



**Template for the review of Decision 2010/477/EU
 concerning MSFD criteria for assessing good environmental status
 according to the review technical manual**

Descriptor 9

Document history				
Version	Date	File name	Authors	Description
1.0	28/04/2014	Annex I D9 manual Milieu cleaned.docx	Milieu	Approach and results from the Art.12 assessment filled up.
2.0	26/06/2014	ComDecRev_D9_V2.docx	EC JRC	Amended and filled with results from the in-depth assessment.
3.0	22/09/2014	ComDecRev_D9_V3.docx	MSFD Expert Network on Contaminants, EC JRC	Amended with comments from the MSFD expert Network on contaminants.
4.0	13/10/2014	ComDecRev_D9_V4.docx	MSFD Expert Network on Contaminants, EC JRC	Amended with comments from the MSFD expert Network on contaminants.
5.0	31/01/2015	ComDecRev_D9_V5.docx	EC JRC	Amended after comments from the 12th WG GES meeting.
6.0	17/03/2015	ComDecRev_D9_V6.docx	EC JRC	Amended with outcome from questionnaire and 2nd meeting of the MSFD expert Network on contaminants.
7.0	30/03/2015	ComDecRev_D9_V7.docx	EC JRC	Amended with comments from DG ENV and MSFD expert Network on Contaminants.

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The review of MSFD Descriptor 9 is being performed by the MSFD Expert Network on Contaminants, led by JRC. The review process was kicked-off during the working meeting of the MSFD Expert Network on Contaminants on 2-4.7.2014 in Ispra, Italy. Based on the exchanges there, a discussion document was prepared and circulated. The state of these discussions was reflected in the draft template document that was presented in October 2014 at the 12th WG GES meeting. These activities allowed the compilation and analysis of all necessary information for the identification of main issues and gaps and initial recommendations for the way forward, and with it the first phase of the review process was completed.

The second phase of the review process should then allow the finalization of conclusions and recommendations (which may include proposals for dedicated work items for better harmonization, need for additional guidance and eventually proposals for amendments to the Commission Decision). To this end, a questionnaire with specific questions on the main issues identified was circulated among experts and the outcome was analysed and discussed in the second working meeting of the MSFD Expert Network on Contaminants held on 23-24.2.2015 in Ispra. The current state of this second phase is reflected in the second part of the present template.

Descriptor 9: Contaminants in fish and other seafood for human consumption do not exceed levels established by Community legislation or other relevant standards.

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PART I: COMPILATION OF INFORMATION

The first phase of the review process has allowed the compilation of all necessary information to detect possible shortcomings, inconsistencies and gaps, and then to identify and discuss main issues and prepare initial recommendations. The information compiled here served as the basis for the discussions which were then held during the second phase of the review process to shape the final conclusions and recommendations presented in the Part II of this template.

1. Approach

1.1 General guiding principles for the review

The review of the Com Dec 2010/477/EU for D9 considers experiences made so far in the practical implementation, analyses the Commission Decision text in view of the current state of science and prepares proposals for action in the MSFD Common Implementation Strategy (CIS) (Working Group on GES), including the eventual revision of the Commission Decision. EC JRC is responsible for coordinating the review process of Descriptor 9.

Descriptor 9 considers the presence of hazardous substances (i.e. chemical elements and compounds) or groups of substances that are toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern, in edible tissues (muscle, liver, roe, flesh, soft parts as appropriate) of fish, crustaceans, molluscs and echinoderms, as well as seaweed, caught or harvested in the wild in the different (sub) regions destined for human consumption against regulatory levels set for human consumption.

1.2 Definitions

The term **contaminants** in Descriptor 9 is interpreted as "substances for which regulatory levels have been set for human consumption or for which their presence in fish is relevant"¹. Hazardous substances are substances (i.e. chemical elements and compounds) or groups of substances that are toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern.

Fish and other seafood are interpreted as including fish, crustaceans, molluscs, echinoderms, and seaweed or plants caught or harvested in the wild as well as farmed shellfish in the different (sub) regions,

¹ JRC, 2010. Task Group 9 Contaminants in fish and other seafood

which are destined for human consumption. This excludes farmed fish since their contaminant burden is linked to their feed and additives.

Levels established by Community legislation are considered to be the regulatory levels set in European Community legislation for public health reasons.

Other relevant standards are other national and international (e.g. WHO, FAO...) standards and recommendations set for substances and/or for fish and other seafood which are not covered by and are not in contradiction with the European legislation.

1.3 Linkages with existing relevant EU legal requirements, standards and limit values

Descriptor 9 is directly linked in the Decision to other European legislation, relating to food safety.

Member States need to monitor and assess the possible presence of substances, for which maximum levels are established at European level for seafood products meant for human consumption, in particular through Regulation (EC) No 1881/2006 and amendments. This framework provides also the basis for setting GES for this descriptor.

The potential use of an alternative approach, such as assessments using WFD EQSs (some of which are based on food legislation values, e.g. PCBs/dioxins) and environmental assessment criteria (EACs) or levels of biological effects response, is discussed further in this template.

1.4 Linkages with international and Regional Sea Conventions (RSCs) assessment criteria and standards

With its CORESET project, **HELCOM** indicates that the ecological objective for the seafood safe to eat of the Baltic Sea Action Plan (BSAP) could be measured using the same biota sampled for the purpose of core indicators for the concentrations of hazardous substances in the environment (D8). The quality boundaries recommended by HELCOM are those used in the EU legislation. In addition, HELCOM mentions that seafood safety can also be assessed by other safety limits, which are not based on legislation but on research by the European Food Safety Authority, for example.

Similarly, **OSPAR** has not developed specific standards related to seafood safety and also recommends the application of EU legislation.

1.5 Descriptor specificities should be highlighted and justified (e.g. if it is recommended to combine several descriptors together)

As with MSFD Descriptor 8 ("Concentrations of contaminants are at levels not giving rise to pollution effects"), MSFD Descriptor 9 tackles the issue of marine chemical pollution but with the protection of human consumers as its goal. Both descriptors are dealing with contaminants, so they should be discussed together. However, it is important to note that they have different objectives and characteristics:

- Protection of the environment (D8) versus protection of human health (D9).
- The thresholds and methodologies for assessment of GES are different.
- The considered substances and investigated matrices do not always coincide. Sampling in environmental programmes may be carried out in different tissues, including muscle and liver, depending on the contaminant studied, while human health programmes focus on edible parts of

the fish (mainly muscle). Moreover, the trophic level and the size of the organisms considered under D8 are not necessarily the same as under D9.

- The organizational bodies in charge are different.

For these reasons, although there is a strong link between Descriptor 8 and Descriptor 9, they require a separate approach under the MSFD.

Moreover, there are a number of issues related to Descriptor 9 that could also be related to other MSFD descriptors:

Microbial Pathogens: D9- D1, D2, D4, D5; Litter-associated contaminants: D9- D10, Biota sampling D9-D3, Biotoxins: D9-D5.

Coordination among the different descriptors and at an organisational level will be needed for an efficient implementation. Discussion fora and responsibilities should be well defined.

1.6 Analysis of whether the criteria and/or indicators and/or methodological standards for the particular descriptor are likely to be common across the EU or need aspects to be specific at region or other scales

Considering the strict EU legal framework on contaminants in foodstuffs, there is a strong element of commonality across MS, as demonstrated through the Article 12 assessment and JRC in-depth assessment. It is therefore likely that the definition of GES, at least for indicator 9.1.1, will be common across the EU.

1.7 An indication of whether a quantitative GES definition for the descriptor will be possible or whether a qualitative/normative definition only should be used (on the basis of Article 3(5))

Considering the nature of Descriptor 9, quantitative boundaries for GES are expected at least at criterion level.

1.8 Climate sensitivity

Climate change might affect contaminant exposure and toxic effects. A changing climate may influence contaminant fate and transport, release contaminants currently stored in abiotic media and affect the transfer of pollutants through food chains to humans (Schiedek et al., 2007).

2. Analysis of the implementation process

2.1 Summary of the findings relating to the determination of GES and specifically the use of the Decision criteria and indicators, based on the Commission/Milieu Article 12 reports and the JRC in-depth assessment **Descriptor 9**

All but two of the assessed MS defined GES for Descriptor 9. Information was very heterogeneous amongst MS, in terms of the substances, the species and the tissues analyzed and the regulatory levels considered for the assessments. Nevertheless, most assessments were carried out for the substances included in the Regulation (EC) No. 1881/2006 and consequently, the limits proposed there were the most commonly utilized. A number of other standards were also mentioned, sometimes without a clear specification of the regulation to which they relate and two MS did not define GES in a way that would allow it to be measurable.

Three MS defined aggregation rules and five MS highlighted the importance of the traceability of the samples in order to know where at sea the detected pollution occur. One MS stressed the necessity of coordination with food authorities and neighbouring countries and the establishment of a specific monitoring programme for this descriptor.

Criterion 9.1. Levels, number and frequency of contaminants

Only six MS defined GES to cover all components of criterion 9.1, which includes the frequency of regulatory levels being exceeded. The remaining MS defined GES only to cover the levels of contaminants.

The existence of a strong EU legal framework for the protection of human health from the contamination of foodstuff means that GES boundaries for the actual levels of contaminants should be quantitatively defined for the substances covered by the legislation. The relevant standards for other substances should, as far as possible, be agreed and their use harmonised.

There is no specific EU recommendation or threshold about the number of contaminants which exceed maximum regulatory levels and the frequency of regulatory levels being exceeded and, consequently, MS basically did not provide any data in this regard. Under food legislation, batches of food exceeding the limits have to be removed from sale – there is a 100% compliance requirement.

Regional coherence for descriptor 9

All MS except those from the Black Sea defined GES for Descriptor 9. The coherence in the Mediterranean and North East Atlantic is high while in the Baltic it is moderate. In the Baltic region, three MS defined GES only by providing limit values which are consistent with the current EU foodstuffs limit values instead of having a direct or inferred reference to relevant EU legislation (i.e. compliance with Regulation 1881/2006). In the North East Atlantic and Mediterranean regions almost none of the countries provided details about the specific substances or species covered in the GES definition while in the Baltic many of the MS provided such information. Only some MS from the Mediterranean region added a specification regarding the origin of the seafood. In the North East Atlantic two MS added restrictions, one excluded migratory species from its GES and the other excluded measurements using the livers of fish (because the limit is not related to safety and the level of non-compliance would be expected to be high).

3. Analysis of the current text of the Decision

The text of descriptor 9 has been analysed by highlighting Com. Dec. text in order to check and identify where there may be terms or topics that need to be made more explicit, removed or incorporated.

Descriptor 9: *Contaminants in fish and other seafood for human consumption do not exceed levels established by **Community legislation** or **other relevant standards**.*

*In the different regions or sub-regions, Member States need to monitor in **edible tissues** (muscle, liver, roe, flesh, soft parts as appropriate) of **fish, crustaceans, molluscs and echinoderms**, as well as **seaweed, caught or harvested in the wild**, the possible presence of **substances** for which **maximum levels are established at European, regional, or national level** for products destined to **human consumption**.*

9.1. Levels, number and frequency of contaminants

- *Actual levels of contaminants that have been detected and number of contaminants which have exceeded maximum regulatory levels (9.1.1)*
- *Frequency of regulatory levels being exceeded (9.1.2).*

The text should be revised in order to address the lack of accuracy and to clarify certain terms:

- Indicator 9.1.1 should say “actual concentrations” instead of “actual levels”.
- The relevance of “frequency of regulatory levels being exceeded” should be clarified.
- Inclusion of “location” or “traceability” in the text.
- The appropriate combination/elimination of the terms “actual levels”, “number” and “frequency” has to be decided. Options include:
 - Keep the text as it is now.
 - Join the three terms in one only indicator.
 - Keep two separate indicators but with the terms combined in a different manner, e.g. 9.1.1 including actual levels and 9.1.2 including number and frequency.
 - Remove number of contaminants and leave one only indicator including actual levels and frequency.
- Consistency is needed as for the Commission Decision texts for D8 and D9: D8 only refers to concentrations of contaminants and D9 refers to concentrations and frequency.

4. Identification of issues

This section presents the main issues and findings resulting from the previous assessments (the Commission/Milieu Article 12 reports and the JRC in-depth assessment), and from discussions held within the MSFD Expert Network on Contaminants during the first phase of the review process for Descriptor 8. The identified issues are accompanied by initial recommendations for the way forward in addressing them and diverse comments, which could support further decisions and actions.

1. AIM OF DESCRIPTOR 9

Issue: The purpose for D9 assessments.

Comments: If the purpose of D9 is to provide an assessment on the contamination of fish and seafood in the environment, from a human health perspective, the typical control type monitoring performed by responsible authorities, i.e. focused on species most likely to be non-compliant, would not be well suited for this purpose nor easily coordinated across regions. With the exception of a few substances or substance groups, limit values across different legislations have typically been set for different purposes and build on different assumptions, and are therefore neither directly compatible nor easily applied under D9. If the purpose is to prevent adverse effects on human health from seafood consumption, food safety regulations and food safety procedures that are already in place would provide sufficient protection. However, advice is also required to limit consumption of oily fish to avoid exceeding health based

guidance values for exposure to dioxins (as for large predators and mercury). This applies even though they are compliant with the limits.

2. RELATION BETWEEN DESCRIPTORS 8 AND 9

Issue: The distinction between Descriptor 8 and Descriptor 9.

Recommendation: As previously explained, both descriptors are closely related, but require a separate approach under the MSFD since they have different objectives and characteristics. However, in the WFD, the two approaches (protection of the environment and protection of human health) are integrated into one EQS, so these are not separated. It should be clarified whether a combination of measurements to provide data for both descriptors could be also used for MSFD.

Comments: Although sometimes the regulatory levels for contaminant in foodstuff seem to be too high to be suitable as indicators of pollution of the marine environment, the Directive 2013/39/EU takes some maximum levels from the food legislation. According to the WFD Guidance document No. 27, the EQS stated in the Directive is always based on the most stringent QS from the assessment, so compliance with an EQS will automatically mean that other receptors are protected, even if they are not explicitly addressed in the EQS (i.e. EQSs are protective of human health but may be unnecessarily tight since food law requires controls to be risk-based and proportionate). However, the limits in the Regulation 1881/2006 as amended apply only to edible parts, generally muscle meat. If the whole fish is tested, including liver (which has a separate, higher limit under Reg. 1881/2006) there will be a lot of non-compliance with the EQS, e.g. for dioxins. On the other hand, for WFD, according to the recent WFD CIS Guidance No. 32 on biota monitoring, lipid normalisation should be performed, while the standards according to Reg. 1881/2006 are not necessarily expressed on the basis of lipid content and it is agreed that lipid normalisation would not be required to address human health related issues under D9 when using the standard for e.g. dioxins. So even if the same substance and the same quality standard (to protect human health) is assessed, different conclusions can be made depending on whether the assessment is performed under D8 or D9.

Issue: The potential options for cost-effective and coordinated sampling strategies between Descriptors 8 and 9.

Recommendation: Given the different aims of D8 and D9, there is limited scope for usefully integrating D8 and D9 sampling (i.e. same sampling for the assessment of concentrations of contaminants in the environment as for seafood consumption safety monitoring). Nevertheless, sampling synergies are desirable and should be explored and decided and information exchange between national food safety and environmental authorities should be encouraged.

Comments: Biota sampling for D8 is usually carried out on specific sizes, many times the smallest ones not being useful for D9 as unique source of data. D8 might be relevant for D9 if the species taken for D8 are commercially exploited and of a marketable size. Moreover, data for D8 could be generated in the same matrix as in D9, e.g. using the muscle of the fish, as recommended for many substances in some RSCs.

Furthermore, D8 shellfish data are often from beds not intended for human consumption, although there is nothing to prevent individuals collecting and eating them.

On the other hand, D9 can only rarely provide samples and data for D8. For D9, it is appropriate to target the highest risk species, which may not be the ones selected for D8. D9 data could be suitable for D8 only if the species fulfils the criteria of an indicator species for D8 (e.g. should reflect the local conditions, be key species for the ecosystem, be high sensitivity to contaminants...) and if it can be corrected for age and trophic status (for assessing compliance, although not trends). Therefore, some basic information has to be known about the sampling location/ homing behaviour or come from not-fed in situ cultivated species (e.g. sea bed or hanging cultures).

Any extra monitoring could be carried out as an alternative to the specific monitoring carried out by the Food Safety authorities, but improving upon the sample traceability. However current D8 objectives usually focus only in few target species (1-3 species, including mussels, fish and snails), while the monitoring for D9 should focus on a higher number of species and sizes. This would imply a much higher effort and would be conditioned by the capacities of MS.

According to the JRC's Task Group 9 Contaminants in fish and other seafood: "There rarely is a well-defined established simple quantitative link between levels of contaminants in marine environment and levels in fish and other seafood, demonstrating a general research need on transfer of contaminants from the marine environment to the fish/fishery species. In general it would be interesting to identify possible relations between contaminant levels in sediment, and tissues (such as liver and muscle) of fish and other seafood." This point of view is not necessarily accurate. In the marine environment many organisms get their contaminant levels from food or from water (e.g. filtering organisms) and from sediments. Moreover, elevated concentrations of contaminants in marine environmental matrices are not necessarily directly linked to bioaccumulation and/or effects on marine organisms. This is due to the behaviour of chemicals, e.g. bioavailability, distribution, patterns of accumulation and intracellular availability, but also to characteristics of organisms, e.g. metabolic capacity, excretion, storage and mobilisation from tissue compartments. The biomagnification of the levels of the persistent pollutants through the food chain should be of great interest for D9 since predatory fish might be relevant for human consumption too, so the selection of the right trophic level for monitoring should be taken into account.

The WFD CIS Guidance No. 32 on biota monitoring biota guidance includes a general text on the design of a cost effective monitoring programme, which perhaps could be also used for the MSFD.

3. SUBSTANCES (CONTAMINANTS) FOR WHICH GES CRITERIA SHOULD BE ESTABLISHED

Issue: The appropriateness and feasibility of selecting a European core set of substances to be monitored by all MS and specifying it in the Commission Decision text.

Recommendation: A list of contaminants for GES assessment should be established based on:

- Minimum requirements: All Chemical contaminants included in the EU Regulation 1881/2006 as amended should be included under D9.

- Country specific solutions should be allowed, therefore only a broader description of prerequisites is needed. However, there is lack of national standards for contaminants in food.

Issue: The contemplation of biotoxins under D9.

Recommendation: It seems to be more appropriate to leave this issue to food safety control programmes where biotoxins are included in any case.

Comments: Biotoxins are not included in the regulation 1881/2006, but included in Regulation 853/2004. If the systems work properly they are not a human health issue either as, as soon as they appear, shellfisheries are closed. However, this information and data are environmentally relevant, since when a shellfishery is closed, it is a result of a previous analysis which does not fulfil the established criteria.

Issue: The contemplation of pathogens under D9.

Comments: The introduction of microbial pathogens are not mentioned in the COM DEC2010/477/EU indicators although it appears as “Biological disturbance” in the Table 2 of Annex III of the MSFD. However, there is no clear understanding as to under which MSFD descriptor the pathogens should be dealt with. They could be considered under D1 (as natural occurring organisms), under D2 (as non-indigenous species), under D4 (as they are part of marine food chains), under D5 (as toxic algae can be related to eutrophication), and/or under D9 (as contaminant in seafood).

The occurrence of microbial pathogens in the marine environment may be the consequence of a number of different reasons, including indirect effects from a sub-GES situation with respect to ecosystem structure and function (that would allow pathogens to proliferate). To include pathogens under D9 would imply that all shellfish collected off the shore must be safe to eat. There would be a cost to preventing *Escherichia coli* entering the sea that society will not be willing to pay (i.e. zero agricultural run-off, or small sewage plants / septic tanks needing energy intensive UV treatment, etc.).

There is already a legal framework requiring Member States to improve and/or survey the quality of shellfish waters and edible products. The environmental requirements of the shellfish waters are listed in the Annex 1 of Shellfish Water Directive 2006/113/EC and include water physico-chemical parameters, chemical contaminants (e.g. heavy metals, IPA, organohalogenated substances) and also faecal coliforms in shellfish (flesh and intervalvular liquid) as microbiological indicator. This Directive has been repealed at the end of 2013 by the WFD, which should ensure the same level of protection of these water bodies, thus contributing to the quality of bivalve molluscs directly edible by man. Under Regulation 854/2004/EC, *Escherichia coli* is monitored to establish hygiene status of classified shellfish production areas. The Regulation 882/2004/EC lays down general rules for the performance of official controls to verify compliance with rules aiming at: preventing, eliminating or reducing to acceptable levels risks to humans and animals, either directly or through the environment; and guaranteeing fair practices in feed and food trade and protecting consumer interests, including feed and food labelling and other forms of consumer information. The Regulation 2073/2005/EC provides the microbiological criteria for edible shellfish based on levels of *E. coli* and the occurrence of *Salmonella* spp. This leads to an overall relationship among WFD, Food Hygiene Regulations and the MSFD. In this latter however, such link is highlighted in relation to

chemical contaminants in seafood, but not for microbial contaminants. GES criteria and indicators for microbial pathogens could be identified within the D9 based on the current legal framework. The objective is not to completely eliminate the faecal contamination in shellfish waters (impossible), but to reduce it as much as possible according to WFD microbiological parameters.

The MSFD Competence Center has developed a document “Discussion document_Pathogens under MSFD_18_6_2014.docx” (which can be found at CIRCABC JRC MSFD D8+D9), which contains some considerations on this topic that can be helpful with the discussions.

4. SPECIES/TISSUES

Issue: The tissue in which measurements should be conducted.

Recommendation: Only the edible tissues, as specified in the legislation, should be considered.

Issue: The knowledge of biological parameters.

Recommendation: Biological factors, such as trophic level of fish, diet, condition, and age, are not presently included in EU foodstuff regulations and are not needed for checking compliance with Regulatory standards. However, these parameters should be monitored because they can provide help in the data interpretation, particularly in the event of a non-compliance.

Issue: Farmed species.

Recommendation: Farmed fish should not be considered, since their contaminant burden is linked to their feed and additives. Concentrations in farmed fish therefore relate to husbandry and bear little relationship to the environment in which they are reared and thus are not appropriate for inclusion in MSFD. However farmed molluscs should not be associated with the same caveats as they are only passively allowed to settle and grow on artificial submerged surfaces without added feed and additives.

Issue: The consideration or not of migratory species.

Comments: The contaminant burden in migratory fish may not reflect primary uptake in the MSFD area where it is caught or even European waters depending on the species. It is not clear then how to interpret the data and link these to GES. It is still crucial to know the origin where (or where not) the contamination occurred to lead to potential measures in such cases. Information from migratory fish might be useful as a measure of control for management measurements at GES at the biggest European geographical scale.

Issue: The consideration or not of edible jellyfish.

Comments: Jellyfish are not mentioned in the Commission Decision text for descriptor 9, but they might get more popular in coming years and can be already found in some European restaurants, so they could also be a potential human health concern.

Issue: Fish and seafood coming from European region overseas.

Recommendation: Fish and seafood coming from European regions overseas (e.g. Reunion, in the Indian Ocean, which is clearly not part of European waters) can be directly supplied into Europe without any third country controls and would be monitored under the Commission Regulation EC 1881/2006, but they seem to be out of the scope of the MSFD.

5. METHODOLOGICAL STANDARDS

Issue: The appropriate thresholds for the assessment of GES.

Recommendation: The primary thresholds for the assessment of D9 should be those set in the EU food regulations. Other relevant standards can be relevant for the substances and/or for fish and other seafood which are not covered by the European legislation. However, care must be taken in selecting the limit values, having in mind that the purpose of Regulation 1881/2006 is food safety and not assessment of marine seafood contamination. For example, for PAHs the limit values in Regulation 1881/2006 refer to smoked and fresh foodstuff. Only limits for unprocessed seafood should be used for MSFD purposes.

Issue: How to deal with limit values from different legislations for some substances.

Comments: As said before, the derivation of WFD EQSs in biota has considered both ecotoxicological exposure and human protection, so they might also cover D9 objectives. The application of proposed non-EU legislative thresholds for D9 could lead to some inconsistencies with SANCO food safety assessments (for example for PBDEs) and these issues need to be explored and reconciled. However, limits provided by food safety regulations should be used as a priority.

Issue: Substances for which no maximum level in food has been set.

Recommendation: If specific hazards are known, there are necessary tools to conduct a risk assessment and there are legal powers to take action where necessary, it would seem incongruous to say it would not be relevant to D9.

Comments: It has been suggested to apply specific quality analysis for these samples following EU specific directives.

6. NUMBER OF CONTAMINANTS WHICH HAVE EXCEEDED MAXIMUM REGULATORY LEVELS/ FREQUENCY OF REGULATORY LEVELS BEING EXCEEDED

Issue: The appropriateness of including those parameters under Descriptor 9.

Recommendation: The potential elimination of these parameters has to be considered.

Comments: Some pollutants (e.g. metals) will probably not be 100% compliant of the legislation levels in all samples and species. Whether a certain percentage of non-compliance could be acceptable, especially if a decreasing trend is detected, or not (it does not go for human consumption) has to be clarified.

The frequency of (non)compliance (and the similar “number of contaminants in (non)compliance”) would only make sense if all countries had the same monitoring with respect to monitoring frequency,

geographical coverage, number of samples, sample size, set of contaminants measured, species, etc. This is not the situation today, and it is probably not the best way forward. Moreover, it is not clear how to establish thresholds for frequency of (non)compliance (and the similar “number of contaminants in (non)compliance”), e.g. which percentage of exceeding per sampling set, coupling it to an absolute upper limits. Therefore, perhaps “number of contaminants which have exceeded maximum regulatory levels” and “frequency of regulatory levels being exceeded” should be removed from the Commission Decision.

7. MONITORING

7.1. TRACEABILITY

Issue: Traceability of the samples.

Recommendation: The traceability of the samples is essential. Methodologies, for fisheries purpose and consumer protection purposes, are developing rapidly.

Issue: How precise fishing location has to be known.

Recommendation: The regional/sub-regional level would be the minimum level of geographical knowledge that is acceptable.

Comments: Sampling strategy and requirements are not presently specified in EU foodstuff regulations. Some suggestions include:

- Based on the ICES boxes approach. This is used in some MS, but it is not clear to what degree is used by others. For example, it would be with difficulty applied in the Mediterranean Area.
- Information on fish stock.
- Not very precise, at regional/sub-regional level would be enough. This would not help much if measures are required, as the area of concern would be unknown, but in order to assess the environmental state of a region-subregion, location is not needed to be very precise, being enough the fishing area.

7.2. SAMPLING STRATEGIES

Issue: The frequency of monitoring.

Comments: It is not clear whether regular monitoring of all chemical contaminants in Regulation 1881/2006 in fish and seafood would be feasible and/or relevant. As most environmental contaminants slowly bioaccumulate, short term fluctuations in levels are highly unlikely. Once per MSFD reporting cycle might be a sensible minimum monitoring frequency. Where concentrations are close to the limits (or of increasing concern), or if the effectiveness of measures requires monitoring then MS could monitor more frequently.

Issue: The appropriate number of samples to assess the actual levels of contaminants.

Comments: It is not clear whether this should refer to the number of environmental samples, or samples per batch (fish landing).

Fish species, size, and age all matter for contaminant uptake and with respect to these parameters the sampling changes over time depending on the focus of the food safety control. For each species, the number of samples should result in a normal distribution. It might be convenient that for each species, a pilot sampling was performed to optimize the sampling size.

There are two relevant EC regulations strongly linked to the 1881/2006 that include directions on how to sample from a batch of fish, and how to sub-sample. These regulations concern 589/2014 (recently updated for dioxins/PCBs) and 333/2007.

Issue: The appropriate sampling collection.

Comments: Samples for this purpose are typically collected from a variety of points along the processing chain:

- At sea: e.g. extra sampling for MSFD purposes.
- At fishery landing points, when the catch location is known.
- At retail level. In some cases, it is not possible to know the geographical origin of the fish. Furthermore, foodstuffs may have been contaminated during processing and the data therefore not informative of environmental conditions. Finally, at market level the biological variability (size, age, etc.) can be very high.

Issue: The basis of the monitoring approach and accordingly the selection of representative number of species.

Comments: Some suggestions include:

- The selection of species should be based on their relevance for human consumption, and the amount caught by fishermen in the sea area under consideration. Task group 9 report should be taken into account.
- Risk based to protect consumers, protection of sectors at the highest risk (“worst case scenario”).
- Based on the trophic level, investigate one species per each trophic level (Shellfish, Fat fish...). However, the most contaminated fish could not be important as food.
- Indicator species should be defined for certain sea regions or sub-regions to ensure consistency between MS. Again, the most contaminated fish could not be important as food.

None of the points above are specified in EU foodstuffs regulations. A risk based approach can take the above points into consideration, but a risk based approach also means that a degree of flexibility must be allowed to reflect country specific situations. In this case, “risk-based” has to be defined (e.g. to look at oily fish because they have higher contaminant levels or to look at non-oily fish because they are most landed). As we are looking for non-compliances, the risk to take into account would be the highest risk of contamination, but only species that are sold commercially for consumption should be included.

7.3. AGGREGATION

Issue: The appropriate way to treat the data (mean concentration, maximum levels...).

Comments: 100% compliance is required under food regulations, thus statistics are not required. This is the ideal situation (unfortunately not real), and consequently frequency of non-compliance per specie could be used as an indicator or for the evaluation of concentrations data available.

Statistics should be relevant to assess the trend of the occurrence level.

7.4. MONITORING PROGRAMMES

Issue: The harmonization of the monitoring programmes.

Comments: The monitoring programmes have been already designed by MS with differing degree of consultations at regional and EU level, so there could be still lack of consideration of the lessons learnt (In-depth assessment, article 12). An insufficiency in harmonization among MS at regional or EU level might lead to new inconsistencies in the second MSFD reporting cycle, if not addressed before the establishment of the monitoring programme for that cycle.

Moreover, although it has been recognized that the traceability of the samples is essential for an appropriate assessment of D9, according to the information provided by experts during the first phase of the review process (summarized below), this issue is not well covered in the designed monitoring programmes for Descriptor 9:

Belgium: Monitoring programmes under public consultation: Coordination with institutions for D8 and with Food safety legislation for D9.

Croatia: Public consultation of monitoring programmes is finished. For D9 same biota species as for D8 from common sampling will be analysed.

France: Monitoring programmes under public consultation. For D9, monitoring programmes are based on existing programmes, considering the EU legislation 1881/2006, and including microbiological contamination. Periodic fishery cruises under D3, which could provide biota samples for analysis of contaminants under D9. There is lack of traceability in the seafood monitoring programmes. Using of existing monitoring network stations with additional sampling coming from D3 cruises for off-shore waters.

Germany: Regarding D9, the traceability of fish and seafood catches is not very good.

Ireland: Working on drafting the monitoring programmes. D9 is well covered (although not reflected in the reporting process due to a technical transfer error) and relates to shellfish waters and port-based seafood monitoring. D9 monitoring will continue with port-based and shellfish waters monitoring.

Italy: For D9 there are some problems to collect data from Food Safety authorities, so there will be monitoring programmes in addition to human's health existing programmes.

The Netherlands: Monitoring programmes decided. For D9, monitoring programmes are based on existing programmes considering EU-legislation. Exploring the possibilities of combining the current food safety monitoring programme at sea (D 9) and the environmental monitoring programme (D 8). There are plans to combine the sampling of biota for both monitoring programmes in the Dutch part of the North Sea. For food safety monitoring programme the mixed samples of fish are used and the contaminants are analysed in edible parts of biota (filets). However, for the environmental monitoring individual fish of different length classes are used and the contaminants in liver or in whole biota are analysed. It will

therefore be difficult to combine analysis of contaminants for both programmes. (Sampling combined, analysis separated).

Norway: Alignment with WFD, and probably also with MSFD, though Norway does not implement the MSFD. Arctic issues to be addressed through OSPAR/AMAP.

Romania: Monitoring programmes under public consultation. For D9 same biota species as for D8 from common sampling will be analysed (sampling combined, but analysis and interpretation separated). Romania defines GES for Descriptor 9 with respect to levels in accordance with EU regulations legislation. Contaminants (heavy metals, OCP, PCB, PAH) data in biota are collected in the frame of national monitoring or research projects. Molluscs (mussels, snails) and fish are collected during NIMRD research cruises, for both D8 and D9. Microbiological contamination of molluscs is assessed in the framework of Shellfish Waters Directive. Periodic fishery cruises under D3 can provide biota samples for analysis of contaminants under D9. Molluscs are analysed as whole soft tissue, and fish as dorsal muscle (filets).

Spain: Monitoring programmes soon under public consultation. For D9, data will be collected from Food Safety Agency, which should improve the traceability and identified the origin of the samples collected in the Spanish marine areas in order to solve the gap identified in the initial assessment or the quality status report.

United Kingdom: Broad monitoring programmes have been consulted upon. There is a one-off monitoring project taking place for fish under D9 (chemical substances only), as earlier food monitoring has usually involved sampling at point-of-sale (retail outlets). Therefore information on catch locations was not available and samples could be guaranteed not to have suffered contamination during commercial fish processing. A good description of UK marine monitoring can be found at the UKDMOS (UK Directory of Marine Observing Systems) website. This includes monitoring that is not MSFD-related.

PART II: CONCLUSIONS AND RECOMMENDATIONS

After completion of the information compilation phase, a questionnaire with specific questions on the main issues identified was circulated among experts and the outcome was analysed and discussed in the second working meeting of the MSFD Expert Network on Contaminants. Based on these findings and discussions, this section compiles and presents the final conclusions and recommendations derived from the review process, including the reasoning behind the recommendations and the proposed way forward.

5. GES criteria (in accordance with Art. 9.3)

5.1 Conclusions on the use of the existing Decision criteria and indicators

Recommendation 1: The Descriptor 9 is proposed to be retained, although substantial changes in the overall structure are proposed to make it clearer and align with Descriptor 8, based on the discussions during the review process.

Concentration of Contaminants (9.1)

Recommendation 2: Establish an EU-wide minimum list of elements and/or parameters for assessing GES:

- Substances included in the EU Regulation 1881/2006 as amended.

Additionally, Member States should add country (region)-specific substances for which available assessments have shown indications of risk to the assessment whenever possible.

Recommendation 3: GES threshold values are the limit values as set in Regulation 1881/2006 and amendments. Only limit values for unprocessed seafood must be considered for MSFD purposes.

Recommendation 4: The traceability of the samples is essential in order to know where at sea the detected pollution occurs.

Number of contaminants which have exceeded maximum regulatory levels (9.1.1)

Recommendation 5: This part of the indicator 9.1.1 to be removed.

Frequency of regulatory levels being exceeded (9.1.2)

Recommendation 6: This indicator 9.1.2 to be removed.

6. GES methodological standards (in accordance with Art. 9.3)

6.1 Aggregation rules

Recommendation 7: While D8 and D9 are closely related, they are separate descriptors within MSFD, therefore require separate reporting.

Recommendation 8: The level of compliance of concentration of contaminants/aggregation rules needed to establish whether an area is or not at GES has to be established.

7. Specifications and standardized methods for monitoring and assessment (in accordance with Art. 11(4))

7.1 Specifications on methods for monitoring

7.1.1 Collection of data

Recommendation 9: Farmed shellfish cannot be excluded.

Recommendation 10: Information/data exchange between Environmental and Food Safety Authorities is crucial for the assessment of Descriptor 9.

Recommendation 11: Samples can be obtained from cruises or fish markets, as long as the location is known.

Tentative revised Commission Decision text taking into account the above recommendations

There is not final agreement among experts on specific wording. Therefore, further discussions are needed in the eventual revision of the Commission decision text.

Descriptor 9: Contaminants in fish and other seafood for human consumption do not exceed levels established in the Commission Regulation (EC) No 1881/2006 as amended or other relevant standards.

— 9.1. Concentration of contaminants

In the different regions or sub-regions, Member States need to monitor the possible presence of contaminants for which maximum levels are established at European, regional, or national level in edible tissues (muscle, roe, flesh, soft parts as appropriate) of fish and seafood destined to human consumption (crustaceans, molluscs and echinoderms, as well as seaweed, caught or harvested in the wild, and farmed shellfish), that carry the greatest risk of exceeding the limits, and that also provide information on the state of the environment.

8. Rational and technical background for proposed revision

8.1 Justification and technical background justifying the above recommendations

Explanation for Recommendation 1

The purpose of Descriptor 9 is the assessment of contamination in fish and seafood in the environment, from a human health perspective. MSFD is not meant to protect the consumers, but to ensure that the environment produces healthy food. The assessment under MSFD could identify how environmental pollution causes high levels of contaminants in fish and seafood for human consumption.

One important issue is the opportunity to make links with traceability. Limitations could exist for the coverage of areas not covered by Food Regulation (they consider only Target areas).

Explanation for Recommendation 2

The comparability among marine regions is possible considering the list of regulated substances in the EU Food Legislation as a minimum list of element of parameters for all EU MS, and country (region)-specific substances should be added whenever possible and/or necessary. The difficulty would be the different species, sizes, sampling period, etc. in different regions.

Biotoxins are beyond the scope of D9 because they are not indicative of environmental status and are already covered in food safety control programmes.

Pathogens are not chemical contaminants and there are other regulations in place for their assessment (Shellfish water Regulation). Therefore, pathogens do not have to be assessed under D9. However, they should be assessed as part of the ecosystem.

Explanation for Recommendation 3

The limit values should be as set in Regulation 1881/2006 and amendments. However, care must be taken, having in mind that the purpose of Regulation 1881/2006 is food safety and not assessment of marine seafood contamination. For example, for PAHs the limit values in Regulation 1881/2006 refer to smoked and fresh foodstuff. Only limits for unprocessed seafood should be used for MSFD purposes.

The WFD EQS consider human health data, where available, but they are not food safety limits for consumer protection under Descriptor 9.

Substances with no limit values set in the Food regulation are not minimum elements for assessing GES, but they could/should be assessed if specific hazards are known. MS can derive their national standards, but the derivation is out the scope of MSFD.

Explanation for Recommendation 4

Traceability of samples to catch/collection area is essential. Not including information on the location would limit the use of sampling for other purposes than food safety. The regional/subregional level is the minimum acceptable level of geographical knowledge. The results should be integrated in a regional/subregional basis, using common criteria for species, sizes and sampling season. However, more accuracy would help to plan measures and evaluate the efficiency of adopted measures.

Explanation for Recommendation 5

The part of the indicator 9.1.1 regarding the number of contaminants which have exceeded maximum regulatory levels is proposed to be removed. This information might not be very relevant and does not take into account the number of times that this exceedance occurred or the distinction between the different contaminants. Aligning with D8 would denote that substances are evaluated on individual basis. Multiple substances are reported separately as being beyond food safety standards.

Explanation for Recommendation 6

The indicator related to the frequency of regulatory levels being exceeded is proposed to be removed. This is a good criterion to assess the ecological status of a subregion from a human safety point of view, but it is not relevant for compliance checking for MSFD. The threshold related to this indicator would be, as for D8, determined as GES and therefore not need to be specified in the Commission Decision. Moreover, the frequency of exceedances will be highly dependent upon the sampling strategy/design and this is unlikely to be consistent across MSs.

Explanation for Recommendation 7

D9 assessment is centered in human health protection, consequently the environmental representativity is limited and different results for D8 and D9 evaluations could be obtained. D8 and D9 have different objectives, so the lists for both descriptors have not to be directly related.

Explanation for Recommendation 8

100% compliance, as required in Food legislation, seems to be unachievable, particularly for some metals. Further discussions are needed to establish the level of compliance of concentration of contaminants/aggregation rules.

Explanation for Recommendation 9

Only edible tissues have to be assessed, as specified in Food legislation.

Farmed fish should not be considered, since their contaminant burden is likely to be linked mainly to their feed and additives. Concentrations in farmed fish therefore relate to husbandry and bear little relationship to the environment in which they are reared and thus are not appropriate for inclusion in MSFD. However farmed molluscs should not be associated with the same caveats as they are only passively allowed to settle and grow on artificial submerged surfaces without added feed and additives.

Migratory species are important for MSFD for assessment of GES at regional/European geographical scale, and should be taken into account, although they should not be included as minimum elements for GES assessment: Similar to D8.

MSFD does not apply to overseas territories, so the fish and seafood from European areas overseas are out the scope of MSFD.

Explanation for Recommendation 10

Information and data exchange between Environmental and Food Safety authorities is crucial, but currently not implemented in all MS. The MSFD expert network on contaminants should play a key role in triggering this.

Explanation for Recommendation 11

Samples can be obtained from cruises or fish markets, as long as the location is known. One advantage of the fish markets is their good representativeness of the food supply available for consumers compared with analysis of samples coming from cruises. However, to highlight hotspots, cruises seem to be more relevant.

Compliance should be based on human consumption and, among them, focus should be on highest risk species in order to get a conservative assessment (and to limit the number of samples). The main issues are the communication between Food and Environmental authorities and the traceability of the samples.

9. Other related products

9.1 Proposed way forward for identified issues

Issue	Way forward	Timeline
D9 set-up in Member States.	Preparation of a summary document and eventually need for guidance on “best practice”.	<i>Started/Finalized 2015.</i>
Need of information/data exchange between Environmental and Food Safety authorities.	To evidence and communicate to MSCG.	<i>Started/Finalized 2015.</i>
Traceability of samples taken by Food Authorities.	Guidance needed on traceability of seafood, supporting harmonized approaches. Identify who best can prepare it.	<i>Until 2018.</i>
Level of compliance of concentration of contaminants/aggregation rules.	Further discussions within the MSFD Expert Network on Contaminants.	<i>Until 2018.</i>

10. Reference Documents

- Article 12 Technical Assessment (Milieu ltd, 2014).
- Coherent geographic scales and aggregation rules in assessment and monitoring of Good Environmental Status – analysis and conceptual phase, (Deltares, 2014).
- Commission Directive 2001/22/EC of 8 March 2001 laying down the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs.
- Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.
- Commission Regulation (EC) No 565/2008 of 18 June 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs as regards the establishment of a maximum level for dioxins and PCBs in fish liver.
- Commission Regulation (EC) No 629/2008 of 2 July 2008 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs.
- Commission Regulation (EU) No 1259/2011 of 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs.
- Commission Regulation (EU) No 420/2011 of 29 April 2011 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs.
- Commission Regulation (EU) No 488/2014 of 12 May 2014 amending Regulation (EC) No 1881/2006 as regards maximum levels of cadmium in foodstuffs.
- Commission Regulation (EU) No 835/2011 of 19 August 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels for polycyclic aromatic hydrocarbons in foodstuff.

- Common Implementation Strategy for the Water Framework Directive (2000/60/EC). 2011. Guidance Document No. 27. Technical Guidance For Deriving Environmental Quality Standards Technical Report - 2011 – 055.
Common Implementation Strategy for the Water Framework Directive (2000/60/EC). 2014. Guidance Document No. 32 on biota monitoring (the implementation of EQS_{biota}) under the Water Framework Directive. Technical Report - 2014 – 083.
- Common Understanding of (Initial) Assessment, Determination of Good Environmental Status (GES) & Establishment of Environmental Targets (Articles 8, 9 & 10 MSFD), (DG GES, 2014).
- First steps in the implementation of the Marine Strategy Framework Directive - Assessment in accordance with Article 12 of Directive 2008/56/EC, (CSWD, 2014).
- In-Depth Assessment of the EU Member States' Submissions for the Marine Strategy Framework Directive under articles 8, 9 and 10. 2014. JRC Scientific and policy reports, Report EUR 26473 EN.
- MSFD GES workshop on Eutrophication and Contaminants, October 2012.
- MSFD Task group 9 report. 2010. Contaminants in fish and other seafood. EUR 24339 EN.
- Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.
- Review of Methodological Standards Related to the Marine Strategy Framework Directive Criteria on Good Environmental Status (JRC, 2011).
- Review of the GES Decision 2010/477/EU and MSFD Annex III Approach and outline for the process, (EC- Committee/07/2013/03rev, 2013).