ANNEX III

PT ANALYSIS – USE AND APPLICATION

This Annex provides summary information on the composition, use and application and health effects for each product type based on a literature review and data from available SDS in order to identify potential exposure and risks posed to human health for the end-user of a biocidal product. In each case a number of issues are noted regarding the use of the product and 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 in Chapter 4 of the report.

For each product type, an example of the typical composition is provided. However, it should be noted that in each case this is provided by way of example only, and therefore does not exclude the fact that other products within the product type may contain concentrations of the active substances outside the percentage concentration or range listed.

Product Type 1 - Human hygiene

Disinfectant - antimicrobial personnel hand wash

Composition (typical):

- Chlorohexidine Gluconate: CAS No. 18472-51-0; EC No. 242-354-0; EU classified; Present in product at 4%;
- Propan-2-ol: CAS No. 67-63-0; EC No. 200-661-7; EU classified; Present in product at 1-5%;

Product (hand wash) is classified for irritation to eyes. Care must be taken to avoid contact with the eyes as could cause conjunctivitis and severe corneal damage.

The frequency of skin irritation is concentration-dependent and so could cause dermatitis when used frequently for antiseptic hand-washing, particularly if hands are not adequately rinsed after washing.

Typical use - used by professionals in hospitals and workplaces where there is a need to disinfect the hands of workers. Hand wash products will be rinsed off after short term use. It is used in hospitals routinely to disinfect/as antiseptic on the skin of healthcare staff, to disinfect the skin of patients, etc. It is used externally only and must not be ingested or come in contact with eyes. In a clinical environment staff can use a hand wash more than 30 times/day which could lead to some dryness and potential irritation of the skin over time and constant use.

Active ingredient: Chlorohexidine gluconate is bactericidal in nature and is recommended as a relatively non-toxic skin antiseptic. It binds strongly to the skin, mucosa and other tissues and is poorly absorbed through the skin. Direct contact with brain tissue and meninges should be avoided.

Issues noted regarding use of hand wash:

- Where dryness or irritation develops there can be a reluctance to use hand wash as frequently as is required;

- Persons do not use the hand wash correctly and/or do not wash their hands thoroughly, too short a duration of washing time;
- Wearing jewellry etc.;
- Persons do not adequately dry their hands after washing;
- Persons perception that wearing surgical gloves negates the need to hand wash;
- As chlorohexidine is a cationic molecule its activity can be reduced by natural soaps, various inorganic anions, non-ionic surfactants, and hand creams containing anionic emulsifying agents.
- For the same/equivalent hand wash product, noted there were variances in the SDSs information available;
- Differences in the classification assigned was noted and for the active substances the CLP classification was not always included;
- Sodium hydroxide (which is classified as C; R35) can be present as a component in antimicrobial hand washes and yet this was not included in Section 3 of the SDS (on composition), of some of the SDSs. Regarding the presence of sodium hydroxide, there are specific concentration limits laid down in EU classification legislation, which can impact on the classification of the final product, in this case the antimicrobial hand wash. Section 3 should contain all hazardous components and the percentage/concentration level present in the product, as these can cumulatively cause the final product to be classified for that end-point.

Product Type 2 - Disinfectants and Algaecides not intended for direct application to humans or animals

(A) Disinfectant

Scenario I: **Peracetic acid (peroxyacetic acid solution, *PAA*)** as a sanitizing agent or disinfectant. Generally this disinfectant is a mixture also containing hydrogen peroxide and acetic acid in an aqueous solution. The concentration of the various components of this disinfectant will vary dependent on its intended end-use.

Composition (typical):

- **(Active) - Peracetic acid:** CAS No.79-21-0; EC No. 201-186-8; EU Index No. 607-094-00-8 (EU Harmonised Classification and concentration limits); Present in the product at 5% or 2-3%.
- **Hydrogen Peroxide:** CAS No. 7722-84-1; EC No. 231-765-0; EU Index No. 008-003-00-9 (EU Harmonised classification and concentration limits); Present in the product at 20% or 10-12%.

Product Classification:
This disinfectant, as a mixture, is classified as corrosive (causing burns); is harmful by inhalation, in contact with the skin and if ingested. It also is oxidising and so contact with combustible materials may cause fire.

Uses of Peracetic acid:
Peracetic acid is used in food processing and handling as a disinfectant for food contact surfaces, for fruits, vegetables, etc whereby it can remove deposits, suppress odours and for stripping biofilms from food contact surfaces. Additionally peracetic acid can be used in the circulation, cleaning and sanitizing of equipment such as tanks, pipelines, pasteurizers and aseptic equipment in dairies, breweries and the beverage sector.

Peracetic acid is also used as a chemical sterilizing agent for specialised medical equipment such as endoscopes, arthroscopes etc. By virtue of the nature of this sterilising task the peracetic acid is supplied in a much higher concentration (ca 35%

peracetic acid solution) which is then diluted to the lower level working level of 0.2% within the processing/washing machine in the endoscopy suite.

Properties of Peracetic acid:
Peracetic acid is an oxidising agent used for disinfection and sterilization at relatively low temperatures. It is water soluable and leaves no residue after rinsing. It is used as an antimicrobial agent and can be added to process water or applied directly to food products to kill pathogenic bacteria. A concentration of 0.2% peracetic acid is active against all micro-organisms, including bacterial spores, and is effective in the presence of organic matter at low temperature.

From an environmental perspective peracetic acid rapidly breaks down to end products of water, oxygen and acetic acid and so is considered to be environmentally friendly. It can be highly corrosive.

The mode of action of peracetic acid is deemed to be similar to other oxidising agents in that it denatures proteins, disrupts the cell wall permeability, and oxidises sulphydryl and sulphur bonds in proteins, enzymes and other metabolites.

Peracetic acid is considered as unstable during storage, particularly when diluted, losing its strength/potency over time. When in storage the container (original container with venting closure) must be sealed, with the venting closure kept tightly closed, kept in an upright position in a well ventilated dry place/store room, away from heat, direct sunlight and/or sources of ignition.

While peracetic acid is highly effective and widely used it can also adversely affect man, in particular, with respect to chronic/excessive exposure, with the potential to be very irritating and burning to skin, eyes, nose, throat and lungs, which can result in permanent scarring of the skin, cornea and throat if exposure continues.

Issues relating to use:
- The quality of SDSs examined for this product are not wholly compliant with the required EU format;
- These SDSs do not have the required CLP classification for the substances as components in this product;
- The information regarding PPE and engineering controls lacks detail and use/exposure related data;
- It should be noted that in 2014 the ACGIH (USA) introduced a Short Term Exposure Limit (STEL of 15 mins,) of 0.4ppm, for peracetic acid (PAA). This updated information could be included in the SDS;
- Note based on the classification of various endpoints for this mixture, re-classification will be required in 2015 under CLP. It should be noted that in addition to re-classification, this product (as a mixture) may require revised classification so as to comply with the classification rules of the CLP Regulations (for mixtures);
- Regarding the information on PPE, the SDSs do not provide the required detail e.g. for gloves/face/goggles/ etc.;
- This product is classified as corrosive and can cause serious damage to eyes, and yet the SDSs examined do not make adequate mention or provide sufficient information regarding eye wash stations etc in case of accident/emergency, should major contact/exposure occur;
- Difficulties arise where workers do not follow the instructions regarding dilution activities, decanting procedures, disposal of residue and/or empty containers, correct storage, etc;
- Difficulties also arise where the information/instruction regarding dilution, decanting procedures, disposal of residue and/or empty containers, correct storage

etc is not sufficient, is lacking or is not clearly presented in an understandable manner for workers to implement.

Notwithstanding issues about SDS classification, insufficient information or content detail, other failures arising can affect how professional users handle biocidal products and/or implement controls measures. Such failures can lead to or contribute to possible exposure e.g.

- No or insufficient information relating to policies and operating procedures;
- Failure to develop an adequate site specific risk assessment taking account of the tasks involving the use of the biocidal product;
- Failure to take account of SDS information;
- Failure to take account of other/additional manufacture's instructions regarding the disinfectant/sanitizer;
- Failure by workers to follow instructions, in particular regarding dilution process;
- Failure to provide PPE or inadequate/inappropriate PPE;
- Failure to maintain PPE;
- Failure by workers to use PPE correctly;
- Failure to implement and ensure adequate controls measures are in place and used by relevant workers;
- Failure to dispose of empty containers in accordance with local regulations and in a manner to ensure exposure cannot occur.

Regarding use in Endoscopy Suite

- Failure to use appropriate engineering controls;
- Failure to maintain engineering controls;
- Failure to monitor that exposure events are not occurring;
- Failure to ensure the endoscopy washer is adequately maintained and operating efficiently and effectively;
- Failure to follow operating procedures regarding the use of the sterilant (biocidal product) in the endoscopy suite.

Scenario II: **Bleach**

Uses:
Bleach is universally used as a general all-purpose disinfectant and so is used by professionals at work in laboratories, hospitals/health care facilities, schools and premises which have hard surfaces which require disinfection, public water supplies, laundries, disinfection of swimming pools and by members of public in their homes.

The difference between the bleach available and used by the general public and those in an industrial setting relates to the concentration of the active ingredient present in the product, although domestic strength will also be used in the workplace depending on the needs/demands of the disinfection required.

Properties:
Bleach containing sodium hypochlorite is a strong and effective disinfectant but it can readily be deactivated in the presence of organic material, which has implications regarding usage/duration/replacement of solution e.g. when soaking/cleaning equipment on laboratory bench top (stirrers/probes/pipettes etc).

Low concentrations of free available chlorine have a rapid effect on mycoplasm and vegetative bacteria, while higher concentrations of chlorine are required to achieve effectiveness against M.tuberculosis, showing that the concentration of sodium hypochlorite in the bleach is determined by the intended use of the bleach.

Bleach can corrode metal and damage paintwork, and it decomposes over time. It should be mixed with cold water, as hot water will decompose the sodium hypochlorite and thus render it ineffective.

Health Effects (Bleach):
Can be toxic by all routes
Is corrosive to skin and cause serious damage to eyes
Ingestion can cause burns to the mouth, throat and oesophagus
Can cause sickness, sore throat, nausea, headaches, confusion, tightness of chest and general irritation - blisters.

The possibility of these effects occurring will depend on the route of exposure, the duration of exposure and concentration of the product being used. They can occur via splashes to the skin and eyes, via ingestion of the product, or via the production of chlorine gas which is inhaled.

Issues arising regarding the use of this product:
The primary problems and failures which can arise when using this product relate to the following:

- The provision of incorrect, insufficient information e.g. mis-classification, failure to account for all the properties of all the ingredients and not just the active ingredient, failure to take account of the assigned concentration limits of various ingredients e.g. where an ingredient, classified as R31 (liberates toxic gas when in contact with acids), is present at >5% then the product should be classified accordingly (not always the case or where there are ingredients are classified as R34 and present in the product at 2-5% then the product must be classified for this end-point).

  One SDS lists an incorrect CAS No. while some of the SDSs examined were not EU compliant and/or did not take account of the CLP Regulation regarding classification of substances (since 2010).

  The detail in many of the SDSs, especially regarding control measures, was lacking and/or did not provide sufficient information to implement adequate or appropriate protection measures.

- The difficulty associated with this type of hazardous product (Bleach) is that it is so universally used and available (including in the home) that workers can be complacent regarding its use and the possible health effects should exposure occur.

  Workers must know about the correct dilutions required and how to make up solutions safely and correctly.

  Training, adequate operating procedures, provision of appropriate PPE etc, and supervision, instruction in use is essential.

  In particular there is a need for workers to understand the risks associated with the products, its incompatibilities with other cleaning agents which could contain acids, and the risks associated with incorrect storage etc. Additionally where the product is mixed with products containing ammonia chloramines which are highly irritating gases, can result.

- The need for a site related risk assessment taking account of the use/handling/storage/disposal of this product is essential.

- Finally while not directly associated with exposure during use it is important for workers to understand that protein aceous/organic material can and will deactivate this disinfectant in that it will not be effective, as well as the fact that the material will deactivate over time. Therefore, when making up solutions it is important that a policy be developed to ensure that the solution being used by workers is effective and doing its intended disinfectant role efficiently. If this is not the case those workers assumed to be protected will in fact be at risk from the agents the product, as a disinfectant, is meant to kill/get rid of.

(B) Algaecides

Algaecides products used to kill or inhibit algae. These can be used in swimming pools, spas, or other water areas. Algaecides containing Polyquats are generally available in up to 30% concentration of active the ingredient (for private/amateur usage) and up to 60% for use by professionals.

The advantages to using polyquats algaecides is that they do not foam (in the water), do not contain metals, do not create a chlorine demand and clarify the water. However the product is hazardous and must be used in a safe manner and in accordance with the manufacturer's instructions, in particular in accordance with the requirements set down in the SDS and on the label of the product.

How Polyquat algaecides work:
Polyquats kill and control the growth of algae and microorganisms by disturbing their normal metabolic process of the living cell. In effect they kill when the positive charged polymer attaches itself to the algae or bacterial cell wall thus blocking the access and egress of nutrients and waste, causing cell death within hours of application. The method employed by polyquats to control and kill algae is referred to as suffocation.

The disadvantage of using polyquats algaecides is that the algaecidal benefit achieved lasts only a couple of weeks which therefore requires regular use of the product which can in turn lead to more/increased opportunities for potential exposure and risk to the user of the product.

Composition (typical)/Actives:
- **Poly quaternary ammonium chloride:** CAS No. 25988-97-0; Is classified. Present in product at 23%.
- **Copper sulphate pentahydrate:** CAS No. 7758-98-7; EC No. 231-847-6; EU Index No. 029-004-00-0. Is classified (has EU Harmonised classification).

Health effects:
Harmful if swallowed.
Can cause serious irritation to the eyes.
Very toxic to aquatic life both acute and chronic.

It is noted that when comparing two SDS for the same product including the same active ingredients, the classification for the active differed between the two documents. While products/mixtures are self-classified, the rules and calculations should assist in ensuring a consistency in the classification for each end-point, based on the ingredients in the products and the percentage of the ingredient present.

Issues arising regarding the use of this product:
As with other biocidal products, algaecides are available to both the private/amateur user and the professional user but with higher concentrations of the active present in the latter product.

The SDSs examined were not fully compliant with the EU requirements, in particular regarding the need for specific detail/information regarding PPE (skin/eyes) rather than giving a generic pictogram and/or no explanation.

The importance of accurate information in the SDS is essential as with the use of any hazardous product placed on the market. In one SDS there is an incorrect CAS No. listed. Another SDS failed to include the EU Index No. for another ingredient whereby this No. indicates the mandatory harmonised classification for that particular component.

Employers must consider hazardous substances, such as algaecides in their site specific risk assessment and develop and provide operational procedures so their workers can be safe when using these products. However if the information in the communication from the producers of the algaecides is incorrect, not accurate, lacking detail or not upto date, then employers down the supply chain will not be able to develop suitable assessments to protect their workers.

As above:

- Workers must trained, instructed, supervised and provided with sufficient and correct information;
- Workers must be provided with the necessary PPE as per the SDS and based on the risk assessment;
- PPE must be stored, cleaned and maintained properly;
- Workers must understand and comply with the controls and protection measures laid down in the risk assessment.

Product Type 3 - Veterinary Hygiene

While this product type relates specifically to veterinary hygiene the materials in question are primarily referring to products used for disinfection, sanitising and overall antimicrobial functions. i.e. many of the products relevant to this grouping also come within the scope of other product types e.g. PT 1 & 2, whereby they are used for the same purpose or function but outside the specific confines of veterinary hygiene. For this reason the controls measures, necessary information, and any identified failures in the existing systems and how they impact on professional users of these products as used under PT 1 & 2 also apply for this Product Type per product/usage/potential for exposure.

However unlike hospitals etc dealing with human patients, the risk of exposure can be increased within this product type, by virtue of the fact that here the patients are animals, who can spread and contaminate areas and further reaching surrounds, based on the inherent actions of those animals as part of their nature and natural behavioural patterns/activities, thus requiring a clear and constant regime of disinfection and sanitisation etc.

While the range of disinfectants are similar to those used under product type 2 e.g. for hard surfaces, furniture, instrumentation, housing, floors, bedding, treatment rooms etc. consideration must be given to the any risk associated with individual zoonotic diseases or tropical diseases which may require specialised treatment and control, including possibly specialised products or product application variances.

The need for accurate, correct and adequate information regarding the use and controls when using these products is essential and should be provided to professionals users from those who produce and supply the products.

As mentioned the control of chemicals and the protection of workers is subject to the requirements and protection measures coming under the scope of Directive 98/24/EC. This particular worker protection legislation provides the means to protect workers so long as it is understood and fully implemented at the workplace, by all workers concerned. Compliance with this legislation must be in place in all workplaces for all workers. However it becomes more difficult to ensure implementation and compliance when the work activities and workers are off-site.

Likewise where the workers in question are clearly within the scope of an organisational/ workplace structure the requirements including training, dissemination of information and implementation of operating procedures etc can be implemented and monitored in a consistent and planned manner. However where the veterinary practices involve other locations and other workers, then policies and procedures must be developed and implemented which allow for the same level of protection of those workers also.

Additional concerns when dealing with veterinary hygiene scenario
While the products may be the same as in product 1 & 2, the systems of work and regime may and will differ. In animal shelters/wards etc, the use of shared housing or the risks of mixed/shared bedding will determine a specific cleaning regime to ensure adequate disinfection and avoidance of communication of disease/pathogens. Also the cleaning and sanitisation regime will take account and be dictated by the excretory, feeding, grooming, behavioural habits etc of the animals.

Outside the more formal setting of a veterinary practice/hospital e.g. farm/hatcheries/piggeries/zoos etc., animals are moved/brought in and share living environments. Additionally animal behaviours include direct contact with each other and their bodily fluids thus requiring disinfection controls to allow for these activities also.

Users of these products:
Within formal veterinary practices and workplaces the persons using these products are primarily professional users, who if/when provided with sufficient information and associated training regarding usage, should be able to work safely with these products.

However other work environments and users also use these products and need to be adequately protected also.

(i) Farms - as discussed previously, the nature of working on a farm as a self-employed person at work and considered to be a professional user of biocidal products, this user may in reality not have sufficient information/knowledge or understanding of the risks involved, together with not having the required risk assessments and operating protocols, equipment and control measures available at other industrial/workplaces.

(ii) Animal shelters - often times volunteers work at these types of premises and as part of their work activities perform disinfection procedures, for which they should also be adequately protected and informed regarding working safely so as not to be at risk from exposure to the products being used. However while they would not be considered 'employed' they could be deemed to be a sub-set of professional users in that they are required/asked to perform disinfections activities using these products or are working in the vicinity of these products being used. Notwithstanding this fact however, those in charge of facilities where volunteer personnel help out are legally obliged to ensure that *'others potentially affected by a work activity*' are not at risk from such activities.

(iii) Veterinary personnel working off-site - where veterinary staff must work off-site, they need to be provided with adequate information and all necessary protection and

control measures to ensure they can do the activities safely and without risk. This may entail the need to develop or modify procedures to take account of any changes or potential increases in the risk of exposure due to being off-site.

All procedures and control measures relating to these products will be based on the information supplied via the SDS and any other manufacturers instructions/recommendations, taking account of the classifications assigned and the form in which the product is used. Therefore as before, the information provided must be valid, correct, adequate and sufficient to ensure controls can be in place to protect the users of the products, irrespective of the workplace/environment or location.

As some of the products used have already been considered under product type 1 & 2 the example (for PT3) used below relates to a specific disinfectant products which are more commonly employed within the veterinary hygiene sector, particular over more recent times.

Product - standard disinfectant for cleaning and sanitising surfaces.

Composition (typical) including actives:

- **Pentapotassium bis(peroxymonosulphate) bis(sulphate):** CAS No. 70693-62-8; EC No. 274-778-7; Present in the product at 40-50%. This substance has been registered under REACH.
- **Copper sulphate pentahydrate:** CAS No. 7758-98-7; EC No. 231-847-6; EU Index No. 029-004-00-0. Is classified (has EU Harmonised classification).
- **Benzoic acid:** CAS No. 65-85-0; EC No. 200-618-2.

Various versions of this product are currently on the market, together with SDSs per product with slight difference in composition depending on product and purpose. However considering the composition together with the percentages of each component in the product, the classification of this product needs to be revisited.

Where the classification of the overall product or mixture does not fully identify all hazards of all ingredients, as per the EU methodologies outlined for the classification of mixtures, then the SDS prepared for the product will also not identify all hazards for the user of the of the product. This being the case then the follow-on risk assessment, control measures, safe operating procedures etc for the protection of users will not be sufficient or adequate.

Considering this cleaning agent is used widely for veterinary hygiene purposes and that professional users may include persons who may not be fully informed or trained in procedures and could also be used or cause exposure to volunteer workers, this is not acceptable. Responsibility rests with those producing products to ensure that the information including the identification and classification of products is complete and correct. Persons, including professional users, down the supply chain, rely on the information provided by those who place the product on the market initially.

SDSs were not completely in line with the EU required format and for the substances as components of the mixture/product do not always include the CLP classification, which is required for substances since 2010.

For such products, in the associated marketing literature, emphasis is placed on the fact that when the product is diluted to the concentration required for cleaning/disinfection, the product is safe. While this is a fact, the emphasis as set out in the literature does not allow for the fact that the user must handle and use the product in its original/more concentrated form in order to dilute it to the final dilution required and that exposure of the user to the concentrate could potentially occur during this process.

Other issues relating to professional users:
The issues already mentioned regarding the implementation of the Chemical Agents Directive (98/24/EC) and possible non-compliance or incomplete compliance of this legislation together with the associated risk assessment and procedures required for safe use, apply regarding this product also.

Also where workers are not informed, instructed, trained, supervised, monitored etc do not understand the risks or if they have not been given the correct information in the first place, then these workers, as professional users, are at risk and can be adversely affected should exposure to the product occur.

Product Type 4 - Food and Feed area

Of primary interest for this PT are those biocides used in the food and feed area for the purpose of reducing the level of food pathogens and/or to minimise the risks of food borne diseases. Generally disinfection is performed on working surfaces and areas such as floors, cleaning of utensils etc. The range of premises/industries associated with this PT include, the food/drink and milk industries, slaughterhouses/ abattoirs/ butcheries/ hotel kitchens/ canteens and restaurants. Overall therefore the level of professional use will be in a fixed employment/setting and should have an organisational structure which will provide training/instruction/supervision and associated control and protection measures as required by Directive 98/24/EC. However as before this becomes problematic where the professional is a lone worker, involved in mobile catering etc or is self-employed, including those agriculturally based.

The protection of professional users of these PT 4 biocides depends on all work systems and requirements to protect workers at work while using hazardous products, being implemented and maintained. Additionally these systems and controls measures depend on the adequacy and information provided to ensure risk assessments and control measures are suitable and sufficient to protect those users.

The disinfectants most commonly used in the food (drink) and feed area include:
(a) Quaternary ammonium compounds (Quats) which are surface active agents, some of which can be skin, eye and/or respiratory irritants or corrosive. They are can be used in combination with other (compatible) agents;
(b) Alcohols used primarily for hand hygiene purposes and can be irritant;
(c) Peracetic acid as a powerful oxidising agent which is also extremely corrosive and can be used for spraying and/or fogging;
(d) Hypochlorite and organic chlorine-releasing compounds which are corrosive and even when diluted can be eye and skin irritants and can be used as foam; and
(e) Aldehydes can also be used for specific purposes and tasks and are hazardous. These would not be used for normal disinfection regimes.

Peracetic acid and sodium hypochlorite have already been considered in earlier PTs. Therefore for this PT we look at the Quats as our example, knowing that these are the most commonly used biocides in this sector.

Quaternary Ammonium compounds:
Quats are generally odourless, colourless and deodorising. They can have some detergent action and are overall good disinfectants. However some Quats may become deactivated in the presence of soaps and their antibacterial activity can be reduced in the presence of organic material.

Unlike bleach, Quats can be used to both clean and sanitise surfaces, but they require a longer contact time with the contaminated surface than bleach.

Uses:
Disinfection in this sector can be performed as:

Mist or Foam spraying - whereby aerosols are generated which could lead to whole-body exposure or the user. Suitable RPE and PPE must be used and the professional must be trained in the procedures and associated safe systems of work.

Fogging - like mist and foam application fogging generates aerosols but in this case the droplets are much smaller and the primary risk is that of breathing in the droplets. Due to the small size of these droplets they can remain airborne for longer and spread further. As above this practice and use should only be performed under strict supervision, in line with specific operational procedures and systems of work, including appropriate control measures. Professional users performing fogging must be adequately trained and informed of the risks and how to react safely in emergency situations.

Soaking, manual disinfection - these uses include using mops, cloths, wipes and brushes and are the normal methods of daily disinfection employed in this sector. For these uses small amounts of disinfectants are used, the risk of spreading via the airborne is reduced due to the nature of application and the concentration of the products are normally less/diluted. Notwithstanding this however the risks associated with the inherent toxicological properties of these products include irritation, corrosive effects etc to the eyes, skin, respiratory system and whole-body, should contact occur. Professional users applying these methods must also be trained, provided with adequate systems of work and means to protect themselves, based on correct information and relevant risk assessment(s).

Composition (typical) including active(s):

- **Benzoic acid:** CAS No. 65-85-0; EC No. 200-618-2.
- **Bromoacetic acid:** CAS No. 79-08-3; EC No. 201-175-8.
- **Decanoic acid:** CAS No. 334-48-5; EC No. 206-376-4.
- **Octanoic acid:** CAS No. 204-677-5; EC No. 124-07-2.

Other issues relating to professional users:

(a) As the risk assessments and controls to work safely with these products rely on the information provided by the manufacture via the SDS and other product data, it is essential there is no confusion and room for mis-interpretation by the downstream users of these products. In this case a range of SDSs for Quats containing products/disinfectant listed benzalkonium chloride as their active ingredient. In so doing however at least four different CAS and EU Nos were supplied (depending on the carbon chain length), and while most used the same EU classification, only one CAS no. provided a direct link to the mandatory EU classification.

Many of the available SDSs were not wholly compliant with EU requirements and format.

It is noted that these products vary in range/concentration of the active ingredient present with the average content being 5-15%. While for mixtures, EU CLP is not yet required, only two of six EU based companies SDSs examined, provided the EU required CLP classification for the individual components or substances contained in their product (required for substances since 2010). The importance of such information cannot be stressed enough as this is the starting point for

employers/professional users of the products when considering how to work safely with the products and to ensure that exposure cannot occur or if potentially possible that the users is adequately protected from exposure.

(b) For some of the applications of this products e.g. fogging/misting/foaming, these procedures are relatively specialised and require training and supervision as well a level of competence, indicating that these practices would not and should be used by professional users who have not been trained, do not understand and/or do not have the appropriate PPE/RPE and other associated preventive and control measures in place in a collective fashion, as required. However for other applications, including surface and utensil cleaning/disinfection, exposure can occur to professional users who have not received training or have received inadequate training and information. Also such practices are amongst those most likely to be performed at smaller premises or mobile units, implying that fixed controls and administrative information etc such as operating procedures, adequate hygiene facilities, suitable PPE, relevant SDSs may not be available or provided to those users. These are the most likely persons to be exposed without adequate protection or knowledge to assist them while working with these hazardous products.

(c) It is noted that when the CLP for mixtures formally comes into force in 2015 the classification of these products will require revision, in particular when considering the percentage of active present and the nature of the hazardous effect i.e. some of these products may find that their classification may be elevated from irritant to corrosive, thus requiring a review and consideration of the other associated information in the SDS regarding control and protection of the workers from exposure.

Product Type 5 - Drinking Water

Water intended for human consumption shall be free from microorganisms and parasites or other substances that may pose danger to human health. The mode of action of most of the disinfectant applied is based on their strong oxidising property. Chlorine is the most widely used disinfectant for the inactivation of waterborne pathogens in drinking water supplies. Chlorination is relatively simple and cost effective and can be used successfully for varying size of water supply systems including large industrial or municipal plants. Chlorine can be added to water either as a liquid or gas. The disinfection process is generally carried out in specially designed contact tanks which contain a series of baffles aiding contact with the water for a set length of time, to ensure effective disinfection, before the water is sent out into the distribution network.

However chlorine is a toxic substance and those working with it in this capacity can be at risk should exposure occur.

Users of Chorine under PT5:
Under this PT the professional user will be primarily be working in an industrial or municipal employment structure at a fixed plant/workplace. In this event therefore the necessary information, training, supervision and systems of work and required control measures should be in place, implemented and monitored regularly as required under the Workplace legislation and in particular the Chemical Agents Directive (98/24/EC).

There may be situations where smaller professional users are involved with a disinfection process for drinking water but normally at this level those professionals will be using smaller quantities and non-gaseous forms of chlorine or chlorine related products. For such workers the importance of following correctly and precisely the

instructions regarding dosing and protective measures, as laid down in the associated SDS, is essential. Additionally in these circumstances it may be possible to used tabs or tablets for the process which by virtue of their physical form reduces the risk of exposure to the chlorine which can exist when the chlorine is in liquid form i.e. splashes, aerosols, contact with skin/mucous membranes etc.

Composition:
In this case composition relates to chlorine as substances used in the disinfection process of drinking water, as it is at the concentrated (100% chlorine level) where exposure can occur.
Chlorine is a gas at room temperature and pressure, but is often transported as a liquid at higher pressures and/or lower temperatures.

Chlorine: CAS No. 7782-50-5; EC No. 231-959-5; Index No; 017-001-00-7********

******The harmonised classification for Chlorine under the CLP Regulation was amended under Commission Regulation No. 758/2013, thus changing the classification of this substance as listed in Annex VI of the CLP Regulation (7th August 2013). All SDSs for Chlorine should take account of this amendment and the classification changes introduced, in particular where this may require consideration and/or update of the other elements of the SDS including control and protective measures recommended.**

Updated EU classification:

Ox. Gas 1; Press. Gas Note U; Acute Tox. 3* H331; Eye Irrit. 2 H319; STOT SE 3 H335; Skin Irrit. 2 H315; Aquatic acute 1 H400;
GH S03; GH S04; GH SO6; & GH S09;
Danger
M 100

The classification and labelling of chlorine depends on the physical state of the actual product that is being used.

The M - factor for aquatic acute toxicity is harmonised as M-100 and should not be changed by industry

Note: The Technical Committee of the Chlorine REACH Consortium in fact recommends a stricter classification for chlorine when performing self-classification including Acute Tox. 2 H330 & Aquatic chronic 1 H410 & M-1

Professional Users:
Chlorine as a concentrated substance is not normally present in consumer products or provided for consumer use. However consumers and smaller professional users can be exposed to chlorine when it is present (small percentages/diluted products for disinfection) e.g. chlorine based bleach. It is essential that these professional users follow instructions and the information provided in the SDS for the relevant product.

Workplace exposure to concentrated chlorine can occur either in a chlorine manufacturing facility or in various industrial or manufacturing facilities using chlorine, including municipal water treatment plant providing water for consumption.

Professional users can be exposed to chlorine during production, distribution, storage, maintenance, sampling testing and other activities involving handling of the substance. Therefore while closed systems are used where possible during some of these activities the potential for exposure to this hazardous can occur. As chlorine is irritating and can be corrosive (depending on the concentrations involved), exposure should be limited as

far as is reasonably practicable and protective equipment for eyes/skin and an appropriate full-face respirator or self-contained breathing apparatus should be accessible and ready to use during these procedures.

At all workplaces with chlorine on-site, workers should be given thorough training, be supervised, have monitoring and warning systems in operation and ensure that suitable and adequate work processes and safety equipment is available/used, including practiced emergency procedures in case of accidents and releases.

Taking account of the above, it is important that professional users are:

- Informed, trained, supervised and protected with necessary protective/preventive and appropriate control measures.
- Ensure the SDS and any other associated instructions are available/upto date, understandable and implemented on-site.
- Ensure the SDS for Chlorine is in accordance with CLP Regulation.
- Ensure SDS is amended/revised in accordance with the 2013 update to the EU harmonised Classification for Chlorine.

Product Type 6 - Preservatives for products during storage

A preservative can be a naturally occurring or synthetic substance that is added to a wide range of products to prevent decomposition by microbial growth. For the purpose of this Product Type (6) cleaning agents have been examined, with respect to biocidal substances added to these products as a preservative. However it should be noted that certain biocides present as preservatives in a diverse range of cleaning products may also serve as disinfectants (i.e. duality in role).

Preservatives used in liquid washing products and cleaning products include isothiazolinones, benzoic acid, and bronopol. It should be noted also substances such as QACs, glutaraldehyde, formaldehyde or formaldehyde releasers can also be used in these products for both disinfectant and preservation purposes.

The purpose of choosing cleaning products as an example PT6 is that while they are used by the general public/consumers, they are widely used by workers especially those who may work alone as caretakers/janitors/cleaners/maintenance personnel as well as being used in various other trades etc. These category of workers are often times self-employed and/or lone workers who may not be formally trained and informed of the risks and the required level of control measures to adequately protect themselves and others who may be exposed to their products. The primary source of information for such workers will be provided in the SDS, where these workers are aware, provided or know to obtain this data from the producer of the product. For this reason the comment above is worrying in that it is not always transparent from the SDS as to what preservatives are present and what hazardous properties these components may possess. While the classification and risks relate to the concentration present, given these professional workers there is increased probability that standard operating procedures etc will not be in place or implemented. This is a foreseeable risk and so the information provided must be clear, understandable and emphasised for these workers also.

Example of preservative (active):
CMI/MI (3:1) is a mixture of 5-Chloro-2-methyl-2H-isothiazolin-3-one and 2-methyl-2H-isothiazolin-3-one. It is a hazardous mixture added as a preservative to cleaning agents which are then mostly handled and used in a liquid or spray form, thus allowing for direct contact with skin, eyes and mucosal membranes, as well as potential for aspiration if proper and appropriate protection is not provided to the worker involved.

While the actual amount/concentration of the CMI/MI preservative in these product is very low (e.g.0.05-0.2%) the risk of exposure increases where workers are not trained and do not use adequate measures to protect themselves from exposure. CMI/MI is a known skin sensitiser and corrosive.

CMI (3:1): CAS No. 55965-84-9; EU Index No.: 613-167-00-5 (has an EU harmonised classification). Present in cleaning agents at 0.05-0.2%). **[T; R23/24/25, C;R34, R;43, N; R50-53].**

Note: Where CMI is used in Film preservative i.e. PT7 (below), this mixture is phased out since Feb. 2011, based on EU decision.

Exposure
The risk of exposure and the risks relating from exposure to these preservatives relates directly to the quantity of substance being handled or used by the workers and the level of control, training, supervision, which should be based on adequate risk assessment. Where all measures and procedures are performed safely with appropriate controls etc, in accordance with worker protection legislation, then the risk, should exposure occur, is moderate. This scenario relates primarily to those manufacturing (a) the preservatives initially i.e. in concentrated form and (b) those using the concentrated preservatives to manufacture and/or formulate the final cleaning product.

Product Type 7 - Film Preservatives

Product Type 7 deals with preservatives that are added to a vast range of products used in industrial settings and manufacturing, for various professional/occupational activities and non-professional environments or scenarios. However the purpose for their inclusion in these products is the same throughout i.e. to control microbial organisms, which could otherwise cause deterioration of the product and to ensure the product integrity during normal shelf-life.

The most common products to which these preservatives (as biocides) are added include, water based paints, inks, adhesives, sealants, cleaning materials, etc. Given that paints are used by persons working in industrial settings, by trained professionals, self-employed tradesmen, non-professional persons and in the home, care and attention must be paid with respect to the ingredients incorporated in the paint product and the potential for exposure to the paint, taking particular account of the activities and tasks being performed.

For the purpose of PT7 section, water based paints will be the focus, knowing that paints are used universally and widely by persons at work whether trained or not, in industrial and/or remote settings, by persons trained/monitored/supervised or not.

When considering paints, a wide range of preservatives can be added therefore again only two examples have been examined in order to consider the risk of exposure and potential for adverse effects to the user.

Potential for Exposure:
The potential for exposure will vary greatly depending on the activity and environment of where the paint/preservatives are being used, for example,

(a) Paint manufacture - during the process of paint manufacture preservatives are added to the product. To this end therefore workers are required to handle concentrated amounts of preservatives and so control measures must reflect the inherent hazardous properties of these components, the physical form of the

preservative and the methodologies used on-site to add the substance e.g. automated system/closed/semi-closed system/segregated system or by hand etc. These operations and protection of the workers must be implemented in accordance with an appropriate site specific risk assessment, taking account of the SDS and classification of the preservative and any concentration limits applied. Where the information, training, control measures and information used to develop the risk assessment, together with training and supervision is implemented fully then workers can work safely with these materials.

(b) Paint formulation - where workers are required to mix paints, again workers can work safely with these materials once the risk assessment, the control measures, training and supervision is in place and the SDSs and other product data from the manufacturer is accurate and correct.

(c) Painters working off-site - the concentration of preservative in paints as finished products is small and normally would not warrant the paint/product to be classified for any particular hazardous property specific to the preservative. However many of the effects associated with these preservatives relate to skin/eye contact and sensitisation and so it is important that these workers understand and are provided with adequate means to avoid contact with the paint, and to protect themselves while working. Such workers may come from a specific painting company and as such have received training, been given a risk assessment and training, and be familiar with SDSs and content. However for this trade, many workers are self-employed or from small firms which potentially have not instigated training, or considered the full range of controls and protection necessary for its workers as required by the Chemical Agents legislation and other associated workers protection legislation. Therefore while the quantity of preservative present in paint is small and can be controlled and worked with safely, lack of training and knowledge and failure to operate good work practices and operating procedures means that the risk of exposure can be increased due to these failures.

Examples of preservatives as actives ingredients:

- **1, 2- Benzisothiazolin - 3 - one (BIT):** CAS No. 2634-33-5; EC No: 220-120-9; Index No: 613-088-00-6 (has a harmonised EU classification). Present in the product at 0.1 - 0.2% *********
- **2-Methyl-4-isothiazolin - 3 - one (MIT):** CAS No. 2682-20-4; EC NO. 220-239-6. Present in the product at 0.1- 0.4% ********

NOTE:

********:-** *Based on the percentages of the above preservatives present typically in paints (as per a sample of SDS examined) these percentages are higher than the concentration limits listed the EU proposal published in February 2013 (as amended)(BIT 0.02%; MIT/BIT 1:1 0.02%; CIT/MIT 3:1 0.0015%). Where these percentages are higher than the concentration set down by the EU, the product (paint) may require a revised classification based on the end-point and percentage of preservative in the paint.*

General issues for users;

The health effects associated with BIT in its concentrated form include acute, toxicity if swallowed, skin irritation, serious eye damage, skin sensitisation, and very toxic to aquatic organisms, while for MIT the effects include, acute oral toxicity, severe burns to skin and eyes (corrosive), skin sensitisation, toxicity and irritation if inhaled and very toxic to aquatic organisms.

Given the very small amount/percentage present in the paint product these effects do not warrant classification of the paint for these end-points. The risk from exposure regarding these end-points relate to those workers who may be required to use the

more concentrated form of the preservative e.g. during the manufacture of the preservatives initially or during the production of the paint, whereby the concentrated preservative is being handled/added to the paint product. Such workers can work safely with these substances and products subject to adequate risk assessment and controls being implemented, together with training, monitoring and supervision at the workplace, as required under worker protection legislation.

However given, in particular that paints containing such preservatives are so widely used by all category of workers, including professional workers who may not have received training, or understand or be provided with the necessary controls and protective measures, the risk when using these products can increase, in particular, for effects relating to sensitisation issues where a person can become sensitised (H317/R43) and as such may not be able to work with that product in the future.

It is essential that those at the manufacturing stage of the preservatives and those products containing the preservatives, generate accurate and correct information which then forms the basis for control measures and protection developed and used by downstream users.

For those using paints in remote settings who are not by trade 'painters', then these workers, e.g. caretakers, maintenance persons, general labourer etc, are even less lightly to be fully trained and supervised in the use of paints (as chemical mixtures, containing biocides as a preservative in the mixture). The primary means of getting information to such persons is via the SDS and as such, issues regarding concentration limits and in particular whether a mixture should be classified for endpoints including sensitisation, must be correct and is the responsibility of manufactures to provide updated information, taking account of all their customers downstream, including the smaller users and any foreseeable events/exposure risks to these persons also.

Product Type 8 - Wood Preservatives

This product type covers a wide range of users i.e. Industrial, professional and amateurs. For the purpose of this task (*Task 2 and relevant to Task 4*) the focus will on the professional user outside the Industrial setting. The reason being that when considering potential exposure to professional users, within the industrial setting there must exist a formal structure and organisation within the plant, which should ensure that the requirements of the worker protection legislation is being implemented fully. Such factory/industrial sites will be subject to inspections by national enforcement agency inspectorates. As these sites are plants/factories they will have fixed engineering controls and systems of work to provide protection, including such items as spray boxes and fixed splash guards in place. This is not to say that exposure does not occur and/or accidents or events, which can lead to exposure can happen, but only that the mechanism to deal with such events, the level of information/equipment and control measures available on-site and remedial action can be implemented/instigated without delay and to the level required to prevent a worsening/spreading of the event and/or exposure.

For other professional users of wood preservatives this is not always the case. These workers normally apply the products *in situ* for preventive or curative treatment of wood, meaning that they are mobile and work at various locations with these hazardous products.

Uses:
Wood preservatives are used to treat wood either preventively or curatively in order to increase the durability and life-time of the wood. To this end therefore wood

preservatives can act to prevent/retard the biological degradation by fungi, bacteria and/or wood-boring insects or can be used to remedy infestations once they have occurred/been identified.

The selection of a particular wood preservative by a professional user will depend on issues such as, the end-use of the treated wood, the nature of the biological hazard, the anticipated service life of the wood, and any other actions which may need to be performed to the wood after treatment e.g. painting. The range of wood in question can include, fence, post or poles, wooden frames, roof timbers, house foundation treatment, etc. The techniques employed by professional users to apply wood preservatives can include, spraying, injection, brushing, wrapping, foundation treatment, and fumigation. Note fumigation is a very specific activity and usually employed by trained contractors who specialise in this type of work, with very specific methodologies and requirements associated with the operation, including control measures relating to during and after the application i.e. before the premises, area is/can be returned to 'normal use'.

Wood preservatives are mixtures containing at least one active ingredient, which is the component which specifically had the biocidal property thus making the wood preservative effective for its intended purpose. As with other biocidal products, adequate protection of the users should exposure occur, relates to all the hazardous ingredients in the product and the percentage present, knowing that this can lead to overall classification of the wood preservative product and as such determine the level and what control measures and protection must be taken to ensure safe usage.

Composition (typical) including active(s):

[Relating to common wood preservative products which can be procured by professional users at building suppliers and hardware outlets]

- **Permethrin:** CAS No. 52645-53-1; EC No. 258-067-9; EU Index No. 613-058-00-2 (has Harmonised classification which is mandatory); Is present in wood preservative products at ca <1%.
- **Propiconazole:** CAS No. 60207-90-1; EC No. 262-104-4; EU Index No. 613-205-00-0 (has a Harmonised classification which is mandatory). Generally present in wood preservatives at ca <1%.

One wood preservative product identified is used/produced for professional users including brushing, coarse spray or dipping, contains upto 5% permethrin and ca 5.5% propiconazole etc and is classified accordingly, taking note of the risk of serious damage to eyes and its sensitisation property/effects.

(a) Permethrin (an active ingredient in wood preservative product):
Permethrin is an effective insecticide which is used to control various wood destroying insects, during larval and/or adult stages of their life-cycle. Permethrin, like all synthetic pyrethroids, kills insects by strongly exciting the nervous system. It acts by contact and ingestion by the insect. Permethrin is particularly effective against all wood boring insects and termites.

While permethrin is a hazardous substance, it is generally present in low quantities i.e. <1%, and so, when wood preservative products are used correctly, taking account of all controls measures and protective measures recommended, this active should not cause a risk of harm should exposure to the user occur.

It should be noted that in March 2014, the EU Biocidal Products Committee adopted its opinion on the approval of Permethrin as an active substance used in Product Type 8 biocides, in accordance with Article 89(1) of Regulation (EU) 528/2012 (BRP).

The EU recommendation is that Permethrin is classified as a skin sensitizer (under CLP Cat 1B). According to CLP for mixtures containing permethrin: permethrin when present at 1% or more in a product then the product should be classified as a skin sensitizer. Additionally, for already sensitized individuals, if the substance is present at a concentration of 0.1% or more in the product an SDS must be provided.

Issues arising regarding the presence of Permethrin:
Having examined a number of SDSs commonly used by professional users outside the industrial environment the classifications varies, and so the control measures and understanding of the level of concern and ensuing protection will also vary.

One producer, producing three versions of a wood preservative product, containing the same ingredients/active at the same concentrations, listed a different classification for the permethrin active and only two of the three referred to the potential for the product to produce an allergic reaction (based on the concentration of the actives, even though these were the same in all three products).

Additionally some SDSs failed to include the CLP classification for this substance within the product SDS even though CLP classifications must apply to substances since 2010.

Lastly some SDSs provided incomplete classification for permethrin, while others failed to identify the EC No. and very few acknowledged the EU Index No. which provides the mandatory/harmonised classification requirements.

Commonly used wood preservative products which are solvent based and contain permethrin can have between 50-100% Naphtha (white spirit). While white spirit is not an active ingredient it is a very hazardous component, which can, on repeated exposure, cause skin dryness or cracking to the skin. This effect can therefore lead potentially to an increased risk to skin as a potential route of exposure for the product.

Professional Uses (outside the Industrial setting) include:
Professional users will normally use, brushing, spraying, dipping or soaking to apply wood preservatives *in-situ*. While these persons are professional users they work at locations which can vary and will not have the fixed protection and/or containment measures nor fixed engineering controls which exist in the industrial setting.

For this reason they will need to depend and determine the control measures necessary based on the information supplied to them via the relevant SDS. Where this information is incomplete, not accurate/incorrect or there is insufficient detail included then the control measures required may not be implemented and the professional user can be at risk from potential exposure to the product.

For example where a professional is treating wood at a remote location using a spraying technique there exists the risk of exposure via aspiration of droplets of the liquid wood preservative and of contact to skin and eyes. Therefore it is essential that these possible routes of exposure are protected using suitable and appropriate PPE.

Health effects associated with wood preservatives:
- Repeated exposure may cause skin dryness or cracking;
- Harmful and may cause lung damage if swallowed;
- May produce an allergic reaction;
- Is flammable

Additionally in high concentrations/high level of exposure:
- vapours and spray mists can be narcotic, may cause headache, fatigue, dizziness and nausea;
- There is the possible risk of serious damage to eyes;

- Vapours/aerosol spray may irritate the respiratory system;
- Droplets of product aspirated into the lungs through ingestion or vomiting may cause a serious chemical pneumonia.

Issues which contribute to exposure to professional users:
The importance of the SDS must be continuously emphasised as this is the information on which professional workers depend and use to determine the most appropriate and suitable level of protection they require in order to work safely with these products.

Likewise it is essential that the requirements/responsibilities/obligations set out in the relevant worker protection legislation, particularly the Chemical Agents Directive 98/24/EC are implemented and complied with, including workers' obligations to protect themselves and others who may be adversely affected by their work activities. This includes activity based risk assessment, correct operating procedures etc.

As above:
- Workers must trained, instructed, supervised and provided with sufficient and correct information;
- Workers must be provided with the necessary PPE as per the SDS and based on the risk assessment;
- PPE must be stored, cleaned and maintained properly and in accordance with manufacturers' instructions;
- Workers must understand the information and training provided;
- Workers must use (correctly) the PPE provided;

(b) Creosote (CAS No. 8001-58-9; EC No. 232-287-5)**:**
Creosote is the general name given to a mixture which can contain numerous components. Creosote prepared from coal tar is the most common form of creosote used in the workplace as a wood preservative. It is used as a fungicide, insecticide, miticide and sporicide to protect wood and increase the life expectancy of wood compared to untreated wood.

Most of the creosote used is applied via pressure impregnation of the wood. However creosote can also be applied by professional users via, dipping, deluging, spraying or brushing.

While creosote is a complex mixture, based on the potential severity of health effects associated with the components of creosote, it, as a product, is classified within the EU as a carcinogen, and restrictions regarding the placing and use on/in the market of creosote are in force. These restrictions are intended to limited the risk of exposure, uncontrolled usage, protect the general public (including DIY persons) and ensure those (professionals) using creosote do so in a safe manner.

Restrictions:
The restrictions originally introduced under the scope of the Marketing and Use Directive (76/769/EEC), are now imposed under the REACH Regulation (EC) No. 1907/2006 (Annex XVII).

The restrictions prohibit the use and sale of creosote to amateur users, general public, and DIY users, and limits its use for retreatment purposes *in situ* by professional users, based on the concentration of benzo[a]pyrene and water extractable phenols present in the product.

In effect therefore creosote can mainly be used only for wood treatment in industrial settings or by professionals *in situ*.

Regarding placing on the market, treated wood can only be used for specific purposes by professional users and industrial use, for example, in electric power transmission and telecommunications, for fencing, for agricultural purposes and in harbours and waterways. However this limitation does not cover the placing on the market of second-hand treated wood for re-use, subject to the restrictions for their use at specific locations or for specific uses, e.g. inside buildings, toys, playgrounds, parks, outdoor leisure facilities, etc.

Therefore even with the restrictions imposed within the EU there is potential for professional users to be exposed to creosote when performing various treatment and retreatment work activities. In particular there is the potential for exposures to occur when professional users are working *in situ*, should they not be informed/understand the risks, where they do not have an adequate risk assessment specifying the control measures and protection required to ensure they are safe while performing their work.

Note: *Creosote the product also has an EU classification i.e. (harmonised) Cat 2 carc; R45 (under CLP would be Carc. 1B; H350.*

Health effects:
Chronic exposure to vapours can cause lung irritation.
Repeated exposure to small doses over time can cause blistering, peeling or reddening of the skin, through irritation, damage to the eyes, and/or an increased sensitivity to sunlight.
Via ingestion can get burning in the mouth and throat and stomach pains.
Accidental ingestion of large amounts could result in bad skin rash, eye burns, convulsions, kidney or liver problems, unconsciousness or death.
Chronic exposure, in particular via skin, can cause cancer.

Issues arising regarding this product:
The difficulties arising and where there exists the potential for exposure to professional workers, relate mainly to the location, duration, frequency of use, together with the problems identified regarding an adequate risk assessment and implementation of the required control measures and protection against exposure.

As above an adequate risk assessment and the ensuing determination of the control measures required to protect the professional user is dependent on the information provided to the users from the producer of the creosote product, in particular the relevant SDS and label on the product. Therefore where this information is faulty, inadequate, not correct or lacking in sufficient detail, then the risk of exposure increases for the professional user.

This risk of exposure is further exacerbated when the professional worker:

- Is working *in situ*;
- Does not have the SDS;
- Does not understand the SDS;
- Does have the correct PPE etc;
- Does not have any standard operating procedures for doing the task;
- Does not know what to do should exposure occur;
- Has not received any information, training, instruction in working with creosote as a hazardous product;
- Is not supervised and/or monitored to ensure the professional user is doing the work safely and in accordance with the risk assessment and any additional recommendations relating to the safe use of this product.

Issues re SDS for creosote:
As stated the SDS is vital as a means to communicate information about the product and any hazardous properties or potential adverse effects which could arise should exposure

occur to those using the product, including sufficient and correct information regarding the handling/storage/use/control measures/PPE (RPE), disposal requirements etc.

A selection of SDSs were examined and inconsistencies were found regarding the information and details provided regarding the classification of the components in creosote and creosote itself as a wood preservative product.

It is noted that some producers have classified the product as a category 1 carcinogen, while the EU harmonised classification lists it as a Cat 2 carcinogen. Similarly for various other end-points there is a stricter classification applied. However for mixtures a producer must self-classify his product and in so doing inconsistencies can arise whereby some manufacturers may over classify so as to err on the side of caution. The difficulty arising then however is that the downstream professional must use this information to determine his risk assessment and how to work with the substance safely. Such variances could therefore lead to different assessment outcomes and the use of different control measures etc.

As before these SDSs failed to list the CLP classification for each individual component (as substances). Also did not include the EU Index No which would indicate/provide the harmonised classification for the substance/ingredient in question - both in its former and current CLP format).

***Note**: As creosote the mixture has an EU classification for carcinogenicity i.e. under CLP Cat 1B carc; H350 or formerly Cat 2 carc R45, not only does the Chemical Agents Directive (98/24/EC) apply but also the more stringent Carcinogens Directive (2004/37/EC). This Directive requires the control measures to be **so far as is technically possible** which requires control measures to be used which might not have been proportional to the risk should the exposure relate to a hazardous chemical agent but not a carcinogen. As with the Chemical Agents these legislative responsibilities apply to all workers and professional users whether they work at or in an industrial installation or plant or in a remote and/or temporary location. The level of control required under the carcinogens directive would be almost impossible to implement/comply with fully regarding engineering controls etc for most of the operations and work activities performed by professional users working in situ.*

Product Type 9 - Fibre, leather, rubber and polymerised materials Preservatives

This PT relates to biocides added to products or materials used to make end products for the purpose of preservation of either fibrous or polymerised materials e.g. leather, rubber, paper or textiles, in order to control the possibility of microbial deterioration. When considering the risks from potential exposure to professional users regarding this product type then the primary risk relates to the points at which the preservatives are added during the initial production of materials and/or during the production of products made from these materials which then contain the added preservative/biocide. The biocides in question are added to the paper, fabrics, textiles or leather at production stage and so those workers must and should be protected when all required worker protection legislation, risk assessments, correct operation procedures are used/implemented together with the required control and protective measures.

However the risk to those professional users using end products containing preservatives is much reduced and would depend on the process/pattern of use, together with the duration and frequency of use/contact, with the material. The percentage of preservative can range between 0.5 - 1.5% by weight of the material to be protected. However preservatives can also be applied to the surface of a material e.g. floor tiles, by adding the preservative to a mix or solvent solution and using application methods

including dipping/spraying/brushing. These handling techniques could lead therefore to a higher level of exposure including direct skin contact from splashes and/or aerosol generation.

Typical (Active) Ingredient:

- **2-Octyl-isothialine (OIT):** CAS No. 26530-20-1; EC No. 247-761-7. Present in products between 0.5 and 2.5%.

OIT - Is used as a preservative in various household products including paints, carpets backings, vinyl floors, mattress covers, rubber/polymer products, foams, adhesives, textiles and leather.

- **Propiconazole:** CAS No. 60207-90-1; EC No. 262-104-4; EU Index No. 613-205-00-0. Present in biocidal product at upto 20-30%

Propiconazole - is used as a preservative for polymerised materials in particular in vinyl floor tiles.

Normally these biocidal products are added at the manufacturing/formulation stage and as such are present in a mixture. Therefore the risk of exposure to workers will relate to the percentage of the active present in the mixture/product.

Health - the primary route of exposure to these actives is via the dermal route e.g. skin corrosion (OIT as a substance) and skin sensitisation (OIT & Propiconazole).

Exposure:

The greater risks from exposure to workers may occur in workplaces/industry where these products are manufactured or formulated (used), noting that these biocidal products are added at the stage of producing the final materials. Such professional users/workers are therefore working within an environment which must comply with and implement the requirements of worker protection legislation together with the specifics as required under the Chemical Agents legislation, including the need for risk assessment, provision of information, provision of adequate and appropriate control measures, training and supervision of the workers involved etc.

Regarding those workers who handle and use the biocidal products (which can contain upto ca 25% of the actives) the information supplied by the manufacture is vital and must be recent and accurate, in particular relating to the identification and classification of any potentially hazardous inherent properties of the biocidal product. It is noted that the relevant SDSs require consideration regarding the CLP Regulation whereby changes may be required which can affect the overall classification of the product. Under CLP mixtures containing greater than 0.1% of a sensitiser will require the mixture to be classified for sensitisation and, as such, may impact on the other information provided in the SDS and relied upon by the professional users of these products, including the level of control and protection they must take.

With respect to those professional workers using the end materials, which have had the biocidal product added during manufacture, the risk from exposure to the actives is reduced, based on the final quantity actually present in the material, and will depend on the operating procedures being used by those professional workers. Generally good hygiene practices, dermal protection and good ventilation etc taking account of manufacturer's instructions, should ensure that these users are protected. However as mentioned, the SDS will need to be re-examined based on CLP for Mixtures (2015) and may cause the mixture to be re-classified which can cause a need to revise the information provided to downstream users. Additionally the work performed by these workers e.g. laying vinyl floor covering etc are often performed by small and/or self-employed contractors who, while trained in the task, may not be trained and/or

understand the risks associated with exposure/SDS/control measures and adequate protection for themselves and others based on these risks.

Product Type 10 - Construction material Preservatives

There are four primary ways in which professional users could potentially be exposed to biocides which are added or used as preservatives for construction materials, i.e. PT 10. However it should be noted that depending on when and how the masonry/construction materials are being treated with such preservatives, could influence whether the product/preservative in question belongs to PT 7 (film preservatives) or PT 10, or both PTs. Therefore depending on which scenario is being considered will affect the potential level of exposure which can occur when these materials are used/handled by professional users.

Preservatives are added to concrete to protect them against infection by microorganisms during storage thus ensuring the quality and functionality of liquid additives until their final use in concrete. Preservative preparations generally belong to the following groups, e.g. compounds that give off formaldehyde, isothiazolinone/benzisothiazolinone, bronopol, and phenolic compounds. Oftentimes products contain a combination of these basic substances so as to optimise the efficacy of the biocidal product.

Potential for Exposure:

(I) Preservatives added at final product manufacture/formulation (admixtures)

(a) The manufacture of products/preservatives in an industrial setting, for use downstream on or in construction materials, whereby these products are in their concentrated form i.e. pre-dilution and pre-addition to final product. As this workplace is at the industrial level, in a fixed setting, the requirements and associated controls and level of protection of the workers are and must be implemented by employers, and in accordance with the requisite worker protection legislation, in particular, taking account of the requirements and controls of the Chemical Agents Directive 98/24/EC, together with adequate supervision, monitoring of the work and workplace, and the provision of relevant and appropriate training, information and instruction. In this case where workers are trained and implement all required control and preventive measures, the risk to the health from possible exposure should be minimal.

(b) The second level of professional users who could potentially be exposed to these biocidal preservative relate to those persons adding the admixtures (containing the biocidal active components) to the mortar/concrete/cement. These workers as above must also be fully trained and supervised.

Additionally there are the professional users who pour concrete etc on-site which contain the biocidal preservative and are primarily part of the construction industry sector. However given the nature of the work and the possibility of mobile site work etc the level of control and protection must be closely monitored to ensure that all worker protection measures are being implemented whether at the base plant or at a remote site. The onus of responsibility remains with the employer to protect all his employees, including the need to prevent exposure to hazardous chemical agents and mixtures while performing a work activity irrespective of site/location. This includes the provision of upto date information, and following/understanding and implementing the requirements set down in valid safety data sheets and any additional information supplied from

producers/manufactures of products being used. While the site/workplace in question for this scenario may vary, including conditions and climatic variances etc the level of protection as required by the worker protection must be implemented, including the provision of information, training and instruction. In theory these workers should not be at a higher risk of exposure that those in (a) but in reality, the risk can be increased due to the nature of the work, the workers involved and the removed location where conditions on site may vary from site to site.

(c) This scenario relates to those professional users who are self-employed or maintenance/repair type users. The amount of construction materials being used will generally be of lower quantity and can be purchased/used as ready mixes, thus avoiding the need to add preservatives before application. This being the case their risk of exposure should be greatly reduced and by following best practice and using suitable control measures including hygiene and personal protective equipment, such users should be able to work with these materials in a safe manner.

(II) Surface application, masonry cleaners etc

(d) This final group of workers are possibly the ones who could be most at risk from exposure to the biocidal preservative for construction materials. The reason for the higher risk relates to the application method of such preservatives, whereby in this scenario, they are applied to the surface of the construction materials rather than added to concrete etc mixture. The method of application can be spraying, brushing, using roller or in some cases wetting the surface material. Work can be performed on tiles, roofs, walls, patios. It can be done both internally and externally in buildings. Such work can be performed by specialist contractors, whose workers will be trained and must be supplied with all necessary information and the requisite control and protection measures, to ensure they are not at risk from exposure while doing this work. However additionally, the same work, using the same products, the same methods of application but on a smaller scale, can be performed by professional users who are possibly not trained/work alone, are self-employed etc and so are at a higher risk of exposure to these products.

Relating to the above four scenarios it is those working at (d) that potentially are at increased risk, particularly if not trained or provided with adequate preventive measures. As with all the PTs to-date the information coming to the downstream user is critical as this is what will form the basis of protection for these users when handling the chemicals in question.

Concerns arose here where it proved to be very difficult to locate the required SDS in some cases, and those relating to the construction materials, provided little or no information regarding the add mixtures (regarding biocidal preservatives).

For masonry cleaning products the SDSs were more readily available and accessible. Some of the active components that are present can be corrosive, irritating to the eye/skin and/or respiratory tract. As it is used as a liquid the risk of exposure to the eyes/nose/skin/mucous membranes in general and to breathing by the worker is high and must be adequately protected against. The risk increases for those workers who are not trained, do not have an understanding of safe systems of work, are not provided with the SDSs and are not provided with or use the proper control and protective measures required when working with such a hazardous mixtures.

Examples of Common Active

- **Tebuconazole** (CAS: 107534-96-3; EC 403-640-2)

General comments on Exposure Risk:

When considering these biocidal preservatives added to a product or add mix then the risk is controllable and should be minimal to the professional worker subject to the complete requirement of worker protection are implemented. However when dealing with the concentrated product initially consideration must be given to the category of worker performing this task and the location of where the task is being performed.

Where the users are within an industrial context and trained or where the workers are fully trained construction workers the risk is controlled and therefore reduced. However within the construction sector there are workers who can be casually employed/unskilled labourers. For these professional users (using the products for work activities) it is essential that they also are fully protected and aware of the risks associated with exposure, in particular where they are required to directly handle the product and/or perform and follow directions regarding dilution etc.

Likewise in the construction sector, there can be various sub-contractors employed and it is necessary to ensure that these professional workers are protected equally and provided with the necessary controls, information and protective equipment, while they are using these chemicals.

Other than for toxic washes and surface solutions, in my opinion the quality and acquisition of specific information regarding the biocidal components proved quite onerous, with many of the manufactures requiring the user to make specific contact in order to get this type/level of information. While this route can work, taking into account the range of workers who fit the category of professional users, this option in my opinion will not always be followed and so this information will not be acquired prior to using the products in question.

Product Type 11 - Preservatives for Liquid-cooling and Processing Systems

This PT includes biocidal products used as preservatives of waters and other liquids in cooling and processing systems to control harmful organisms and biological growth, including bacteria, algae, protozoa etc. The process and method of cooling water is also a perfect environment for the growth of microorganisms which can cause problems including an increased risk of legionella, biofilms, accelerate corrosion and can reduce the efficiency of heat exchange. For these reasons it is essential that liquid cooling systems are treated (with biocidal products) in order to reduce and control the growth of unwanted microorganism. Very severe cases of microorganism contamination if untreated can result in complete failure of the cooling system.

The successful use of biocidal products in liquid cooling systems relies on dosing the system with a predetermined dose or quantity of the biocide, for an appropriate duration, with the need to repeat the process over time. The most commonly used biocides belong to two major category of chemicals i.e. (a) Oxidising and (b) non-oxidising substances.

(a) Oxidising biocides: Chlorine is an example of an oxidising biocide. It is a hazardous substance but also is one of the most cost effective products available. Oxidising products can cause a decrease in the PH of the water being cooled, while chlorine is ineffective at a PH of 7.5 or above. Most oxidising products will increase the corrosivity of the cooling water. Additionally oxidising biocides do not have the ability to disperse i.e. aid in the removal of dead microbiological growth.

(b) Non-oxidising biocides: These biocides work by interfering with the metabolism of the organism and thus kills the organism. However there is a specificity associated with these products meaning that organisms are affected differently by these

products and so those less or unaffected by the product will replace those killed by a single dose of the product. For this reason therefore usually more than one product is used or used alternatively with an oxidising product. Non-oxidising product are generally more costly due to requiring higher dose for effectiveness and the longer duration contact time needed. 2,2 Dibromo-3-nitrilopropionamide (DBNPA) is an example of a non-oxidising biocide used in liquid cooling systems.

Typical Actives/biocidal substance:

- **Chlorine:** CAS No.: 7782-50-5; EC No.: 231-959-5. EU Index No. 017-001-00-7, with an EU harmonised classification assigned. Present approx. 99%.

Non-oxidising

- **2,2-Dibromo-3-nitrilopropionamide (DBNPA):** CAS No.: 10222-01-2; EC No.: 233-539-7. Present in product at 20-25%.

Risk of Exposure:

Chlorine is a very hazardous substance which can be used/handled in gaseous, liquid or solid (tablet) form. The risk of exposure increases depending on the physical form of the substance being used, with the gaseous form being the most hazardous form. High levels/concentrations of gas can cause an oxygen deficient atmosphere. As Chlorine is an oxidiser it can initiate and sustain the combustion of flammable materials in its vicinity. Also as chlorine is heavier than air means that pockets of chlorine gas can linger and/or accumulate in a workplace at low level.
Chlorine is an skin and eye irritant. It can burn the skin and eyes also. Most importantly Chlorine gas, when inhaled can be fatal, including burning of lungs and pulmonary oedema and at lower levels will cause coughing respiratory irritancy and possible chest pain.

The production of chlorine at the manufacturing/industrial level must be closely monitored and must be controlled to protect the workers. Those working in this environment must be fully trained, supervised and protected against potential exposure to chlorine, including the possibility of emergencies arising. Risk assessment and appropriate control measures must be performed and implemented at all times for all workers concerned. Workers must be trained and provided with all necessary information, protective equipment and training in its usage, including the ability to recognised changes in the operation which could indicate a release of the substance.

Chlorine is used commonly in water/liquid processing systems. It is generally transported in a closed environment and must be stored in a dedicated and well ventilated area on-site, which is equipped with suitable alarms etc. Chlorine used on site e.g. a municipal water premises, must only be handled by fully trained operatives who must be supervised while performing work activities involving the use of chlorine. Generally it is applied on a continuous basis using specific equipment/dosing appliances, whereby splashes etc should be reducing and avoided, subject to adequate training and the use of accepted and safe operating procedures.

Concentrated chlorine (either as a gas or liquid) would not usually be used by smaller untrained professional workers. For the larger industrial setting workers, however, where possible, use of chlorine in its gaseous state should be avoided where possible and practical.

DBNPA is the active ingredient used in a biocidal product at ca 20-25% concentration. Biocidal products containing DBNPA at ca 25% are classified as harmful if swallowed, risk of serious damage to eyes, and may cause skin sensitisation. It is produced for industrial usage and must be formulated into a liquid concentrate or can be used in powder form or as time-release as tablets. While the higher risk of exposure relates to the actual industrial manufacture of this product, risk can arise during the handling and

use of the material i.e. the formulation and dilution and application of the material. Therefore as with all hazardous chemicals, the SDS recommendations and information must be valid, up-to-date and implemented by workers. Thorough training and site supervision must be implemented at such places of work. These products are generally not available to consumers and would be more difficult also for small self-employed workers to obtain.

Note: the SDSs for DBNPA as an ingredient in various biocidal products reviewed varied in quality and standard and so the information between SDSs were inconsistent etc. This fact makes it very difficult for the smaller possibly untrained professional user to ensure he is being fully and appropriately protected against possible exposure. The responsibility to provide correct and adequate information rests with the supplier/manufacturer of the substance initially and then the producer of the product incorporating the component. Manufacturers of ingredients must be aware of the products their customers are producing using their substances and ensure that their substances are being correctly represented via labelling and classification downstream.

Product Type 12 - Slimicides

Slimicides are products with biocidal capacity and are used to control and kill slime-forming microorganisms in a range of industrial processes including wood, paper and oil processing. Slimicides can be liquid or powder and can be applied on a remote feed basis (pump or drip feed) or involve more direct contact with users where the application requires e.g. dipping/spraying/brushing/wiping/soaking or in any other means used to ensure the surface of the structure is adequately wetted with the slimicides, including consideration of the required duration of contact with the product and the correct concentration of the product in order to achieve positive action. However these points and consideration also can contribute to the potential increased risk to professional user should contact/exposure occur during these activities.

Anti-slime agents (slimicides) can include chemicals types such as organic sulphur, bromium and quaternary ammonium compounds and/or aldehydes.

Slimicides are used in the treatment of industrial and process water, paper industry, in photographic wash water/other process fluids, in fuel/oil storage tanks etc.

For the purpose of an overview of PT12 the following two actives were examined, noting the percentage/concentration of these actives that can be present in the products and the potential health effects which could occur if workers are exposed.

Actives:

- **Bronopol:** CAS No.: 52-51-7; EC No.: 200-143-0. Present in product at 9-11% concentration.
- **Glutaraldehyde:** CAS No.: 111-30-8; EC No.: 203-856-5. EU Index No. 605-022-00-X, with an EU harmonised classification assigned. Present in product at 10-50%.

Risk of Exposure:

The nature and pattern of use of slimicides relates primarily to industrial and larger fixed workplaces and as such workers must be fully protected in accordance with relevant workplace legislation and in particular with respect to the chemical agents requirements including adequate risk assessment, the provision of appropriate and suitable control measures and associated protective equipment and where necessary respiratory protection. Additionally these professional users must be provided with information, training and supervision, including monitoring where appropriate.

The protection of workers/professional users of biocides must be provided with upto-date information disseminated via the relevant safety data sheet, which forms the basis of site specific risk assessment and contribute to the assigned control measures and means of protecting the users from exposure and thus ensuring the risk of exposure is kept to a minimum and is controlled.

Slimicides are mainly used for larger processes in a controlled environment. However where there is the need and use of these products by other professionals on a smaller scale and potentially in a remote environment by users who are not fully trained or supervised and/or who may not fully appreciate the risks associated with exposure, then additional consideration must be given to these professionals to ensure they are not at increased risk should exposure occur.

Glutaraldehyde
When slimicides (containing glutaraldehyde) are used in water processing, the solution can be added in pellets either manually or using automatic dosing equipment thus reducing the risk of exposure. Also for off-shore operations the solution is generally added using an automatic pumping system thus avoiding potential contact/exposure for this task. Likewise in the paper and pulp industry the solution is added using pellets and automatic dosing equipment.

However there are patterns of use involving smaller quantities being added to washes etc where exposure and contact can occur.

SDS & CLP & Slimicides
As with previous biocidal products I have noted some inconsistencies and inaccuracies in the quality of the SDSs available, together with the classification and format of the SDSs being provided.

In particular for glutaraldehyde, as a component of slimicide products, it should be noted that while this substance currently has a harmonised EU classification which is mandatory, its classification has been assessed at EU level (June 2014) and is revised. The changes to the classification for glutaraldehyde will impact and require all slimicide products with glutaraldehyde to be reconsidered and amended as necessary. These changes include a stricter/more sever classification regarding respiratory sensitisation, corrosivity (including respiratory tract), contact with skin, toxicity etc. Attention should be given to changes in concentration limits also as this will impact on product/mixture containing glutaraldehyde.

This RAC revised harmonised classification and labelling for glutaraldehyde was adopted and will become the entry in Annex VI (CLP Regulation) subject to agreement i.e. will become mandatory.

Product Type 13 - Working or cutting fluid preservatives

Industrial processes depend on and require activities such as grinding, cutting or boring etc of metal and other materials. The equipment requiring cutting fluids include items such as lathes, milling machines, saws, gear-cutting machines, grinding wheels etc. The primary function of working or cutting fluids in this capacity are to cool and provide lubrication during the activity. The benefits of using cutting fluids include extending the life of the tools or grinding wheels being used as well as ensuring a better finish on the material being cut due to the fluid assisting in friction reduction at the point of contact. Additionally the cutting fluids help to remove the swarf/particles from the cutting zone and assists in the reduction of particulate waste which can potentially become airborne.

Cutting fluids that contain water may be spoiled by bacteria and/or fungi and so biocidal preservatives when added to the fluids protect the fluids from microbial attack either through elimination and exclusion of the micro-organisms or more realistically by reducing the level of microbial presence to avoid them being the cause of deleterious effects.

In particular micro-organisms can spoil metal working fluids (MWFs), for example as free living organisms in the water phase and metabolise compounds that migrate from the oil phase. Additionally biofilms can develop on the surface of the fluid, in particular given that these fluids are held in sumps, tanks, vats etc. The open nature of these storage tanks provide an ideal opportunity for microbial contamination.

Common Actives that can be present MWFs:

- **Sodium pyrithione:** CAS No. 3811-73-2; EC No.: 223-296-5. Present in the product at 40-50%.
- **2-Bromo-2-nitropropane-1,3-diol:** CAS No.: 52-51-7; EC No.: 200-143-0. Present in products upto 30%.

Both these actives are classified and can cause adverse health effects in operatives should exposure occur. In particular the effects relate to serious eye damage and irritation, harmful if swallowed, and skin and respiratory irritation.

Risk of Exposure:

There is a high risk of potential exposure of professional users to these cutting fluids, including any biocidal preservatives added to the fluids. However the risk will be dependent of whether the biocide is (a) added to coolant formulation initially thus functioning as an in-container preservative in the fluid which in effect reduces the need to handle the concentrated biocide at the end-site i.e. location where the activity requiring the coolant/cutting fluid is being used, or (b) biocidal product is added at the end-site, which can provide more immediate remediation, and allows for the biocide selection, quantity can be adjusted as required, but also requires the concentrated product to be present, stored and handled on-site by workers.

Additionally the risk of exposure will depend on how the biocide is added to the fluid e.g. using a pump or other metering device (automated or semi-automated) thus reducing potential contact points with operatives or if it manually dispersed by the operative. Regarding the latter method of addition, this requires the professional user to be fully trained and protected, including the provision of information, training and supervision together with adequate controls measures etc in accordance with EU worker protection legislation.

Obviously there is the potential for exposure to workers during the manufacture and formulation of these products but as with any hazardous chemical the controls and requirements are already in place through chemical/worker protection legislation and so like other hazardous chemicals, if implemented fully and appropriately on-site, including control, protection and preventive measures, these workers can work safely with the products.

Those users who use biocidal preservative on site (industrial and engineering sector) can be at higher risk depending on the nature addition of the preservative (which can contain high percentage of hazardous active, but also, due to the nature of storage of the fluids containing the preservatives. Open tanks and storage vessels, in close proximity to the work being performed, containing these products which are then added via a pump or line or manually can lead to exposure to the mixture. While the actual final concentration of preservative mixed with the fluid is small i.e. diluted to ca 4% concentration, given the inherent toxicological properties of some of the actives, then contact with the fluid

could potentially cause adverse effects, in particular, where the fluid are dispersed and can be inhaled, aspirated or come in contact with skin, eye and mucous membranes. Similar to those manufacturing and formulating the biocidal preservatives there currently exists adequate controls and requirements to ensure that workers are protected against such events. However this is always subject to those requirements being implemented and monitored on-site with the assurance that workers using these products are aware of the risks and the need to use protective measures always.

Regarding those professional users, who may be self-employed, not trained or not fully compliant/knowledgeable with respect worker protection legislation, chemical agents exposure, etc and who may not have received specific training or instruction, for this PT, they would not be deemed to be at high risk. The reasons for this assumption relate to the fact that where such workers use or do the tasks which may require coolant/lubrication fluids, these fluids would not be from a storage tank, of large quantity and where biocidal preservative are present in the fluid these would more than likely have been added at the formulation stage. In order therefore to control any residual risk from exposure to the fluids with potentially diluted preservative present, good hygiene practices, together with appropriate personal protective measures and precautions, in accordance with any instructions provided and the valid SDS would be sufficient to ensure safe work.

Similarly within the agriculture sector, farmers may use these fluids when performing certain activities. If the farm is a large enterprise or factory type workplace then the workers will be similar to those from an industrial engineering setting. For small farms/self-employed person these users will be analogous to those non-trained workers and use the fluids in small quantities with already added preservatives rather than accessing them from large storage vessels, thus reducing the risk of exposure.

Product Type 14 - Rodenticides

Rodents can carry diseases, cause damage to buildings, and spoil foodstuffs. Rodenticides are products used to control/kill rodents in particular referencing mice and rats but can be effective for other rodent species. The use of rodenticides covers many sectors and premises and are used by a variety of persons, trained and untrained, amateur and/or professional, dependent on where the infestation occurs, e.g. industrial settings/factories, farm/agricultural premises (large and small), Sewers/waste/landfill and other municipal type premises, private homes, schools, outdoor facilities/parks/golf courses etc.

Depending on the premises and size of infestation, rodenticides might be used infrequently e.g. home setting or school or on a regular planned campaign (generally for the larger industrial workplaces etc). However in general rodenticides are not used in a preventive manner but rather when the rodents are present and/or causing problems/damage.

Rodenticides come in various formats and/or formulations, e.g. pellets, loose grain based/baits, wax blocks, gels or pastes. Most come in a ready-to-use state. However what does vary is the quantity of rodenticide potentially be handled by the user, together with whether or not the 'bait' is in a container or requires placement in a container or spreading/placement on the desired location.

The active ingredients of rodenticides are extremely hazardous and by virtue of their function as a rodenticides, their mechanism/mode of action can also have potential to cause serious damage to humans. This being said however the amount of active

present in the rodenticide product is extremely 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, with the risk from potential exposure kept to a minimum.
The targeted route of concern in this case for these products is the oral route followed by skin and inhalation. This relates to the fact that the rodents mostly are required to eat/swallow the bait/rodenticide available. The active components can be very toxic or toxic via this oral route so that following ingestion the effect is systemically transmitted throughout the body for maximum effect. For workers the risk of exposure through the oral route is far less than via the skin or inhalatory routes and if all potential routes of exposure at a workplace are implemented the risk can be fully controlled subject to good hygiene measures and supervision together with adequate separation of eating/drinking/etc areas from the chemical handling/processing locations.

Rodenticides are classified into two distinct groups:
(a) Anticoagulants - cause thinning of the blood, leading to haemorrhaging and death, and
(b) Non - anticoagulants - basically products which do not have the ability to causes anticoagulation i.e. 'others'.

Common Actives:

(i) Anticoagulant products can contain:

- **Brodifacoum:** CAS No.: 56073-10-0; EC No. 259-980-5. EU Index No. 607-172-00-1, with an EU harmonised classification assigned (***See Note 1 below)***. Present in product at 0.005%.
- **Flocoumafen:** CAS No. 90035-08-8; EC No. 421-960-0. EU Index No. 607-375-00-5, with an EU harmonised classification assigned. Present in product at 0.005%.

(ii) ***Non- anticoagulant products can contain:***

- **Alphachloralose:** CAS No. 15879-93-3; EC No.: 240-016-7. EU Index No. 605-013-00-0, with an EU harmonised classification assigned ***(See Note 3 below)***. Present in product at 4 %.

Note 1
The existing EU harmonised classification for Brodifacoum has been reviewed and amended for inclusion in Annex VI, CLP Regulations. The revised classification reads as:
Repr. 1B; H360D *(Repr. Cat. 2; R61)*
Acute Tox. 1; 300 *(T+; R26/27/28; T; R48/23/24/25)*
Acute Tox 1; 310
Acute Tox. 1; 330
STOT RE. 1; H372
Skin Sens 1; H317 *(R43)*
(with specific concentration limits for HH effects)
Aquatic Acute 1; H400 *(N; R50/53)*
Aquatic Chronic 1; H410
M-factor Acute = 10
M-factor Chronic = 10

These amendments to the classification will require the SDS for Brodifacoum to be revised accordingly together with any potential impact it may introduce regarding existing controls. Additionally any SDSs and associated information/instructions currently being provided regarding products containing Brodifacoum will need to be reviewed to ensure that they take

account of this revised classification of effects which could potentially/adversely affect users.

Note 2
The existing EU harmonised classification for Chloralose has been reviewed and amended for inclusion in Annex VI, CLP Regulations. The revised classification reads as:

Acute Tox .4; H302
Acute Tox.4*; H332
STOT SE 3; H336 *(R67)*
Aquatic Acute 1; H400
Aquatic Chronic 1; H410
M-factor Acute = 10
M-factor Chronic = 10
**** = minimum classification***

These amendments to the classification will require the SDS for Chloralose to be revised accordingly together with any potential impact it may introduce regarding existing controls. Additionally any SDSs and associated information/instructions currently being provided regarding products containing Chloralose will need to be reviewed to ensure that they take account of this revised classification of effects which could potentially/adversely affect users.

Risk of Exposure:
Without taking into account any changes to the harmonised classification of these actives, currently manufacturers, formulators and those using rodenticides in an industrial type setting are adequately covered by existing controls and legislative requirements, once these responsibilities and provision are fully implemented on-site and the users receive suitable training/information and instruction and are provided with all necessary protective equipment.

Separate to those who regularly use in-house rodenticides e.g. in factories, they are those professional users who work specifically in the sector dealing with pest control and infestations. These experts can be called upon to come and deal with an infestation either by an employer, a school or recreational facility or by the general public (for private dwellings) etc. However it is noted that farmers are less likely to call in such expertise and will more often than not treat/deal with an infestation personally (probably without any specific training). Irrespective of who makes contact, these professionals specialise in pest/rodent control and as such must be fully trained and knowledgeable about the products they use, including all precautions to be taken to ensure safe handling and placement of baits etc, thus ensuring they and others in the vicinity are not affected by their work activities.

For the smaller and probably untrained professional users and farmers, these persons again are not at high risk once they follow basic best practice, use proper hygiene measures and protective equipment, given that the primary route of concern for PT14 products is ingestion i.e. the oral route. It should be remembered that the major routes of concern for workers are via inhalation and dermal contact. Regarding ingestion as a route of exposure in the workplace this can be eliminated through proper supervision and hygiene measures, together with the strict adherence to segregation of eating/drinking/smoking/applying cosmetic etc from areas where these products are used and the thorough washing of hands.

Note: *A major concern arising with regard to PT14 products relates to potential* ***Accidental Poisonings****. In particular regarding those users within the scope of the*

untrained professional user and farmers. These persons are at a higher risk of not understanding, nor fully complying with instructions , including quantities/type of container type of bait that is most appropriate and location, then once left unattended and/if placed in an incorrect or vulnerable place, there is the risk of others, in particular children coming in contact with the bait unwittingly. Where children/toddlers are concerned, all new objects found on the ground must first be placed in the mouth i.e. ingestion!. While the quantity of toxic active is of a minute percentage, the body weight of child (compared to a 70kg man) and a varying metabolic activity, implies a higher risk of poisoning i.e. serious effect to a child. Also it should be noted that a farm is a workplace, the farmer is the professional user, but this premises is also a home and children have free access to the out-houses, sheds, buildings and surrounds and so can be at high risk if they ingest the product by accident. Under workplace legislation these is a legal obligation to ensure that work activities (including any chemical products, used) should not in any way adversely affect others in the vicinity of the workplace. The term 'other' in this case does not only refer to adult or other workers but to children in the vicinity also.

While existing controls appear to be adequate for all professional subject to these provision and requirements being implemented, there is a gap regarding assurance that the instructions regarding placement and selection of bait containers and indeed which type of bait to use is not so clearly outlined, especially for the smaller/untrained professional user and farmers/janitor/caretakers/handymen etc.

While the SDS is the essential document for the provision of detailed information, for this particular PT (14), it might be possible to take certain elements of the SDS and reproduce these (and their information) in a separate and more comprehensible way for the targeted group who could inadvertently be the cause of accidental poisonings. In order to use the product these users do not need immediately information relating to LD or LC 50s, the level of Tox/Ecotox and Phys/chem data in the SDS. Also the SDS does not focus on pattern of use while this document could include the risks, hazardous properties, effects, essential controls and PPE together with information on placement/quantity/location/container to use and when to retrieve residual/spent bait from an area.

'***Bait must be placed according to product type label and pattern of use, depending on the site and type of infestation arising.***'

Product Type 15 - Avicides

Avicides are biocidal products used in the control of birds (other than by means of repulsion or attraction or by using physical trapping methods). Birds can cause the spread of disease, damage building structures, damage food stuffs, at airports, in factories, cause noise, be aggressive etc thus requiring the need to control their numbers/remove them from the location or certain environments. Problems associated with birds can depend on the species, the number of birds present and their chosen location. Where possible physical methods of control will be used but where impractical or not possible then avicides must be employed. The mode of action of an avicide will depend on the chemical/product elected. The number of avicides available within the EU is relatively limited. Equally the use of avicides must be performed by specialist persons with specific training and licensed.

To this end therefore the use of avicides by the smaller non trained professionals and the general public is not an issue. Where a problem arises with birds persons will and should contact their local authority or a specialist company to arrange removal via the most appropriate method of control.

Some Avicides in Use:

- ***Alphachloralose:* -** This active ingredient is hazardous (see above PT14). For avicidal purpose it is present in the product at upto 2%. It ia generally added to the bait as a powder and mixed with mineral oil so that the product will adhere to the bait and thus be ingested. This product acts as a bird stupefyer, whereby the alphachloralose has narcotic effects on the birds, which can then be re-zoned. By virtue of the nature of using this product, the time required in completing the activity successfully and the need to understand specific concentrations etc this type of avicide can only be used by specialists. ***Note: alphachloralose has been reviewed and as such its classification has been revised for inclusion in Annex VI of the CLP Regulation. To this effect any SDS and other instruction, exposure/protection and control currently in existence should be reviewed and revised where necessary to ensure continued protection of the professional users who handle/use products containing alphachloralose.***

- ***Carbon dioxide: -*** Carbon dioxide is used as a gas for euthanasia of nuisance, where others means of control are not possible or practical and relocation is not a feasible option. It causes respiratory acidosis in target animals, culminating in death. There is no classification of carbon dioxide for human health but it does carry the hazard statement **Pres. Gas H280 (**contains gas under pressure; may explode if heated) on the label. The use of carbon dioxide for this purpose requires specific expertise and equipment and can only be performed by specialists. From a toxicological perspective, assessments have demonstrated that the risk to professional uses are considered to be negligible and this product may be used safely subject to best practice, appropriate precautions and suitable controls being implemented by those workers. Under normal conditions the user should not be required to enter the container or chamber. Should this event arise however then additional precautions, including the use of self-contained breathing apparatus must be implemented based on specific/activity risk assessment. ***Note: the smaller, non-trained user must never be involved in this operation and so is not at risk.***

- ***Paraffin oil mixed with 1-2% formalin -*** this method involves the coating, dipping or spraying of eggs in-situ. The product (egg-oil product) penetrates the egg, preventing the exchange of gases and cause asphyxiation of the embryo. This product is an avicide but in itself is of minimal risk to the user. However again due to the activity required the application of this product is generally performed by those persons who are trained in bird control and should implement best practice in accordance with legislative requirements, and based on risk assessment. The formalin is added to the egg-oil to increase the lifetime of the oil i.e. as a preservative.

Note: Using formalin at upto 2% will need to be reviewed in the light of the proposed EU revision of formaldehyde to include classification as a Cat1 carcinogen, mutagenicity and concentrations limits set for below the 2%.

Product Type 16 - Molluscides, Vermicides, and products to control other Invertebrates

This product type includes mollusicides, vermicides and products for other invertebrates which require control or killing, through the use of biocidal products, due to the destruction these organisms can cause to soil, crops etc. However regarding vermicides

i.e. those products used to specifically target and kill worms, some of their commonest active ingredients are now severely restricted and not readily available. Also there would appear to be a cross-over between some products which technically are PT 18 (insecticides) but which can kill these insects at their larval/pupae/maggot/worm phase of the life cycle. Therefore where these products are used and have affect at this particular point of the life cycle they could *(in my opinion)* be PT16 (vermicides) also. Likewise products which in effect cause the preservation of wood by killing the wood worm present which are infesting and damaging the wood could also be included in PT 16 *(in my opinion)*, where the function of the product is primarily to kill the worms in the wood, thus leading to the secondary effect of preserving the wood e.g. Cuprinol Wood Worm Killer.

Mollusicides act to kill snails and slugs and are used widely in gardening, green facilities and agriculture, which otherwise can damage crops grounds, grass areas, flower beds, green-houses etc. Typically these products are applied as pellets, granular baits, sprays, or dusts in the soil surrounding the crop or area to be protected against infestation. The risk or level of exposure can be dependent on the means of application linked to the actual quantity of the product being handled by the user. These products would be deemed to have a moderate mammalian toxicity profile but where accidental ingestion occurs in man, in particular, children, and pets or other domestic animals, the effects can be detrimental.

The persons most at risk from exposure to these products are those working in the manufacture of the active ingredients and/or those formulating the final product, using concentrated actives for inclusion in the product mix. However as with previous product types, these operations are must be controlled and carried out in accordance with all worker and chemical handling legislation, together with the provision of information, training and instruction on the use and handle of the materials. Where all necessary control and protective equipment etc is provided and workers are informed and trained etc then existing control measures are deemed to be adequate to ensure that those at risk from exposure can work safely with these chemicals.

Metaldehyde works primarily in the stomach of the slug or snail, producing its toxic effect after ingestion. Metaldehyde is probably the most commonly found mollusicide active ingredient currently available, in particular noting the EU ban on Methiocarb which came into effect September 2014.

Every precaution should be taken to ensure products containing metaldehyde are not mistaken for food or feed. It is harmful if swallowed and must be kept out of reach of children and pets. Breathing in dust, contact with skin etc should be avoided and workers should be adequately protected against such events.

Risk of Exposure:
The risk of exposure by smaller, possibly untrained professional is minimal subject to those workers exercising good hygiene practices and ensuring that their skin face/eyes and mouth cannot become contaminated/in contact with the product. These workers must know never to eat/drink/smoke while spreading these products, use thorough hand washing and ensure that any contaminated clothing and other PPE is removed.

Note: (1) Many of the SDSs readily available for these products (containing Metaldehyde) require update and improvement regarding EU format and quality of information contained therein. It was also noted that some of the SDSs (from EU sources) failed to include the percentage (%) i.e. how much/concentration of the active metaldehyde was present in the product. SDSs are the main stay of information for the smaller professional user of biocidal products and so they must be complete, give accurate/valid/understandable and upto date information, especially where these

workers are working alone, may not be formally trained and may not understand fully the technical elements of the data sheets.

Note: (2) While the EU Ban on Methiocarb came into force (in the EU) since September, 2014, it is noted that SDSs and information including marketing information about or for products containing methiocarb are still reality available on-line. While it takes time to implement such changes/revisions, in the interim the persons most likely to access this data and act upon this information are the smaller professional users of such products. It is noted that sales of these products continuing methiocarb ceased at the end of August 2014, and then a twelve month time-period/permission to use up existing stocks which having been purchased prior to the ban date and are now being stored.

Product Type 17 - Piscicides

Piscicides belong to PT17 and are biocidal products used for the control and killing of fish. The presence of alien or non-indigenous fish can cause deterioration and a major threat to native biota and habitats in aquatic ecosystems, via competition with or predation on the native species, structural damage to the habitat or cause a loss of genetic integrity as well as the economic ramifications to such changes for associated fishing industry sectors.

Where other methods of eradication or removal of these alien fish is not possible or feasible then chemical eradication using biocidal products i.e. piscicides may be the only option. Depending on the Member State involved, restrictions on the use of piscicides may exist. For those Member States which allow the use of piscicides the most common products are those containing active ingredients such as rotenone or pyrethrins. The use of piscicides is a highly specialised activity and can only be performed with by authorised persons trained in the procedures i.e. this is not a work activity or product which would or should be used by the smaller non-trained and/or self-employed professional user.

Risk of Exposure:
There are two main groups of workers who potentially are at risk from exposure to these biocidal products:

(a) Those involved in the manufacture/production of the active ingredients for the piscicide product. As stated many times these persons must and should be fully trained, provided with all necessary control measures in the workplace, including engineering and personal protective equipment, and generally work safely in accordance with both general workplace safety legislation and chemical agents legislation.

(b) Those professional users of the products who handle, disperse and apply the products as required. Again these persons will be specially trained in the use and handling of these products and must be protected in accordance will all worker and chemical legislation.

As before I note a variance in the quality of the SDSs available for these products, where some fail to list the percentage of the hazardous active ingredients present in the product. Others are not presented in the required EU format and some do not take account of the CLP Regulation for the revised/updated classification of substances as components in a mixture.

Common Actives:

- **Rotenone:** CAS No.: 83-79-4 and EC No.: 201-501-9. EU Index No. 650-005-00-2, with an EU harmonised classification assigned. Present in product at 5.0%.

***Rotenone* -** Rotenone is classified by WHO (2000) as moderately hazardous. As a substance rotenone is EU classified as toxic if swallowed, causes skin and serious eye irritation, may cause respiratory irritation and is very toxic to aquatic life with long lasting effects.

Rotenone, used as a piscicide, interrupts cellular respiration in gill-breathing fish. Acute exposure to toxic levels reduces cellular uptake of blood oxygen, resulting in blood acidosis and finally death from tissue anoxia, causing cardiac and respiratory failure. It is believed that fish are more sensitive to rotenone as it is rapidly absorbed into the bloodstream from water flowing across the gill membrane.

Rotenone is believed to be moderately toxicity to humans via the oral route, with children being more sensitive to acute effects. Human fatalities are rare due to the fact that rotenone is only sold/available in low concentrations (5% concentration in the biocidal product) and so there is insufficient active present based on an oral dose of 300-500mg/kg reported. Acute local effects in humans include conjunctivitis, dermatitis, sore throat, congestion and vomiting, while inhalation of high doses can cause increased respiration following by depression and convulsions.

As the greatest risk to humans relates to those applying the product and other support/ancillary staff handling the products prior to dispersal. The risk of inhalation must be addressed for both the product as a dust or liquid (aerosols from spray). To this end professional users must be equipped with the appropriate respirator, face/eye protection, nitrile gloves, tyvek (hooded) coveralls etc.

Product Type 18 - Insecticides, acaricides and products to control other arthropods

See Annex V

Product Type 19 - Repellents and Attractants

Biocidal products can be used to attract or repel a range of organism including fleas, mosquitos, dogs, cats, hares, foxes etc. Depending on the purpose or need to control these organisms or certain species will reflect the activities of the user. For example a farmer, forestry worker or persons working in certain conditions or climates, as well as the non-professional/amateur usage associated with these products. Insect repellents can be applied to clothing, skin, on surfaces or around plants, to prevent insects from landing or climbing on the surfaces to be protected thus helping to prevent and/or control insect-borne diseases.

Exposure:
The professional user most at risk, should exposure occur to a hazardous product or to the hazardous ingredients present in a product, are those directly involved in the manufacture of the active ingredients and those using those components to manufacture and/or formulate the final product as a biocidal mixture for the purpose of repelling or attracting unwanted organism. These workers are within the scope of all required worker protection legislation and must be protected from risk while working, using all required control measures and protective equipment, together with the provision of

adequate information training and instruction in the handling and using these chemicals or mixes.

Attractant products are used mainly to gather or bring the target species to a specific location (for capture/kill/eradication etc) or to encourage its entry into a trap scenario.

Repellents work in the reverse in that they cause the insect or target species to avoid the location or to prevent the potential bite/penetration/puncture etc of the vulnerable surface e.g. skin, by the organism. Taking skin as an example, repellent biocidal products can come in the form of liquid, pressurised products (aerosols or sprays), lotions, creams, coils, candles, vapourising mats or materials (including textiles) impregnated with the product.

While some of these products are for non-professional users, this is not to say that those smaller, self-employed professional do not have access and do not actually use these products also, in the course of their work activities, in particular where they require such products outdoors for gardening/landscaping purposes, e.g. as granules/pellets or liquids around shrubs/plants etc. These products are readily available through standard retail outlets and so can be purchased by these professionals also.

There are a range of products available to the non-professional i.e. amateurs and are often applied by them without reading or having a thorough understanding of the instructions provided.

Finally there are a group of workers who are in contact with and use these products as an inherent part of their work activities i.e. as a means of protecting themselves while at work. These can be in the form of creams/lotions etc to repel insect bites or be present in their coveralls and clothing i.e. fabric/material impregnated with the product. While this may reflect a personal usage, the need to use these products relates to their work activities and so could be deemed to be a element of protection provided by an employer to his employee.

Note:
The difficulty with these products relates clearly with the problem of distinguishing between the defined professional user and the amateur consumer. Products used by professionals should have a high level of efficacy since the objective is to eliminate the infestation, while consumers just require the repulsion of the immediate threat. However those at work are covered by the worker protection legislation and its associated control and protective measures requirements, and as such must also use these products to protect themselves at work, even where the products are not an element of the work activity itself.

Common actives:

- **N,N-Dmethyl m-toluamide (DEET):** CAS No.: 134-62-3; EC No.: 205-149-7. EU Index No. 616-018-00-2, with an EU harmonised classification assigned. Present in product at between 25-40%.
- **Methyl nonyl ketone (MNK):** CAS No.: 112-12-9; EC No.: 203-937-5. Present in the product at ca 3.6%.
- **Pyrethrins (including cinerins):** CAS No.: 8003-34-7 and EC No.: 232-319-8. Present in the product upto 5%.

DEET - is probably the most commonly used mosquito repellent. DEET works by activating an olfactory receptor neuron in the antennal sensilla of mosquitos, thus repelling the mosquitos from the smell of the chemical repellent. DEET is often times used in combination with other insecticides and can in fact strengthen the overall toxic effect indicating that DEET probably has neurological effects in addition to its olfactory effect.

DEET is absorbed through the skin and so it is important to use as low a concentration necessary to provide the desired effect. Even low concentrations of DEET will protect against most bites. DEET is harmful if ingested and could be fatal if a large quantity is swallowed. To this end it is important to take care when applying to the hands and face of children who may place them in their mouths and/or suck. It should not be applied to areas with cuts/sores/blisters or around the eyes. Under normal circumstance DEET can cause stinging and slight to moderate eye and mucous membrane irritation, or exacerbate a pre-existing skin condition. If large amounts are inhaled, ingested or applied topically to skin there is the potential for severe toxicity. Children are particularly vulnerable to toxicity and so it is recommended that products with upto 10% concentration only should be applied where necessary for children.

Note: *There is a classification proposal (submitted in Feb. 2014) for DEET, to include STOT SE 1; H370 (Causes damage to organs). While this is not agreed , it is important that such information is noted and monitored to ensure that should changes be introduced regarding a stricter/revised classification, then the associated SDS and information must also be reviewed and revised accordingly and without delay, for supply downstream to those users of the products.*

Pyrethrins - Pyrethroids are highly toxic to fish, with their toxicity increasing with temperature. Pyrethrins are present in the piscicide product upto 5%. Pyrethrins present as a liquid can be dispersed in the water or when sprayed directly onto the fish species to be controlled. Pyrethrins can be harmful by inhalation, skin and if swallowed. Therefore as this is a liquid to be dispersed in water or sprayed, then the professional users must be trained in the procedures and provided with adequate protective equipment and measures to avoid the risk of exposure. It should be noted that as well as the biocidal active ingredient, the product may also contain other hazardous components against which workers must be protected in accordance with the chemical agents directive 98/24/EC.

Product Type 20 - Control of Other Vertebrates

PT20 covers biocidal products used to control 'other' vertebrates i.e. vertebrates other than those vertebrates which may be controlled using different biocidal products types. Therefore PT20 products can be used for the control and kill of vertebrates including, rabbits, foxes, voles, moles etc, where these animals are deemed to be pests and can cause destruction of property, crops, land, and/or carry/cause disease etc. The products can be used indoors as a fumigants e.g. food areas/stores or outdoors e.g. laid in burrows of animals.

However it should be noted that products under this PT can only be used by licensed specialists (pest control companies, environmental specialists etc) and so the smaller professional (without training) and others/amateurs cannot acquire and may not use these products, thus these persons are not at risk from direct exposure associated with the use of products containing hazardous components.

Additionally, with regard to the use of these products (PT20), they are not the first consideration when there is a need to control vertebrates. The products are used only when all other measures of controlling the problem have been considered, have proved to be unsuccessful, are not technically feasible or practicable or are disproportionately costly making the method not viable. These other methods include the displacement/removal/rezoning of the vertebrate(s) in question, which can entail netting/capture/caging etc, or where this is not an option, then the shooting/kill of the vertebrate(s). These methods (non-biocidal usage) can be performed by a range of

persons including farmers, smaller professionals or amateurs, are subject to any requirements/restrictions imposed and in accordance with national laws and practices but are outside the scope of this study.

Risk of Exposure:
As expected those persons involved in the actual manufacture and/or formulation of these products (PT20) are potentially at risk from direct exposure during the processing stage should adequate controls and protective measures not be fully implemented to protect these workers. However if working in line with all requirements together with the provision of appropriate training, information, instruction, supervision, and using adequate control measures, then it is possible to work with these hazardous components and end-products.

As these products should not be available to amateurs and untrained professionals and cannot/must not be used by these persons then the risk of exposure is not an issue.

Workers at potential risk of exposure during the use of products for the control of other vertebrates are those persons who are specifically trained and expert in the use and control, of vertebrates as pests. By virtue of being professionally trained in usage infers that these professionals are also trained in the safe use, handling and disposal of the products and any residues remaining on completion of the activity.

Note: There is one category of worker who could be at risk should the above mentioned professionals return the area prematurely back to workers for normal use/work following a fumigation activity. In other words these workers *(others affected by a work activity in accordance with Directive 98/24/EC - chemical agents*), while not using the biocidal product may be adversely affected, if the biocidal fumigant remains in their work area/plant and they enter the zone, assuming that the area is adequately cleared and safe to enter. Such events should not occur where the professional users of these products are fully trained and vigilant in the required operating procedures including the return of workplaces back to normal use.

Common Actives:
Upto recently two of the most commonly available active ingredients used were (a) Chloropicrin (CAS No. 76-06-2) and Aluminium Phosphide (CAS No. 20859-73-8). ***However Regulation (EU) NO. 1381/2011, relating to the non-approval of active substances, means that Chloropicrin products are now withdrawn from the market (for sale and supply) since June 2012, with the phase for storage and use ceasing in June 2013. Therefore products containing Chloropicrin should not now be available, on sale, in storage or be used after these dates.***

Aluminium Phosphide as an active ingredient is available in various biocidal products for the purpose of controlling animals such as rabbits, moles, voles, rats etc. Aluminium phosphide containing products can be in pellet, tablet, granular form or in sachets of powder. Most commonly used is the pellet/tablet form which is placed inside the offending burrow(s) using an approved applicator/equipment. The burrow is then covered over. When placed in a burrow (soil) aluminium phosphide will rapidly hydrolyse to produce phosphine gas and aluminium salts. Phosphine gas is rapidly absorbed, inducing oxidative stress in mammalian cells and when in a sufficiently high dose will cause methaemoglobinemia in the mammal concerned. Aluminium phosphide is very toxic and must only be handled by trained professionals in accordance with recommended operating procedures.

Note: the classification of aluminium phosphide has been amended (RAC, 2011) and the revised EU harmonised classification is mandatory for use/classification of this substance alone or when used in a mixture /product. SDSs relating to products containing aluminium phosphide do not always

reflect this revision. As stated for other product types, the need to update and provide accurate information to the users is vital. For products containing this substance and requiring specialist knowledge/expertise means that these operatives, in particular, will be aware, understand and follow closely the information in the relevant SDS. Therefore it is extremely important that the information in the SDS is correct, including any changes to the classification of the hazardous components within the product.

- Aluminium Phosphide: CAS No.: 20859-73-8; EC No.: 244-088-0. EU Index No.: 015-004-00-8 with an EU harmonised classification applied. Present in the product at 56-57%.

As per the 5th ATP (EU) Regulation No. 944/2013 (*published 10/03/2013*), the revised classification for Aluminium Phosphide includes:

Water-react. 1; H260; In contact with water releases flammable gases which may ignite spontaneously.
Acute Tox. 2; H300; Fatal if swallowed.
Acute Tox. 3; H311; Toxic in contact with skin.
Acute Tox. 1; H330; Fatal if inhaled.
Eye Irrit. 2; H319; Causes serious eye damage.
Aquatic Acute 1; H400; Very toxic to aquatic life.

The primary concern to professional workers relates to the risk via inhalation given the nature of this product usage as a fumigant. With respect to the dermal route and oral routes, while this substance is hazardous, the means of protection against potential exposure can be achieved by using adequate and correct PPE together with required best practice and hygiene measures.

Additional changes to EU legislation have introduced more stringent requirements for those professionals who use/handle and apply aluminium phosphide. As from the 26th November, 2015, users will have to have completed an assessment in order to purchase or use aluminium phosphide products. This training/certification covers issues such as legislation, safety, labelling, product containers, storage and transport, record keeping, the use of application equipment and the handling and disposal of excess pesticides and spillages.

Note: Regulation (EU) 1034/2013, made in accordance with Regulation (EU) 528/2012, approves aluminium phosphide as an active substances for use in biocidal products for product-type 20, subject to certain specifications and conditions.

Product Type 21 - Antifouling Products

See Annex V

Product Type 22 - Embalming and Taxidermist Fluids

Product Type 22 relates to biocidal products used specifically in two specialist activities i.e. embalming and taxidermy. Both taxidermy and embalming involve the preservation of animal and human corpses respectively. However taxidermy deals with the external skin, without the additional activities associated with internal organs/cavities and arterial administrations i.e. embalming

(a) Taxidermy - is the term use to describe the means of reproducing a life-size three-dimensional representation of an animal (birds or fish) for permanent display. It mostly entails the removal of the skin (can include feathers or scales) in an intact fashion (minus internal organs etc) which is then cleaned, preserved using chemicals or tanned, and then mounted on an artificial structure or form, reflecting the animal and the pose required. The skin type will determine whether the skin is chemically preserved or tanned. Additionally taxidermists may sometimes use insect repellents (PT19) to ensure against degradation or deterioration of the skin.

Taxidermists can work as specialists in museums or as professionals and/or for commercial purposes. Such professionals, as specialists, will normally have received training in the skills of taxidermy, including the use of any hazardous chemicals. Smaller non-trained professionals will not perform this activity and so are not at risk from the activities and any chemicals used for this purpose. A small group of amateurs may also perform their own taxidermy on animals etc they have hunted but are not deemed to be professional taxidermists and so are outside the scope of this study. Currently there is not requirement for specific licensing to be a taxidermist but a range of courses and training is available to those who wish to undertake this work.

(b) Embalming - is the preservation of human corpses either for short or long-term duration e.g. where the burial takes places days after the death, or the body has a communicable disease, PM etc. While taxidermy is practiced throughout the EU, embalming is not so prevalent in some MSs. The process of embalming and whether or not it is performed can be related to cultural differences, climatic factors or religious beliefs etc.

Embalming is the process of chemically treating corpses so as to reduce the presence and growth of micro-organisms for public safety reasons, to retard organic decomposition and to restore acceptable physical appearance. The objectives of embalming is disinfection, preservation (short and long-term) and tissue fixation for restoration.

Following surface disinfection of the body, embalming fluids are arterially administered, with the quantity varying dependent on whether preservation is for short term or long term duration. Organs in the abdominal and thoracic cavities are administered at specific concentrations as cavity embalming fluids. Where the body is being embalming for the purpose of body donation (medical schools/hospitals, colleges and/or universities) i.e. research or teaching reasons, the body is immersed for upto 15 days in a preservative, whereby the body is for long-term preservation (ca 2 years). The amount of preservative used will depend on the duration of preservation required and be affected by the physiology of the corpse in question e.g. weight/size/degree of emaciation etc.

Persons performing embalming procedures are generally associated with the medical/mortuary and possibly forensic sectors and will have received specific and specialist training in this work, including the risks associated with using chemicals/biocidal products as preservatives which could be hazardous to their health should exposure occurs.

This work should and is never performed by amateurs or other non-trained professionals

NOTE about Formaldehyde (*as it relates to this PT)*
Upto now formaldehyde (CAS No. 50-00-0) has been the preservative most prevalently used as a formalin solution/embalming fluid.
Formaldehyde is a gas at room temperature and is available commercially as a solution in water called formalin. Formaldehyde is highly toxic, is corrosive, causes severe injury to the upper GI tract when ingested. It can irritate the eyes and mucous membranes,

cause headaches, produce a burning sensation in the throat and can trigger asthma like symptoms. More recently it has been identified as being carcinogenic and mutagenic. As a hazardous substance it can cause adverse effects in man via inhalation, ingestion and skin/eye contact.

Due to the hazardous nature of this chemical, and more recently it carcinogenicity considerations, formaldehyde has been discussed and some restrictions/prohibitions and a general phasing out is being considered. It is currently under review at EU level. Currently formaldehyde is banned from use in certain applications e.g. preservatives for liquid-cooling and processing systems, slimicides, metal-fluid preservatives and anti-fouling products. Additionally where finished products contain in excess of 0.05% must include a warning that the product contains formaldehyde.

Commission Regulation (EU) No. 605/2014, amended the classification entry for formaldehyde as listed in Annex VI (Table 3.1) of the CLP (EU) Regulation (No. 1272/2008). *This CION Regulation comes into effect in April 2015. For substances classified, labelled, packaged or placed on the market before December, 2014, this Regulation takes effect from 1st December, 2016. For mixtures, containing formaldehyde, will require re-labelling by 1st June, 2017.*

The revised classification of Formaldehyde is:
Carc.1B; H350 - *May cause cancer*
Muta.2; H341 - *Suspected of causing genetic effects*
Acute Tox. 3*; H301- *Toxic if swallowed*
Acute Tox.3*; H311 - *Toxic in contact with skin*
Acute Tox.3*; H331 - *Toxic if inhaled*
Skin Corr.1B; H314 - *Causes severe skin burns and eye damage*
Skin Sens.1; H317 - *May cause an allergic skin reaction*
[Plus a range of concentration limits assigned relating to various effects, & Note B,D]

SDSs for formaldehyde and products containing formaldehyde will need to be revised to take account of this more stringent/stricter classification. In particular as this substance is now classified as a carcinogen the requirements as laid down in the Carcinogens Directive will apply and take precedence over the Chemical Agents requirements with respect to protection of workers and the workplace whereby it will be required that control/protection measures against exposure must be implemented to the stricter level of 'as far as is technically feasible'.

As a CMR, and with further restrictions pending for this substance, alternative substances must be considered and developed in order to replace/substitute formaldehyde where possible for certain activities. For embalming activities changes/moves to Iodine (including polyvinylpyrrolidone) have taken place and are being used more frequently.

Iodine
Iodine is currently being used in embalming fluids for short term preservation of bodies prior to burial/cremation. However iodine is not a long-term (preservation) embalming solution and is best used for sanitizing processes at embalming (post death) and it can arrest the activity of bacteria in the remains on a short-term basis **only**.

Additionally, iodine is not a tissue fixative and so for this element of embalming, iodine does not serve as a suitable substitute/tissue fixative.
Active
- **Iodine:** CAS No.: 7553-56-2; EC No.: 231-442-4. EU Index No.: 053-001-00-3 with an EU harmonised classification applied. Present in the product at 1.15 -

1.54% iodine in the form of 12.8% PVP-Iodine, i.e. concentration range of available iodine is 0.29 -1.54% in embalming fluid for short-term preservation of the body.

- **Polyvinylpyrrolidone iodine (PVP-iodine):** CAS No. 25655-41-8. Present in product at 12.8%.

Classification

(a) The current harmonised classification for Iodine is:

Acute Tox.4*; H332 - Harmful if inhaled
Acute Tox.4*; H312 - Harmful if in contact with skin
Aquatic Acute 1; H400 - Very toxic to aquatic life
M=1

but *there is a proposal that additional classification be considered i.e.:*

Eye Irrit.2; H319 - Causes serious eye irritation
STOT SE 3; H335 - May cause respiratory irritation
Skin Irrit.2; H315 - Causes skin irritation

--if and when this is agreed, SDSs for iodine and products containing iodine, should be amended accordingly. However, while the information on such changes should be in the SDS (for products/mixtures) with respect to individual components in the mixture i.e. Section 3 of the SDS, this revision will not (on its own) cause the product to be re-classified or where previously not classified will not cause the product to be newly classified, based on the end-points and concentration of iodine in the products as approved.

(b) Currently PVP-Iodine does not require classification in accordance with the criteria of the CLP (EU) Regulation No. 1272/2008. However it should be noted that some companies (their SDSs) have included a 'self-classification' for this substance, as follows:

Eye Irrit.2; H319 - Causes serious eye irritation
STOT SE 3; H335 - May cause respiratory irritation
Aquatic Chronic 2; H411 - Toxic to aquatic life with long lasting effects

--If considering and applying this same ('self') classification for PVP-Iodine in a product ,caution must be adopted regarding the possible impact it may have (if any, dependent on the % present in the product) on the overall classification of the product, as well as the need for the SDS to reflect this self-classification of the component in the product.

Note: For information, Commission Regulation (EU) No. 94/2014, gave formal approval of Iodine, including polyvinylpyrrolidone iodine, as an existing active substance for use in biocidal products for PTs 1, 3, 4 and 22 (embalming). The date of Approval is 1st September, 2015 until 31st August, 2025.

Potential Exposure re Iodine during embalming:
Amateurs/the general public are not at risk as they will not be performing this activity. Smaller untrained professionals will not be at risk as they will not be performing this activity.

Those performing the activity are trained professionals who will be trained in the skills and activity itself, together with training, information, instruction and the provision of controls measures and suitable protective equipment, as required and in accordance with worker protective legislation.

Also with respect to the activity of embalming this is normally performed in a controlled laboratory/suite or room with fixed controls and strict adherence to standard operational procedures and protocols e.g. hospital/morgue/university/research facility/medical school.

Taking into account the persons doing embalming and their training, the level of control, and location, the risk of exposure via ingestion is minimal. The primary routes of potential exposure therefore are the skin/eyes (through contact) and via inhalation. In this environment, with trained professionals and appropriate protective equipment, exposure to skin and eyes can be avoided. Likewise, with available engineering controls etc the risk of exposure can be reduced and any residual risk remaining can be avoided, using collective means of protection.

Finally there is OELV (STEL - 15 mins) existing for Iodine i.e. 0.1 ppm (1.0 mg/m^3).