the market. This responsibility extends to those using their substances and/or their substances for inclusion in products. In other words manufacturers are obliged to communicate down the supply chain. Also, and mostly because of REACH, communication also goes up the supply chain from customers and downstream users to their suppliers and further up until the information is communicated and acquired by the relevant manufacture. Manufacturers therefore are aware of the variety of uses and environmental settings to which their chemicals are being applied. This information should be used and reflected when compiling SDSs so as to make the information practical and useable down the supply chain.

While the case study has primarily focused on workers, in particular those professional workers who may be operating as self-employed or untrained, in small operations without the support structure normally available in larger workplaces, the risk of exposure and the uses of disinfectants containing sodium hypochlorite, are analogous to the risks and potential for exposure that can occur to consumers/the general public who also use these products. However, the main difference is that the consumer, while using the products for the same purpose and in the same manner, will not (a) be supplied with the same level of information (b) will not have the direct protection of the worker protection legislation to ensure their safety health and welfare at work.

To this end consumers or members of the public will only receive a safety data sheet if they know to request this document from the vendor/supplier. This rarely if ever happens. By not having the valid SDS means the consumer is not informed regarding the detailed information relating to storage/handling/use/disposal, exposure risk and recommended controls and protective equipment required, together with other information regarding broader risks and routes of exposure/emergency scenarios i.e. information in an SDS in addition to the formal classification of the product based on CLP criteria alone.

There are also no means of ensuring that consumers will follow the dilution and use instructions which are contained on the packaging of the product. In fact given observed human behaviour (outside the workplace and working frame of mind), consumers are apt to use more of a product that specified, or use a stronger more concentrated form of the product than specified, on the presumption that this 'will do the job faster' or ' this will do the job better'.

While the means or methods of protection will be the same for a professional user and a consumer when using the same product under the same or similar conditions of use, the requirements to ensure that a consumer is protected/trained and provided with the necessary protective equipment etc does not fall within in the scope of that legislation.

A number of recommendations were made regarding the information provided in a SDS. The need for manufacturers to provide essential information in a clear and precise manner in order to encourage professional users to comply with the information provided in a SDS was highlighted. The information provided in the SDS must be clear, understandable and specific and avoid contradiction. Also when considering the smaller professional users, it is important that the sections of the SDS dealing with issues such as emergencies, accidental spills, storage, handling, disposal and exposure controls are clear, comprehensible and can, in reality, be practically followed in all workplace scenarios.

In some of the workplaces being examined, an SDS may be available, but are in an office which is often times locked and empty at the time these professional users are working. Equally the SDSs may be stored in a file and are never taken out, read or distributed further than that office. Therefore some of the improvements required to address this concern relate to the need for behavioural changes also.

Training of small professionals was also identified as an area of concern. There is no single means of addressing this concern successfully in order to safeguard all persons fitting into this category of worker, which therefore requires to be approached on a sectoral basis, specific to the product type. In the case of disinfectants this would require tailored approached to those working within agriculture, education, health and the food industry/catering.

Consideration should also be given to those who sell disinfectants at the local retail level e.g. supermarkets and other shops/outlets. Through the retailers associations, mangers of such shops should be aware of the differentiation between professional users and the general public. A stronger onus should be placed on ensuring they are supplying the SDSs to those persons who are using the products in a professional capacity.

4.9 Conclusions

The analysis of control measures applied under EU worker health and safety legislation as well as chemicals legislation indicated that where appropriate risk mitigation measures are put in place and worker protection legislation is adhered to, there should not be a requirement for further measures to address exposure risks. The analysis of the various product types, and in particular the example of the use of 'bleach' and the active

substance sodium hypochlorite under PT 2, 3 and 4, showed that risks to users are addressed through the conditions of approval of the active substance, the application of appropriate risk mitigation measures specified at the stage of authorisation as well as control measures applicable under EU worker health and safety and chemicals legislation. This was also reflected in the responses received to the stakeholder consultation, where the majority of respondents did not feel that there was a need for additional measures to reduce the risks from biocidal products.

However, in each case it was highlighted that the risk of exposure from the use of biocidal products can arise as a result of poor application of recommended control measures. Also, where the products are authorised for general consumer use, such users will not be supplied with the same level of information and will not have the direct protection of the worker protection legislation to ensure their safety health and safety. In both cases, further measures in the form of education and training initiatives and the provision of information on the use of the product are necessary. For the professional user, industry guidance or more formal requirements such as a scheme for certification of professional users are also required. These are considered in the context of the application of integrated pest management principles under Chapter 7, which focuses on training and information.

5 MONITORING THE USE OF BIOCIDAL PRODUCTS

5.1 Introduction

As the use phase of biocidal products is not regulated systematically under the BPR, provision was not made under the BPR for the collection of data on biocidal products. However, it is recognised that in order to harmonise the placing on the market and the use of biocidal products in the EU, the monitoring of the use of biocidal products could be performed in a harmonised way and may be supported by IT tools.

The main aim of this task is therefore to investigate the current approaches used by Member States to monitor the use of biocidal products, whether specific IT tools were used by Member States to support this, and if so whether any of these approaches could be adopted on an EU-wide basis in order to put in place a harmonised approach to the monitoring of the use of biocidal products.

In this regard, consideration should also be given to the methods by which data on the use of plant protection products is collected, and whether the approach adopted under legislation on pesticides could be applied to the monitoring of the use of biocidal products.

5.2 The statistics regulation

As part of the EU Thematic Strategy on the sustainable use of pesticides, Regulation (EC) No 1185/2009 concerning statistics on pesticides[31] ("the Statistics Regulation") was introduced in order to provide a mechanism by which data on the use of pesticides could be obtained so as to measure the impact of the Thematic Strategy and the impact of the Sustainable Use of Pesticides Directive. The Statistics Regulation was published on 10 December 2009 and came into force on 30 December 2009, requiring Member States to collect statistical data on both the sales (placing on the market) and use of pesticides. The first year of sales data was required for 2011, to be delivered in December 2012. The first sales report was therefore due to be provided to Eurostat by the beginning of 2013. Thereafter, data on pesticide use is required for a representative selection of crops for one year during the period 2010-2014, is to be delivered in December 2015.

Article 3 of the Statistics Regulation sets out that Member States are to collect the data necessary for the specification of the characteristics listed in Annex I (statistics on the placing on the market of pesticides) on an annual basis and for the specification of the characteristics listed in Annex II (statistics on agricultural use of pesticides) in five-year periods by means of:

- Surveys,
- Information concerning the placing on the market and use of pesticides,
- Administrative sources, or,
- A combination of these means, including statistical estimation procedures on the basis of expert judgements or models.

The statistics on the agricultural use of pesticides are to cover the quantity of each substance listed in Annex III in kilograms used on the selected crops, and the area in hectares treated with each substance. The reference period shall be a maximum of 12 months during the period 2010-2014, covering all plant protection treatments associated directly or indirectly with the crop.

[31] Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides, OJ L 324/1, 10.12.2009.

While information on the agricultural use of pesticides is not to be provided to Eurostat until the end of 2015 and therefore will not be available until 2016, the statistics on sales (placing on the market) should already be available. However, this has not yet been published. As Eurostat is to aggregate the data before publication in accordance with the chemical classes or categories of products indicated in Annex III, taking due account of the protection of confidential data at the level of the individual Member State, data on the active substance cannot be published, only the aggregated data. Eurostat is therefore currently working with National Statistical Institutes to find a solution in order to be able to publish a first set of data for the reference years 2011 and 2012.[32]

To support this, the PPPR (recital 44) establishes provisions on record-keeping and information about the use of plant protection products in order to increase the efficiency of monitoring and control and to reduce the costs of monitoring water quality. Article 67 states that producers, suppliers, distributors, importers, and exporters of plant protection products shall keep records of the plant protection products they produce, import, export, store or place on the market for at least 5 years. Professional users of plant protection products shall, for at least 3 years, keep records of the plant protection products they use, containing the name of the plant protection product, the time and the dose of application, the area and the crop where the plant protection product was used. Further on producers of plant protection products shall undertake post-authorisation monitoring on the request of the competent authorities.

It should be noted that recital (5) to the Statistics Regulation states that "it is anticipated that, taking into account the results of the evaluation of Directive 98/8/EC and on the basis of an impact assessment, the scope of this Regulation will be extended to cover biocidal products." However, it was recognised in recital (4) that since the effects of the Biocidal Products Directive would not become apparent until the first evaluation of active substances for use in biocidal products is finalised, neither the Commission nor most Member States had sufficient knowledge or experience at that stage to propose further measures regarding biocides. The review of the active substances used in biocidal products has now been extended until 2024, and the Commission is not due to report on the implementation of the Statistics Regulation until the end of 2016[33], therefore it is unlikely that steps will be taken to amend the Statistics Regulation for some years. In the intervening period, the BPR was introduced which required the Commission to consider the most effective approaches for monitoring the use of biocidal products. Therefore, where an appropriate approach is found, there may ultimately be no need to amend the Statistics Regulation in the future.

5.3 National approaches to monitoring

Information on the current approaches used by Member States to monitor the use of biocidal products, and the use of specific IT tools was sought as part of the stakeholder consultation. Within the questionnaire sent to stakeholders, Member States were asked the following questions:

- Does your country collect data on the use of biocidal products? If so, specific information was sought on the type of data, the period covered, and the reasons for collecting this data.
- Does your country use specific IT tools to support the monitoring of the use of biocidal products?
- Does your country have a scheme in place to monitor the use of illegal products?

[32] This information was provided in response to a Parliamentary Question raised on 22 January 2014 asking for details of when data on the sale of pesticides would be published. http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2014-000570&language=EN

[33] Regulation (EC) No 1185/2009, Article 7.

5.3.1 Monitoring of illegal products

Of the 21 Member States that responded to the questionnaire, two thirds of the Member States indicated that they have a system of inspections in place to monitor the use of illegal products. In some cases this is focused specifically on biocidal products or even specific product types, where routine inspections of biocidal products available on the market are carried out to check that the product is authorised, is correctly labelled, and complies with the conditions of authorisation, for example where use is restricted to professional users. In other cases, inspections of biocidal products are carried out as part of a wider framework of inspections covering REACH and other chemicals legislation, where random checks of a company, which may be announced or unannounced, are carried out to check compliance with a number of pieces of chemicals legislation.

In each case, the focus of inspections is to check that products placed on the market are authorised. In one Member State, having identified that there was a large number of biocidal products on the market which were not authorised, a Differentiated Enforcement Policy[34] has been applied for biocidal products since 2009, in order to allow companies an opportunity to obtain an authorisation. The Board for the Authorisation of Plant Protection Product and Biocides (CTGB) established a procedure to assess and process applications for the authorisation of groups of notified biocidal products, which were placed on a list of condoned products which did not have to be removed from the market pending a determination on the application for authorisation, unless risks were identified during the assessment. Products were classified into three risk categories of high risk profile (category red) for which applications for authorisation had to be submitted by 16 December 2010, normal risk profile (category orange) for which applications for authorisation had to be submitted by 16 June 2012, and low risk profile (category yellow) for which applications for authorisation has to be submitted by 16 May 2013, and a decision on these taken by the CTGB no later than September 2014. As a result, any biocidal products remaining on the Dutch market which were unauthorised and had not been notified to the CTGB under this process were considered illegal. Throughout the process, a weekly updated list of biocidal products notified under the Differentiated Enforcement Policy was published, containing the name and scope of permitted use as well as the classification of these products. There now only remain a limited number of products in the low risk category for which a decision on authorisation is still to be finalised.

For those Member States that indicated that they did not have a specific scheme in place to monitor illegal use, reference was made to a number of other mechanisms used to monitor the placing on the market of biocidal products. In some cases, market investigations are carried out concerning specific product types and uses. In other cases, enforcement of illegal products was carried out in response to complaints received, in many case from other companies, of illegal placing on the market of biocidal products. One Member State authority allows information to be submitted electronically on its website regarding the sale of illegal biocidal products[35]. This information is then followed-up by the enforcement authorities, and in some cases may lead to prosecution. Where numerous reports of illegal use relate to a specific product, this can also be used as the basis to initiate a targeted enforcement campaign, concerning a specific product.

Finally, a number of Member State authorities also referred to mechanisms to assist in the exchange of information, for example where bilateral agreements on co-operation and exchange of information have been established between different national authorities, or the establishment of joint Working Groups involving a number of authorities in order to examine ways of improving enforcement of illegal products. One

[34] http://www.ctgb.nl/en/biocidal-products/topics-related-to-biocidal-products/differentiated-enforcement-policy-for-biocidal-products

[35] http://www.kemi.se/en/Content/Enforcement/Tipping-the-Swedish-Chemicals-Agency/

Member State also referred to the use of the results of monitoring residues in water or food, as an indication of the illegal use of biocidal active substances.

Overall therefore, reference was made to the following types of enforcement action:

- Inspections / checking product authorisation;
- Market investigations;
- Campaigns concerning specific PTs;
- Information exchange;
- Reactive enforcement based on reports of illegal products.

5.3.2 Data on the use of biocidal products

Of the 21 Member States that responded to the questionnaire, only nine Member States indicated that they collect data on the use of biocidal products. The nine national systems of monitoring are outlined in the table below. However, in almost all cases the data collected covers data on the placing on the market of biocidal products, and in Slovenia this is restricted to data on the placing on the market of biocidal products which are classified as dangerous. In Hungary, the data collected relates specifically to aerial and ground operated mosquito control.

MS	System of monitoring
Belgium	As part of the Programme for the Reduction of Pesticides and Biocides, a register is kept of **products placed on the market** for the first time. The Belgian authorities are under a legal obligation to prepare an annual report of products placed on the market for all PT. The report gives information on the name, number and quantity of biocidal products and the active materials placed on the market in general as well as their distribution between the 4 classes and 22 product types. Overall quantities of active materials are given in it as well as general information on legislative requirements. The data distinguishes between class A (forbidden for public use) products and according to PT. The annual report has been published each year since 2011, though contains data since 2005. The data is collected in order to give an indication of the products available on the market, how to prioritise enforcement, safe use etc. and to provide valuable information on the (possible) impact on health or environment.
Croatia	Certified **professional users** are required to collect data on the quantities of biocides used, target organisms controlled, and where the activities are performed (e.g. parks, schools, etc.). The data is submitted annually to the Croatian Public Health Institute. If the biocidal product is classified as dangerous under CLP, an annual report on the quantities of biocides imported or manufactured should be submitted to the Croatian Institute for Toxicology and Anti-doping. The data is collected by the national authorities in order to monitor quantities of biocides used and target organisms. The requirement only applies to professional users.
Denmark	The Danish Product Register includes details of all chemicals sold in Denmark each year, listing the quantity of each chemical produced each year. The Danish **EPA collects data** on **annual sales of biocides** and pesticides in order to provide information to the public and others. The data covers the amount sold per product and per active substance for each PT. The data does not distinguish between professional and non-professional use of biocides. http://www2.mst.dk/Udgiv/publikationer/2013/10/978-87-93026-49-0.pdf.
Finland	Annual data is collected by the Finnish Safety and Chemicals Agency (TUKES) on the **quantities of biocidal products manufactured, imported and exported** for PTs 8, 11, 12, 14, 18, 19 and 21. This reflects those PTs that are authorised at present and once new PTs are authorised they will be added to the requirement to produce this data. The data specifies the active substances as well amounts of products 1) produced in Finland, 2) imported to Finland, 3) sold in Finland, and 4) exported from Finland. The information is to be submitted annually to TUKES by 31 March of the following year. The data only distinguishes between professional and non-professional use where the product is only approved for professional use. In addition, under the Chemicals Act (599/2013), the manufacturer or the importer of biocidal products is to notify the competent authority of the quantities of the **chemicals produced, sold and used when requested**. In addition, farmers and feeding stuff producers are required to keep data on any use of plant protection products and biocides, based on Regulation No 183/2005 on the requirements for feed hygiene[36], which describes general rules on feed hygiene, conditions and arrangements

[36] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down

MS	System of monitoring
	ensuring traceability of feed and conditions for registration and approval of establishments.
France	Details of all products placed on the market under BPR Article 89 (transitional measures) are provided prior to placing the product on the market for registration. Details of the quantities of the active substance in the product **placed on the market** are kept annually. The data does not distinguish between professional and non-professional use. The data is collected in order to know the exposure levels of the environment, and to inform the general public and professionals. The database helps customers to choose biocides that are placed to the market in accordance with the BPR.
Germany	Currently, under the ordinance for the notification of biocidal products (Biozid-Meldeverordnung), the Federal Institute for Occupational Safety and Health (BAuA) is to be notified of all biocidal products which are to be **placed on the market** under the transitional rules. However, the notification does not include any data on production or sale amounts. In addition, BAuA also maintains a list of biocidal products already authorised. From the beginning of 2014, applicants are now asked to provide information about the **annual amount of their biocidal products** that are placed on the German market when applying for authorisation. http://www.baua.de/de/Chemikaliengesetz-Biozidverfahren/Biozide/Produkt/Zugelassene-Biozidprodukte.html
Hungary	Data about aerial and ground operated **mosquito control (PT 18)** is collected annually which includes the time and treated area, the amounts of active substances and products used, the machinery used, and the operator personnel (professional use only). The data is collected to provide information on human health and environmental impacts.
Slovenia	In Slovenia, the Act on chemicals, Act on biocidal products together with the Rules on Communicating Data on chemicals and biocidal products requires data on biocidal products to be collected. Data is collected for all biocidal products on the quantities **placed on the market**, the quantities which have been withdrawn from the market, and stocks of biocidal products. Following a change in legislation in 2014, data on the quantities of biocidal products which have been withdrawn from the market is no longer collected and data on the quantities of biocidal products placed on the market is now only collected for biocidal products classified as dangerous. With regard to stocks of biocidal products, those **who professionally use** biocidal products are required to communicate to the CORS information on the quantity of biocidal products purchased, stocks held and **quantities used as well as the purposes for which they have been used**. This data has been collected annually since 2008, with data submitted on 31 March of the following year, using data on biocidal products and their annual volume from safety data sheets. The data does not distinguish between professional and non-professional use. The data is collected for a number of reasons: safety at work, health protection, environmental protection, protection and rescue, customs, national statistics, monitoring of trends, comparison with data on monitoring, biomonitoring, etc.
Sweden	Statistics on **quantities of active substances in pesticides sold** (both plant protection products and biocidal products) are kept, based on information from the holders of pesticide approvals. The data does not cover PT not yet included in the authorisation process. http://www.kemi.se/en/Content/Statistics/Pesticide-statistics/ The chemical products register kept in accordance with the Swedish Chemical Agency´s Chemical Products and Biotechnical Organisms Regulations (KIFS 2008:2) also includes data on all biocidal products, with a few exemptions, and contains details of active substance, product type, use of the product, labelling, and manufactured and imported volumes. http://www.kemi.se/en/Content/Statistics/Overview-of-chemicals

With regard to data on the actual use of biocidal products, only four Member States indicated that they collect data on the use of biocidal products or will do so in the future, and in two of these countries this requirement only covers professional users of biocidal products. In Finland, under the Chemicals Act (599/2013), the manufacturer or importer of a biocidal product is to notify the competent authority of the quantities of the chemicals produced, sold and used when requested, though to date, information is only collected on the quantities of biocidal products manufactured, imported and exported, not also their use.

In Croatia and Slovenia the requirement to provide data on the use of biocidal products only applies to professional users. In Croatia, certified professional users are required to

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requirements for feed hygiene, Annex I, Part A, II, 2(a).

collect data on the quantities of biocides used, target organisms controlled, and where the activities are performed (e.g. parks, schools, etc.) In Slovenia, those who professionally use biocidal products are required to communicate to the Chemicals Office of the Republic of Slovenia information on the quantity of biocidal products purchased, stocks held and quantities used as well as the purposes for which they have been used. All certified professional users are required to submit annual data on quantities of biocidal products used, target organisms controlled, and where the activities are performed, which is then used to identify trends in use over the years and whether there are new organisms that the companies are controlling. The data provided is therefore similar to the provision of statistics on pesticides as covers area of use and organisms controlled. In Hungary, the data collected relates specifically to aerial and ground operated mosquito control, and includes information on the time and treated area, the amounts of active substances and products used and the machinery used. Finally, in Belgium, from 2016, a register of the sale and use of biocidal products that are prohibited for public use is to be established.

It is evident that there is currently very little information collected on the use phase of biocidal products across the EU. This has been identified as a major drawback to developing further actions or policies on the sustainable use of biocidal products, as not enough information is available on the actual use of biocidal products.

5.3.3 IT tools used to support the monitoring of biocidal products

Of the nine Member States that indicated that they collect data on the placing on the market or use of biocidal products, six referred to specific tools used to collect data to support the monitoring of biocidal products. The following tools were referred to:

- In Belgium, a register of the sale and use of biocidal products that are prohibited for public use is being developed for use from 2016 onwards;
- In Croatia, the legislation sets out the specific format in which certified companies should submit data;
- In Finland, companies can submit the amounts of products via a web-form on the internet;
- In France, an IT tool called SIMMBAD is used;
- In Slovenia, the Chemicals Office of the Republic of Slovenia maintains a national list of chemicals placed on the market in Slovenia, using an electronic IT tool (Information System for Chemicals).
- In Sweden, a chemical products register is maintained.

The submission of data using standard forms in Croatia and Finland has worked well over the years as companies are aware of the legal requirement in each case to submit this annual data. In some cases, submissions are not made timeously, and the authorities are required to issue reminders. However, other than this the collection of data in these countries works well. With the exception of the SIMMBAD tool used in France therefore, either a standard form is used which can be submitted electronically or in hard copy as is the case in Croatia and Finland, or a register has been or will be established which presents the data in its final format, but is not intended itself to be an interactive IT tool for the submission of data between companies and the national authorities.

Further information on the SIMMBAD tool is provided below.

SIMMBAD

SIMMBAD (**S**ystème **I**nformatique pour la **M**ise sur le **M**arché des **B**iocides : **A**utorisations et **D**éclarations)

SIMMBAD is a computer system used to monitor and inform of the placing on the market of biocidal products. The platform therefore has a professional and a general public access gateway.

For professionals:
The SIMMBAD website was specifically set up as a means of exchanging information between companies wishing to market a biocidal product and the National Health Security Agency for Food, Environment and Labour (Anses) in France.

As such, SIMMBAD allowed companies to file an online application for placing on the market of a biocidal product in a completely paperless secure process and provided for professional, real-time monitoring of the progress of the dossier for authorisation. However, since the entry into force of the BPR, applications for authorisation must now be submitted through the R4BP3, and it is therefore no longer possible to transmit these via SIMMBAD. SIMMBAD however still provides a platform for dialogue with the administration in this regard and includes support documents for the authorisation process.

Moreover, following the entry in force of the CERTIBIOCIDE scheme, professionals are required to use SIMMBAD in a variety of ways:

- Training centres: request accreditation;
- Enterprises that use and/or sell/buy biocidal products: enter the annual declaration of biocidal products placed on the market, including information on the personnel involved in these activities;
- Enterprises that distribute biocides: maintain (declaration of, modification & withdrawal to) the biocidal products sales registry;
- Individuals: find an accredited training centre, request training, follow-up on training and request delivery of certificates upon completion of training.

For the general public
SIMMBAD also allows the public access to summary information on authorisations that have been granted for biocidal products and access to a list of registered products.
https://simmbad.fr/servlet/accueilMinistere.html
https://simmbad.fr/servlet/documentation.html

It should be noted that while SIMMBAD is the only example found of an IT platform used in the Member States for the product authorisation procedure as well as exchange of information between companies and the national authorities, it has to a large degree now been replaced by R4BP which is used EU-wide, and is considered further below.

5.4 EU it tools for monitoring

Details of all authorisations granted for biocidal products are to be kept on the Register for Biocidal Products (R4BP), which is established and maintained by ECHA in accordance with Article 71 BPR. The R4BP is to be used by applicants to submit applications and data for all procedures under the BPR, and thereafter for the exchange of information between competent authorities, ECHA and the Commission and between applicants and competent authorities, ECHA and the Commission.

The competent authorities and the Commission will update the information in the R4BP following any decision they take relating to the authorisation of a biocidal product. In particular, they will update the information in the R4BP relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled, or for which a parallel trade permit has been granted, refused or cancelled. The Commission will, in particular, update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled.

Biocides submissions under the BPR started on 1 September 2013. All applications for product authorisation are therefore now submitted through the Register for Biocidal Products (R4BP 3), which acts as the central hub. The International Uniform Chemical Information Database (IUCLID 5) is used to collect, organise and store the data on active

substances and biocidal products. For an application, an IUCLID 5 dossier is prepared and submitted to ECHA and the national authorities through R4BP 3. R4BP 3 is a living system and is therefore not only used to submit the dossier but also to communicate any updated information and any changes made during the authorisation process go through the system.

As an IT platform, the R4BP3 provides functions which enable the industry and the authorities to both comply with the legislative requirements and exchange information between them. From this, data could be collected on the quantities of biocidal products placed on the market across the EU according to product types as well as data on the active substances within these. Data on these parameters could first be extracted from the information available in the system, based on the estimated quantities indicated in an application for authorisation. This could also be supplemented by asking companies to submit annual data on the quantities actually placed on the market each year, which could differ somewhat from the estimates provided in the original application. It should be noted that under Article 68(1) of the BPR, authorisation holders are required to keep records of the biocidal products they place on the market for at least 10 years after placing on the market, or 10 years after the date on which the authorisation was cancelled or expired, whichever is earlier. Authorisation holders are to make these records available to the competent authority on request. As a first step therefore, Member States competent authorities could be asked to request that this information is submitted to them by authorisation holders in their country. Where possible, in the future this data could be submitted by authorisation holders directly to the competent authorities through R4BP, and made available to ECHA and the Commission for EU-wide analysis.

The possibility of extending the R4BP tool in future to include the collection of data on both placing on the market and use of biocidal products was discussed with a number of Member States and generally it was felt that it would be useful to have a mechanism at the EU-level by which data on the use of biocidal products could be obtained. To do so, the Commission would need to establish an appropriate legal basis for monitoring and the collection of statistics on the use of biocidal products (this could either be done by way of an amendment to the Statistics Regulation or the BPR) and a requirement to submit annual data on use through the R4BP. At present Article 71(3) of the BPR requires applicants to use the R4BP to submit data for all procedures covered by the BPR. Article 71(8) also gives the Commission power to develop rules on the types of information to be entered in the R4BP.

On a practical level, the Commission would need to explore with ECHA how to develop a further module within the R4BP for the submission of this data by authorisation holders. In turn, consideration would also have to be given to the practicalities of how data on the actual use could be collected. One option would be to place a requirement on professional users of biocidal products as a condition of certification, where certification is made mandatory (see recommendations in Section 7, similar to the current position in Croatia and Slovenia, where professional users are required to submit annual data on use of biocidal products. Data on use could either be submitted to the authorisation holder or the competent authority, which in turn would be required to submit the data directly using R4BP. Alternatively, where a mandatory scheme of certification is introduced (see recommendations in Section 7), the R4BP could be extended to cover the process of certification and submission of data required as a condition of certification, as has been done in France using the SIMMBAD IT tool. In each case the information sought should cover the details of the biocidal product, the date and quantity used, the target organisms controlled, the area where the product is applied, and any risk mitigation measures applied/precautions taken when applying the product.

In the case of general consumer use, it will be extremely difficult to collect data on actual use. Given the limited number of biocidal products that are authorised for general

consumer use at this stage, the collection of data should focus on professional use of biocidal products. However, as further product types come through the authorisation procedure, mechanisms to collect information on use by the general public should be considered. For example, the possibility of collecting this information from retailers at the point of sale to the general public could be considered or a voluntary reporting requirement.

5.5 Conclusions

Monitoring of the use of biocidal products is required as data is currently lacking and very little information is collected at present across the Member States. The information provided by Member States on data collected indicates that very few of them collect data on the use of biocidal products. Of those that do, the data collected is limited as covers data on the placing on the market of biocidal products (i.e. sales data), rather than actual use.

There are currently no available IT tools in the Member States, which could be developed for use across the EU-28 in order to monitor the use of biocidal products. The SIMMBAD tool used in France, is the most advanced system of data collection, but its functionality has to a large part been superseded by the ECHA IT tool, R4BP. It therefore appears that the R4BP would be the most appropriate way at the EU level to promote harmonised monitoring of the use of biocidal products.

The following recommendations are made:

1) As a first step, authorisation holders should be required to provide data on the annual amounts of biocidal products placed on the market in each Member State. There is adequate provision under Article 68(1) BPR for competent authorities to request that records of biocidal products placed on the market be made available. This information should therefore be requested by each Member State from authorisation holders;

2) The Commission could investigate with ECHA the possibility of extending the functionality of R4BP in order that it serves as an EU-wide tool for the collection of data. If considered appropriate, an individual module could be included to allow for the direct submission of information on use, and appropriate amendments could be made to the BPR to include a requirement for monitoring and submission of annual data on use through R4BP. It is suggested that information to be submitted could include the date and quantity of biocidal product used, the target organisms controlled, the area where the biocidal product is applied, and any risk mitigation measures applied/precautions taken when applying the product.

3) In order to collect data on use of biocidal products, a reporting requirement could be imposed on professional users. Where a mandatory scheme of certification is introduced (see recommendations in Section 7), the Commission and ECHA could also consider extending the R4BP to cover the process of certification and submission of data required as a condition of certification.

4) Mechanisms to collect information on use by the general public could be considered once further products for general use are authorised. It is suggested that these could potentially include a reporting requirement by retailers at the point of sale or a voluntary reporting requirement.

5) Where the BPR is amended to include a requirement for monitoring and the submission of annual data on the use of biocidal products using the R4BP, the review of the Statistics Regulation in 2016 will not need to consider extending its scope to include biocides.

6 SPECIFIC RISKS POSED BY THE USE OF BIOCIDAL PRODUCTS IN SPECIFIC AREAS

6.1 Introduction

According to Article 12 of the Sustainable Use Directive, the use of pesticides shall be prohibited or restricted to the minimum necessary in areas used by the general public such as public parks and gardens, sports and recreation grounds, school and children's playgrounds etc., and in protected areas, such as Natura 2000 sites, or protected areas as defined in the Water Framework Directive 2000/60/EC. A similar approach could be adopted in relation to biocides, as seen already in some Member States.

This task therefore considers the risks posed by the use of biocidal products in specific areas and whether additional measures, namely EU-wide restrictions, are required to address those risks.

6.2 Consultation responses

As a first step, information was sought on what measures are currently taken by Member States to prohibit or restrict the use of biocides in specific areas. Within the questionnaire sent to stakeholders, Member States were asked the following question:

- Does your country prohibit or restrict the use of biocides in certain areas, such as public parks and gardens, sports and recreation grounds, school and children's playgrounds, nature conservation areas etc.?

Almost half of the Member States (10) that responded to the questionnaire stated that they did not have specific prohibitions or restrictions in place covering the use of biocides in certain areas. A number of Member States noted that the active substance approval and product authorisation offers sufficient controls and such restriction would be applied in any case where the risk assessment of a specific product leads to specific risk mitigation measures, which would be clearly mentioned on the product label. In addition, three Member States that had indicated that they did have in place specific prohibitions or restrictions, referred to the restrictions imposed as part of the product authorisation, whereby any proposed use in vulnerable areas and outside would be checked and evaluated as part of the approval procedure and risk management measures set when products are approved, or in some cases the approval is not granted. Another Member State commented that sensitive environments are subject to generic legal protections, in addition to more general pollution prevention measures.

With regard to current prohibitions or restrictions in place in the Member States, 11 Member States responded that they did have in place specific prohibitions or restrictions covering the use of biocides in certain areas, though as noted above three responses related to the approval of the active substance. Of the remaining eight, one Member State only allows certified professional users to use biocidal products in these specific areas. However, this relates to a requirement for certification of professional users rather than there being a blanket ban or restriction on the use of biocidal products in those areas. Similarly, one Member State referred to there being controls on the application of mosquito controls by aerial spraying, which requires authorisation by the National Public Health and Medical Officer Service. However, this relates to a requirement for authorisation for aerial spraying rather than a restriction placed on the use of biocidal products in specific areas.

Two Member States responses referred to the provisions in place to restrict the use of plant protection products in specific areas. One Member State referred to permission being required for the use of pesticides in certain areas, such as around apartment

buildings, school yards and play grounds and water protection areas. However, this requirement stems from Article 12 of Directive 2009/128/EC on the sustainable use of pesticides, and therefore does not cover biocidal products. Similarly, another Member State referred to a proposed law to restrict plant protection products in specific areas (Project 6525 – Projet de loi elative aux produits phytopharmaceutiques). The Law of 19 December 2014 on Plant Protection Products was recently adopted in December 2014 and makes provision for implementing Regulations to be adopted covering a number of aspects, including providing for additional reduction or prohibition of use of PPPs, and reduction of risks in certain zones. There will be a complete prohibition on the use of PPPs in 'public spaces' from 1 January 2016 and restrictions on the use of PPPs in other zones including protected areas under the national laws transposing the Water Framework Directive and Habitats Directive and recently treated areas used by or accessible to agricultural workers. As noted however, these prohibitions and restrictions will apply to plant protection products in implementation of the requirements of Article 12 of the Sustainable Use Directive, and do not extend to cover the use of biocidal products. Other Member States have in place similar provisions for plant protection products, as outlined in their National Action Plans, developed in accordance with Sustainable Use Directive.

Another Member State made reference to Annex XVII of REACH which is used to restrict and prohibit the use of certain biocides and their treated articles in certain areas. For example the use of creosote is prohibited in public parks, playgrounds etc. The list of restrictions in Annex XVII to REACH only refers to Creosote as an example of an biocidal active substance and a few substance such as Chromium VI compounds which might be used as co-formulants next to general restriction criteria for certain classified substances such as carcinogens mutagens or reprotoxic substances of Category 1A or 1B or 2.

The remaining three Member States provided the following examples:

MS	Restriction in place
Belgium	In the Flemish Region, a Flemish decree prohibits (or limits) the use of pesticides and biocides by local authorities for outdoor use. An annual list of PT14 products (rodenticides) that can be used by way of exception is published annually.
Finland	A prohibition on the use of anti-fouling products in freshwater was established in 2004 since fouling is negligible in freshwater and therefore anti-fouling products do not require to be used. The use of impregnated wood and timber close to wells, in contact with food material and drinking water is restricted. It is also recommended not to use impregnated wood and timber in groundwater protection areas.
Germany	Several regulations in Germany restrict the use of antifouling products. Examples are: a) Delegated act concerning shipping on Lake Constance: According to the delegated act underwater paints of boats and waterway facilities have to be in a way that they do not have adverse effects on the water. There are recommendations concerning the use or avoidance of concrete active substances by the Lake Constance Foundation. b) Delegated act concerning the Wakenitz: According to the delegated act vessels having an underwater paint with a toxic effect are not allowed to be used on the Wakenitz and the Ratzeburger lakes. c) Delegated act on recreation of the Ruhrverband in force for several water reservoirs: According to the delegated act underwater paints of vessels are not allowed to contain substances hazardous to water.

6.3 Exposure risks in specific areas

Some Member States have taken additional measures to prohibit or restrict the use of biocidal products in specific areas. However, in order to assess whether additional measures are required at the EU level, further information is required on any additional risks in specific areas which are not already addressed by existing controls under EU health and safety and environmental legislation. Within the questionnaire sent to stakeholders, Member States and NGOs were therefore asked whether they consider that

additional measures are required to address exposure risks posed by the use of biocidal products in specific areas that are not adequately covered by existing risk mitigation measures?

Of the 17 Member States that responded to this question, nine Member States considered that additional measures were not required. Of the eight Member States that considered that additional measures were required, four did not provide any further details of the reasons for this or the product types that they considered that additional measures were required for. One Member State commented that professionals have a higher exposure risk as they use the compounds more frequently and for longer periods than the public. This is further considered in Chapter 4 which considers whether additional provisions are required to reduce the risk to users, in particular professional users.

The remaining three Member States provided the following information:

PT	Use	Application	Exposure risk
All	All	All	Poor application of PPE as RMM. There is a general gap in recommendation of engineering and technical RMM (e.g. dosing system, special packaging, spraying devices with controlled droplet size, closed systems) as these kinds of measures are not considered, assessed, and/or recommended, at all.
PT 21	Antifouling paints	Leisure boats	Sensitive areas like nature or water conservation areas
PT 18	Insecticides	Use in sensitive areas	Sensitive areas like nature or water conservation areas
PT 18	Control of mosquitos	Aerial spraying	Spraying in inhabited areas.
PT 19	Repellents	Spray and roll-on.	Dermal exposure to children. Over exposure to repellents.
PT 21	Antifouling products	Leisure boats	Consumer's attention needs to be directed more to the labelling and to keeping children out of reach when using hazardous paints. Differences in hazardous of antifouling paints used on east/west coast of Sweden needs to be brought to attention through labelling.

In each case these comments relate to product types where biocidal products have been approved under the BPR. These exposure risks are therefore considered alongside any that are identified during the analysis of the main product types, PT 8, PT 18, PT 19 and PT 21 set out below.

In addition, NGO's were also asked whether they considered that additional measures were required to address any exposure risks posed by the use of biocidal products in specific areas. Of the six NGO's that responded to the questionnaire, all considered that additional measures were required. NGO's considered that similar to the requirements introduced under the Sustainable Use Directive, additional measures should be introduced for biocides to minimise exposure in sensitive areas. Sensitive areas should include not only public parks, schools etc. but also designated nature conservation sites such as Natura 2000 and areas for drinking water abstraction. The following measures were recommended:

- identification and publication of all sensitive areas in each Member State;
- establishing mandatory and specific IPM and proper use measures for those sensitive areas, e.g. establishing buffer zones to prevent negative impact of biocides on the aquatic environment and non-target organisms, prohibiting

applications with a high risk of emission into surface water, sewage system, ground water or into marine ecosystems;
- using biocidal products only when necessary following prioritisation of preventative measures and biocide-free alternatives;
- weighing the benefit for the community (protection of vulnerable groups and the environment) over economic interests within an impact assessment;
- establishing a record keeping system and a report system for biocidal product applications in sensitive areas;
- ensuring that application of biocidal products is only taken by professional and certified users in sensitive areas;
- conducting specific awareness raising campaigns for decision-maker, professional users and the general public in sensitive areas;
- researching further the various exposures to environmental toxicants which can occur at school in several EU countries, so as to reflect the variety of situations, including biocidal products, in order that there is more information available on the situation within schools.
- clear recommendations including pictures should be drafted and distributed widely to kindergardens, schools, and other public places where (young) children may be present;
- specific advice should be given to pregnant women by health professionals and/or women of childbearing age (even before the beginning of pregnancy) on avoiding the use of pesticides and pest control products at home as well as disinfectants on a daily basis. To do so, it is important that a budget is made available to fund public campaigns on avoiding or reducing to the very minimum the use of biocidal products.

As can be seen, a number of these recommendations cover actions that are already taken by certain Member States, for example the requirement that the biocidal product is only applied in the sensitive area by professional or certified users. A number of other recommendations reflect the principles of IPM which are considered in the next Chapter of the report. The remaining recommendations relate to guidance or information, education or training initiatives, which are also considered in Chapter 7.

6.4 Use, application and control measures for specific product groups

In order to consider the use of biocidal products in specific areas and whether additional measures are required to address any identified exposure risks, specific product types were selected for further analysis. Given that the majority of active substances approved to date under the BPR concern product types 8 (wood preservatives) and 18 (insecticides) and recently a number of active substances have also been approved for product types 19 (repellents and attractants) and 21 (antifouling products), these specific product types were selected for further analysis. The selection of these four product types also reflects those referred to in the responses from Member States outlined above.

Information on the applications for each product type selected has been obtained from a literature review and expert knowledge and complemented with the information from stakeholders in response to the questionnaires.

The results from previous research projects have also be used. For example, in one project by Hydrotox, several outdoor applications were identified which might affect specific areas. This concerns wood preservatives used for fences, rodenticides used outside of buildings, cooling water biocides, insecticides applied for mosquito control and against oak procession moths, or antifouling agents released during the application, use life and removal stages. Many biocides applied by consumers indoors (especially Product Types 1, 2, 18 and 19) may cause exposure to residential bystanders. Therefore, private homes could also be considered as a "sensitive area" from a human health view.

Industrial uses such as paper making processes or metal processing (Product Type 12 and 13) might also cause occupational exposure.

Following identification of the use and application for each of the product types, a review of the control measures used to address any exposure risks when applying each product has been carried out.

Such control measures stem from the conditions of approval imposed when approving the active substance, the risk mitigation measures applied when authorisation the biocidal product, as well as key requirements under various pieces of EU health and safety legislation (outlined in Chapter 4) and water legislation, including the Water Framework Directive 2000/60/EC. The analysis has considered key requirements and control measures that are applied for each product type.

Under the EU Water Framework Directive (Directive 2000/60/EC) emission control measures and environmental quality standards are being established for priority substances. Annex I of Directive 2008/105/EC on Environmental Quality Standards describes 33 priority substances and eight other pollutants which are referred to in Annex X of the Water Framework Directive. The first list included Diuron and Isoproturon both used as PPP and biocides and some "old" biocides removed from the market such as Chlorpyrifos or Pentachlorophenol. With the last amendment by Directive 2013/39/EU further biocidal active substances have been included and inland surface water environmental quality standard (EQS) of 0.0025 µg/l for Irgarol (Cybutryne), of 0.065 µg/l for Terbutryn and of 0.00008 µg/l for Cypermethrin have been established.

Table: Priority substance of the WFD with relevance to biocides

Use	Application	Exposure risk
Diuron	330-54-1	PT 7, 10
Isoproturon	34123-59-6	PT 7, 10
Trichloromethane	67-66-3	Disinfection by-products (DBP)
Cybutryn	28159-98-0	PT 21
Cypermethrin	52315-07-8	PT 8
alpha-Cypermethrine	67375-30-8	PT 18
Terbutryn	886-50-0	PT 7, 9, 10
Trichloromethane	67-66-3	DBP
Dichloromethane	75-09-2	DBP Bromodichloromethane
Trichlorobenzene	12002-48-1	DBP Trichlorobenzene-1,2-diol

One priority substance, Trichloromethane, is a well-known disinfection-by-product resulting from the use of active chlorine compounds such as chlorine or sodium hypochlorite. For the priority substances Dichloromethane and Trichlorobenzene there exist related disinfection by-products (Weinberg et al. 2002)[37].

With Directive 2013/39/EU also the "watch list" monitoring mechanism has been introduced. Here, a maximum of 10 substances are defined for which Union-wide monitoring data should be gathered in order to support future prioritisation of

[37] Weinberg, H. S., Krasner, S. W., Richardson, S. D., Thruston, A. D., 2002. The Occurrence of Disinfection By-Products (DBPs) of Health Concern in Drinking Water: Results of a Nationwide DBP Occurrence Study. EPA/600/R-02/068 http://www.epa.gov/athens/publications/reports/EPA_600_R02_068.pdf

substances. The first watch list includes several pharmaceuticals and is currently being discussed.

Annexes I and II of Directive 2006/11/EC on pollution caused by certain dangerous substances discharged into the aquatic environment, define various dangerous substances, families and groups. List II of Annex I refers to certain categories of substances such as biocides and their derivatives. Any discharge of these substances should be subject to prior authorisation which specifies emission standards.

6.5 Monitoring of biocides in the environment

At this juncture, it is worth noting that the identification of further priority substances and their monitoring in the environment is a prerequisite for setting environmental quality criteria and for developing suitable indicators describing progress in sustainable use. The occurrence of biocides in the environment has been addressed in several reviews[38].

As noted above some active substances have been included as priority substances under the Water Framework Directive 2000/60/EC (Isoproturon, Diuron, Naphthalene) or in national legislation e.g. in the German Surface Water Ordinance. In Germany a unique EQS for biocides, pesticides and their metabolites of 0.1 µg/l has been recommended by drinking water suppliers, which is in line with Directive 98/83/EC on the quality of water for human use.

The NORMAN network aims at exchanging information on emerging environmental substances, and encourages the validation and harmonisation of common measurement methods and monitoring tools. Among the interested stakeholders are competent authorities reference laboratories, research centres and academia, industry, and governmental institutions and standardisation bodies.[39]

In November 2012 a NORMAN workshop on monitoring strategies for biocides was organised by the German Federal Environment Agency with about 65 experts from 11 member states. The workshop was intended as a kick-off to stimulate joint activities between European countries on biocide monitoring, including prioritisation, sampling and analytical methods development and establishment of a common database and data exchange facilities.

Among the NORMAN list of emerging substances are biocides (Chloroxylenol, Chlorophene, Triclocarban, 2 -Chloroacetamide), biocide transformation products (Methyl triclosan) next to numerous disinfection-by-products (e.g. Penta-chloropropanone, Tetrachloropropanone, Trichloropropanone, Dibromo-propanone). The list of candidate emerging substances from October 2013 mainly refers to biocides (123 from about 190 substances). In total 44 of these biocidal active substances have a dual use as plant protection product.

A follow up project for developing a suitable monitoring strategy for biocides has been initiated by the German Federal Environment Agency (FKZ 3712 67 403) and will be finished in 2015. Summarising, monitoring of biocides in environmental media is being increasingly addressed. A follow up Norman workshop on monitoring of biocides is planned for June 2015. Until such time that monitoring of biocides in environmental media is carried out, monitoring of priority substances under the Water Framework

[38] Knechtenhofer et al., 2007; Bürgi et al., 2009; Kahle et al. 2009; Wittmer et al. 2011; Gartiser et al 2012; Ruedel et al. 2012, Altenburger et al. 2015

[39] Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances http://www.norman-network.net/

Directive, as set out above, should be used to inform the assessment of specific risks to the water environment from biocidal products.

6.6 Analysis of specific product types

Each of the above control measures, where relevant, is discussed in relation to the specific product type analysed. A summary of the identified risks and risk mitigation measures proposed for each of the product types assessed is provided below.

6.6.1 Product type 8 (wood preservatives)

Biocidal products of PT 8 are used for the preservation of wood by the control of wood-destroying or wood-disfiguring organisms. Wood preservatives are used for both preventive and curative treatments of wood. The target organisms are wood-destroying or wood-disfiguring fungi and insects such as the house longhorn beetle or termites. Preventive treatments are usually applied to wood at industrial treatment plants before the wood is put into service whereas curative treatments are mostly applied to wood in-situ by professionals or amateurs.

The Water Framework Directive (WFD) 2000/60/EC sets environmental standards for priority substances such as Cypermethrin and Terbutryn. The inclusion directives for wood preservatives often state that treatment of wood intended for outdoor constructions near or above water will not be allowed (e.g. Cypermethrin). The establishment of drinking water protection zones for pesticides applies for both plant protection products and biocidal products.

The risk mitigation measures proposed for biocidal products of PT 8 have been evaluated in a research project on behalf of the German Environment Agency (Gartiser et al. 2011). The Inclusion Directives for active substances describe different risk mitigation measures which are to be considered during the authorisation of biocidal products. A full list of the different risk mitigation measures is provided in the analysis of PT 8 at Annex V. These include the following measures:

- Restriction K-HDO as wood preservative to industrial use in fully automated and closed equipment.
- Restriction of use for the treatment of wood that may enter in direct contact with infants (e.g. K-HDO).
- No in-situ treatment of wood outdoors with Boric acid, Propiconazole, Tebuconazole, or Tolylfluanid.
- Restriction of in situ treatment of wooden structures near water, where direct losses to the aquatic compartment cannot be prevented, or for wood that will be in contact with surface water (e.g. Thiacloprid).
- Use of appropriate personal protective equipment for reducing human exposure through industrial and/or professional use (most wood preservatives).

However, these risk mitigation measures are often subject to the clause "unless data is submitted to demonstrate that the product will meet the requirements." The use of personal protective equipment (PPE) for reducing exposure and ensuring the safe use of the product is not considered acceptable for non-professional users. While spraying of wood preservatives by amateur users is not allowed in many Member States, most competent authorities suggest that spraying by non-professional users should not be allowed if the exposure resulted in the need to use PPE. The use of water soluble packaging for wood preservative concentrates has been suggested for avoiding exposure during the filling and loading phase (Gartiser 2011, 2012).

For many PT 8 active substances risks to human health and the environment have been identified, which require appropriate risk mitigation measures that may be difficult to control.

- Safe operational procedures shall be established for most wood preservatives used in industrial plants. This requires the development of best practices and education and training.
- For most preserved wood, the most significant losses to the environment take place during the service life phase. Several risk mitigation measures have been proposed to reduce risks to the environment. The adequate use of treated wood in their respective intended use classes determines the leaching of wood preservatives to water next to the use of top coats. For some active substances their use for outdoor constructions near or above water is not allowed.
- Impregnated wood becomes a treated article whose marketing and use in construction will not easily be controllable. The labelling of treated articles directly relates to the use phase of impregnated wood. While the provisions of the BPR on treated articles certainly improves the situation especially for treated wood imported, market surveillance is challenging.
- Next to the service life also the end of life phase may significantly contribute to the overall emissions to the environment (e.g. incineration of treated wood).

These points demand for further measures to be implemented to ensure a sustainable use of PT 8 active substances. While risks to specific areas are already addressed though use restrictions set in the conditions of approval of the active substance or authorisation of the biocidal product, such as the restriction on the treatment of wood intended for outdoor constructions near or above water, further measures are required to ensure the proper application of RMM. As noted above, these rely on compliance with the labelling of the product regarding both use and disposal, the development of best practices and education and training. Recommendations regarding information, education and training are made under Chapter 7.

The full analysis carried out for PT 8 is set out in Annex V.

6.6.2 Product type 18 (insecticides)

Biocidal products of PT 18 are mainly used indoors to control arthropod pests such as cockroaches, pharaoh ants, termites, fleas, spiders, dust mites, or bed bugs. Outdoor uses for the control of wasps and hornets (the last being considered protected animals) are less common. Large or local scale mosquito control through the treatment of water bodies with larvicides and the control of the oak procession moths are further examples for outdoor applications. Insecticides used in animal housing and manure storage systems are closely linked to veterinary hygiene biocidal products (PT 3). Product type 18 covers professional and non-professional users.

The risk mitigation measures proposed for biocidal products of PT 18 have been evaluated in a research project on behalf of the German Environment Agency (Gartiser et al. 2011). The Directives for insecticidal active substances and (draft) CARs refer to the use restrictions for fumigants to specifically trained professionals while applying appropriate personal and respiratory protective equipment. Phosphine releasing compounds may only be applied by professionals in the form of ready-to-use products. The use of applicators may be a measure to reduce risks. Additional RMM are the information of potential bystander and the removal of food before application, the keeping of waiting periods which ensure compliance with the Maximum Residue levels (MRLs) on food and feed allowed and the proper disposal of unused products. The minimisation of exposure of insecticides to humans, to non-target species and to the aquatic environment has been challenged. For example, products shall be positioned away from external drains and unused products shall be disposed properly and not washed down the drain. The CARs also describe restriction of the application areas such as only indoor use in crack and crevices or in concealed locations inaccessible to man and domestic animals for avoiding secondary exposure. Other RMM concern the restriction of use in animal housings to those without an effluent to the sewer system or direct release to surface water.

For some PT 18 active substances risks to human health and the environment have been identified, which require appropriate risk mitigation measures that may be difficult to control. A full list of the different risk mitigation measures is provided in the analysis of PT 18 at Annex V. These include the following measures:

- For some active substances, such as alpha-Cypermethrin, acceptable risks for professional users are only achieved when wearing protective clothing.
- The environmental risks of some active substances, such as alpha-Cypermethrin, require a restriction of the application frequency for total surface treatment or barrier application or crack and crevice treatment to 1 to 2 applications per year, which is difficult to control.
- A label restriction of the use of alpha-Cypermethrin in sensitive areas, such as hospitals, kitchens, restaurants, food-processing and storage areas is required to avoid residue contamination of food.

These points demand for further measures to be implemented to ensure a sustainable use of PT 18 active substances. Any risks to specific areas however are already addressed though use restrictions set in the conditions of approval of the active substance or authorisation of the biocidal product. Any further measures required would therefore be measures to ensure the proper application of RMM such as education and training (see recommendations in Chapter 7).

The full analysis carried out for PT 18 is set out in Annex V.

6.6.3 Product type 19 (repellents)

Biocidal products of PT 19 are used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals. Several of the actives are naturally occurring substances such as oils and extracts. For some actives such as Decanoic acid or Geraniol, both being approved for PT 18 and PT19, there is a fluent transition from the repellent to the insecticidal effect.

Product type 19 covers professional and non-professional users. The application to children is of specific concern. Repellents are used as aerosols, pump sprays, creams, and moistened paper or cloth. Products may be designed to be applied to the exposed skin and thus dermal absorption may be important. Repellents are also used in treated articles such as clothes or mosquitos nets intentionally incorporating an insect repellent. Whether such a product is a biocidal product or a treated article depends on whether the biocidal function is primary or not. There are also products with a cosmetic purpose, which serve an equally important biocidal purpose such as insect repellent sunscreens.

For some active substances the (draft) CARs refer to their potential of being skin sensitisers. Other active substances such as Ethyl buthylacetylaminopropionat or DEET should not or only carefully be applied to children. DEET has also been identified as emerging polar contaminant in the outflow of sewage treatment plants and should be included in routine monitoring programmes. No suitable risk mitigation measures for the environment have been proposed so far.

For some PT 19 active substances hazards to human health have been identified, which require appropriate risk mitigation measures that may be difficult to control. A full list of the different risk mitigation measures is provided in the analysis of PT 19 at Annex V. These include the following measures:

- Products containing e.g. Ethyl buthylacetylaminopropionat may require use restrictions such as “not to be applied to children’s hands” or “avoid breathing spray”.

- The application of DEET requires limitation of primary exposure to human skin, especially for children (restriction of concentration, treated area and frequency). DEET should not be applied at all to children below 2 years. DEET has been identified as an emerging polar contaminant, as it is regularly detected in the outflow of municipal treatment plants.

No risk mitigation measures for the environment have been proposed and therefore it is not considered that further measures are required to address risks in specific areas. Although PT 19 biocidal products do not seem to present a priority product type, further measures to ensure a sustainable use of PT 19 biocidal products certainly would help to consider the above points regarding human health. Such measures are considered further in Chapter 7.

The full analysis carried out for PT 19 is set out in Annex V.

6.6.4 Product type 21 (antifouling products)

Antifouling products (AFP) are used to prevent surfaces from unwanted growth and settlement of fouling organisms. Target organisms are all microbes and higher forms of plant or animal species, micro- and macro-organisms (bacteria, algae and crustaceans) in seawater and freshwater that may settle on ship hulls and other surfaces. Fouling in general is unwanted, as e.g. increased flow resistance on ships leads to an increase of fuel consumption. This product type covers the professional and non-professional user.

According to competent authorities, the first assessment reports of antifouling active substances demonstrated some unacceptable risks either for human health (during professional use), and/or for the environment (in the harbour or marina during the service life, or during the application or maintenance and repair activities). The suitability of the proposed risk mitigation measures has raised questions, with no clear conclusions in the assessment reports.

For most antifouling active substances evaluated under the BPR risks on human health and to the environment have been identified, which cannot be tackled only during product authorisation. A full list of the different risk mitigation measures is provided in the analysis of PT 21 at Annex V. These include the following measures:

- For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Where exposure cannot be reduced to an acceptable level by other means, products shall be used with appropriate personal protective equipment.
- For non-professional human health risks these are only acceptable if PPE such as masks or gloves are used, which cannot be ensured or enforced in practice.
- Member States may restrict the use of antifouling products in sensitive areas and local authorities might enforce restrictions when establishing marinas in those areas.

These points demand for further measures to be implemented to ensure a sustainable use of antifouling products. While risks to specific areas are already addressed though use restrictions set in the conditions of approval of the active substance or authorisation of the biocidal product, as Member States may restrict the use of antifouling products in sensitive areas as a number of Member States have already done, further measures are required to ensure the proper application of RMM. As noted above, these rely on compliance with the instructions regarding application and use contained in the labelling of the product and safety data sheet, the establishment of safe operational procedures as well as the use of PPE amongst other measures. Recommendations regarding information, education and training are therefore made under Chapter 7.

The full analysis carried out for each product type is set out in Annex V.

6.7 Conclusions

In order to consider the use of biocidal products in specific areas and whether additional measures are required to address any identified exposure risks, the information available on the uses, application, exposure risks and control measures applied to specific product types was reviewed. Given that the majority of active substances approved to date under the BPR concern product types 8 (wood preservatives) and 18 (insecticides) and recently a number of active substances have also been approved for product types 19 (repellents and attractants) and 21 (antifouling products), these specific product types were selected for further analysis.

The analysis of these four product types showed that any risks to specific areas are already addressed through use restrictions set in the conditions of approval of the active substance or authorisation of the biocidal product. While further measures are required to ensure the proper application of RMM identified, these largely relate to measures to increase the dissemination of information to the end-user, education and training.

The responses received from Member States also reflected this position, the majority of which did not consider that further measures were required. Where risks were identified in the responses from Member States, the analysis of PTs 8, 18, 19 and 21 showed that these exposure risks would be covered by RMM at the authorisation stage. While the responses received from NGO's felt that further measures were required and made a number of recommendations in this respect, these covered actions that are already taken by certain Member States, for example the requirement that the biocidal product is only applied in the sensitive area by professional or certified users, or related to the principles of integrated pest management (IPM) or information, education or training initiatives, which are considered in the next section of the report.

It is therefore concluded that in cases where an exposure risk arises, this is as a result of poor application of recommended control measures rather than there being a gap in the protection in specific areas. Further legislative measures setting out an EU-wide restriction on the use of biocidal products in specific areas, such as freshwater bodies, are not recommended. It remains open to Member States to impose such restrictions as a condition of authorisation on a case-by-case basis or through legislative measures at the national level, as a number of Member States have already done. However, training and provision of information is key to ensure that RMM are applied in order to protect specific areas and therefore recommendations in this regard are made in Chapter 7.

It should however also be noted that objectives of a sustainable use of biocides goes beyond the objectives of product authorisation. While product authorisation only allows market access of biocidal products which are considered being safe in terms of quantitative risk quotients, a sustainable use of biocides intends achieving the objectives of hygiene, preservation and pest control with the least possible adverse impacts to the environment and society (including human health). Article 1 of the Sustainable Use Directive describes the objective to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides. Further measures with regard to the development of best practices aimed at the sustainable use of biocidal products are therefore considered in Chapter 7 on the application of integrated pest management principles.

Finally, until such time that monitoring of biocides in environmental media is carried out, Member States should seek to utilise information available from other monitoring regimes such as the monitoring of priority substances under the Water Framework Directive. This could usefully inform the assessment of specific risks to the water environment from biocidal products.

7 INTEGRATED PEST MANAGEMENT PRINCIPLES

7.1 Introduction

The Sustainable Use Directive establishes a framework for Community action to achieve the sustainable use of pesticides. Annex III of the Directive sets out the general principles for integrated pest management (IPM), which are included in the box below:

ANNEX III of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides- General principles of integrated pest management

1. The prevention and/or suppression of harmful organisms should be achieved or supported among other options especially by:

- crop rotation,
- use of adequate cultivation techniques (e.g. stale seedbed technique, sowing dates and densities, under-sowing, conservation tillage, pruning and direct sowing),
- use, where appropriate, of resistant/tolerant cultivars and standard/certified seed and planting material,
- use of balanced fertilisation, liming and irrigation/drainage practices,
- preventing the spreading of harmful organisms by hygiene measures (e.g. by regular cleansing of machinery and equipment),
- protection and enhancement of important beneficial organisms, e.g. by adequate plant protection measures or the utilisation of ecological infrastructures inside and outside production sites.

2. Harmful organisms must be monitored by adequate methods and tools, where available. Such adequate tools should include observations in the field as well as scientifically sound warning, forecasting and early diagnosis systems, where feasible, as well as the use of advice from professionally qualified advisors.

3. Based on the results of the monitoring the professional user has to decide whether and when to apply plant protection measures. Robust and scientifically sound threshold values are essential components for decision making. For harmful organisms threshold levels defined for the region, specific areas, crops and particular climatic conditions must be taken into account before treatments, where feasible.

4. Sustainable biological, physical and other non-chemical methods must be preferred to chemical methods if they provide satisfactory pest control.

5. The pesticides applied shall be as specific as possible for the target and shall have the least side effects on human health, non-target organisms and the environment.

6. The professional user should keep the use of pesticides and other forms of intervention to levels that are necessary, e.g. by reduced doses, reduced application frequency or partial applications, considering that the level of risk in vegetation is acceptable and they do not increase the risk for development of resistance in populations of harmful organisms.

7. Where the risk of resistance against a plant protection measure is known and where the level of harmful organisms requires repeated application of pesticides to the crops, available anti-resistance strategies should be applied to maintain the effectiveness of the products. This may include the use of multiple pesticides with different modes of action.

8. Based on the records on the use of pesticides and on the monitoring of harmful organisms the professional user should check the success of the applied plant protection measures.

Previous studies on the sustainable use of biocides have covered integrated pest management principles. For example, the study on the '*Assessment of different options to address risks from the use phase of biocides*'[40] noted that many of the IPM principles may be applicable for biocidal products as well and that since biocides are used in urban environments, the range of options for reducing the use of biocides by non-biocide prevention and control methods are much wider than for plant protection products. IPM

[40] COWI, Assessment of different options to address risks from the use phase of biocides, Final Report, March 2009, available at http://ec.europa.eu/environment/ppps/pdf/final_report0309.pdf

principles could at least be applied to specific product-types such as rodenticides, insecticides, repellents and attractants, and also potentially wood preservatives and anti-fouling products. IPM measures may however be relevant for a wider range of product-types in the long-term. For example, where there is a good system of Hazard Analysis and Critical Control Points (HACCP) in place within the food sector, the need for disinfectants may be reduced significantly.

The German Federal Environment Agency initiated two research projects covering the use phase of biocidal products. In the first project, the study on "*Thematic Strategy on Sustainable Use of Plant Protection Products – Prospects and Requirements for Transferring Proposals for Plant Protection Products to Biocides*", the prospects and requirements for transferring measures proposed in Sustainable Use Directive to the biocide area were analysed. The study focused on wood preservatives (PT 8), insecticides (PT 18) and antifouling agents (PT 21)[41]. A systematic analysis of the instruments described in the Thematic Strategy and Directive 2009/128/EC indicated that the structure can be transferred to the biocide area. This concerns e.g. education and training, requirements for sale, the establishment of awareness raising programmes, control of the machinery for biocide application, the development of best practice standards based on integrated pest management principles, and the collection of statistics on biocide consumption. The analysis revealed that some of the instruments of Directive 2009/128/EC could be transferred to the biocides area when considering biocide specific characteristics: Unlike plant protection products, the intended use of some biocides is to be directly applied in water bodies (e.g. PT 2, 11) or indoors (e.g. PT 2, 8, 18). For some product types such as PT 7, 8, 10, 21, emissions during the service life of biocides (e.g. through leaching) are more relevant than during the application phase.

In a follow-up project, *"Reduction of environmental risks from the use of biocides: Environmental sound use of disinfectants, masonry preservatives, and rodenticides"* the prospects for transferring measures in the Thematic Strategy were analysed, and the analysis has been expanded to cover in particular disinfectants (PT 2 and 3), masonry preservatives (PT 10) and rodenticides (PT14)[42]. In this context a European workshop on '*Reducing negative impacts of biocide use on the environment – Towards efficient EU legislation*' took place in March 2014 in Berlin, to present the results and discuss UBA's approach towards appropriate EU legislation in a broader context with other Member States. Around 50 experts from Competent Authorities, the European Commission, user associations of biocides, industry representatives and NGOs participated in the workshop. The study concluded that the development and promotion of IPM guidance for pest control is considered one of the most promising instruments for the sustainable use of biocides. For disinfectants the HACCP as a preventative approach for food safety may serve as an example for a hygiene management tool, comparable to IPM, whereas for masonry and film preservatives (PT 7 and 10) no such concept exists. While for public health disinfectants (PT 2) and veterinary hygiene disinfectants (PT 3) numerous good and best practice documents are available, there is a lack of such documents describing the application and safe handling of paint and plaster that contain biocides, except technical data sheets and informal guidance documents offered by formulators. As a consequence a set of leaflets on best practice for different stakeholder groups has been developed by an ad-hoc working group task force. With respect to rodent control (PT 14) there is a multitude of documents from authorities, industry, and professional associations describing the elements of IPM and criteria of good practice.

[41] Gartiser, S., Lüskow, H., Groß, R. 2012. Thematic Strategy on Sustainable Use of Plant Protection Products – Prospects and Re-quirements for Transferring Proposals for Plant Protection Products to Biocides. UBA Texte 6/2012. See http://www.umweltbundesamt.de/sites/default/files/medien/461/publikationen/4261.pdf

[42] FKZ 3711 63 410: Reduction of environmental risks from the use of biocides: Environmental sound use of disinfectants, masonry preservatives, and rodenticides (ongoing).

In May 2014, the VCI and VCH issued a joint position statement on the sustainable use of biocidal products[43] in order to establish a common understanding on sustainable use of biocidal products inside VCI and VCH and to form the basis of discussions within the industry and with competent authorities, scientists and professional audiences. The position statement discusses the current state of the discussion on sustainable use, by reference to the conclusions set out in the report on the "*Thematic Strategy on Sustainable Use of Plant Protection Products – Prospects and Requirements for Transferring Proposals for Plant Protection Products to Biocides*". It commented that while use-related analogies can be drawn between sustainable use of insecticides or rodenticides and plant protection products, this is usually not possible for other product types, in particular disinfectants which are likely to constitute the by far largest share of authorised biocidal products. As a result, a different basis is required for defining "sustainable use" of disinfectants. Due to the wide range of biocidal products, with different forms of application and three different categories of user, VCI and VCH are of the view that it is not possible to develop just one set of measures for the sustainable use of all biocidal products, and that any measures for the sustainable use of biocidal products therefore need to be examined on a case-by-case basis, specific to the use, product-type and active substance.

7.2 Consultation responses

Information on IPM principles was sought as part of the stakeholder consultation. Within the questionnaire sent to stakeholders, Member States were asked the following question:

- On the basis of the general principles set out in Annex III of Directive 2009/128/EC on the sustainable use of pesticides, what integrated pest management (IPM) measures have been adopted in your country?

Of the 21 Member States that responded, five did not provide any information, three stated that IPM principles are not applied to biocidal products, and the remaining 13 provided information on IPM measures that have been adopted for pesticides. These include the following measures:

- National Action Plan – Five Member States referred to the national action plan that had been adopted in accordance with Article 4 of the Sustainable Use Directive. The Belgian action plan to reduce the risks and impacts linked to pesticides (NAPAN) sets out measures to be taken at both the federal and regional level. At the federal level, the principles of IPM are set out in information provided to users and integrated within training. At the regional level, criteria for IPM will be set out in 2014. In Slovenia, the national action plan includes the option to upgrade integrated pest management measures as part of agro-environmental payment scheme, the preparation of pest management guidelines for each agricultural sector, and measures for research work in the field of agriculture. It should be noted that by now all Member States should have developed and published their national action plans for PPP under the Sustainable Use Directive.

- Use of Guidelines – Four Member States referred to the use of guidelines. In Germany, plant protection products must only be used according to good practice, which includes IPM principles, and therefore guidelines on crop- and sector-specific guidelines have been adopted for a number of plants and crops. In Greece, IPM guidance documents for each of the cultivated crops are in the

[43] Joint position of VCI (German chemical industry association) and VCH (German association of chemical trade and distribution) on the Sustainable use of biocidal products, available at http://www.vci.de/Der-VCI/Internetveroeffentlichung/Seiten/VCI-VCH-Position-Sustainable-Use-of-Biocidal-Products.aspx.

process of being developed on the basis of IPM principles as well as on the basis of crop specific guidelines. In Malta, guidelines are to be developed for professional users for the main crops in Malta (vines, olives, potatoes and tomatoes) which will include crop or sector-specific guidelines for integrated pest management. Further guidelines will be developed for annual crops, field vegetables, greenhouse crops, and fruit trees as well as guidelines which are specific to local pests.

- Information – A number of Member States referred to the provision of information. For example, in Finland a web portal is currently being developed to provide information for professional users on IPM.

- Training – Five Member States referred to training. In Ireland, the concepts/principles and techniques of IPM are an integral part of the training courses for advisors, distributors and users. In particular, the Wildlife Aware Course includes a section on IPM. Industry is also aware of the concept and principles of IPM through the CEN Standard (CEN TC 404 – Pest management services). In the Netherlands, there is a requirement for users to 'demonstrate sufficient knowledge of integrated pest management', although this is currently being developed in order to ensure that it is workable and enforceable requirement. In Finland, IPM is included in voluntary training of professional users of PPP-substances.

- Specific legislative measure – In Finland, it is a requirement under the Plant Protection Products Act (1563/2011) that professional users of PPP-substances must follow the general principles of IPM (Article 13(4) of the Sustainable Use Directive requires the NAP to set out how the general principles of IPM will be implemented). The Finnish Ministry of Agriculture and Forestry has also issued a decree (6/2012) outlining the general principles of IPM, which professional users of plant protection products must observe.

- Qualification of professional user – In Finland, IPM will become a part of the compulsory qualification (valid for 5 years) of professional users after 26 November 2015.

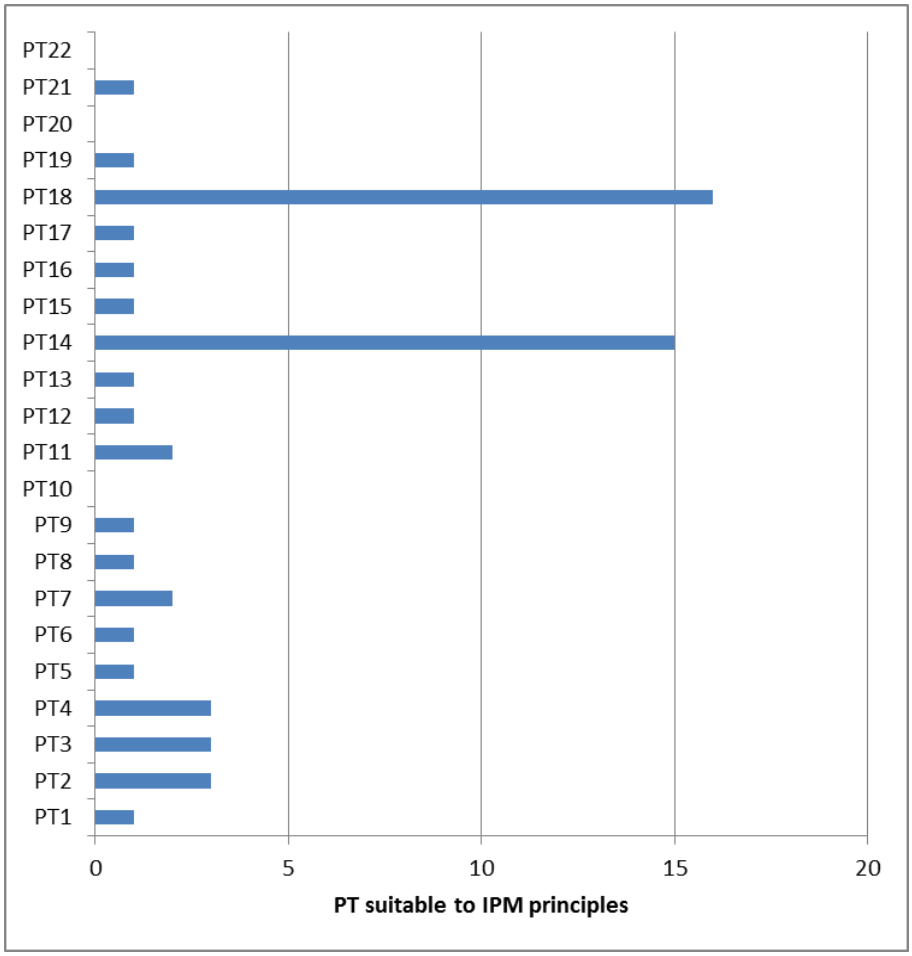
- Monitoring – In France, monitoring or pest populations and resistance is carried out.

- Linked to payment of subsidies – In Belgium, compliance with the criteria for IPM will be a condition for obtaining financing from 2016 onwards. In Finland, from 2015 onwards, IPM guidance will be included in the Farm Advisory System (FAS). In Slovenia, In Slovenia, the national action plan includes the option to upgrade integrated pest management measures as part of agro-environmental payment scheme.

Thereafter, both Member State authorities, NGO's and industry were asked whether they consider that IPM principles could be applicable to biocidal products, either generally or to specific product-types and if so, which PT they could be applicable to?

Of those who responded to the industry questionnaire, 39 respondents (38%) left the question blank or stated that it was not applicable, 19 respondents (18%) did not consider that IPM principles could be applicable to biocidal products, while 46 respondents (44%) considered that IPM principles could apply to biocidal products. While IPM principles could be generally applied to most product types, in almost all cases it was felt that IPM principles would have to be product-specific, with reference being made to specific product types.

The following chart shows the number of times a product type was referred to within the responses of those stakeholders that considered that IPM principles could be applied to biocidal products. As can be seen, a third of those that considered that IPM principles could be applied to biocidal products, considered that IPM principles were suitable for PT 14 (rodenticides) and PT 18 (insecticides). This reflects the fact that it is these two product types that have been authorised to date, and therefore for which such measures can be taken. However, with the exception of PT 10, PT 20 and PT 22, all other product types were referred to at least once within the responses from industry.



The responses from Member States produced a similar result, with almost all Member States indicating that they considered that IPM principles could be applied to biocidal products, though such principles would need to be product specific. Approximately a third of Member States referred to the suitability of PT 14 and PT 18 for the application of IPM principles, again due to these products already having been authorised, though other product types were also mentioned in particular main group 3 (pest control) and in some cases Member States considered that IPM principles could apply to all product types. For main group 3 (pest control) measures could be established to enable the users to decide whether pest control is really necessary.

Specific applications in which IPM principles could be applied included spraying biocides. While in some cases the principles of IPM may be more suitable to specific product types, even those product types, for example the application of PT 11 in closed-systems, could be considered for IPM principles. Additionally, IPM if applied to biocidal products could help in reducing or slowing down the development of resistance particularly for disinfectants and PT 14 and PT 18.

For PT 14 and PT 18, one Member State commented that IPM principles have already been mentioned on the labels of certain rodenticide products. Specific IPM principles that could apply to these two product types include the development of anti-resistance strategies in order to maintain the effectiveness of the products, and monitoring the success of the applied treatment based on the records on the use of the biocidal products and on the monitoring of harmful organisms.

One Member State made the distinction between IPM principles applied by professional and non-professional users. For non-professional user, it was considered that IPM principles would be desirable for biocidal products, especially for disinfectants and insecticides. For professional user, engineering and technical measures, such as dosing systems, reduction in packaging, closed systems, etc. would be beneficial. However, the Member State did not think that the principles of IPM could be transferred completely to biocides, as would need to be adapted to the specific properties of biocides compared to plant protection products, with consideration being given also to how such principles could be enforced. Based on a set of core principles that could be applicable to all product types, codes of best practice should be developed for all PTs (or specific uses) that consider all basic principles in enforceable details. For industrial applications, the principles should be included in BREFs under the Industrial Emissions Directive.

A number of difficulties in applying IPM principles to biocidal products were highlighted by Member States. These centred on the difficulties in establishing IPM principles for all product types, given the variety of product types, applications and users. As a result, IPM principles will need to be product specific and given the differences in product types, a phased approach to the application of IPM principles should be taken. Another difficulty highlighted was that of enforcement. While the use of plant protection products can be related to subsidies in the agricultural sector, there is no similar mechanism to control the application of IPM principles for most biocidal products. Finally, one Member State also commented that diverging definitions of 'professional user' may prevent harmonised implementation of IPM principles.

The responses from NGO’s also supported the development of IPM principles for biocidal products, though again raised the issue of enforcement. One NGO commented that IPM should be mandatory as good practice to minimise the impacts of biocidal products. Another NGO felt that IPM was essential in order to minimise the risks from biocidal products, use and dependency and as a result it is important to implement both generally and product-type specific IPM principles, which should enable users to decide whether and when an application of a biocidal product is really necessary. It was considered that the general principles for IPM in plant protection could be also used for other (biocidal) pest management issues.

7.3 Sustainable Use Directive

The IPM principles set out in Annex III of the Sustainable Use Directive are of relevance to biocidal products. Whilst the first principle on the prevention and/or suppression of harmful organisms sets out a number of options, which apply specifically to crops and thus the application of plant protection products, the overall principle of prevention applies equally to biocidal products. It is a key component of the sustainable use of biocidal products that these should only be used where necessary and therefore measures to prevent the problem arising in the first place should always be taken where possible. Similarly, the other IPM principles, which require monitoring of harmful organisms, consideration of the use of alternative and non-chemical methods, a decision as to whether and when to apply biocidal products and the choice of biocidal product, use of only the appropriate amount of product necessary, development of anti-resistance strategies and the requirement to check the success of the product applied, are equally of relevance to biocidal products. The elaboration of these principles in relation to one

type of biocidal product has already been seen through the development of best practice for rodenticides.

Enforcement of IPM principles remains an issue, as unlike with PPP, where compliance with IPM principles is linked to the payment of agricultural subsidies, there are no similar incentives within the field of biocidal products. In order to ensure compliance with IPM principles, these should be developed within the context of best practice documentation. As outlined in Chapter 3, there are then a number of options that could be used to ensure compliance with best practice documentation.

Aside from the IPM principles set out in Article 14 and Annex III, there are other key provisions of the Sustainable Use Directive which are relevant to biocidal products and are therefore considered further here. These include Article 4 on national action plans, Article 5 on training, Article 6 on requirement for sales, Articles 7 on information and awareness-raising, and Articles 8 and 9 on equipment and methods of application. Articles 11 and 12 on specific measures to protect the aquatic environment and drinking water and to reduce risks in specific areas have been considered in Chapter 6 on the specific risks posed by the use of biocidal products in specific areas.

7.3.1 National action plan

Article 4 of the Sustainable Use Directive requires Member States to set up quantitative objectives, targets, measures and timetables to reduce risk and impacts of pesticide use on human health and the environment. The plan is also to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides. Whilst there is no similar requirement under the BPR, Belgium has developed a Programme for the Reduction of Pesticides and Biocides, and thus included biocides within its action plan for pesticides. Further information on the national plan, NAPAN, is set out below:

Nationaal Actie Plan d'Action National (NAPAN)

The Nationaal Actie Plan d'Action National (NAPAN) sets out the Belgian action plan to reduce the risks linked to pesticides, setting out 184 actions related to the risk management of pesticides. As the NAPAN is made up of a Federal part as well as separate action plans for the Flemish Region, Walloon Region and Brussels Capital Region, the NAPAN Task Force coordinates its implementation and the involvement of all competent authorities.

The Belgian NAPAN has been in place since 1995 and therefore predates the requirement for a national action plan (NAP) for pesticides under Directive 2009/128/EC on the sustainable use of pesticides. In addition, it goes further than required under EU legislation, as voluntarily includes biocides within the action plan, as includes both the Federal Pesticide Reduction Programme (FPRP), and the three Regional plans. In each of the Federal plans, the term "pesticide" refers to all PPP and biocides. The FPRP aims to reduce, the risks and consequences of the use of PPP and biocides for human health and the environment, including a reduction in the use and placing on the market of these products if reduction of such use is the most suitable measures to ensure a reduction in risk.

The legal basis for the plan for biocides is set out in the Act of 21 December 1998 on the product standards for the promotion of sustainable production and consumption patterns and for the protection of the environment and public health, which provides for a federal reduction programme, which must be updated every two years. The Programme for the Reduction of Pesticides and Biocides (PRPB) (see www.prpb.be) sets out three priority actions focused on an evaluation of the PRPB, actions to reduce the risks of pesticides and biocides, and communication and public awareness.

The PRPB includes recommendations on PT 8 and PT 14. After 7 years experience of implementing the PRPB, the criteria for pesticides is much more precise as only dealing with one sector. For biocidal products, measures are not so well developed. Under the programme, an annual report of products on the market is prepared for all PT, and there are other actions for specific PT such as disinfectants in nurseries. An evaluation is made of the actions carried out under the programme.

The NAPAN requires, amongst other things, that at each point of sale of PPP and biocides, balanced information will have to be available for non-professional users. General information is therefore to be made available about the risks of the use of PPP and biocides to human health and the environment, including on the risks, exposure, proper storage conditions and instructions for the use, application and disposal without

causing any danger, in conformity with the legislation on waste, as well as about alternative solutions that entail a smaller risk.

It should also be noted that a number of Member States are also in the process of developing their own strategies for the sustainable use of biocidal products. In particular, the German Federal Environment Agency issued a position paper setting out a 'Proposal for a concerted European approach towards a sustainable use'[44] in December 2014, which sets out the rationale for a concerted European effort and includes a list of possible actions at the national level. The Danish Environmental Protection Agency is also currently undertaking a study on solutions and tools for sustainable use of biocides, with a view to developing a Danish strategy on the sustainable use of biocides. Whilst these developments at the national level do not replace the need for a collective European solution to the sustainable use of biocidal products, in the absence of a legislative requirement to develop a national plan for biocidal products, they serve as useful examples to other national authorities that may be encouraged to take a leading role in the sustainable use of biocides. Where possible, the Commission could seek to support such initiatives at the Member State level.

7.3.2 Training

Article 5 of the Sustainable Use Directive requires Member States to ensure that all professional users, distributors and advisors have access to appropriate training by designated bodies and have established certification systems. The subjects to be covered by training and certification are set out in Annex I of the Sustainable Use Directive and include the hazards and risk associated with pesticides, notions on integrated pest management strategies and techniques, measures to minimise risks to humans, non-target organisms and the environment, and use of pesticide application equipment and its maintenance.

As part of the stakeholder consultation, Member States were asked whether they operate a scheme for the certification of professional users. The following Member States have in place either a general certification scheme for professional users of biocidal products or have in place training requirements and/or certification for specific products, primarily in the area of pest control.

MS	General certification scheme or training requirements
Austria	The special profession of a **"biocide controller"** is a regulated trade under Art.94 of the Austrian Trade Act. To follow this trade a certificate of professional competence is required and a state-licence has to be granted by the Federal Ministry for Science, Research and Economy.
Bulgaria	The National centre of infectious and parasitic diseases (NCIPD) is responsible for certification of operators carrying out **disinfection** and pest control activities of persons and entities acting as specialised companies and organisations engaged in these activities.
Croatia	According to the Law on communicable diseases and Veterinary Law, companies working in the area of **disinfection** and pest control and in veterinary hygiene should have a licence for their professional activities. The decision on eligibility as well as measures for prevention and control is issued either by the Ministry of Health for communicable diseases or the Ministry of Agriculture for animal diseases.
Denmark	In Denmark, rat control officers have to be certified by the Danish Nature Agency to control rats (not mice) using **rodenticides (PT14)**. PT8 and other PT's trained professionals have to have a **gassing certificate** to be allowed to control pests using gassing. The certificate depends on the target organism. The courses are exclusively for persons that use biocides occupationally.
Estonia	The Estonian Biocides Act requires professional users to have a relevant certificate or evidence of education and training in relevant areas, as administered by the Estonian Qualifications Authority.

[44] http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/position_biocides.pdf

MS	General certification scheme or training requirements
	In addition, those who provide **pest control services (PT 8 and PT 14 – 20)**, must have a qualification certificate, following training and examination by the "Union of Estonian Disinfection and Pest Control Enterprises". For other PTs it is sufficient to have completed the appropriate trade education and/or training course which give evidence of the relevant skills and knowledge to use and to know relevant biocides and hazards.
Finland	According to the Finnish Chemical Act (599/2013), **pest control operators** (PCO) must have completed a qualification on the use of biocidal products intended for pest control **(PT14 and PT18)** and be included within the register of PCOs to be maintained by TUKES by the end of 2016. The education and qualification events were planned to start during the second half of 2014.
France	In France a "professional user" is a holder of an individual certificate granted in accordance with the Decree of 9 October 2013 concerning the conditions for the exercise of the activity of professional user and distributor of certain types of biocidal products (**Certibiocide** – see below).
Germany	For second generation anticoagulant **rodenticides** only trained or certified pest controller are allowed to apply them.
Greece	Professional users of **PT14, PT18 and PT19** under the competence of the Ministry of Rural Development and Food must be authorised by the Ministry on the basis of their University Degree and the specific knowledge gained during their studies.
Hungary	Professional users must have a membership of the national Council of Hungarian Paramedical Professionals (for **PT. 14, 18 and 19**).
Latvia	Requirements are in place for professional users, which provide **disinfectant, disinfectant and anti-rodent services**. Prior to commencing an activity, a professional user shall submit an application with the following information: type of business, name, scope, education documents and certificates of disinfector. The certificate of disinfector is issued in accordance with the Regulation on requirements regarding disinfection and pest control services.
Malta	Professional users are those that handle and use biocides as part of their work, following either in-house training or completion of a recognised training course. The MCCAA carries out audits for MSA 2000:2009 certification of all major **pest control companies**.
Netherlands	In the Netherlands, there is a **Certified Pest Animal Management scheme**, operated by the NVPB, the trade association of pest management companies. Companies that can demonstrate that they meet the standard can be accredited, and the scheme is run by independent accredited certification bodies.
Spain	In Spain, there is a definition of professional users for **PT 2, 3, 4, 14, 18 and 19** as well as a definition for training professional users. The certification of professional users depends on the activity, with those responsible for the design of the treatment required to hold a specific certificate of professional qualification, having carried out associated training of 540 hours. A worker who applies the biocidal product is required to hold a specific certificate of professional qualification, having undertaken 370 hours of associated training.
Sweden	In Sweden, there are three different licenses for trained professional users, So, SoX and AV. In Sweden, two types of licence (So and SoX) are required under the Environment Code (1998:808) for professional users working with **measures against vermin and pests** and for professional users working with gases to treat vermin and pests. In each case, training is carried out by the Public Health Agency. The Swedish Work Environment Authority also requires a licence for other activities (AV), e.g., the **use of wood preservatives and antifouling products**, and provides training courses for wood impregnation industries, which includes knowledge in occupational safety and risks for the environment.

As can be seen from the scope of the systems in place in the Member States, in almost all cases these apply to disinfection activities and pest control activities. In Estonia and Sweden, the requirement for certification also applies to the use of wood preservatives under PT 8. The most comprehensive (covering certain products of PT 2, 3, 4, 8, 14, 15, 18 and 20) and recently introduced scheme therefore is the mandatory training scheme, Certibiocide, which was introduced in France in 2013 and comes into effect at the beginning of July this year. Further details are provided below:

CERTIBIOCIDE

The CERTIBIOCIDE scheme is a mandatory training scheme in France. Professional users and/or those exercising an activity involving the distribution of biocidal products intended only for professional use must hold an individual certificate for "professional user activity and distribution of certain types biocidal products intended exclusively for professionals". Thus, the acquisition of biocidal products intended exclusively for professionals is only open to holders of the certificate.

Training centers need to register and be accredited by the Ministry. Registration is done on the SIMMBAD.fr platform. Only training centers which have previous accreditation for "Certiphyto" (trainings on PPP) can subscribe to become "Certibiocide" training providers.

There are nine different trainings and certificates under "Certiphyto", corresponding to the different users / activities that may be involved, and there are as many accreditations. One center may therefore only be accredited to deliver one out of the nine different training and certificates. Delivery of accreditations is regulated under Article R.254-1 et q. of the Rural and Maritime Fisheries Code. Accreditation is delivered pursuant to an audit undertaken by a third party certifier. This certified in turn also needs to have been recognised by the State.

Certain products of PTs 2, 3, 4, 8, 14, 15, 18, and 20 are covered by the certification requirement, in particular disinfectants of surfaces in contact with foodstuffs or veterinary hygiene, rodenticides, avicides, insecticides, wood preservatives, and control of other vertebrates. These PTs are targeted because their uses and applications are often made by a company in private homes, placing sensitive populations (children, elderly etc.) at risk in case of misuse. The scheme therefore covers products intended only for professional use and that are not used exclusively within the production cycle.

The certificate can be granted following completion of a three-day (21 hours) training course addressing all the points necessary for efficient and safe use of biocidal products. Individuals already holding an individual certificate "Certiphyto" valid for "business use of plant protection products" and / or activities "for sale, sale of plant protection products" in specified categories may obtain their "biocide certificate" following one day (7 hours) training. Certificates are valid for five years maximum, or until the expiration of the "Certiphyto" which granted access to the one day training. Renewal of certificates follows the original granting procedure.

Upon hiring individuals, companies have three months to ensure they are in possession of a valid certificate. In the meantime, these individuals must be accompanied by a holder of a valid certificate in the performance of any activity that falls under the scheme. Furthermore, only a 10^{th} of the entire company personnel that perform activities relevant to the scheme can benefit from this derogation.

Companies that use and/or sell/buy biocidal products that fall under the scheme are required to make a yearly declaration to the Ministry, indicating inter alia the number of personnel that perform activities relevant to the scheme as well as their individual certificate number, and the number of personnel benefitting from the above-mentioned derogation. Moreover, the information contained in the latest declaration must be kept up-to-date.

Companies that distribute biocides that fall under the scheme are required to hold a sales registry that identifies inter alia products and quantities as well as each buyer's individual certificate number.

The requirement for the certificate comes into effect from 1 July 2015, approximately 2 years after the publication of the implementing Order of 9 October 2013, leaving enough time for all actors (enterprises, users, distributors, training centres) to prepare and comply with this regulatory scheme.
http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000028214219&categorieLien=id

As part of the stakeholder consultation, Member States and industry were also asked what education/training initiatives and guidance is available to professional users on the application/use of biocidal products? The following types of training were referred to:

- Training provided in accordance with the requirements of EU occupational health and safety legislation;
- Training as part of a certification scheme provided at dedicated training facilities;
- External training provided by organisations, industry associations, consultants, Ministries/regulatory bodies and education institutions;
- Internal training organised by companies, e.g. A.I.S.E members organise training for their clients on use and safety;
- Internal leaflets and presentations;

- Technical manuals and other training literature, such as a cleaning protocol;
- Technical service representatives who will provide on the job advice and training to ensure that products are used correctly;
- Videos on the correct use and application, as well as information available on the product website or product label; and
- Technical support by telephone and email.

It is evident therefore that varying levels of training and certification are already provided to those involved in the application of biocidal products. It is recommended that this could be harmonised at the EU level, by introducing a requirement for all professional users and distributors of biocidal products to have access to appropriate training and have established certification systems. From a review of the systems of certification in operation in the Member States, this is already well advanced in most Member States in the field of disinfection and pest control, and will be aided by the development of the CEN 16636 standard for pest management services. A certification scheme should also be considered for PT 8 on wood preservation and PT 21 on antifouling products.

7.3.3 Requirement for sales

Article 6 of the Sustainable Use Directive requires Member States to ensure that distributors have sufficient staff in their employment that are certified and that are available at the time of sale to provide adequate information to customers as regards pesticide use, health and environmental risks and safety instructions to manage those risks for the products in question. Member States are also to take necessary measures to restrict sales of pesticides authorised for professional use only to those who are certified. Where pesticides are sold to non-professional users, distributors are to provide general information on the risks for human health and the environment of pesticide use as well as regarding low-risk alternatives.

As part of the stakeholder consultation, industry stakeholders were asked what steps they take to ensure that biocidal products produced solely for professional use do not get into the general public/consumer supply chain. Almost all responses referred to the labelling of the product which will indicate where a product is 'for professional use only'. However, reference was also made to the following measures:

- In addition to labelling, the product is accompanied by a document informing the customer that the product is for professional use only;
- Literature and point of sale material indicates when a product is for 'professional use only';
- Packaging size is not only suitable for general consumer use;
- Products are not available on general consumer market /are not available for purchase online;
- Closed supply chains for professional users only (accessible by distributors and professional wholesalers only) and therefore products are not available directly to individual consumers;
- Sold through professional distributors who carry out checks to ensure that professional use products are only sold to those that are considered professionals;
- Internet sites are checked to ensure that professional products are not made available to amateurs. As a result, some product advertisements have been removed from websites;
- Sales representatives are trained to check that sale is not to someone with a residential address;
- Products can only be sold to certified pest controllers;
- Point of sale controls requiring proof of training before a professional user is able to buy a product approved for professional use only; and

- Products are placed in an area of the shop that is for professional users only.

It should be noted that in the Netherlands, the Ministry for Infrastructure and Environment commissioned a report on the possibility of restricting sales of biocides to behind the counter. The research project involved consultation with retail associations, consumer organisations, environmental organisations and a number of producers and suppliers of biocides, case studies on the effect of a 'behind the counter' obligation, an inventory of other countries experience with such an obligation and a final workshop with stakeholders. The report concluded that "an obligation to sell biocides to non-professional users from behind a counter appears to have predominantly counterproductive effects for health and environment" and could lead to the use of more harmful alternatives and to an increase in internet sales, which are hard to regulate. For most companies such an obligation would incur considerable investment and costs which may lead some companies to reduce the biocides they place on the market. There was little support for a 'behind the counter' scheme from most of industry as well as the largest consumer organisation.

Following on from the study on a 'behind the counter' obligation, the Dutch Ministry for Infrastructure and Environment then considered whether a 'cashier check' could be introduced, which would require the seller to ask what the customer knows about the product and whether they need information on the use of the product at the point of sale. This would require there to be someone in the shop that is able to answer any questions, not necessarily the cashier, who has had training in order to be able to give advice, similar to the requirement for PPP under Article 6 of the Sustainable Use Directive. At this stage the 'cashier check' has not yet been introduced for biocides but investigations have been carried out as to whether it may be worthwhile for biocides that are available for the general public. The aim is that the general public should be more informed and have better knowledge of what they buy. Overall, the investigations show that it would cost a lot, and the benefit to the public would only be marginal, and it is therefore unlikely that the Dutch government will go ahead with the proposal. The outcome of the investigation is due in Spring 2015.

It therefore appears that there is little support for 'behind counter' sales restrictions in the Netherlands or an information requirement at the point of sale. The German Federal Environment Agency however in its position paper 'Proposal for a concerted European approach towards a sustainable use' advocates that the point of sale should be used to provide information and advice to users. To ensure that advice can be given for certain products self-service and internet sales should be prohibited for products with certain products or products which are not authorised for the general public. Biocidal products that are authorised solely for professional use should only be sold to person who have received training and are certified. For product which are authorised for use by the general public it would be sufficient in most cases to provide general information.

Where the use of biocidal products is restricted to professional use only, steps can be taken to ensure that such biocidal products do not get into the general public/consumer supply chain. Industry stakeholders have outlined the various measures already taken in this regard, some of which already involve restrictions on the sale of products for professional use online, or through the use of closed supply chains accessible by distributors and professional wholesalers only. While the requirement for certification of professional users of a number of product types (as recommended above) will assist in this regard, as will enable distributors to ensure that professional use products are only sold to those that are considered professionals through evidence of certification, further consideration needs to be given to restrictions on internet sales. Where an EU-wide certification scheme was introduced for particular product types, one option may be to require proof of certification at both the point of sale, and online, for example by requiring a certification number to be entered as part of the details to be completed in

order to purchase a product online. For non-professional users, further steps to ensure dissemination of information are outlined below.

7.3.4 Information

Article 7 of the Sustainable Use Directive requires Member States to inform the general public and to promote and facilitate information and awareness-raising programmes and balanced information relating to pesticides for the general public, and in particular regarding the risks and the potential acute and chronic effects for human health, non-target organisms and the environment arising from their use, and the use of non-chemical alternatives.

It should be noted that under Article 17(5) of the BPR, Member States are to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use, which therefore already puts in place an equivalent requirement within the BPR.

As part of the stakeholder consultation, Member States, industry and NGO's were asked whether they used information mechanisms, such as information campaigns for professionals and businesses and/or the general public, in order to encourage the sustainable use of biocidal products. The following measures were listed by stakeholders:

- The use of leaflets, flyers and brochures and publication in journals to provide information;
- Information available online, both through company, industry association and NGO websites;
- Public information campaigns;
- Scientific conferences and congresses, to which biocidal product professionals and businesses are invited;
- Information sessions and workshops on the use of biocidal products;
- One Member State is also in the process of introducing web-rooms for retailers and professionals in order to provide easy, simple and targeted information regarding the biocide regulation, which will be promoted using a series of videos.

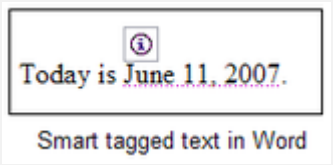
As was highlighted in Chapter 3 on best practices, the consultation respondents referred to a number of information campaigns, both at a national level such as the Danish 'THINK' campaign, websites run by the competent authorities in a number of Member States and brochures produced by the national authorities. There are also a number of industry association initiatives such as the Campaign for Responsible Rodenticide Use (CRRU) and information produced by CEFIC, as well as the website of one NGO, which also produces printed materials and gives advice via email, phone, and at consumer events, meetings and workshops.

As can be seen from the Danish 'THINK' campaign which uses a website, music clip and a mobile phone app to provide information, use is increasingly being made of internet and mobile phone technology to distribute information to the end-user, examples of which are set out in the box below:

Technology tools for information dissemination

A **QR code** (abbreviated from **Quick Response Code**) is a barcode machine-readable barcode that contains information about the item to which it is attached. Many manufacturers of biocidal products now include a QR code on the label of the product, which can be read by an imaging device (such as a camera). In most cases this links directly to the product manufacturers website, enabling the user to obtain more detailed information on the product.

Smart tags are an early selection-based search feature, which recognises certain words or types of data and converts it to a hyperlink. Smart tags (indicated by a purple dotted underline) therefore can provide direct links from a document to a website. By clicking on a smart tag (no keyboard commands are required), the selection-based search command brings up a list of possible actions for that data type.



Smart tagged text in Word

Bayer Product Manual

The Bayer Product Manual phone application provides key information on all core Bayer CropScience UK products, including directions for use, active substance information, advice on resistance management, key product usage information, and safety precautions. By searching by either the active substance or the product, you can obtain information on what the product contains, what it controls, important information, directions for use, pests controlled, crop specific information (application and resistance management) company advisory information, safety precautions, seed tag label information and risk & safety information. The Bayer Product Manual application is to be used as a reference guide for UK growers and agronomists and contains data for the UK market only.

The Bayer Garden Doctor website and phone application allows the user to select by pest, disease, plant type or other category, the problem that they wish to control. This then provides a list of the available Bayer products to control the particular pest or disease, and a link to the product details, which include the months of the year, its capacity and composition. The user is instructed to always read the label and product information before use and to pay attention to the risk indications and follow the safety precautions on the label.
http://www.bayergarden.co.uk/GardenDoctor

BAYER
Garden Doctor

7.3.5 Equipment

Article 8 of the Sustainable Use Directive requires Member States to ensure that pesticide application equipment in professional use is subject to inspections at regular intervals, and by 2016 this is to have been inspected at least once. The inspections are to verify that pesticide application equipment satisfies the relevant requirements listed in Annex II, in order to achieve a high level of protection for human health and the environment. Under Article 9, aerial spraying is prohibited unless subject to a derogation where specific conditions are met, including that there is no viable alternative and that the pesticides are approved for aerial spraying following a specific assessment.

First, it should be noted that compared to plant protection products, requirements relating to equipment are not as relevant for biocidal products as mainly concern items like gloves and other protective clothing rather than machinery. In some cases application by spraying may be used, which could be restricted, but this could be done by means of conditions attached to the authorisation rather than imposing specific requirements for machinery or equipment.

Information on the relevancy of the role that improved performance of the equipment used for applying biocidal products could play in sustainable use was sought as part of

the stakeholder consultation. Within the questionnaire sent to stakeholders, industry was asked the following question:

- To what extent would measures for the harmonisation of the equipment for applications minimise exposure and guarantee a targeted dosage of biocides? Are there existing standards for equipment in use or other initiatives for standardisation of equipment?

Of 104 industry respondents, 50 either did not answer the question, stated that the harmonisation of equipment was not relevant for their product, or indicated that harmonisation measures would not minimise exposure and guarantee a targeted dosage for biocidal products. 54 respondents provided further information, the majority of whom referred to current measures to minimise exposure and avoid overdosing. These included the following existing measures:

- The use of automated systems, such as clean-in-place (CIP) systems for sectors such as the food industry, requiring high levels of hygiene;
- Calibrated dosing in industrial applications, for example of PT 6 where regular maintenance of the plant ensures that there are no risks of overdosing;
- Any equipment used is subject to appropriate procedures for qualification and calibration;
- Automated dosing control via high-performance liquid chromatography (HPLC) measurements of the amount of dosed active substance;
- Ready to use products with specific application rates, e.g. pre-packed bait boxes for rodenticides (PT 14);
- Regular maintenance and systematic calibration of sprayers for antifouling paints;
- Product instructions that contains recommendations on the equipment to be used, e.g. airless spray gun along with operating pressure and tip sizes, which optimises the application of paint, minimises waste and ensures proper application;
- Standard regulation inspections/service of existing equipment used; and
- Standards for disinfection equipment, e.g., RKI or CEN.

The prevalent industry view was that harmonised measures on the performance of equipment for the application of biocidal products were not required. Existing equipment is considered fit for purpose and there is no need for harmonisation especially as different doses will need to be applied in different situations and different products have different viscosities thus requiring different equipment. The equipment used depends on the particular application and biocidal product used, as in many cases the application of biocidal products will be by brush or dip for which standards for equipment are not relevant. In many cases the application of biocidal products is done using closed systems, which therefore avoids exposure and overdosing. Application equipment in the pest industry covers a wide range of industries and is already standardised. In all cases, equipment must be appropriate and adequate for the product and where relevant, must be appropriately maintained and calibrated.

Very few industry respondents considered that harmonisation measures would be useful. The majority that commented on the use of equipment, felt that harmonisation of equipment would be extremely difficult to achieve, and would not result in an increase in efficacy (perhaps even potential loss of efficacy) or the protection of either humans or the environment. In some cases harmonisation of equipment would involve large replacement costs, without additional benefits. It is unlikely that a broad approach to the harmonisation of equipment would minimise exposure or guarantee a targeted does of biocides, as specific biocides often require specific application equipment for accurate application. However, one stakeholder commented that as standards for equipment in use by professional pest controllers can vary across the EU, it would help to have equipment set and checked that the correct quantities are being used, as indicated in the

risk assessment. Standards to which producers and users can refer would therefore be useful.

While it was recognised by stakeholders that the use of appropriate dosing equipment is an important factor in the use of some biocides, measures for harmonisation should not be taken for the sake of harmonising as there are other factors that need to be considered in order to minimise exposure, including the selection of the appropriate product, determination of weather conditions, level of infestation etc. It was therefore suggested that equipment should only be standardised to address specific risks rather than applying this approach as a matter of course. Where there is a concern over the use of equipment this could be specified in the product authorisation by stipulating that the product may only be used with a certain type of equipment that meets a specified standard.

The correct dosing according to the label instructions is essential. It was commented that if dosage is not correct, this is a result of the poor training of the technician rather than poor or failing equipment. Further steps can be taken with regard to training therefore, before considering the harmonisation of equipment. As noted above, industry has developed a number of ready to use products, such as pre-packed bait boxes, to ensure that the correct quantities are used and avoid exposure risks.

Finally, it should be noted that a number of companies have developed packaging that controls the amount of product applied. In addition to the example of pre-packed bait boxes for rodenticides, doseage control systems have been developed for disinfectants and surface cleaners. One example is the doseIT range of products which have been developed by a UK company and are aimed at companies employing large numbers of cleaning staff, such as contract cleaners and hotel groups. The doseIT range has been designed to simplify the dissemination of information to the end-user, by controlling the amounts applied to 20ml doses. DoseIT requires no dispensing equipment as the dosage control cap dispenses 20mls of product providing strict quantity control and an alternative to static dosing systems[45].

7.4 Conclusions

As was highlighted in Chapters 4 and 6, the key measures to reduce the risks from the use of biocidal products are the provision of information and education/training, rather than further legislative measures in the context of the BPR. The provisions of the Sustainable Use Directive on training and information are therefore highly relevant.

However, it is not appropriate to look simply at extending the scope of the Sustainable Use Directive to biocidal products, due to the number and diverse nature of biocidal products. Instead the principles of IPM should be adapted to specific biocidal product types, as part of the development of best practices for that product type. As outlined in Chapter 3 on the dissemination of best practice, there are then a number of options that could be used to ensure compliance with best practice documentation. At this stage, IPM principles are most suited to be adapted to PT 14 and 18. We have already seen the incorporation of IPM principles within the Guideline on Best Practice in the Use of Rodenticide Baits as Biocides in the European Union, and specifically how IPM principles are applied to the outdoor use of SGARs.

When the IPM principles are considered as a suitable management system for pest control, similar approaches developed for sectors with biocidal uses which combine preventive measures, monitoring and a reasonable use of biocides could be regarded as equivalent. One example is the concept of Hazard Analysis and Critical Control Points

[45] http://www.cloverchem.co.uk/2013/uk/range_sub.asp?range_sub='52'

(HACCP) which is applied as a preventive approach to food safety. Similar hygiene management plans also exist for hospitals and other health care facilities as well as for the swimming water and drinking water sectors. For the biocides sectors best practices could be regarded as comparable to IPM.

On the requirement for a national action plan, Belgium has developed a Programme for the Reduction of Pesticides and Biocides, and thus included biocides within its action plan for pesticides, and a number of Member States are also in the process of developing their own strategies for the sustainable use of biocidal products. These developments at the national level serve as useful examples to other national authorities that may be encouraged to take a leading role in the sustainable use of biocides. The Commission could consider introducing a requirement for a NAP for biocides under the BPR, to describe how principles for IPM are implemented by all professional users. In the meantime, where possible, the Commission could seek to support initiatives taken at the Member State level to develop strategies on the sustainable use of biocides which incorporate best practices.

As outlined in Chapters 4 and 6, training is a key measure to ensure the sustainable use of biocidal products. In approximately half of the Member States, a system of certified training is more or less in place, in addition to other forms of training operated internally by companies. It is evident therefore that varying levels of training and certification are already provided to those involved in the application of biocidal products. It is recommended that this could be harmonised at the EU level, by introducing a requirement for all professional users and distributors of biocidal products to have access to appropriate training, to establish certification systems, and designate the areas of activity that should be covered. Based on a review of existing certification systems in Member States, this aspect is already well advanced in most of them in the field of disinfection and pest control, and will be aided by the development of the CEN 16636 standard for pest management services. A certification scheme should also be considered for PT 8 on wood preservation and PT 21 on antifouling products. A phased approach to the introduction of training requirements for all professional users should be adopted according to product type as required.

With regard to information and awareness-raising, Member States are already required to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use under Article 17(5) BPR. However, further measures are required to ensure that information is reaching the end-user. The following recommendations are therefore made:

1) Awareness raising campaigns aimed at general consumers of biocidal products should be carried out at EU and national level;

2) Depending on the needs identified by follow-up measures, targeted campaigns should be implemented, if necessary;

3) In-store leaflets summarising the critical steps for use of the product, and for the protection of man and the environment could be produced;

4) Information websites or other means should be used to informing the consumer, e.g. quick response codes providing a link to the manufacturers website or mobile phone applications providing more information on product.

8 ECO-LABEL

8.1 Introduction

Regulation (EC) No 66/2010 on the EU Eco-label[46] (the "Eco-label Regulation") lays down rules for the establishment and application of the voluntary EU Eco-label award scheme. It applies to any goods or services that are supplied for distribution, consumption or use on the Union internal market whether in return for payment or free of charge. The EU Eco-label criteria shall be based on the environmental performance of products, taking into account the latest strategic objectives of the Community in the field of the environment. They shall be determined on a scientific basis considering the whole life cycle of products[47].

The promotion of eco-labels with relevance to biocides is one potential measure for supporting sustainable use of biocidal products. However, the Eco-label Regulation does not currently apply to biocidal products. Indeed, such substances run counter to most general requirements for EU Eco-label criteria of Article 6(1) of the Eco-label Regulation, namely the environmental performance of products, the substitution of hazardous substances, environmental impact reduction and net environmental balance.

In accordance with Article 6(6) of the Eco-label Regulation, the EU Eco-label may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR) under the CLP Regulation[48], nor to goods containing substances referred to in Article 57 of REACH[49]. However, the Commission may grant derogations for specific categories of goods under Article 6(7) of the Eco-label Regulation. These derogations are subject to several conditions:

- Goods do not exceed a low threshold[50] of substances that are identified on the REACH candidate list (Article 59(1) of REACH) and that meet the REACH Substance of Very High Concern (SVHC) criteria;
- Substitution of the substance(s) is not technically feasible ;
- Goods have a 'significantly higher overall environment performance' than other goods of the same category.

The purpose of this task is therefore to consider whether an eco-label could be attributed specifically to biocidal products.

8.2 Consultation responses

In considering whether an eco-label could be attributed specifically to biocidal products, views on the possibility of developing an eco-label for biocidal products were sought as part of the stakeholder consultation. Within the questionnaire sent to stakeholders, NGOs were asked the following question:

[46] Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel, OJ L 27/1, 30.1.2010.
[47] Regulation (EC) No 66/2010, Article 6.
[48] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, OJ L 353, 21.12.2008.
[49] Regulation EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, OJ L 396, 30.12.2006.
[50] The threshold is set at 0.1% 'in an article or in any homogeneous part of a complex article'.

- Do you consider that an eco-label or other scheme to highlight the better profile (for environment and public health) of certain biocidal products could be developed for biocides?

Of the six NGOs that responded, only one considered that an eco-label could be developed for biocides, and would be useful in order to provide information on the product life cycle. One other NGO was in support of an eco-label for biocide-free products. However, this latter organisation together with the remaining four NGOs did not consider that an eco-label could be developed for biocides. One NGO commented that eco-labels and biocides are simply not compatible due to their very nature. Another NGO strongly disapproved of an eco-label as it considered that labels or other schemes used to compare biocides are market instruments that have very limited effect on sustainable use and can even counteract this objective.

The view of NGOs strongly indicated that eco-labels should not be permitted on any product containing harmful chemicals. A specific eco-label for biocides would send the wrong signal to the consumer, given that causing negative effects to living organisms is the intended purpose of any biocide. It should be clear that the development of an eco-friendly product is neither possible for a pesticide, nor for a biocide, the very aim of which is to kill living organisms or harm them. Such a label also raises the risk of unnecessary and non-proper use of those products by giving the impression that the product is harmless for the user and the environment. Over-dosages, ignoring IPM principles, ignoring risk and safety introduction at the packaging etc. could potentially contradict the aim of sustainable use. An eco-label should have a strong accuracy and reliability, and should be distinguished from any kind of "green washing". Eco-labels should therefore only be used for the promotion of biocide-free alternatives, which would help to raise awareness and to minimise the use of biocides.

As an alternative, the NGOs consulted suggested that the following measures could more beneficially be used to support innovation:

- The public should be provided information about the benefits and risks associated with biocidal products and ways of minimising their use (Art.17(5) BPR), and existing information should be improved;
- The development of an eco-label for biocide-free alternative technologies with less risk to human health and the environment. This concept would stimulate innovation and the development of new products. For example new materials for house façades to avoid both the application of biocide-treated façade paints and the high emissions of them into the environment during rainfall (see German eco-label: Blauer Engel Wärmedämm-Verbundsysteme RAL UZ140).

Member States, industry and NGOs were also asked whether they had any suggestions as to ways in which the sustainable use of biocidal products could be encouraged or improved. A variety of measures were provided by way of example in the question, including the use of an eco-label.

In making suggestions as to ways to encourage/improve the sustainable use of biocidal products, only one NGO mentioned the use of an eco-label to encourage the sustainable use of biocidal products, though as a second step only after the sale of biocidal products to consumers was stopped.

Out of 21 Member States that responded to the questionnaire only one Member State made reference to the use of eco-labels, to say that they did not support eco-labels for biocides, only for (biocide free) alternatives.

From the 104 industry responses, seven respondents made reference to the use of an eco-label. One company noted that currently, paint (indoor and outdoor) can be labelled

with an EU Eco-label[51] and the Nordic Swan Eco-label. However, while outdoor paint is close to PT8, and there is a description of how to interpret when a paint is a biocidal product and not, biocidal products are out of scope as the product group does not include preservation products for wood impregnation, amongst other products. It was suggested however that biocidal products could be included in the criteria to provide guidance for consumers and professionals in finding an environmentally advantageous protection.

One company felt that an eco-label could be used to promote less toxic substances and products, while another company considered that an eco-label could be developed for both the biocidal substances and for each product type. Another suggestion made was that an eco-label be granted together with the approval. However, by way of response to this comment, the purpose of the authorisation is to show compliance with the BPR, and therefore an additional 'label' or 'logo' indicating that a product is authorised would be unnecessary.

With the exception of this limited support from industry therefore, the results of the stakeholder consultation showed that an EU Eco-label was not appropriate for biocidal products.

8.3 EU Eco-label criteria

In order to investigate the possibility of applying an eco-label to biocidal products, the Eco-label Regulation has been analysed to identify what criteria will require to be met in order to comply with its requirements. The Eco-label Regulation lists a set of general requirements that shall be taken into account when determining EU Eco-label criteria for products. These include consideration of the following:

(a) the most significant environmental impacts, in particular the impact on climate change, the impact on nature and biodiversity, energy and resource consumption, generation of waste, emissions to all environmental media, pollution through physical effects and **use and release of hazardous substances**;

(b) **the substitution of hazardous substances by safer substances**, as such or via the use of alternative materials or designs, wherever it is technically feasible;

(c) the potential to reduce environmental impacts due to durability and reusability of products;

(d) the net environmental balance between the environmental benefits and burdens, including health and safety aspects, at the various life stages of the products;

(e) where appropriate, social and ethical aspects, e.g. by making reference to related international conventions and agreements;

(f) criteria established for other environmental labels, particularly officially recognised, nationally or regionally, EN ISO 14024 type I environmental labels, where they exist for that product group so as to enhance synergies;

(g) as far as possible the principle of **reducing animal testing**.

Taking this list of criteria, analysis of the BPR has been carried out and a comparison made between the Eco-label Regulation and the BPR, in order to identify where the provisions of the BPR applicable to the authorisation of a biocidal product already cover or contain equivalent requirements to the criteria to be met.

[51] Commission Decision 2014/312/EU of 28 May 2014 establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes, OJ L 154/45, 3.6.2014.

Eco-label Regulation general awarding criteria	BPR potential equivalent criteria (authorisation of biocidal products)	Assessment
Determination on a scientific basis considering the whole life cycle of products, of the most significant environmental impacts, in particular the impact on climate change, the impact on nature and biodiversity, energy and resource consumption, generation of waste, emissions to all environmental media, pollution through physical effects and use and release of hazardous substances; (Article 6(3)(a))	Applicants must provide very detailed information on the environmental impacts of the biocidal products (Annex II) Ecotoxicological studies - toxicity to aquatic organisms - Terrestrial toxicity - Effects on birds - Effects on arthropods - Bioconcentration, terrestrial - Bioaccumulation, terrestrial - Effects on other non-target, non-aquatic organisms - Effects on mammals - Identification of endocrine activity Environmental fate and behaviour - Fate and behaviour in water and sediment - Fate and behaviour in soil - Fate and behaviour in air - Definition of the residue - Monitoring data Possibilities of reuse or recycling Conditions for controlled discharges /incineration	Unlike the Eco-label Regulation the BPR does not take into account the whole life cycle of products during the approval of an active substance. There is for example no reference to the environmental/ energy/ climate change impact during the manufacturing phase.
The substitution of hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible; (Article 6(3)(b))	Where an application for authorisation relates to a biocidal product containing an active substance which is considered as a candidate for substitution (Article 10 BPR), a comparative assessment will be carried out. Where the comparative assessment demonstrates that: a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages; and b) the chemical diversity of the active substance is adequate to minimise the occurrence of resistance in the target harmful organism, the making available on the market or the use of that biocidal product containing the active substance that is a candidate for substitution will be prohibited or restricted (Article 23 BPR).	Both the Eco-label Regulation and the BPR contain substitution requirements. However, as a result of the substitution criteria in the BPR, the biocidal product containing the active substance that is a candidate for substitution will be prohibited or restricted where there is another authorised biocidal product or non-chemical method available, and therefore not eligible for an Eco-label. The substitution criteria under the Eco-label Regulation on the other hand considers the substitution of hazardous substances by safer substances, which would already have been taken into account in the composition of the product, and thus not prevent it being placed on the market at this stage. Candidates for substitution would not be considered as low-risk biocidal products (see below).
The potential to reduce environmental impacts due to durability and reusability of products; (Article 6(3)(c))	N/A	There is no reference to such requirements in the authorisation procedure. The nature of biocidal products is such that they have specific application doses and

Eco-label Regulation general awarding criteria	BPR potential equivalent criteria (authorisation of biocidal products)	Assessment
		frequencies and are not suitable for reusability. The authorisation of a biocidal product will include instructions for safe disposal of the product.
The net environmental balance between the environmental benefits and burdens, including health and safety aspects, at the various life stages of the products; (Article 6(3)(d))	As above, applicants must provide very detailed information on the environmental impacts of the biocidal products (Annex II BPR). A detailed risk assessment is carried out in order to allow a decision to be taken on both the active substance approval and authorisation of a biocidal product.	As stated above, the BPR does not take into account the whole life cycle of products during the approval of an active substance.
Social and ethical aspects, where appropriate; (Article 6(3)(e))	N/A	This is not reflected in the BPR.
Criteria established for other environmental labels; (Article 6(3)(f))	N/A	Criteria under other Eco-labels (Blue Angel and Nordic Swan) are considered below.
The principle of reducing animal testing (Article 6(3)(g))	The requirements during the approval and authorisation procedures aim to reduce animal testing by making data sharing compulsory.	Both the Eco-label Regulation and the BPR contain provisions aimed at reducing animal testing.

The EU Eco-label for textile products (2009/567/EC) allows the use of biocidal products provided that these have low risks (former Annex IA of Directive 98/8/EC) and confers to the textiles additional properties directly aiming at protecting human health (e.g. biocidal products added to textile nets and clothing to repel mosquitoes and fleas, mites or allergens) and where the active substance is authorised for the use in question. Similar provisions exist for the EU Eco-label for textile floor coverings (2009/967/EC) and footwear (2009/563/EC).

The provisions of the BPR applicable to the simplified authorisation procedure for low-risk biocidal products under the BPR have also been analysed to assess where equivalent requirements exist to the criteria to be met under the Eco-label Regulation. With the exception of the criteria under Article 6(3)(b) of the Eco-label Regulation, the assessment remains the same as for biocidal products subject to national or Union authorisation. In respect of the Article 6(3)(b) criteria, potential equivalent requirements exist for low-risk biocidal products under the simplified authorisation procedure.

Eco-label Regulation general awarding criteria	BPR potential equivalent criteria (simplified authorisation procedure)	Assessment
The substitution of hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible; (Article 6(3)(b))	The simplified authorisation procedure (Article 25 BPR) encourages the use of products that are less harmful for the environment, human and animal health. An applicant for authorisation may be made under the simplified authorisation procedure if the biocidal product is an 'eligible biocidal product' (Article 25 BPR). A biocidal product is eligible if all the following conditions are met:	Both the Eco-label Regulation and the simplified authorisation procedure under the BPR contain substitution requirements, which would have been taken into account in the composition of the product. Annex I of BPR includes active substances that were identified as presenting a low risk under REACH or the BPD, substances identified as food additives, pheromones and other

Eco-label Regulation general awarding criteria	BPR potential equivalent criteria (simplified authorisation procedure)	Assessment
	f) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex; g) the biocidal product does not contain any substance of concern; h) the biocidal product does not contain any nanomaterials; i) the biocidal product is sufficiently effective; and j) the handling of the biocidal product and its intended use do not require personal protective equipment. An active substance can be included in Annex I of the BPR if there is evidence that it does not give rise to concern.	substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food.

As the Eco-label Regulation only sets out general criteria that will apply to all groups of products, the specific criteria developed for groups of products should also be considered. The more specific EU Eco-label criteria for each group of products are developed and adopted through a procedure that involves the Commission, Member States competent bodies and other stakeholders (See Article 8 and Annex I of the Eco-label Regulation).

However, currently the EU Eco-label criteria do not apply to any biocidal products as in accordance with Article 6(6) of the Eco-label Regulation, the EU Eco-label may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with the CLP Regulation, nor to goods containing substances referred to in Article 57 of REACH.

Based on the exclusion criteria set out in Article 5 of the BPR, the following substances must not be approved:

- carcinogens, mutagens and substances toxic for reproduction category 1A or 1B according to the CLP Regulation;
- endocrine disruptors;
- persistent, bioaccumulative and toxic (PBT) substances; or
- very persistent and very bioaccumulative (vPvB) substances.

While both the Eco-label Regulation and the BPR contain exclusions, the BPR only excludes from its approval procedure category 1A or 1B carcinogens, mutagens and substances toxic for reproduction, as well as active substance which are considered to have endocrine-disrupting properties or which meet the criteria for being PBT or vPvB. While derogations to the exclusion criteria are available under the BPR, even if such substances were approved, an application for an eco-label could only be made by way of derogation under Article 6(7) of the Eco-label Regulation. This is also the case for all biocidal products which contain substances which are toxic or hazardous to the environment, which would otherwise not qualify for an EU Eco-label.

The Commission may grant derogations for specific categories of goods under Article 6(7) of the Eco-label Regulation though. Only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared

with other goods of the same category, the Commission may adopt measures to grant derogations from Article 6(6) of the Eco-label Regulation.

Where a product contains an active substance that is a candidate for substitution, it cannot therefore be subject to derogation.

8.3.1 Specific product group criteria

An EU Eco-label is awarded to products on a case-by-case basis. However, the Commission is first required to develop EU Eco-label criteria for a group of products or agree on their revision, following consultation with stakeholders including the European Union Eco-labelling Board (EUEB) and Member States under Article 7 of the Eco-label Regulation. Thereafter, EU Eco-label criteria are set out in Commission Decisions, which establish the ecological criteria for the award of the EU Eco-label to particular product groups and also contain the basis on which Article 6(7) derogations may be requested. Commission Decisions follow a similar structure containing an Annex listing the aims of the criteria, followed by a list of criteria and general information on the assessment and verification requirements and process. Each criterion is then expanded upon in turn and includes the basis for possible derogations.

While biocidal products may be referred to in various ways in this criterion, if they are mentioned at all they are often either entirely excluded or limited rather than being provided for express derogations. Specific product-group criteria therefore lists:

- those substances that are specifically excluded;
- the hazardous substances and mixtures that are excluded from the EU Eco-label scheme (in tabular form) as a result of Article 6(6) of the Eco-label Regulation (i.e. Eco-label may not be awarded to these substances, preparations or mixtures) when ingredients included in the table are present in concentrations above or equal to a certain low threshold[52]; and
- derogations from the list of hazardous substances and mixtures, including for certain surfactants that may include biocidal ingredients as well as for biocidal ingredients themselves.

Such derogations are set out for biocidal ingredients within the criteria established for all-purpose cleaners and sanitary cleaners (Commission Decision 2011/383/EU), detergents for dishwashers (Commission Decision 2011/263/EU), hand dishwashing detergents (Commission Decision 2011/382/EU), and laundry detergents (Commission Decision 2011/264/EU). These derogations for biocidal ingredients also follow a similar structure. Three requirements are in turn provided with additional details, and means of assessment and verification, depending on the product type:

1) Biocides may only be included as a preservative in the appropriate dosage[53],

2) Packaging/communication on the product cannot claim or suggest that it possesses an antimicrobial action,

3) Certain biocides[54] may only be allowed if their bioaccumulation potentials are below a certain threshold[55]. This last requirement is only provided for all-purpose cleaners and sanitary cleaners (see below).

[52] Such thresholds were often found to be set at 0.010%.
[53] Surfactants that may contain biocidal ingredients are usually provided their own specific derogation.
[54] The following ingredients were identified (although not all can be derogated upon for all product types) - H410/R50-53 Very toxic to aquatic life with long-lasting effects; H411/R51-53 Toxic to aquatic life with long-lasting effects; and H412/R52-53: Harmful to aquatic life with long-lasting effects.
[55] The threshold is set at log Pow (log octanol/water partition coefficient) < 3,0 or an experimentally

8.3.2 Decision 2011/383/EU on all-purpose cleaners and sanitary cleaners

As an example of the ecological criteria applied to a specific product group, the ecological criteria and requirements for derogations established for all-purpose cleaners and sanitary cleaners under Commission Decision 2011/383/EU is further analysed.

The criteria and associated derogations is set out in the Annex to the Decision, which contains a list of 11 criteria. Criterion 3 relates to 'Excluded or limited substances and mixtures' and applies to each substance, including biocides, that exceeds 0.010% by weight of the final product. Criterion 3(e) provides three requirements specifically for derogations applicable to biocides:

1) Biocides may only be included in the product as a preservative, in the appropriate dosage (excluding surfactants which may have biocidal properties[56]);

This is assessed through safety data sheets provided by the applicant, information on concentration of preservatives, and information on the dosage necessary to preserve the product.

2) The packaging / communication on the product cannot claim or suggest that it possesses an antimicrobial action;

This is assessed through verification of texts and layouts of type of packaging.

3) Certain biocides[57] may only be allowed if their bioaccumulation potentials are below a certain threshold[58];

This is assessed through safety data sheets provided by the applicant, and information on concentration. It is noteworthy that this requirement provides for direct derogations to Criterion 1 (Toxicity to aquatic organisms) and Criterion 2 (Biodegradability of surfactants) of this Commission Decision.

8.4 Other types of Eco-label

In addition to the EU Eco-label scheme, there also exist a number of national eco-labels, namely the Blue Angel (Blauer Engel) eco-label scheme in Germany and the Nordic Swan eco-label in Norway. The applicability of these two national schemes to biocidal products and the criteria applied under these schemes to particular product groups has therefore also been considered.

8.4.1 Blue Angel Eco-label

The Blue Angel Eco-label was the world's first eco-label, created in Germany in 1978. It now includes around 12,000 products and services, covering 80/90 product types (entitled 'categories') and 514 trade names. Criteria are developed for each individual product group that must be fulfilled by those products and services to be awarded with the Blue Angel. The criteria are reviewed every three to four years by the Federal Environmental Agency.

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determined bioconcentration factor (BCF) ≤ 100.

[56] Surfactants (H400/R50) are specifically derogated when their concentrations are below 25% in the product. This is a direct derogation to Criterion 2 (Biodegradability of surfactants) within this Commission Decision.

[57] Biocides characterised as H410/R50-53 Very toxic to aquatic life with long-lasting effects, and H411/R51-53 Toxic to aquatic life with long-lasting effects. Moreover, it is noted in the FAQ of the European Commission Eco-label website that 'the derogation for Biocides R50/53 and 51/53 is also valid for Biocides meeting the criteria for classification as 52/53 and also 50 alone and 53 alone, irrespective of the value of their bioaccumulation potential' (http://ec.europa.eu/environment/ecolabel/faq.html) (last accessed January 2015).

[58] The threshold is set at log Pow (log octanol/water partition coefficient) < 3,0 or an experimentally determined bioconcentration factor (BCF) ≤ 100.

The Federal Environmental Agency has a specialist department "Eco-design, Eco-Labelling and Environmentally-friendly Procurement" which develops the specialist criteria in the form of the Basic Award Criteria for the Blue Angel environmental label. RAL GmbH is the awarding body for the environmental label and develops the relevant award criteria in independent expert hearings, involving all relevant interest groups. The Environmental Label Jury is the independent, decision-making body for the Blue Angel and includes representatives from environmental and consumer associations, trade unions, industry, the trade, crafts, local authorities, academia, the media, churches, young people and the German federal states. Finally, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is the owner of the label and regularly provides information on the decisions taken by the Environmental Label Jury.

In order to consider the criteria applied under the Blue Angel Eco-label, specific product types were selected by way of example, which included reference to biocidal products. In each case, these explicitly excluded the use of biocides.

Blue Angel – Product examples

Sanitary Additives / Sanitary Additives Compatible with Clarification Plants – These often involve the use of environmentally harmful biocidal sanitary additives to reduce odour nuisance and gas formation in toilets. Blue Angel-labelled sanitary additives are an alternative that is compatible with wastewater treatment plants.

This Criteria includes the following exclusion of biocides:
3.1.1 Exclusion of Biocidal Properties of the Mixture - "The sanitary additives/product mixtures must not have any biocidal effect on the microorganisms in wastewater treatment plants nor may they have any other adverse impact on the disposal at wastewater treatment plants."
3.1.2 Exclusion of Biocidal Substances - "Biocides within the meaning of the Biocidal Products Directive 98/8/EC (or EU Biocidal Products Regulation – Regulation (EU) No 528/2012) must not be used […]."

This Criteria includes the following exemption for biocides:
3.1.2 "[…] In-can preservatives or mixtures thereof (PA 6) in concentrations that need not be listed in the Material Safety Data Sheet (according to Regulation (EC) No 1907/2006, as amended by Regulation (EU) No. 453/2010, shall be exempt from this requirement. Also exempt are substances approved as food additives in Europe (e.g. citric acid) as well as fragrances and fragrance mixtures as specified under para. 3.5 (e.g. lavender oil). This also applies to surfactants which may have biocidal properties as well."

3.3 c) "impurities in concentrations that need not be listed in the Material Safety Data Sheet. […] Also exempt shall be substances: […] as well as surfactants in concentrations of less than 25% in the product which are classified as H400/R50 (H400/R 50: Very toxic to aquatic life)."

Indoor Pest Control/ Non-Toxic Indoor Pest Control and Prevention

This Criteria includes the following exclusion and exemption for biocides:
"3.1 The agents and techniques must not contain any biocidal substances, with the exception of nitrogen and carbon dioxide which may be used for fumigation purposes."

4 Compliance Verifications: "[…] including a certificate stating that the agent is biocide-free."

3) **Thermal Insulation Material/ Low-Emission Thermal Insulation Material and Suspended Ceilings for Use in Buildings** - Produced in a low-pollutant manufacturing process and pose no health hazard in the living environment. The Basic Award Criteria includes requirements for thermal and sound insulation and defines the limits for emissions from the products. The product must be manufactured using environmentally less harmful substances and materials, from the health point of view, not to have an adverse impact on the living environment, and must not contain any hazardous substances that might well impede waste disposal.

This Criteria includes the following exclusion and exemption for biocides:
3.1.5.3 Biocides – "The insulation material may not contain any biocides."

3.1.6.2 Preservation (contrary to para. 3.1.1, Nos. 1 and 2) – "The coatings of the suspended ceilings may not contain any biocides except for the micro-biocides used as in-can preservatives as listed in Appendix 1 to the Basic Award Criteria RAL-UZ 102 with their respective contents."

It should be noted that among the list of products that has been awarded the Blue Angel label under this

product type, one company 'Odenwald Faserplattenwerk GmbH' produces one product which name includes the use of term 'biocide' - 'premium Bolero biocide und Sinfonia biocide'. On the company's 'OWA' website, a commercial brochure[59] is available for this product which includes the Eco-label's logo and describes the product as "the perfect all-rounder now available with microbicide equipment". The same document also states that "your microbiocidal equipment is effective against bacteria, fungi and yeasts", and highlights that "as the first manufacturer of acoustic ceilings made of mineral wool, OWA was awarded the "Blue Angel" for low-emission building materials. The eco-label confirms that OWA ceiling tiles are made from natural and safe raw materials and, accordingly, can be used in highly sensitive areas, such as schools, kindergartens and hospitals".

The Blue Angel Eco-label often refers to EU norms (whether Directives or Regulations) in the establishment of its different criteria. Moreover, often criteria will seek to eliminate biocides entirely from a product (with a few exceptions which also corresponds to those of the EU Eco-label – i.e. preservatives, etc.). This exclusion can be considered as one of the *raison d'être* or main component of these criteria: i.e. alternatives to typical products must be 'biocidal-free' or they are not considered alternatives at all. While the Blue Angel Eco-label may be granted to products which contain biocides, this is for preservation of fumigation purposes. In some cases however, such as the example provided above of the insulation material, where the microbiocides are stated to be effective against bacteria, fungi and yeasts, there may be ambiguity as to whether this is a 'treated article' under Article 58 of the BPR.

It should be noted that a new approach to the use of in-can preservatives on products has been incorporated into the revised guidance on treated articles (CA-Sept13-Doc.5.1.e (Revision1, December 2014)). Article 58(2) of the BPR requires that 'all active substances contained in the biocidal products' need to be approved or included in Annex I, and that a label on a treated article is to include the name of all active substances contained in the biocidal products. The revised guidance states that this applies to those active substances which contribute to the biocidal function(s) of the biocidal product(s) that were used to treat or intentionally incorporated into the treated article, and not to any in-can preservative contained in the biocidal product.

8.4.2 Nordic Swan Eco-label

The Nordic Swan Eco-label guarantees among other things that climate requirements are taken into account, and that where relevant, CO2 emissions (and other harmful gases) are limited. In order to select the product groups which are most suitable for the Nordic Swan Eco-label scheme, products are analysed for their relevance, potential and how they can be controlled or "steered" (this is referred to as the 'RPS scheme').

There are 63 product groups within the Nordic Swan Eco-label. For each product group, overriding general criteria requirements have been established as well as product-specific requirements.

Again, in order to consider the criteria applied under the Nordic Swan Eco-label, specific product types which included reference to biocidal products have been selected by way of example.

[59] http://www.owa.de/docs/pdf/DS_897_Bolero_biocide_und_Sinfonia_biocide_091103.pdf

Nordic Swan – Product examples

Alternative dry cleaning – The environmental requirements stated in the criteria include the following:

- Classification of chemicals - Chemical products that are used for textile cleaning must not be classified in any of the following danger classes (with applicable risk phrases in parenthesis) in accordance with EU Directive 1999/45/EEC & Safety data sheet according to Directive 2001/58/EC (… includes carcinogenic, reproductive toxic, heritable genetic damage, very toxic, allergenic, environmentally hazardous (incl. the infamous R50s)

- Readily biodegradable surfactants - Surfactants in chemicals that are released into the sewage network must be readily biodegradable according to test method 301 A-F in OECD guidelines

- Anaerobically biodegradable surfactants - Surfactants in chemicals that are released into the sewage network must be anaerobically biodegradable, i.e. at least 60% biodegradable under anaerobic conditions. Exception: surfactants in stain removers

Cleaning products – The criteria contains the following requirements:

– Products must not be classified according to the CLP Regulation. Use of DID list and Safety data sheets to verify.

- The cleaning product must not contain substances that are or may decompose into substances that are CMR.

- Ingredients must not be classified as sensitising/allergenic with the following risk phrases/hazard categories: H334 / R42, H317 / R4. The use of substances classified with any of the hazard statements H410, H411 or H412, or any of the risk phrases R50/53, R51/53 or R52/53, is also limited.

- A list of excluded substances: alkylphenolethoxylates, reactive chloro-compounds, EDTA, nanomaterials… Also includes PBT and SVHC susbtances (cf. REACH).
- Preservatives must not be bioaccumulating.

- Dilution volume & biodegradability is taken into consideration.

Dishwasher detergents and Rinsing agents – This criteria provides for:
- the exclusion of some substances (EDTA, DTPA, Chlorine, alkylphenol…),
- the exclusion of some H/R classified fragrances,
- the exclusion of CMR substances in fragrances,
- the applicability of the Detergents Regulation,
- non bioaccumulation of preservatives,
- biodegradability of surfactants and anaerobically degradability of hazardous surfactants.

DID list and Dilution volume metric used to verify these different requirements are complied with.

Durable wood— Alternative to conventionally impregnated wood - Nordic Swan Eco-label applies to durable wood as an alternative to conventionally impregnated wood and is recognized as having no heavy metals or biocides added.

This Criteria includes the following as part of its environment requirements:
"R3 Biocides - Biocides must not be used for impregnating, modifying or treatment of wood. Biocides means chemical substances used to combat vermin, insects, bacteria, fungi and such (EU directive 98/8/EEC). Biocides encompass also chemicals containing arsenic, copper, chromium, tin, boron or creosote. Declaration that biocides are not used. If no chemicals are used, this must be stated in the process description, (see R1)".

Industrial cleaning and degreasing agents –

This Criteria includes the following as part of its environment requirements:
"R12 Optimising of preservatives - The quantity of preservatives in the product must be optimal in relation to the volume of the product and a "Challenge test" must be performed demonstrating this. […] R13 Biocides - Biocides may be added only as preservatives, not to disinfect surfaces washed with the product. Declaration stating that the product fulfils the requirement."

Under the Nordic Swan Eco-label criteria, for those product groups that refer to biocides, again the criteria stipulates that biocides may not be used within the product, with the exception in the case of industrial cleaning and degreasing agents where they are used as preservatives. As with the Blue Angel and EU Eco-label however, biocidal products are not granted an Eco-label, and instead it is available alternatives to biocidal products such

as durable wood as an alternative to conventionally impregnated wood that benefits from the Nordic Swan Eco-label.

8.5 EU Eco-labelling Board (EUEB) criteria

It is useful also to consider the criteria adopted by the EU Eco-labelling Board (EUEB) in deciding whether or not to evaluate a product group for an EU Eco-label. In accordance with the EUEB's policy document[60] it is noted that "the scheme must prioritise those product groups where the use of the EU Eco-label could make a significant contribution to more sustainable production and consumption". To this end, there are four key issues that are taken into consideration:

- Environmental (and health) relevance and potential
- Market suitability
- Suitability of the scheme as the most appropriate policy instrument
- Ability of the scheme to manage the product group

On the first issue, the aim is to identify if an Eco-label can help to promote products/technologies with a significantly better environmental performance. Due to the inherent nature of biocidal products, the purpose of which is to provide an effective means to kill or control harmful organisms, it is probably that those products that have a significantly better environmental performance are the alternatives available to biocidal products. It is unlikely that a like-for-like comparison of a biocidal product will show 'significant' differences in terms of environmental performance, which therefore supports the position that an Eco-label is only suitable for alternatives that are available to biocidal products or low-risk biocidal products.

In terms of market suitability, given that the market share of biocidal products is understood to be low when compared to plant protection products or pharmaceuticals, and considering the multiple sectors within this, it is unlikely that there would be a large number of companies willing to apply, use and maintain an Eco-label licence for any one individual biocidal product type. The wide variety of products and multiple sectors covered would also affect the ability of the EU Eco-label scheme to manage the product group as any EU Eco-label would have to be developed on a product specific basis and it is unlikely that criteria from other Eco-labelling systems could be adapted. Due to the nature of the products and advertising restrictions in place, environmental claims and environmental performance are not currently used in the marketing of biocidal products, and therefore there is not an existing platform to build upon. On market suitability, the only biocidal products that may be suitable for an EU Eco-label are low-risk biocidal products authorised under the simplified authorisation procedure. Once a low-risk biocidal product is authorised in one Member State it can be freely circulated within the Union provided that the other Member States are notified and have no objections to placing the product on the market. In terms of market share therefore, a low-risk biocidal product may be more suitable to the development of an eco-label.

As a result of both of the above issues, it is not considered that biocidal products generally or any one of the individual product groups would be suitable for the EU Eco-label scheme, and could even undermine the credibility of existing EU Eco-labels. This is not therefore considered to be an appropriate policy instrument to contribute to the sustainable use of biocidal products.

[60] EUEB policy document 'EU ecolabel's tool for evaluation of product groups for ecolabelling (or extension of current groups)', 23 November 2011.

8.6 Conclusions

The analysis of the criteria under the EU Eco-label Regulation and the criteria applied by other national Eco-label schemes in Germany and Norway, shows that biocidal products are not suitable for an eco-label. At present, biocides may only be included in the product as a preservative. Due to the inherent nature of biocidal products, criteria could not be developed under the EU Eco-label Regulation. It was also evident from the results of the stakeholder consultation that an EU Eco-label was not considered appropriate for biocidal products. Only products which offer alternatives to biocidal products should be considered in the further development of criteria for an eco-label.

The following recommendations are made:

1) As is presently the case, an Eco-label should only be considered for biocide-free alternatives.

2) In the future, the European Commission may also consider the development of criteria for an Eco-label for 'low-risk biocidal products'. However, changes to the labelling and advertising provisions recommended under Task 8 (see Chapter 10) would be a first step before considering an eco-label for such products and may in fact render the development of an eco-label for such products as superfluous.

9 VOLUNTARY SCHEMES

9.1 Introduction

The aim of this task is to review voluntary schemes which are currently used to highlight products that have a better environmental and public health profile, and identify those that could be used on an EU-wide basis for biocidal products. While a number of voluntary schemes attached to labels, such as the Eco-label, Blue Angel and Nordic Swan, have been considered under the analysis of the possibility of attaching an eco-label to biocidal products in the previous section, there are a number of other voluntary schemes which are worth consideration.

9.2 Consultation responses

Within the questionnaire sent to industry, stakeholders were asked the following question:

- Does your organisation have experience with an accreditation, ecological standard or other voluntary labelling scheme which could be of interest for biocidal products?

Out of 104 industry responses, over half of respondents did not have any experience with an accreditation, ecological standard or other voluntary labelling scheme. However, from the 58 responses that indicated that they did, the most commonly referred to schemes were those of the EU Eco-label, Blue Angel and Nordic Swan, which are considered in Chapter 8 above. However, in addition to the EU Eco-label, Blue Angel and Nordic Swan schemes, reference was made to the following schemes:

Accreditation, ecological standards and voluntary labelling schemes
Ecocert – certification of organic agricultural products. Ecocert has developed its own specifications for the inspection and certification of products, systems and services. Recognised both in France and elsewhere, these standards are used to conduct inspections on the basis of technical criteria for products including natural cleaning products, paintings and coatings products from natural origin, and inputs eligible for use in organic farming (fertilisers, phytosanitary products, etc). www.ecocert.com/en
Oekotex industry accreditation standards for textile biocidal auxiliary chemicals. The OEKO-TEX® label indicates the additional benefits of tested safety for skin-friendly clothing and other textiles to interested end users. The test label therefore provides an important decision-making tool for purchasing textiles. See www.oekotex.com
SC Johnson's developed the **Greenlist™** process in 2001 to classify ingredients considered for use in their products by their impact on the environment and human health. Through the Greenlist™ process, each potential ingredient receives a rating from 3 to 0 and whenever possible, the company works toward replacing lower rated materials with those that have a preferable environmental or health profile. http://www.scjohnson.com/en/commitment/focus-on/greener-products/greenlist.aspx
The Johnson and Johnson **Earthwards®** process provides a framework for meaningful product innovation and continued improvements to the sustainability of products. The EARTHWARDS® process, establishes pathways to use more sustainable materials and continue to consider the impacts of all ingredients in our products. Every new product and packaging is required to use the Earthwards® approach and meet the outlined environmental, health and safety prerequisites as well as examining the environmental and social impacts of their product. www.jnj.com/caring/citizenship-sustainability/strategic-framework/product-stewardship-earthwards
The **Echo Program** covers products used in AkzoNobel's Marine, Protective Coatings and Yacht (M&PC) markets to reduce their impact on the environment. Using an environmental scorecard, it allows products to be compared on environmental parameters and an 'echo rating' assigned to each, enabling consumers to make informed decisions over which products they use with respect to the environmental impact. Similar tools, including an eco-efficiency analysis, are used in their commercial products range, for example their Intercept® products. http://www.echoprogram.com/en

Accreditation, ecological standards and voluntary labelling schemes
A.I.S.E. Charter for Sustainable Cleaning and Product Environmental Footprint (PEF). The PEF initiative is to develop a harmonised methodology for the calculation of the environmental footprint of products, based on transparent methodology. http://www.aise.eu/our-activities/sustainable-cleaning-78/contributing-to-the-eu-agenda/product-environmental-footprint-pef.aspx
Wood Protection Association Benchmark Scheme. WPA Benchmark is a quality scheme ensures that treated wood is fit for purpose. It provides independent reassurance that timber has been treated correctly for its end-use and will deliver a service life in line with BS 8417 specifications. www.wood-protection.org/quality-schemes.asp
Aquaculture Counsel Stewardship (ASC) is a certification and labelling programme for responsibly farmed seafood. ASC recognises and rewards responsible aquaculture through the ASC aquaculture certification programme and seafood label, the criteria for which sets clear rules for the use of copper based antifouling products (ASC criterion 4.7). www.asc-aqua.org

A number of stakeholders also made suggestions regarding accreditations or other schemes that could be used in the future for biocidal products. One industry stakeholder commented that as logos provided by organisations like ECOCERT are useful and allow access to a particular group of users, a logo should be created to identify any product that has been approved under BPD-BPR and therefore shows that the efficacy and risk assessment evaluations for that product meets the highest standards. This would add value to the BPR itself (higher profile for the benefits brought by the Regulation) and provide an incentive/reward to comply. However, in response to this comment it is noted that since every biocidal product has to be authorised under the BPR, the authorisation itself provides evidence of compliance with the requirements of the BPR, without the need for an additional symbol or logo.

Within the questionnaire sent to stakeholders, industry was also asked the following question:

- What approaches/tools (in addition to any that your company already applies as described above) could be used to highlight the 'green profile' of biocidal products?

It is first worth noting that in response to this question, a number of industry stakeholders expressed the view that biocidal products could not be considered to have a "green profile" and that they could not support a "green profile" for their substances. This is reflected in the fact that there is currently no "green" product certification scheme that accepts biocidal products. It was felt that the promotion of a "green profile" for biocidal products, particularly where these do not work, is the wrong approach. One stakeholder commented that any "green profile" is potentially misleading, and that the biggest problem with the so-called "green" products is that they do not deliver the performance expected when, after all, the product is being used to solve a problem. It is not appropriate to promote and use environmental friendly products (often in high volume) with a low efficiency.

Another stakeholder commented that while a "green profile" often refers to the positive impact or the absence of a negative impact that a given product has on the environment, the use of biocides and the benefits they provide to society are often significantly under-valued. A mechanism to measure the holistic benefit of a product or to provide a given product a "society benefit score" may give a better indication of the value of this product to society rather than an arbitrary "green" designation. They provided the example of the active substances available for rodent control, which are very limited but are essential for effective rodent control. A number of stakeholders felt that the social and economic benefits of biocidal products were not being communicated properly. Biocides are able to

protect aqueous goods (economic impact) and to protect human and animal health (social and environmental benefits) and thus act in a sustainable manner.

Those that felt that the "green profile" of a biocidal product could be highlighted made a number of suggestions regarding approaches/tools that could be used to highlight the 'green profile' of biocidal products, which can be grouped into the following categories:

- Eco-label or other certification scheme – A number of companies felt that biocidal products with a better ecological profile could profit from a special biocidal 'Eco-label', dedicated industry voluntary scheme, logo or green mark or other certification scheme. One company suggested there should be a Carbon Footprint Certificate for nanosilver as a biocide, the use of which reduces energy and water consumption. The possibility of the use of an eco-label is discussed in Chapter 8.

- Other labelling scheme - Companies which have more sustainable production process (less water, energy consumption) and therefore contribute to the sustainable use of cleaning and disinfection products should be able to communicate it to their consumers (via dedicated labelling), as done under the A.I.S.E. Charter for Sustainable Cleaning. Additional stickers, pictograms or signs on labels could also be used to raise attention to certain problems, behaviour, or to do or not to do something.

- Authorisation procedure – A number of suggestions were made that concern the authorisation procedure, namely that the process of authorisation should be accelerated in order that new sustainable biocides (reducing water and energy) can be placed on the market, and therefore by having a greater number of products on the market, it will be possible to indicate those which are more sustainable products. In addition, better use should be made of Annex I BPR. Finally, it was felt that as part of the authorisation process, there should be a more robust benefit analysis, highlighting the need for biocides and their benefit as part of a holistic approach towards the protection of the environment, management of resources, energy efficiency and public safety. For example, the increased fuel consumption/emissions for ships without efficient antifoulant should be highlighted. Biocides do already provide for, and should be further promoted as being part of the solution toward a sustainable future, rather than considered as the source of the problem. The contribution that the current provisions of the BPR play in the sustainable use of biocidal products is discussed in Chapter 2.

- Research and development - To encourage development of more sustainable products (saving water/energy in use) special authorisation rules could be developed for research and development trials. One respondent indicated that it would be helpful to have a temporary and quick form of authorisation to place products for research and development trials on the market, beyond what is already foreseen in Article 56 BPR. Technical innovations on biocidal products in terms of special formulation technologies, where performance of biocides can be optimised and negative impact on the environment can be reduced should be encouraged as this results in a reduction of the overall amounts of biocides that are needed are reduced. The current provisions of the BPR on research and development are considered in Chapter 2.

- Guidance - Technical Guidance that clarifies the meaning of 'naturally derived' or 'botanically sourced' etc, would be very helpful.

- Training - The green profile of biocidal products depends strongly on training and updating of pest controllers. This profession should be officially licensed and recognised. Further information from authorities /EU, and training by associations should be provided.

- Information – One stakeholder recommended that the use of the IUCLID tool or other EU tools for checking the "green profile" of a product would help. Other companies referred to information in general, whether through trade periodicals, training courses, meetings and workshops and promotion via websites or social media.

- Fees – A final recommendation was that there should be reduced authorisation and annual fees that could act as an incentive to deliver more sustainable products.

With the exception of the suggestions made regarding other labelling schemes (linked to compliance with a set of criteria), each of the above approaches/tools are discussed in earlier chapters, namely Chapter 7 on IPM principles and are included in the recommendations made regarding the need for further guidance, training and dissemination of information at the national level. The possibility to introduce varying levels of fees as an incentive to deliver more sustainable products is considered in Chapter 3 on best practices for the sustainable use of biocidal products.

9.3 Case studies

In order to consider whether any of the existing voluntary schemes would be appropriate for use on an EU-level, three voluntary schemes have been selected by way of example for further analysis. In each case the background to the scheme is highlighted and the details of the scheme, in particular the criteria applied, as well as the information provided to the consumer. In particular, where available, the criteria used to establish the 'green' credentials of the product are explained. These are provided by way of example only as a number of other companies may also operate similar voluntary schemes.

The following three examples of voluntary schemes are highlighted in the boxes below:

1) SC Johnson, "Greenlist";
2) AkzoNobel, "ECHO Program"; and
3) Clover Chemical Ltd, "TRECOS".

SC Johnson - Greenlist™

The SC Johnson Greenlist ™ was formally launched in 2001, aiming to continually improve their products with better ingredients. Building on previous work to remove "bad" ingredients from products, Greenlist™ is a process for rating raw materials according to environmental and health impact and continuously improving formulas based on information about ingredients' impact.

The SC Johnson Greenlist™ process includes ratings for all ingredients used in SC Johnson products globally. When evaluating ingredients, products are screened for about 4,600 materials. Formulators are required to choose materials with higher Greenlist™ ratings, which is an integral part of the product development system. A reporting system tracks the scores at the product, division and corporate level.

Organisations involved

Greenlist™ only applies to SC Johnson products. By 2006, external recognition and inquiries encouraged SC Johnson's development of a patent-licensing system that was expected to extend the standards to other manufacturers after 2007. SC Johnson Greenlist™ is now licensed (administered by PE International) free of charge to other third parties (potential suppliers to SC Johnson) that want to improve the environmental profile of their products. Companies licensing it can adapt it to reflect their own unique chemicals and materials. The criteria developed by SC Johnson are not made available but licensees are provided with a framework and proven management system to develop their own criteria and evaluate and report on performance against measurable objectives. Importantly, companies that license the SC Johnson Greenlist™ process must be willing to establish measurable goals and report on them annually.

Products covered

Greenlist™ covers 19 different categories of raw materials – chelants, dyes/pigments, fabrics/wipes, fragrances, inorganic acids, organic acids, inorganic bases, inorganic salts, insecticides/repellents, packaging, preservatives, propellants, sawdust, silicones, solvents, surfactants, thickeners, resins and waxes/candle fuels.

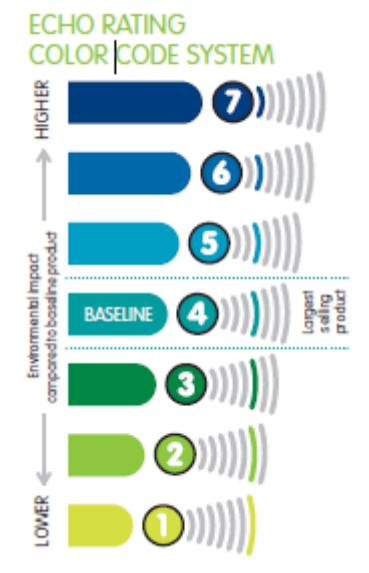
Main criteria used to establish the 'green' credentials of the product

Between three and seven criteria (not published) are developed for each product category, covering toxicity endpoints, environmental endpoints, physical/chemical endpoints, and other endpoints to address significant concerns, such as the presence of endocrine disrupting properties, which would result in a lower score. The criteria are reviewed annually and updated where necessary. Each raw material or component gets a score for each criterion. Each ingredient is given a rating from 3 to 0, a 3 rating being considered the "Best," a 2 rating is "Better," and a 1 rating is "Good". 0-rated materials cannot be intentionally added to new products ("brown list" products) or can only be used at restricted levels (Restricted Use Materials (RUMs)). Where 0-rated materials are used in existing products, SC Johnson is working to eliminate them through reformulation, where the aim is to select raw materials rated "Better" or "Best".

Information provided to consumer

Since March 2009, the company has started sharing information on the ingredients in SC Johnson U.S. and Canada products at the following website, www.whatsinsidescjohnson.com and hopes to expand this initiative to Europe in the near future.

AkzoNobel – ECHO Program



Yacht coatings manufacturers Awlgrip and Interlux launched a new sustainability platform, the ECHO Program, in early 2012, as part of the sustainability commitment by their parent company Akzo Nobel. In order to reduce the environmental impact of its products in three key areas, the ECHO Program includes reduction targets for volatile organic compounds (VOCs), average biocidal emissions for antifoulings and waste reduction. On biocides it aims to continue supplying antifoulings with excellent performance, while reducing the average amount of biocide emitted per square foot coated with antifouling per year by 20% by 2020. In addition, both manufacturers have identified environmental impact ratings for their products, which allow customers to select products that best fit their needs within the Awlgrip and Interlux product range. The ECHO Program sets a baseline for the companies, and allows them to continuously improve their products.

Organisations involved
The ECHO Program only applies to AkzoNobel, Awlgrip and Interlux products.

Products covered
Yacht coatings (PT 21)

Main criteria used to establish the 'green' credentials of the product
An Environmental Scorecard tool has been developed, that assesses the environmental impact and scores products across their entire life cycle from the sourcing of raw materials to waste disposal. Each product is assessed against 9 criteria including solvent emissions, eco-toxicity and climate change. The scores for each criterion are then aggregated to give a total weighted impact rating versus a baseline product which scores 1.0. The baseline product is the largest volume selling product in the category being considered (e.g. finishes, primers etc.). The score is then converted into an 'Echo Rating' and the lower the rating a product has, the lower the relative impact on the environment. It should be noted however that a high Echo Rating doesn't necessarily mean that the product is bad for the environment, but rather that it is not as good as the largest selling product within the companies range. The company is clear that their products are biocidal and do not make claims that they are environmentally friendly, but provide information on the whole paint (i.e. not just the biocide but the other ingredients too, solvents etc) for each of our products. This recognises that antifouling products cannot be considered to be environmentally friendly, but that there are environmental benefits to be gained by choosing water based products over solvent based products which is quantified in the Echo rating. All ratings are relative to the company's largest selling product within that product category. No comparison can be made to products from other suppliers.

Information provided to the consumer
The 'Echo Rating' of each product is displayed via a colour coded system as set out above. The rating and more detailed explanations of the Echo Rating is provided on the schemes website.

www.echoprogram.com

Clover Chemical Ltd - TRECOS

TRECOS is an ecological standard applied by Clover Chemicals Ltd, in order to clarify their product's 'green' credentials. The company has applied the accreditation to a selected range of products in the cleaning industry based on their overall environmental profile, covering aspects such as biodegradability, packaging, energy and transport.

Organisations involved
The TRECOS standard only applies to Clover Chemical Ltd products.

Products covered
Cleaning products

Main criteria used to establish the 'green' credentials of the product
In order to receive accreditation, each product is scored for 10 different environmental factors:

1. Raw materials – Raw materials used are scored for impact.
2. Packaging ratio – Products are scored for their packaging ratio.
3. Environmental hazard classification – Raw materials are scored according to their environmental classification. R50, R51, R52, R53, H400, H410, H412 and H413.
4. Volatile organic compound content – The higher the level of VOCs, the higher the score.
5. Energy – The energy used to obtain the finished product is taken into account.
6. Health and/or physic/chemical properties – The product is evaluated for potential adverse health effects and adverse physic/chemical properties.
7. Consumer use – How often the product is used and the control over its use are scored.
8. Biocidal products – Biocidal products are scored depending upon whether they have a necessary function to protect public hygiene and the registration of the active ingredients in Europe. A high score is given to products that do not have a necessary function to protect public hygiene.
9. Clear labelling – A high score is given to those products without clear user instructions.
10. Biodegradation – The manufacturing process produces waste which is controlled and disposed of in a responsible fashion. This is scored according to the environmental impact of each products waste.

Products are awarded the TRECOS mark if they receive a cumulative low product category score. Biocidal products that do not have a necessary function to protect public hygiene will be given a high score, thus reducing their chances to be accredited under TRECOS.

Information provided to the consumer
The TRECOS logo appears on Clover Chemical Ltd products.

http://www.cloverchem.co.uk/2013/uk/add_docs/enviro_policy.pdf

The main characteristics of each of the examples are set out below:

Scheme	Internal/External	3rd party verifier	Hazard or risk based criteria	Indication on labelling
Greenlist™	Internal	No	Risk based	No
ECHO Program	Internal	Yes	Risk based	Yes
TRECOS	Internal	Not specified	Risk based	Yes

With regard to the advantages and disadvantages of each scheme, the main advantage identified for all of the above three schemes, is that through internal processes, these companies are seeking to reduce the environmental impact of their products by selecting ingredients and raw materials according to the environmental and health impacts. This therefore contributes to the development of products that have a better environmental and public health profile and leads to increasing improvements in this regard.

For example, the SC Johnson 2014 Public Sustainability Report[61] shows that the Greenlist™ process has helped SC Johnson move from 18% "better/best" ingredients in 2001, to 47% today, with the goal of 58% "better/best" ingredients by 2016. Advances have also been made in the reformulation of existing products (innovation).In Raid Ant & Roach Baits, the Greenlist™ process facilitated the replacement of Chlorpyrifos (a legal requirement), a broad-spectrum organophosphate insecticide that is highly toxic to aquatic organisms, can bioaccumulate in tissues of aquatic organisms, and is moderately persistent in the environment. It should be noted that Chlorpyrifos is not supported as an active substance under the Review Programme. Chlorpyrifos was replaced by the approved active substance Abamectin, a biodegradable pesticide that does not bioaccumulate and is produced by natural fermentation.

In each case however, the voluntary schemes highlighted above are internal company processes that enable the company to make a decision over the choice of raw materials, but do not provide a comparison between the different end products. Whilst a rating or standard is applied to their own end products, which in two of the examples can then be ranked against each other, a comparison cannot be made with products from other suppliers. In the case of the Greenlist™ process, the process is available for licensing by other suppliers. However, the criteria applied within the Greenlist™ process is not available, and third parties looking to develop such a process are required to develop their own criteria based on their specific product types. It is therefore not considered that any of these internal company-based approached would be suitable for development on an EU-wide basis.

Rather than a company based scheme, an industry wide initiative such as the A.I.S.E Charter for Sustainable Cleaning would be of more benefit. As indicated below, although the A.I.S.E Charter is a voluntary initiative, with over 200 companies signed up, which represents 85% of the market for the European soaps, detergents and maintenance products. The standard promotes a common approach to sustainability, and following its most recent update now includes a product dimension, where companies can obtain a sustainability assurance for individual product by complying with new Advanced Sustainability Profiles (ASPs) for product categories. ASPs are defined per product category and set relevant parameters and thresholds for resource efficiency and use, concentration, product safety, packaging use and recycling and best use information. The Standard could therefore serve as a useful tool to ensure compliance with best practice.

[61] Available at http://www.scjohnson.com/en/commitment/report.aspx

The A.I.S.E Charter for Sustainable Cleaning

The A.I.S.E Charter for Sustainable Cleaning is a voluntary initiative of the European soaps, detergents and maintenance products industry, which aims to promote a common approach to sustainability practice and reporting based on a lifecycle assessment of the product. Companies seeking to apply the Standard must implement the Charter Sustainability Procedures (CSPs) in their management systems, to a minimum of 75% of their products. When first joining the Charter, the company must be verified by an independent external verifier based on the essential CSPs to ensure that it has in place the necessary processes and control systems and that these are correctly applied. Thereafter, additional CSPs are added when the company is re-assessed every three years. The external verification process ensures that all companies are assessed on an equal basis by an independent auditing body, and are re-assessed to ensure ongoing compliance.

Organisations involved
The Charter is open to all companies that manufacture, distribute, or market soaps, detergents, maintenance products or cleaning systems, whether they are a member of A.I.S.E or not. Since its launch in 2005, more than 216 companies have now joined the scheme.

Products covered
The Charter covers all product categories of the soaps, detergents and maintenance products industry, in both the household and industrial and institutional sectors.

Charter Sustainability Procedures (CSPs)
The CSPs cover the following:
A Raw material selection and safety evaluation
B Raw material and packaging supplier selection
C Packaging design and selection
D Resource use policy (includes energy use, water use, raw material use and packaging material use)
E Occupational health & safety management system
F Environmental management system
G Distribution risk assessment
H Product recall system
I Finished product safety evaluation
J Consumer and user information
K Product performance and review system
L Internal sustainability target setting

Regular upgrades of the Charter ensure that it continues to offer the most advanced sustainability assurance scheme for promoting best practice within the industry, using lifecycle assessment. Following its update in 2010, the Charter now includes a product dimension, where companies can obtain a sustainability assurance for individual product by complying with new Advanced Sustainability Profiles (ASPs) for product categories. ASPs are defined per product category and set relevant parameters and thresholds for resource efficiency and use, concentration, product safety, packaging use and recycling and best use information. ASPs have been developed for household laundry detergents, fabric conditioners, automatic dishwashing detergents, dilutable all purpose and floor cleaners, trigger hard surface cleaners, and hand dishwashing detergents.

The Charter also defines a set of 11 Key Performance Indicators (KPIs), linked to the CSPs. Companies must report annually to A.I.S.E on these KPIs. This information is then used to provide evidence of the progress of the industry as a whole within the annual A.I.S.E Activity & Sustainability Report. The process of implementing the CSPs and measuring and reporting the KPIs therefore helps to drive continuous improvement in sustainable production and consumption.

Information provided to the consumer
The Charter logo can be used on the products of companies that comply with the Charter Sustainability Procedures. In addition, a separate logo is provided for companies that follow the Charter update 2010, and for those products that both follow the Charter update 2010 and meet the specific Advanced Sustainability Profile for that product category (see ASP logo above).

In addition to developing the Charter, A.I.S.E has held training programs and other initiatives to promote the Charter, through National Associations to companies, at workshops and in seminars.
A.I.S.E. also promotes the use of the best / safe use pictograms and sentences, as well as other consumer campaigns, for example to inform the consumer on the changes in the labelling of products, with the introduction of the Charter logo and the best/safe use pictograms. A multilingual website was established, www.cleanright.eu, that offers consumers a wide range of information to help them get the best results from cleaning products in a safe and environmentally responsible way.

http://www.sustainable-cleaning.com/en.home.orb

9.4 WIDES Database

Another tool/approach that has been identified however is the Viennese Database for Disinfectants (WIDES database), which is managed by the Vienna Office for Environmental Protection.

The Viennese Database for Disinfectants (WIDES database)

The WIDES database is an industry-independent information system which allows the user to select disinfectants that combine sufficient effectiveness with minimal impacts on health and environment. It contains information on the established effects of commercially available disinfectants and their ingredients as well as the properties of these products that are relevant for occupational safety and environmental protection. The database was initially developed for internal use by the City of Vienna but was made publicly available in 2009, following numerous requests made by institutions and other interested users.

Organisations involved
The database was developed within the framework of the OkoKauf Wien, a project for sustainable public procurement launched by the City of Vienna. The database is managed by the Vienna Ombuds Office for Environmental Protection (WUA) and in cooperation with the Austrian Society for Hygiene, Microbiology and Preventive Medicine (OEGHMP), the General Accidents Insurance Cooperation (AUVA), the Inter-University Research Centre for Technology, Work and Culture (IFZ Graz) and the Vienna Hospitals Association.

Main criteria used to establish the 'green' credentials of the product
Disinfectant manufacturers wishing to have their products included in the WIDES Database may make an application to the WUA where they fulfil the following requirements:

- Indication of a product frame formulation stating all the active ingredients contained in the product and their exact concentrations;
- Up-to-date product data sheet and safety data sheet;
- Documentation evidencing the listing of the respective product in the list of expertise published by Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (OEGHMP); or
- Listing in the list of disinfectants published by Verbund für Angewandte Hygiene (VAH); or
- Presentation of two independent expert opinions testifying to the product's compliance with the criteria and evaluation methods currently required for a listing by OEGHMP or VAH. The appraisal of the expert opinions submitted is subject to a fee.

Once a product is accepted for inclusion in the database, it is assessed on the following principles:
1) Categorise the most important adverse impacts of disinfectants on human health and the environment. Six impact categories are used: acute toxicity (respiratory tract); irritation and corrosivity; allergic potential; mutagenic, carcinogenic, toxic for reproduction, chronically toxic; behaviour in surface waters; and impact on wastewater treatment plant.
2) The typical ingredients of disinfectants are assessed for the six impact categories. Numbers are assigned to the corresponding hazards, e.g. no.1 = no hazard statement, while no.5 = fatal and can cause severe burns. No assessment number is indicated if the data is insufficient.
3) Products are assessed on the basis of their active ingredients, taking into consideration the respective concentration of the ready for use or diluted liquids, as well as of all further ingredients with hazardous properties as indicated in the safety data sheets. The hazard potential is illustrated by means of colour codes from light yellow (= low hazard potential) to red (= high hazard potential)

Mechanisms of control
The database is continually updated. Further data on disinfecting agents published within the framework of the BPR are being integrated into the database as they become available. The products currently included in the WIDES Database have been tested and listed either by the OEGHMP, or the Association for Applied Hygiene (VAH).

http://www.wien.gv.at/english/environment/protection/oekokauf/disinfectants/index.html

The WIDES database has a number of advantages. It is a user-friendly database that facilitates the procurement of disinfectants (aimed at professional users). The database allows the user to compare products in their final working solution by providing an overview of commercially available products and listing manufacturer's data regarding the area of application, composition and material comparability of these disinfectants. Only products with the same application are compared. In addition, the decision as to which of the six evaluated properties are the most

important ones and must be given priority in selecting a product is left to the discretion of the user. Companies have indicated that the database has been a useful tool also in the formulation of new products, and some now positively advertise that they are on the database.

In Vienna, a list of recommended disinfectants has now been produced. The Vienna Office for Environmental Protection also wants to develop a list of criteria for tendering since other provinces of Austria have indicated that they want to base the procurement of disinfectants on the WIDES database. They are therefore considering establishing a working group to develop a list of criteria which excludes products with certain H-phrases or alternatively developing a new feature in the database so that it is possible to select products by excluding certain H-phrases. Consideration is also being given to whether to expand the database in future

In terms of disadvantages of the WIDES database, the assessment carried out is hazard based and relies on repeatable exposure scenarios that can be mathematically assessed. It is therefore most suited to fixed workplaces with formalised work systems and practices, such as large hospitals, which it was originally developed for. There are also other ingredients in the product, such as surfactants, fragrances, colorants, corrosion inhibitors or complex agents which are only taken into account if their R phrases or H phrase classification is indicated in the safety data sheet. The pool of toxicological data for many hazardous substances is still incomplete, although the database is continually being updated as further data becomes available through the BPR process. Where there is a lack of data this is indicated in the database. As the database was developed to cover product used in the City of Vienna, it is necessarily limited in its scope. The database now includes further products following requests from companies, from hospitals and institutions based outside Vienna, as well as requests to include a number of products used in Sweden. While the database is now open to any company that is interested in having their product included provided it meets the criteria, the Vienna Office for Environmental Protection does not have the resources to develop it on an EU-wide basis.

With regard to the latter disadvantage identified regarding the limited scope of the database, it is suggested therefore that the European Commission/ECHA consider developing a database similar to the WIDES database that would cover products used in all 28 Member States. As the WIDES database can only cover a limited number of disinfectants used in Austria and some in Germany, Sweden and Switzerland, this approach could be used to develop an EU-wide tool. In particular, the EU register for biocidal products (R4BP) contains the necessary data on the human-toxicological and ecotoxicological data for the active ingredients of the different product groups, as well as data at the product authorisation stage, which could therefore be used for the basis of the assessment. While such an assessment could initially focus on particular product types such as disinfectants, as the authorisation process progresses, this could be expanded to cover other product types. There could also be the possibility to make parts of such a database public, where the product type covered included general consumer use. It should be noted that the WIDES database is not aimed at use by general consumers and it is the position of the Austrian Office for Environmental Protection that routine use of disinfectants is not appropriate for households, unless required for a particular disease.

9.5 Conclusions

As we have seen in the previous chapter, a generic labelling or accreditation scheme such as the EU Eco-label is not considered appropriate for biocidal products. A number of stakeholder responses received regarding this task also indicated that biocidal products could not be considered to have a "green profile" and therefore that schemes other than an Eco-label that highlight the environmental and public health profile of biocidal products were also not suitable.

However, a number of voluntary schemes do exist across the EU which highlight the environmental and public health profile of a particular product. In each case these have been developed by industry, where individual companies have developed a process to assist them in making internal decisions over the choice of raw materials, or in the case of the A.I.S.E Charter for Sustainable Cleaning, by an industry association. In the former case, schemes such as Greenlist™ process, ECHO program and TRECOS are useful as contribute to the development of products that have a better environmental and public health profile and help stimulate innovation in this regard. In the latter case, due to the diverse nature of biocidal products, initiatives that cover a sector such as this are also considered particularly useful and therefore the development of a similar approach to other groups of biocidal products should be encouraged.

With regard to steps that could be taken on an EU-wide level to highlight products which have a better environmental and public health profile, the WIDES database in Austria could serve as an example, and be developed further at an EU-level in order to provide a tool for the selection of products that have a lower impact on the environment and human health. Using the information available in R4BP, the European Commission/ECHA could develop an EU-wide version of the WIDES database, for each product type.

10 MARKETING & ADVERTISING PROVISIONS

10.1 Introduction

Under Article 72 of the BPR, advertisements for biocidal products cannot claim that the product is a 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication. The purpose of this task was therefore to consider whether these provisions of the BPR should be revised.

Article 72

1. Any advertisement for biocidal products shall, in addition to complying with Regulation (EC) No 1272/2008, include the sentences 'Use biocides safely. Always read the label and product information before use.'. The sentences shall be clearly distinguishable and legible in relation to the whole advertisement.

2. Advertisers may replace the word 'biocides' in the prescribed sentences with a clear reference to the product-type being advertised.

3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication.

10.2 Consultation responses

In order to seek information on the extent to which the advertising restrictions in the BPR are regarded as too strict, questionnaires were sent to Member States, industry, and NGO's stakeholders, which included the following question:

- At present, advertisements for biocidal products cannot claim that the product is a 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication. To what extent do you feel that the advertising restrictions for biocidal products are too strict?

Of the 21 Member States that responded to the questionnaire, 18 Member States felt that the present advertising restrictions are necessary and therefore should remain. All biocidal products have and should have effects and therefore the risk of such products should not be trivialised. One Member State commented that as advertisements generally only run for a short time, there are difficulties over enforcement and therefore it is better to be relatively strict. A proposal to prohibit all advertisements for biocides in that Member State was unsuccessful. Another Member State commented that there may be scope to address "total brand advertising" and their inconsistencies through multiple advertising modes e.g. print, TV, internet, labels etc. For example, brand advertising (and sales) of biocidal products through the internet can be inconsistent with other advertising or even the authorised labels and claims. The issue of third party advertising on the internet could also be addressed. Another suggestion was that advertisements of uses that are not necessary should be restricted further in order to promote sustainable use. For example, for the sustainable control of pests it would be important to promote alternative measures like traps, fly flaps or nets, giving alternatives for biocide use a more prominent role. However, in order to be able to recommend these products and to include them in the comparative assessments, more information on alternatives (e.g. efficacy) is needed.

Only three Member States suggested that the advertising restrictions may be too strict in certain scenarios. One Member State commented that the restrictions on the use of these terms are stringent for example if the active substance is of natural origin.

Another Member State referred to products like CO2 used as rodenticide and some microbiological products for PT18 which could be seen from the environmental point of view as being better than other conventional products. Another Member State commented that generic prohibitions may not be appropriate for claims such as 'low risk' (for example for products authorised under Article 25 BPR) or 'environmentally friendly' where real environmental benefits can be identified for use. As a matter of principle companies should be free to make product labelling claims which are not inconsistent with the hazard classification, intended uses, and/or product authorisation conditions of a biocidal product. The most important point is that enforcement authorities and industry should have clarity over claims which can or cannot be made on labels of hazardous chemicals. The CLP Regulation already covers this area, but there is some uncertainty regarding the extent to which claims are or are not in scope of CLP requirements (for example company or product range names might in some cases constitute safety claims, but it is not clear whether these are in scope of some labelling prohibitions).

All six NGO's did not consider that the advertising restrictions for biocidal products are too strict. One NGO commented that use of the terms that are prohibited could convince consumers to buy products without thinking about the possibility of alternative methods or prevention, which therefore does not encourage sustainable use of biocidal products. Any relaxation of these restrictions would both counteract the objective of sustainable use (as well as eco-labelling) and would essentially complicate the surveillance activities of the Member State authorities as a case-by-cases evaluation of each product advertising would have to be carried out to evaluate whether the wording used was misleading or not. Advertisements should focus on the concrete purpose and the efficacy of a biocidal product. However, where illegal claims are made these generally dominate the front side of the package, leaving important risk and safety instructions in small text on the reverse side.

One NGO commented that in fact the restriction on using these terms is not strict enough, as does not take into account the cocktail effect. According to another NGO, the existing restrictions should even be strengthened to include additional terms, as other assertions such as to "protect the family" and "be absorbed in the soil" are also now commonly used. It would therefore be useful to carry out a study specifically on the implementation of the advertising and marketing restrictions by companies that place products on the market.

Of 104 industry respondents, almost half (45) felt that the advertising restrictions were too strict. Comments were received regarding the removal of the terms 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' and 'or any other similar indications' from the restriction set out in Article 72 BPR. However, most of the comments received related to the terms "natural" and "low-risk biocidal product".

To the extent that the claim "natural" if made is factually true, certain industry respondents considered the advertising restrictions to be too strict as do not allow consumers to make a product choice based on whether or not the product contains ingredients found in the natural ecosystem, or synthetically made. The belief that the amount of substances added to the ecosystem should be minimised to best protect the balance of nature and the planet is a legitimate one that cannot be encouraged without labelling that allows consumers to identify natural or naturally derived products.

While consumers should not be exposed to misleading claims in biocidal product advertising and labelling, industry stakeholders felt that this must be balanced with the clearly stated aims of Community legislation to promote both the development and marketing of less harmful products as well as their purchase by consumers. If the use of the term 'natural' and similar indications is not permitted at all, manufacturers will

have little commercial incentive to formulate or re-formulate with more expensive, non-chemical and natural ingredients or to invest in or buy from companies which supply such ingredients. Equally, the consumer will find it more difficult to identify and choose products with a more favourable profile. It was the view of certain industry respondents therefore that the current BPR text for Articles 69 and 72 (and the 'restrictions' on use of word 'natural' etc.) contradict some of the aims of the BPR – in particular the objectives referenced in the preamble (paragraphs 29 and 30) that encourage the use of natural and non-toxic ingredients.

With regard to the term 'low-risk biocidal product', it was stated by one industry respondent that since there is a procedure for establishing that a product is "low risk" under Article 25 BPR and Annex 1, there should be some means to benefit from this feature of the BPR. While this must not be done in a way that might lead to the product not being used correctly, there should be recognition of the fact that the biocidal product has been authorised under the BPR for a given application, based on the conservative models and worst-case analysis that is applied, and is expected to be safe for this use.

This position was reflected generally in the responses from a number of industry stakeholders who were of the view that in cases where such a claim is justified (technical and scientific proof and following a comparison to a regular less sustainable product) it should be allowed. This may in turn create an incentive for biocidal products formulators to put more effort into research and development. The current restrictions on advertisement however may lead to unfair treatment of products on the market, despite these having been through a very complex and in-depth evaluation process where the lack of risk to human health and the environment has to be proven. Biocidal product formulators should be able to communicate their contribution to sustainable products/production process to their customers via dedicated labelling.

Even where these terms are retained in the BPR, the advertising restrictions for biocidal products could be clarified providing that terms for example 'low-risk', 'non-toxic', 'harmless', and 'natural' have clear and specific definitions. The result of the advertising restrictions is that rather 'dangerous' products are presented to the public in the same way as rather 'innocent' products and the public cannot make the right choice. A classification should be made available so that the public can distinguish the different levels of danger or environmental impact.

One respondent commented however that any change to current policy would need to be carefully managed to prevent companies giving the consumer a false impression of the 'green credentials' of the product. Should the restrictions be relaxed this should be based on independent guidelines, and not left to product providers. There is also a need not to detract from the fact that these products are used to control pests that can damage health and cause illness, damage and disease, and make these products seem 'safe'. Biocides always are hazardous substances and their intended use is to be toxic towards their target organisms. However, it must be possible to market certain biocidal products with more favourable toxicological profiles and lower environmental and human health risks according to their improved properties for the intended use as compared to other conventional biocidal products

A number of respondents considered that since a decision is taken on whether the biocidal product can be placed on the market or if it poses any risk to the consumer, once authorised, the product should be regarded to be safe and harmless. Named restrictions should therefore only apply to products that have not been authorised yet, but that are allowed to stay on the market because they contain "existing biocidal substances".

10.3 Examples of advertising restrictions

Industry stakeholders were also asked the following question:

- Do you have a biocidal product that you consider having a better profile for environment or health, but where you cannot state this in advertising due to the restrictions laid down in Article 72 of the Biocidal Products Regulation?

40 respondents (38%) indicated that they had a biocidal product that they considered having a better profile for environment or health, but which they could not state this in advertising due to the restrictions laid down in Article 72 of the BPR. However, despite this not all of the companies that listed a product for which they could not make such claims felt that the advertising restrictions were too strict, and vice versa, for some of the companies that did feel that the advertising restrictions were too strict, they did not have a product for which they had been prevented from making such claims due to the advertising restrictions.

Ability to highlight the better environment or human health profile of a product

In a number of cases, general comments were received which related to the stakeholders overall ability to highlight the better environment or human health profile of one product against another, rather than their ability to claim a specific indication in the advertising of the product. For example, in relation to insecticides (PT 18) one company stated that the advertising restriction prevents it from communicating to the customer that co-formulants used in some insecticides are less "toxic" than co-formulants used in others. However, changes to the advertising restrictions would not alter this position as such a product would not be able to claim that it is "non-toxic" which is the term prohibited under Article 72 BPR. Instead, the issue is that the company wishes to compare the toxicity and efficiency of one product against others. As outlined in Chapter 9, one solution to this would be to establish a comparative database similar to the WIDES database for specific product types, using information from R4BP, which would allow the user to select an insecticide with a lower toxicity, yet the same efficacy.

A number of companies also cited the example of surface disinfectant products that contain 5-6% hydrogen peroxide. In such cases, it was stated that the hydrogen peroxide is converted to water and oxygen at the end of the decontamination cycle so has a better environmental profile than other products used for the same purpose. It is stated that such products are co-formulated with plant based surfactants, are biodegradable and do not leave any active residue. However, again this example relates to the ability to highlight the better environment or human health profile of one product over another, rather than an inability to use one of the terms restricted under Article 72 of the BPR.

Nanomaterials

One company provided the production of nanostructured biocidal products based on nanosilver as an example of a product that is affected by the advertising restrictions under Article 72 of the BPR. Nanosilver is stated to have a higher antimicrobial activity compared to the use of the same amount of bulk silver, which therefore means that less material is needed for the same antimicrobial effect, helping to conserve resources. Textiles treated with nanosilver require to be washed less than untreated textiles, thus reducing water and energy consumption and strengthening the carbon footprint. However, the company stated that the advertising restrictions prevent these positive effects being advertised.

In response, it should be noted that there are numerous publications which question the usefulness of silver nanoparticles in textiles (for example, these can be washed

out and therefore lose efficiency). As noted in the preamble to the BPR (paragraph 66), there is scientific uncertainty about the safety of nanomaterials for human health, animal health and the environment. The Scientific Committee on Emerging and Newly Identified Health Risks was asked to assess whether the use of nanosilver could result in additional risks compared to more traditional uses of silver. It delivered an Opinion on 'Nanosilver: safety, health and environmental effects and role in antimicrobial resistance' in June 2014, it which it recommended that more information was required on the possible contribution of Ag-NP to environmental and human toxicity, and to the occurrence and mechanism of antimicrobial resistance. At that stage, a specific human risk assessment for Ag-NP was not feasible as information on possible long term effects were lacking. Therefore, more studies on health effects after long term exposure are needed. Also more exposure data is necessary, as is data on all products containing Ag-NPs as data on exposure levels during use of Ag-NP containing products.

Under Article 4(4) BPR, the approval of an active substance does not include the nanomaterial form unless explicitly mentioned. Nanomaterials are not eligible for the simplified authorisation procedure (cannot be regarded as a "low-risk biocidal product"), and where an application is made for authorisation of a biocidal product in which nanomaterials are used, the risk to human health, animal health and the environment of the nanomaterial must have been assessed separately. Specifically with regard to the example of textiles treated with nanosilver, Article 58 BPR on treated articles provides that where a claim is made by the manufacturer of a treated article regarding the biocidal properties of the article, the label must include the name of all nanomaterials contained in the biocidal products, followed by the word 'nano' in brackets. The use of nanomaterials within a biocidal product must therefore be specifically referred to on the label of the product.

With regard to the remaining examples provided by industry respondent of products which are prevented from using 'low-risk biocidal product', and 'natural', or any similar indication in their advertising, comments are provided in the following table:

Active substance	Stakeholder comments	Response
Indoxacarb	This is the only active bait ingredient classed as 'reduced risk' by the EPA in the US. The better safety/environmental profile of these products cannot be promoted due to the advertising restrictions.	While classified as 'reduced risk' in the US, indoxocarb is not included in Annex I of the BPR (not classified under CLP) and thus is not considered a 'low-risk active substance' within the EU. Indoxocarb has been approved as an active substance under Directive 2009/87/EC, and since its approval a number of biocidal products have been authorised across the EU.
Citriodiol	The active substance Citriodiol® which is sourced directly from an essential oil and modified using a catalyst that mimics the aging process of the oil if left in the originating leaves, cannot claim to be 'natural' or any similar indication. There will be no way for a consumer to quickly gauge whether the competitor DEET product or the Citriodiol® product has been made from a natural source.	Citriodiol is included in the Review Programme (Entry No 609). Citriodiol is produced from Eucalyptus citriodora oil, by a process which converts the citronellal in the oil into p-methane-3,8-diol (PMD). Citriodiol typically contains 64% PMD (PMD Rich botanic oil). It is noted that the UK website of Citriodiol states that it is a "natural" active ingredient effective against a range of biting insects, nuisance insects and ticks, describes the product as "nature's most effective insect repellent" and states that it is "the only naturally sourced ingredient that can now be used as an insect repellent".
Cis-tricos-9-ene (Muscalure)	One company listed lures or adhesive papers with attractants are being prevented from making certain claims due to the advertising restrictions, but did not provide any further information. To date eight	Whilst muscalure is a pheromone derived from natural sources, it is manufactured for commercial use and therefore cannot state to be "natural". Although in many cases the environmental risks of these substances is considered to be less than that of more

Active substance	Stakeholder comments	Response
	ASs have been approved for use in PT 19, of which muscalure is used in fly papers.	traditional biocides, that is not always the case. Like many naturally derived substances, it is also a skin sensitiser.

The final two examples provided by industry respondents referred to cyromazine formulated as 2 % granules, which is approved as an active substance for use in plant protection products under Regulation (EC) No 1107/2009 and therefore is not considered further, and neutral anolyte biocide which is produced by electrochemical activation of sodium chloride solution. The neutral anolyte is an a colourless biocide with a slight smell of chlorine in its mostly concentrated form, which is mainly formed of hypochlorous acid (HClO), and hypochlorite ions (ClO-). As an in-situ generated active substance, which is also covered by the BPR, as part of the evaluation of dossiers for biocidal products, the risk assessment should also include the possible risks from precursor(s). Also, as the conditions for HClO generation may differ considerably, it is generally questioned whether these products are safe, especially for consumer use. It is worth noting that in the US, one company website[62] for neutral anolyte describes it as a "green friendly biocide made from electrolyzed water", and an "eco-friendly biocide" and states that it is "safe for humans, animals, birds, marine life, and the environment".

Finally, it should be noted that reference was not made in any of the industry responses to cases in which the competent authorities have acknowledged that the biocidal product has a better environmental and human health profile than another product, yet which cannot be stated in the advertising. It may be that at this stage, with only a limited number of product types having progressed through the authorisation procedure, that this is something that is likely to arise more in the future following the authorisation of further products.

10.4 Comparison with EU approaches used for other products

In considering whether Article 72(3) of the BPR on advertising should be revised, the advertising requirements that apply to other restricted chemicals such as pesticides under Article 66(2) of Regulation (EC) No 1107/2009, f-gases under Regulation (EU) No 517/2014, and detergents under Regulation (EC) No 648/2004 were analysed as well as the provisions on advertising that were previously contained in the BPD.

The PPPR provides at Article 66(1) that plant protection products which are not authorised shall not be advertised. Article 66(2) then goes on to state that the advertisement shall not include information in text or graphic form which could be misleading as regards possible risks to human or animal health or to the environment, such as the terms 'low risk', 'non-toxic' or 'harmless'. Only in the case of low-risk plant protection products shall the term 'authorised as low-risk plant protection product in accordance with Regulation (EC) No 1107/2009' be allowed in the advertisement. It cannot be used as a claim on the label of the plant protection product.

Regulation (EU) No 517/2014 on fluorinated greenhouse gases contains provisions on advertising within Article 12 which covers the labelling requirements. Under Article 12, the label is required to indicate specified information, in particular a reference that the product or equipment contains fluorinated greenhouse gases or that its functioning relies upon such gases. However there are no limitations or restrictions on the use of specific terms.

[62] http://www.fraccure.com/index-4.html

Article 11 of Regulation (EC) No 648/2004 on detergents sets out the information to be included in the packaging in which the detergents are put up for sale to the customer and all documents accompanying detergents transported in bulk. There are no provisions on advertising, only labelling. The labelling requirements are without prejudice to existing national rules according to which graphic representations of fruits which may lead the user into error as to the use of liquid products, shall not appear on the packaging in which the detergents are put up for sale to the consumer (Article 11(6)).

Other product legislation was also checked for advertising restrictions such as Regulation (EU) No 305/2011 on the marketing of construction products. Directive 2001/83/EC on medicinal products for human use contains extensive provisions on advertising, which includes a general provision (Article 87(3)) that the advertising of a medicinal product shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, and shall not be misleading. Article 90 also specifically requires that the advertising of a medicinal product to the general public shall not contain any material which "suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural".

Finally, Article 22 of the BPD was checked, which previously made provision for the advertising of biocidal products. It set out the requirement "that advertisements for biocidal products do not refer to the product in a manner which is misleading in respect of the risks from the product to man or the environment" and provided that "under no circumstances may the advertising of a biocidal product mention 'low-risk biocidal product', 'non-toxic', 'harmless' or any similar indications". The terms 'natural', 'environmentally friendly' and 'animal friendly' were therefore added to this list with the introduction of the BPR.

It is worth noting that within the original legislative proposal for the BPR (COM (2009) 267 final), and following the European Parliament amendments following a first reading, the terms 'natural', 'environmentally friendly' and 'animal friendly' were not included. However, these were included in what was then Article 71 in Position (EU) No 11/2011 of the Council at First Reading.

The table below summarises the terms covered by the BPD, BPR, PPPR and other product legislation.

	BPD	**BPR**	**PPPR**	**Other product legislation**
Low-risk biocidal product	✓	✓	✓*	Not identified
Non-toxic	✓	✓	✓	Not identified
Harmless	✓	✓	✓	Not identified
Natural		✓		Medical devices
Environmentally friendly		✓		Not identified
Animal friendly		✓		Not identified
Similar indications	✓	✓	✓	Not identified

*In the case of PPP, the term "low-risk" cannot be used. However, only in the case of low-risk plant protection products shall the term 'authorised as low-risk plant protection product in accordance with Regulation (EC) No 1107/2009' be allowed in the advertisement. It cannot be used as a claim on the label of the plant protection product. (Article 66(2) PPPR)

10.5 Potential revision to Article 72 BPR

The overwhelming response from Member State authorities and NGO's to the stakeholder consultation was that the current advertising restrictions are not too strict and should remain as they are.

Almost half of industry respondents however indicated that the advertising restrictions are too strict.

It is apparent from the industry responses and the specific examples of the advertising restrictions referred to by individual companies that the main concerns with the advertising restrictions relate to the restrictions on the use of the terms 'low-risk biocidal product' and 'natural'. We shall therefore consider whether there is the potential to remove either of these terms from Article 72 BPR.

'Low-risk biocidal product'

One notable difference between the BPR and the PPPR is that advertisements for low-risk plant protection products are allowed to state that the product is 'authorised as low-risk plant protection product in accordance with Regulation (EC) No 1107/2009'. It cannot be used as a claim on the label of the plant protection product though.

As noted in Chapter 2, one of the measures introduced under the BPR to encourage the use of products that are less harmful for the environment, human and animal health is the simplified authorisation procedure. The simplified authorisation procedure is based on the principle that once the eligible product is authorised in one Member State it can then be freely circulated within the Union provided that the other Member States are notified and have no objections to placing the product on the market.

Under Article 25 of the BPR, an applicant for authorisation may be made under the simplified authorisation procedure if the biocidal product is an 'eligible biocidal product'. A biocidal product is eligible if all the following conditions are met:

a) all the active substances contained in the biocidal product appear in Annex I and satisfy any restriction specified in that Annex;

b) the biocidal product does not contain any substance of concern;

c) the biocidal product does not contain any nanomaterials;

d) the biocidal product is sufficiently effective; and

e) the handling of the biocidal product and its intended use do not require personal protective equipment.

Annex I of BPR includes active substances that were identified as presenting a low risk under REACH or the BPD, substances identified as food additives, pheromones and other substances considered to have low toxicity, such as weak acids, alcohols and vegetable oils used in cosmetics and food.

EC number	Name/group	Restriction	Comment
Category 1 – Substances authorised as food additives according to Regulation (EC) No 1333/2008			
200-018-0	Lactic acid	Concentration to be limited so that each biocidal product does not require classification according to either Directive 1999/45/EC or Regulation (EC) No 1272/2008	E 270
204-823-8	Sodium acetate		E262
208-534-8	Sodium benzoate		E 211
201-766-0	(+)-Tartaric acid		E 334

EC number	Name/group	Restriction	Comment
200-580-7	Acetic acid		E 260
201-176-3	Propionic acid		E 280
Category 2 – Substances included in Annex IV to Regulation (EC) No 1907/2006			
200-066-2	Ascorbic acid		
232-278-6	Linseed oil		
Category 3 – Weak acids			
Category 4 – Traditionally used substances of natural origin			
Natural oil	Lavender oil		CAS 8000-28-0
Natural oil	Peppermint oil		CAS 8006-90-4
Category 5 – Pheromones			
222-226-0	Oct-1-en-3-ol		
Mixture	Webbing clothes moths pheromone		
Category 6 – Substances included in Annex I or IA to Directive 98/8/EC			
204-696-9	Carbon dioxide	Only for use in ready-for-use gas canisters functioning together with a trapping device	
231-783-9	Nitrogen	Only for use in limited quantities in ready-for-use canisters	
250-753-6	(Z,E)-Tetradec-9,12-dienyl acetate		
Category 7 – Other			
	Baculovirus		
215-108-5	Bentonite		
203-376-6	Citronellal		
231-753-5	Iron sulphate		

Other active substances may be added provided that there is evidence that they do not give rise to concern. In accordance with Article 28(1) and (3) of the BPR, the Commission has the power to adopt delegated acts amending Annex I of the BPR, either to include actives substances that do not give rise to concern, or to restrict or to remove an entry for an active substance. The Commission may amend Annex I either on its own initiative or at the request of an economic operator or a Member State.

As the term 'low-risk biocidal product' is not actually defined as such in the BPR, but a procedure exists for the inclusion of active substances within Annex I and thereafter for authorisation under the simplified authorisation procedure, any changes made to the advertising restrictions should be aimed at those products authorised under Article 25 of the BPR. By linking any exemption to the advertising restriction to the simplified authorisation procedure, there are clear boundaries to when this claim can be stated in advertising materials.

The BPR could therefore be amended so as to include a similar exemption to that contained in the PPPR. Should that be taken forward, the following text is suggested for a revision of Article 72(3):

Suggested revision of Article 72(3)

3. Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication.

However, only in the case of eligible biocidal products authorised under the simplified authorisation procedure set out in Article 25 of the BPR, shall the term 'authorised as a low-risk biocidal product in accordance with Regulation (EU) No 528/2012' be allowed in the advertisement. It cannot be used as a claim on the label of the biocidal product.

However, any proposal to amend Article 72 on the advertising restrictions needs to be balanced against the risk of what the consumer understands by the term 'low-risk biocidal product' used within this statement and the need to ensure that any advertisements do not refer to the product in a manner which is misleading. While industry and competent authorities will have a clear understanding of what the simplified authorisation procedure entails under Article 25 of the BPR, this will not be apparent to the general consumer, who may apply a broader interpretation to the term 'low-risk'.

Under Article 6(1) of Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market ('Unfair Commercial Practices Directive')[63], "a commercial practice shall be regarded as misleading if it contains false information and is therefore untruthful or in any way, including overall presentation, deceives or is likely to deceive the average consumer […]". Reference is made to specific elements such as the existence or nature of the products or the main characteristics of the product such as its risks.

Under Commission Guidance on the Unfair Commercial Practices Directive[64] it is emphasised that any environmental claims must be made on the basis of evidence which can be verified by the competent authorities.

Unfair Commercial Practices Guidance

*"Objective misleading practice: the environmental claim is misleading because it **contains false information** and is therefore untruthful, in relation to one of the items of the list provided for by Article 6(1).*

Example: use of the term "biodegradable" when that is not the case (e.g. on a product for which no tests have been carried out); use of the term "pesticides-free" when the product actually contains some pesticides.

In conjunction with Article 12 of the Directive, this means that any environmental claims must be made on the basis of evidence which can be verified by the competent authorities"

'Natural'

Unlike the term 'low-risk biocidal product' there is no definition or procedure that is capable of setting the boundaries for the use of the term 'natural' in advertising. This

[63] Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive'), OJ L 149, 11.6.2005.

[64] Commission Staff Working Document, Guidance on the implementation/application of Directive 2005/29/EC on Unfair Commercial practices, Brussels, 3 December 2009 SEC(2009) 1666 http://ec.europa.eu/consumers/rights/docs/Guidance_UCP_Directive_en.pdf

is coupled with the fact that the term 'natural' could refer to both a product which has natural ingredients and a product which has naturally derived ingredients. Within this there could then be variance with regard to the percentage content of natural ingredients as almost all natural products contain some non-natural ingredients. There is a common misunderstanding that 'natural' means 'safe', which is not always the case.

Consideration also has to be given to the type of product we are dealing with here. Within the framework of biocidal products, the very nature of which are to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, those active substances that may be regarded as 'natural' may however have environmental risks that are greater than 'non-natural' biocides. Extreme caution has to be exercised as to what a consumer understands to be 'natural' when referred to products of this nature.

It should however be noted that under Category 4 of Annex I to the BPR, 'Traditionally used substances of natural origin' may be included in Annex I. To date a number of natural oils, lavender oil and peppermint oil, have been included within this category and Citronellal has also been included within the catch-all category, 'Other'. It is therefore possible for certain substances of natural origin that are included in Annex I to benefit from the simplified authorisation procedure under Article 25 BPR. Where the recommendations above regarding consideration of a relaxation of the advertising restrictions under Article 72 BPR for those products which are authorised under the simplified authorisation procedure are taken forward, this would therefore allow certain products of 'natural origin' to benefit from this also.

It may be that once further biocidal products come through the authorisation procedure, specific research could be carried out into the composition of such products, and whether an appropriate definition of 'natural' or 'naturally derived' could be developed. At this stage however, without clear and specific definitions of such terms used within the context of biocidal products, the advertising restriction on the use of the term 'natural' should remain.

10.6 Conclusions

While the position of Member State authorities and NGO's is that the current advertising restrictions set out in Article 72 BPR are not too strict and should remain unchanged, industry respondents raised concerns in particular with regard to the restrictions on the use of the terms 'low-risk biocidal product' and 'natural'. Having analysed the provisions under the BPR and the position under other similar product related legislation, it is therefore proposed that the BPR could be amended so as to include an exemption to the advertising restrictions for those products authorised under the simplified authorisation procedure. No change should be made to the advertising restriction with regard to the term 'natural'.

The following recommendations are made:

1) The Commission could consider amending Article 72(3) BPR to include the following exemption:

However, only in the case of eligible biocidal products authorised under the simplified authorisation procedure set out in Article 25 of the BPR, shall the term 'authorised as a low-risk biocidal product in accordance with Regulation (EU) No 528/2012' be allowed in the advertisement. It cannot be used as a claim on the label of the biocidal product.

2) The use of the term 'natural' should remain restricted under Article 72(3) BPR.

3) Where the first recommendation is taken forward by the Commission, this should be implemented prior to considering the future development of criteria for an Eco-label for 'low-risk biocidal products', as recommended under Chapter 8.

4) Research could be commissioned to look specifically at the composition of biocidal products, claiming to be 'natural' in order to establish whether an appropriate definition of 'natural' or 'naturally derived' could be developed.

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