OSPAR COMMISSION

Protecting and conserving the North-East Atlantic and its resources

The OSPAR list of chemicals for priority action
Suggestions for future actions

Hazardous Substances Series

2019

OSPAR Convention

The Convention for the Protection of the Marine Environment of the North-East Atlantic (the "OSPAR Convention") was opened for signature at the Ministerial Meeting of the former Oslo and Paris Commissions in Paris on 22 September 1992. The Convention entered into force on 25 March 1998. The Contracting Parties are Belgium, Denmark, the European Union, Finland, France, Germany, Iceland, Ireland, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom of Great Britain and Northern Ireland.

Convention OSPAR

La Convention pour la protection du milieu marin de l'Atlantique du Nord-Est, dite Convention OSPAR, a été ouverte à la signature à la réunion ministérielle des anciennes Commissions d'Oslo et de Paris, à Paris le 22 septembre 1992. La Convention est entrée en vigueur le 25 mars 1998. Les parties contractantes sont : l'Allemagne, la Belgique, le Danemark, l'Espagne, la Finlande, la France, l'Irlande, l'Islande, le Luxembourg, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni de Grande Bretagne et d'Irlande du Nord, la Suède, la Suisse et l'Union européenne.

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Executive Summary

The vision of the OSPAR Commission and the Convention for the protection of the marine environment in the North-East Atlantic is a clean, healthy and biologically diverse ocean used sustainably. Within the Hazardous Substances Strategy, the Commission has prioritized substances for which measures, actions and background documents were adopted in order to reach the stated vision; cessation of losses, discharges and emissions of contaminants and concentrations of anthropogenic substances close to zero, and for naturally occurring substances at background levels in the North-East Atlantic.

Due to constitutive regulatory work within the European Commission as well as the development of international treaties, the background documents of the prioritized substances have not been continually updated. This report analyzed and evaluated if and which of the OSPAR background documents needed updating, in addition to giving suggestions on potential further actions OSPAR could take in order to protect the marine environment against hazardous substances. This was done by reviewing the current legislative status of the prioritized substances under REACH, the Stockholm Convention, the EU Water Framework Directive as well as the biocidal and plant protection products regulations. Where possible, monitoring data were incorporated in the evaluation.

This report presented generalized groupings of suggested OSPAR actions for each of the background documents; substances which require no additional OSPAR actions; substances which are not considered fulfilling the criteria as hazardous substances and should be removed from the LCPA; substances for which additional actions may be needed; substances which require continuous monitoring and potentially evaluations of needs for additional measures.

In this report it is suggested that OSPAR in the future takes a more active role acting as a safety net for the EU regulations, with the aim of protecting the marine environment in the North-East Atlantic. The OSPAR Contracting Parties should decide on how to follow this advice and decide how the future work within the Hazardous Substance Strategy should be undertaken.

Récapitulatif

La vision de la Commission et de la Convention OSPAR pour la protection de l'Atlantique du Nord-Est est un océan propre, sain et biologiquement divers, exploité durablement. La Commission a classé selon les priorités, dans le cadre de la Stratégie substances dangereuses, les substances appelant des mesures et actions, et pour lesquelles des documents de fond ont été adoptés afin de réaliser la vision d'OSPAR; l'arrêt des pertes, rejets et émissions de contaminants et des teneurs en substances anthropiques proches de zéro, et proches des teneurs ambiantes dans le cas des substances présentes à l'état naturel dans l'Atlantique du Nord-Est.

Les documents de fond sur les substances prioritaires n'ont pas été actualisés continuellement en raison des travaux de réglementation constitutifs au sein de la Commission européenne ainsi que du développement de traités internationaux. Le présent rapport analyse et évalue s'il y a lieu d'actualiser des documents de fond, et lesquels, et

suggère également des mesures potentielles supplémentaires qu'OSPAR pourrait prendre afin de protéger le milieu marin contre les substances dangereuses. Ceci a été réalisé en passant en revue le statut juridique actuel des substances prioritaires dans le cadre de REACH, de la Convention de Stockholm, de la Directive cadre sur l'eau de l'UE ainsi que de la réglementation relative aux produits biocides et phytosanitaires. Les données découlant de la surveillance figurent dans l'évaluation dans la mesure du possible.

Ce rapport présente des regroupements généralisés de mesures OSPAR suggérées pour chaque document de fond; des substances n'appelant pas de mesures supplémentaires de la part d'OSPAR; des substances qui ne semblent pas satisfaire les critères concernant les substances dangereuses et devant être retirées de la LCPA; des substances pour lesquelles des mesures supplémentaires risquent d'être nécessaires; des substances devant être surveillées en permanence et potentiellement évaluées afin de déterminer si des mesures supplémentaires sont nécessaires.

On suggère dans le présent rapport qu'OSPAR joue à l'avenir un rôle plus actif de filet de sécurité dans le cadre de la réglementation de l'UE afin de protéger le milieu marin de l'Atlantique du Nord-Est. Les Parties contractantes OSPAR devront décider de la procédure permettant de suivre ces conseils et d'entreprendre les futurs travaux dans le cadre de la Stratégie substances dangereuses.

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1. Introduction

1.1 Background

The OSPAR Commission is the cooperation between 15 governments and the EU for the protection of the marine environment in the North-East Atlantic. The North-East Atlantic Environment Strategy (NEAE Strategy) implements the Ecosystem Approach (NEAE Strategy Part I) and subsequently five thematic strategies (NEAE Strategy Part II) to address the main identified issues of concern for the North-East Atlantic. The thematic strategies are as follows: the Ecosystem and Biodiversity Strategy, Eutrophication Strategy, Hazardous Substances Strategy, Offshore Industry Strategy and Radioactive Substances Strategy. For each theme, the status of the marine environment is monitored and assessed, and the results are used to follow up implementation of the strategies and the gained benefits to the marine environment. The OSPAR Commission's aim with the thematic strategy for Hazardous Substances is to achieve background concentrations of naturally occurring substances and close to zero-concentrations of anthropogenic substances in the OSPAR maritime area. The Commission's strategic objectives are to prevent pollution by reduction of emissions, discharge and losses of hazardous substances. To achieve these objectives, the OSPAR Commission's main strategic directions are to maintain the List of Chemicals for Priority Action (LCPA) with the associated background documents and the List of Substances of Possible Concern (LSPC), taking appropriate action when needed (OSPAR Commission 2010a).

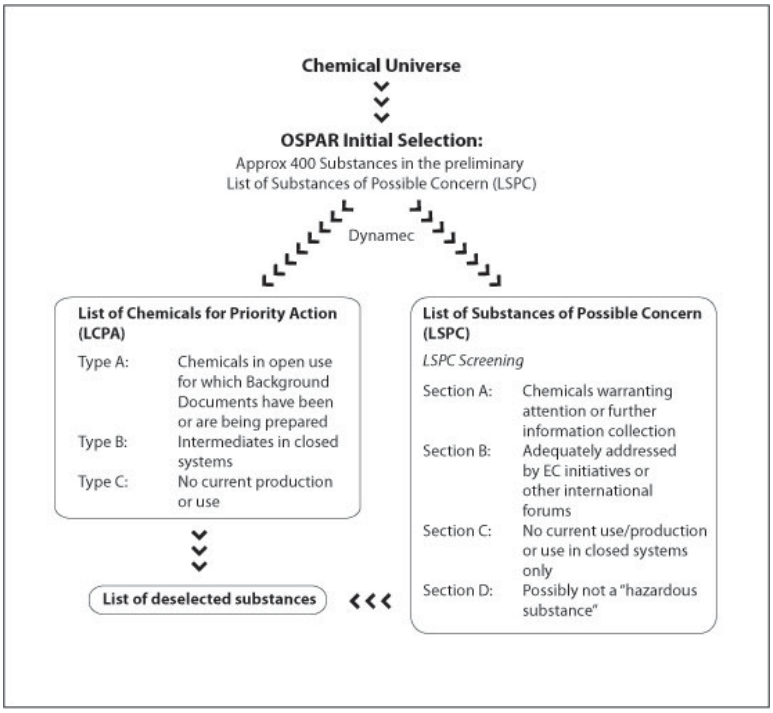

Figure 1. Schematic illustration of the OSPAR selection tool DYNAMEC and the subsequent lists; the List of Chemicals for Priority Action (LCPA) and the List of Substances of Possible Concern (LSPC). Each list is further grouped depending on the

status of the substance, or group of substances (OSPAR Commission 2015; https://www.ospar.org/work-areas/hasec/chemicals/overview)

The OSPAR Commission has defined hazardous substances as substances which are toxic, persistent and liable to bioaccumulate (PBT). Substances which cannot be classified as a PBT substance but give raise to an equivalent level of concern can in individual cases also be classified as hazardous. For the selection of hazardous substances to be addressed under the OSPAR Commissions Strategy and the selection of those substances which should be prioritized in the work of OSPAR, a tool - The Dynamic Selection and Prioritization Mechanism for Hazardous Substances (DYNAMEC) was developed and used (see *Figure 1*). The DYNAMEC procedure largely constitutes of three stages: initial selection of substances, ranking of substances and prioritization of substances. The initial selection of substances to the LSPC is largely based on the available information of intrinsic characteristics of each individual substance compared to OSPAR's cut-off values for PBT characteristics. Substances which did not meet these cut-off values, but still gave rise to an equivalent level of concern, were included on the LSPC if considered necessary, through the "safety-net" procedure. This procedure constitutes of an advisory opinion given from an expert group on the proposals of inclusion of substance on LSPC by Contracting Parties. Ranking of the selected substances was carried out by calculating the effect of the substance, i.e. the direct and indirect effect on aquatic organisms as well as the indirect effect on humans via ingestion of contaminated foods, and by calculating the exposure, i.e. the relative level of measured or predicted volume of the substance in the environment. Additionally, the ranked substances where further prioritized in order to develop OSPAR measures to reach the 2020 cessation target by reducing the discharges, emissions and losses of hazardous substances. As the DYNAMEC is a dynamic selection tool, new information on substances that already are on the LSPC should be reviewed continuously which may lead to additional prioritization or deselection of the substance from the LCPA or LSPC (OSPAR Commission 2002a). For the prioritized substances in LCPA, Type A, background documents were adopted containing extensive information on risks and exposure of each substance, as well as measures and actions in order to reach the OSPAR 2020 cessation target.

There presently exist multiple legislations and treaties which aim to protect the environment from hazardous substances. Within the EU, the Directive for Regulation, Evaluation, Authorization and Restrictions of chemicals (REACH) (in detailed described in Section 2.2), concerns usage and production of chemicals within the EU and aims to protect both human health and the environment from hazardous substances. One of the key processes is the registration of chemical substances to be used and/or manufactured on the European Market. Upon registration submitters need to assess the potential risks and hazards which is presented by the substance. This aims to prevent the substance from being manufactured and used, in such a way that is harmful towards both the environment and human health (ECHA 2018a). However, despite of extensive legislative effort, hazardous substances are still occurring in the environment and the reasons may be numerous. This includes combination effects of several co-occurring substances, hazardous substances which may be imported via products containing hazardous substances, poorly executed hazard and risk assessments as well as exposure scenarios, large production volumes, long-range transport of certain persistent organic pollutants may cause a concern in Europe even though production and use are not within the EU boundaries. The EU Water Framework Directive where Member States are obliged to screen the environment for selected prioritized substances can be

considered as one safety net to tackle these issues arising with REACH (Swedish Environmental Protection Agency, personal communication, 2018-11-30). Due to extensive work within the EU concerning monitoring and regulation of hazardous substances, e.g. REACH and the EU Water Framework Directive, OSPAR decided in 2004 not to continue with the DYNAMEC procedure for the selection and prioritization of substances (OSPAR Commission 2006a). The upkeep of the background documents proportionally halted and most of the background documents have not been updated since 2010 and a review of actions and measures for specific substances has not been undertaken since 2007 (OSPAR Commission 2007a). As a part of the process of deciding on how to continue the work with hazardous substances within OSPAR it was decided at the meeting of OSPAR HASEC (the Hazardous Substances and Eutrophication Committee) in March 2018 that HASEC intersessionally should evaluate if and what background documents for the priority substances that are still needed and if they should be updated.

1.2 Aim and formulated question

The aim of this report is to evaluate if and what background document for the OSPAR priority substances are needed and should be updated.

The questions which are central in the report are as follows:

- Does OSPAR need to update the background documents for the priority substances?
- Can OSPAR additionally contribute to the protection of the marine environment through additional actions for the prioritized substances?

The background documents for substances that are currently on the LCPA, Type A list, were included in this report. The background documents covered the following substances and/or group of substances: cadmium, lead and organic lead compounds, mercury and organic mercury compounds, organic tin compounds, vinyl neodecanoat, perfluorooctanyl sulphonic acid and its salts (PFOS), tetrabrompbisphenol-A (TBBP-A), trichlorobenzene, brominated flame retardants, polychlorinated biphenyls (PCBs), polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), 4-(dimetyhylbutylamino)diphenylamine (6PPD), dicofol, lindane, methoxychlor, pentachlorophenol (PCP), trifluralin, clotrimazole, 2,4,6-tri-tert-butylphenol, nonylphenol/ethoxylates (NP/NPEs), octylphenol, phthalates, polyaromatic hydrocarbons (PAHs) and musk xylene and other musks.

2. Material and methods

2.1 General approach

There are several factors as well as legislations that may determine the need to update the OSPAR background documents. It was decided that the main focus should stay on the current legislative status of the priority substances under the Stockholm Convention, REACH, the EU Water Framework Directive as well as relevant regulations which regulate substances that are used as active substances in biocidal products and plant protection products. In order to cover relevant information, CAS numbers, as mentioned in the background documents or on ECHAs database, was used to find correct legislative information. With the intention to gain some understanding if the current legislative measures and actions are sufficient to minimise impacts on the marine environment, data on status and trends in the

environment for certain OSPAR prioritised substances were included for example by looking into the results of the OSPAR Intermediate Assessment 2017 (OSPAR Commission 2017a). Subheadings 2.2 to 2.6 contain more in-depth information for each of these specific areas. Note that other relevant information may be included, if highly relevant for the evaluation of the OSPAR prioritized substances (e.g. Minamata Convention on mercury).

2.2 The EU Regulation REACH

Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of chemicals (REACH) is an EU regulation concerning the usage and production of chemicals within the EU. The legislation ultimately aims to improve the protection of the environment and human health against potential risks posed by chemicals through earlier and better identification of the intrinsic characteristics of chemical compounds. Additionally, the aim is to create a single chemical market for chemicals while simultaneously promote innovation and competitiveness in the same sector. This is done by implementing the four main processes of REACH, i.e. registration, evaluation, authorization and restriction of chemical substances on the European Market (European Parliament 2007).

Substances, as defined in Article 3(1) of REACH, which are either imported or manufactured at a volume above 1 tonne per year are obliged to be registered in the EU. This includes substances which are not classified as dangerous. Exemptions to the definition are substances which are already considered registered, e.g. active substances in both biocidal products and plant protection products, as well as notified substances as defined in Article 24 of REACH. Furthermore, substances as defined in Article 2 and 9, are also exempted to registration under REACH. This includes but is not limited to radioactive substances, non-isolated intermediates, food-stuff additives, pharmaceuticals, cosmetics and substances used for research and developmental purposes which may be exempted for usage for a five-year period (European Parliament 2007). Substances which cause an increased level of concern by posing an unacceptable risk on human health and the environment may either become authorized or restricted.

Successive phase out substances that present an unacceptable risk to human health and the environment is accomplished by identifying a chemical as a substance of very high concern (SVHC) and making said substance a subject for authorization under REACH. A SVHC will undergo the process of authorization and in due time be replaced with less hazardous substances if economically and technically feasible. Initiation of the authorization process commences by the request of a Member State or by the Commission itself. The initiator notifies parties whom may be affected by the authorisation and prepares a proposal for the substance in accordance with Annex XV under REACH. The proposal constitutes of two parts; the first part contains data on the characteristic properties of the substance as to why it should be recognized as an SVHC. The hazardous properties that classifies a substance as an SVHC are as follows; substances that may be classified as carcinogenic, mutagenic and toxic to reproduction (CMR) in accordance with CLP Regulation category 1A and 1B; substances that may be classified as PBT and vPvB substances in accordance with Annex XIII under REACH; substances which are not classified as a PBT, vPvB or CMR substance but cause a similar level of alarm. The second part covers information on market volumes and uses in the European Union. Substances that might be used as a replacement for the substance of concern should also be noted, if possible. Once established as a SVHC, the substance will be

placed on the Candidate List of Substances of Very High Concern (191 substances present today 2018-08-29). ECHA continuously determines which of the SVHC substances on the Candidate List that should be moved to the Authorization List, Annex XIV under REACH, and consequently in due time phased out from the European Market. This prioritization of candidates is regulated by Article 58(3) of REACH and is based on an evaluation of the intrinsic properties of each substance, wide dispersive use or if the volumes on the European Market fall underneath the scope for of the authorization requirement. Substances listed on the Authorization List are given a last application date and a sunset date and are thus possible to use and/or market if the applicant has authorization for usage (ECHA 2018b).

If a substance is believed to pose an unacceptable risk to the environment or to human health, a Member State or the Commission may initiate a restriction process. Substances that are listed on the Authorization List may also be restricted if needed. The restriction process aims to introduce bans and/or limitations on the manufacturing, usage and placement of the substance on the market. Other relevant conditions of restrictions may also be imposed if needed. The restriction of a compound includes but is not limited to the pure usage of the substance or usage in a mixture with compounds which are not restricted and/or do not require registration within the EU. A restriction proposal is prepared in accordance with Annex XV under REACH and shall contain background information about the substance, such as identified risks and alternative substances, and a justification for the proposed restriction where the environmental and human health benefits resulting from the restriction are explained. The restriction is introduced and registered under Annex XVII under REACH. Restrictions listed in Annex XVII do not apply to substances used in scientific research and development if volumes are below 1 ton per year (however additional exceptions apply), on-site isolated intermediates and to harmful substances found in cosmetic products (due to being covered by other regulations than REACH) (ECHA 2018c).

Substances used on the EU market, which have not previously been subjected to any scrutiny regarding its intrinsic properties, may be evaluated in order to clarify whether allowed usage presents a risk to human health and the environment. The aim is to request additional information from the registrants of the substance to verify the suspected concern. These substances are selected and added by ECHA onto the community rolling action plan (CoRAP) (ECHA 2018d). Selection of substances for the CoRAP process are based on risk-based criteria developed by ECHA and Member States. These selection criteria cover information on the hazardous properties of the substance, and on exposure and tonnage within the EU. Each substance is designated an EU Member State which evaluates and concludes whether the posed risk of the substance is sufficiently controlled with the current controls already in place. If concluded that current controls are insufficient, the conclusion may lead to proposals of risk management measures within REACH, i.e. restrictions, identification as SVHC and/or harmonized classification of the substance. Further actions outside the scope of REACH may also be introduced (ECHA 2018e).

2.3 The Stockholm Convention

Persistent organic pollutants (POPs) are substances which bioaccumulate, persist in the environment and risk causing adverse effects on both human health and the environment. Due to their longevity in the environment, POPs present an international problem as the pollutants easily travel from their sources by long-range transport through water, air and

products. As a result, the protection of POPs requires transnational cooperation. The Stockholm Convention on Persistent Organic Pollutants, from here on referred to as SC, is a global treaty concerning the protection of both human health and the environment from POPs. The SC was signed in 2001 and entered into force in May 2004 and requires all Contracting Parties (CP) to take measures in reducing or eliminating the release of POPs to the environment (SC 2008).

A work group continuously work with the process of nomination, evaluation and recommendation to include new POPs which fulfil the SC criteria; a process which takes three years. In the beginning there were 12 POPs (the Dirty dozen), now the SC presently covers a total of 28 substances, or groups of substances listed in Annex A, B or C of the Convention (or in a few cases added to more than one annex). For substances included on Annex A, CP must act to eliminate and/or prohibit the production and use, as well as the export and import, of intentionally produced POPs; registration of specific exempted productions and uses of the substance is possible in accordance with the named annex and Article 4 of the Convention Text. For substances included on Annex B, CP must act in restricting the production/use, as well as the export and import, of intentionally production of listed POPs; registration of acceptable purposes and for the production of POPs listed in Annex B is possible in accordance with named annex and Article 4 of the Convention Text. For substances included in Annex C, CP must take action in reducing or eliminating the release of unintentionally produced POPs (SC 2008).

2.4 The EU Water Framework Directive

Directive 2000/06/EC of the European Parliament and the Council establishing a framework for the Community action in the field of water policy, or more commonly referred to as the EU Water Framework Directive (WFD), is an EU Directive obligating EU member states to achieve good quantitative and qualitative water status in inland surface waters, coastal waters, transitional waters and groundwater. This includes marine waters up to one nautical mile from shore. The ecological and chemical status are assessed for both surface and ground waters to establish if the water body has a “good status” (European Commission 2016). In order to reach the goal of good chemical status in surface waters, Environmental Quality Standards (EQS), were derived for specific pollutants of EU relevance known as priority substances (PS). The priority substances (or groups of substances), are selected based on the presented significant risk the pollutant poses, to or via, the aquatic environment. This includes an evaluation of the hazardous properties of the compounds, their contamination of European waters as well as other factors, such as volumes used in the EU. Out of the PS, additional focus is given to the pollutants which are persistent, toxic and liable to bioaccumulation, or if they present a similar level of concern. These substances are identified as priority hazardous substances (PHS) (European Commission 2008a). There are currently 45 PS on Annex I of Directive 2013/39/EU (amendment of Directive 2000/06/EC and 2008/105/EC) (European Parliament 2013). To achieve good of the PS, the pollutant/s must meet the EQS. If EQS is not met, additional measures, than what already is being undertaken, needs to be taken in order to reduce emissions, discharges and losses of PS to waters (European Commission 2008a). In addition, those PS that are also of relevance beyond coastal waters should be part of the evaluation of good environmental status in marine waters as regulated by the EU Marine Strategy Framework Directive (2008/56/EC) (European Commission 2008b).

2.5 Active substances in biocides and plant protection products

Several of the prioritized OSPAR substances on LCPA are used as active substances in biocidal products and plant protection products. For these specific usages, the substances are regulated under the Biocidal Products Regulation (BPR). There are mainly two EU Directives which control the usage of biocidal and plant protection products: the Biocidal Products Regulation (BPR) and the Regulation on Plant Protection Products (EC) No. 1107/2009.

The Biocidal Products Regulation (BPR 2012/528/EU), concerns the placement on the market and the use of biocidal products within the EU. The BPR aims to protect both human health and the environment while improving the performance of the biocidal market in the EU (ECHA 2018f). The risks of active substances and products are therefore assessed before placing them on the market. In order for a biocidal product to be approved on the market, the substance must be authorized for usage on the market, and the active substance must additionally be authorized for usage in biocidal products. Active substances in biocidal products will not be authorized if they are either PBT, CMR in accordance with 1A and 1B of the CLP Regulation, endocrine disruptors or if they are considered to be very persistent or very bioaccumulative substances (vPvB) (ECHA 2018g).

Similarly, to the BPR, the active substance in plant protection products (PPP) must be authorized for usage in PPP. This initially obliges approval so that the substance may be used as active substances in PPP. Approval may be granted if the substances can ascertain to be safe for both the environment and human health. Without approval, and subsequent authorization, the active substance is not allowed to be used on the European Market (European Commission 2018).

2.6 Work within OSPAR

Besides from investigating the current status of the prioritized substances under European Commission legislation and the SC, information on the existing OSPAR monitoring strategies and the results thereof, was included in order to gain a more comprehensive view of the status of the substances. It is thus important to understand which priority substances that are monitored by the contracting parties (i.e. included in the harmonized monitoring strategy).

The Comprehensive Study on Riverine Inputs and Direct Discharges (RID), is an OSPAR monitoring programme that focuses on mandatory monitoring and reporting of the loads and concentrations of certain selected contaminants by OSPAR Contracting Parties. Voluntary monitoring of certain contaminants also occurs under RID. The aim of RID is to assess all discharges and inputs of selected pollutants to the OSPAR Maritime Area and its regions which are discharged directly to into the sea or carried via rivers into tidal waters (OSPAR Commission 2015a).

OSPAR is currently undertaking monitoring of airborne contaminants to the OSPAR Maritime Area by implementing the Comprehensive Atmospheric Monitoring Programme (CAMP). The input of atmospheric deposition of contaminants are assessed based on the annual monitoring data and reports of concentrations of certain contaminants via both

precipitation and air. Monitoring and reporting are for some substances mandatory for the OSPAR Contracting Parties, while for some only voluntary (OSPAR Commission 2015b).

Over the period between 2014-2021, OSPAR Contracting Parties are committed to deliver what has been described by the OSPAR strategy and themes, under the relevant provisions of the OSPAR Convention in implementing the OSPAR North-East Atlantic Environment Strategy and the EU Marine Strategy Framework Directive (MSFD, Directive 2008/56/EC). The OSPAR Joint Assessment and Monitoring Programme (JAMP) is a tool for Contracting Parties to do just that as it describes the strategy, themes and products that are needed to be delivered (OSPAR Commission 2014) . The Coordinated Environmental Monitoring Programme (CEMP) constitutes an important part of JAMP as it aims to deliver comparable data from the OSPAR Maritime Area. This data can thus be used in the assessments to address the specific questions raised in JAMP. If these substance are lacking coordination tools, they may be categorized as pre-CEMP which only requires voluntary monitoring on a temporary basis instead (OSPAR Commission 2016).

The OSPAR Intermediate Assessment 2017, from here on referred to as the IA 2017, presents OSPARs progress in realizing its vision of a healthy, biologically diverse and clean North-East Atlantic. The assessment further aims to shed light over the current status, as well as further develop OSPARs understanding, of the marine environment in the North-East Atlantic. It is based on data as produced by the OSPAR monitoring programmes CAMP, CEMP and RID and will be incorporated in this report when possible. As a continuous assessment on the previous QSR 2010 OSPAR assessment, the IA 2017 on hazardous substances incorporates data up to year 2015 (OSPAR Commission 2017a). The monitoring data was compared to the developed Background Assessment Criteria (BAC) and Environmental Assessment Criteria (EAC). The BACs are used to distinguish whether or not the measured concentrations are close to zero for man-made contaminants or near the background for naturally occurring substances; if mean measured concentrations are significantly below BAC, concentrations are said to be near the background for naturally occurring substances. The EACs are used for the assessment of the ecological significance of the concentrations in marine biota and sediments; if EACs have not yet been developed, the European Commission’s maximum levels in food stuff were used instead to assess the ecological significance of measured concentrations in biota or the Effects Range-Low (ERL) level as developed by the United States National Oceanic and Atmospheric Administration (NOAA) for the assessment of the ecological significance in of measured concentrations in sediments (OSPAR Commission 2017e, OSPAR Commission 2017f).

3. Results and discussion of the individual prioritized substances

3.1 Overview

In order to gain a clear overview, this report divided the 26 individual OSPAR background documents into four groups dependent on the current legislative status of the compounds, if and what new relevant information that had emerged since the last update and suggestions on what consequent actions deemed reasonable within the OSPAR framework of prioritized substances. These are the four groups: *substances which requires no additional OSPAR action*; the group contains substances which are considered hazardous but are considered sufficiently regulated, i.e. methoxyhlor, dicofol, endosulphan, trifluraline, pentachlorophenol

(PCP), lindane, musk xylene and other musks, certain phthalates, trichlorobenzenes (TCB), nonylphenol and nonylphenol ethoxylates (NP/NPE) and octylphenol. *Substances which are not considered fulfilling the criteria as hazardous substances and should be removed from the LCPA*; substances which may be demoted from the OSPAR LCPA list as the intrinsic hazardous properties no longer make them of such concern that they need to be prioritized, i.e. 4-(dimethylbutylamino)diphenylamine (6PPD), clotrimazole and neodecanoic acid, ethylene ester. *Substances which may need additional actions*; substances which are currently under CoRAP evaluation, i.e. 2,4,6-tri-tert-butyl-phenol, tetrabromobisphenol A (TBBP-A) and the synthetic musk AHTN. *Substances which requires continuous monitoring and potentially evaluation of needs for additional measures*; this group contains substances which are currently monitored by OSPAR, but despite of them being regulated by the EU (and international treaty's) are still suggested for OSPAR to take additional action, i.e. PCB, PFOS, organic tin compounds (OTC), polycyclic aromatic hydrocarbons (PAH) cadmium, mercury, lead, brominated flame retardants and PCDD/PCDF. For each group, the current legislative status is presented as well as relevant information as presented in the background document. It is important to note that the presented groups are not set in stone; depending on the interpretation of the presented data, different types of actions may be suggested.

It is important to bear in mind that the PBT-assessments differ between the OSPAR background documents; different background documents utilize different PBT-criteria. In a few cases, both the PBT-criteria as described in the EC Technical Guidance Document, under REACH, as well as the OSPAR PBT cut-off values were considered (e.g. the background document on neodecanoic acid). In a few cases, only one of the PBT-criteria were considered for the assessment (e.g. the background document on octylphenol which only uses the REACH PBT-criteria). It is noteworthy that the PBT-criteria somewhat differ between sources which occasionally created situations in which prioritized substances were on one hand classified as a PBT compound by one of the criteria, but not a by the other criteria. The differences are summarised in Table 1.

Table 1. Summary of PBT-criteria as found in the EC Technical Guidance Document under REACH (ECHA 2017) and the OSPAR cut-off PBT values as described in the DYNAMEC Manual (OSPAR Commission 2006a)

Criteria	**REACH**	**OSPAR**
Persistent (P)	Half-life; >60 days marine water >40 days fresh/estuarine water or >180 days marine sediment or >120 days freshwater/eustarine/sediment or soil	Half-life ≥50 days
Bioaccumulative (B)	BCF >2,000 l/kg	Log Kow ≥4 or BCF ≥500 l/kg
Toxic (T)	Long-term NOEC <0.01 mg/l or CMR or chronic mammalian toxicity	Acute L(E)C_{50} ≤1 mg/l or long-term NOEC ≤0.1 mg/l or CMR or chronic mammalian toxicity

3.2 Impact of the REACH authorization process

REACHs main tool in phasing out hazardous substances, as mentioned, largely comes down to the identification of substances as SVHC and the REACH Authorization. A study on the impacts of REACH Authorization, as reported by the European Commission, aimed to obtain quantitative confirmation on the over overall impacts of Authorization. It was concluded, as regard to instances of substitution, that the overall process of Authorization leads to substitution of hazardous substance where it is technically feasible for both SVHC substances on the Candidate List, as well as for substances on the Authorization list. This also applied to situations where it would have been more cost-efficient to apply for Authorization (Mistry *et al.* 2017). Ambiguously, data on sales values and sales volumes of SVHCs subjected to authorisation did not generally divert from the overall EU chemicals market trend. The study however noted that used data was probably not best suitable to use for any observational changes in the market as data was unable to comprise factors which affect the sales and substances volume. Such factors include the fact that SVHC substances may be used as no other efficient less hazardous alternatives were available or that substitution of a SVHC is a time-consuming process for which results may be seen in the future. The study also suggested authorization process in itself to cause an increase in sales/demands of SVHC after the sunset date from companies which have been granted authorisation. However, using data on REACH registrations, as of November 2016, ECHA had identified the cessation of manufacturing and import by in total 103 identified registrants, where 69 had ceased importing and manufacturing of SVHC substances on the Candidate List, and the remaining 34 SVHC substances on Annex XIV of REACH (Mistry *et al.* 2017).

Despite the somewhat ambiguous results of the study, it seems likely that the REACH authorization process and the identification of SVHC actually does have an impact on the use, production and import of SVHC substances. It should however be noted that the fact that a SVHC is included on the Candidate List does not necessarily mean cessation of production/import and use of SVHC as it does not impose any legal measures in restricting the use and production/import of the compounds. The results, suggestions and conclusions drawn in this report are thus generally based on the belief that the current legislative system, as implemented by the European Community through REACH and the SC, are sufficient in the protection of the environment, at large, against hazardous substances if other readily available information (i.e. monitoring data) is not indicating the opposite. A more in-depth analysis of the effectiveness of these actions in the protection of the environment is not done at this time (due to time limitations).

3.3 Substances which require no additional OSPAR action

This report presents several OSPAR priority substances which are suggested to be of low priority for the future work within the OSPAR strategy of hazardous substances. Since publication of the priority substances background documents, including updates and reviews, constitutive regulatory work has been carried out by the European Commission, as well as by global treaty's (Stockholm Convention and Minamata Convention) which have strictly limited the usage of many OSPAR priority substances. The prioritised substances in this group are considered sufficiently regulated under current regulations.

3.3.1 Active substances in biocidal and plant protection products

The OSPAR priority substances which were used as active substances in plant protection and biocidal products, i.e. lindane, methoxychlor, trifluralin, dicofol, endosulphan and pentachlorophenol (PCP) and its salts and esters are banned for use on the European Market. For a detailed overview of the legislative status of named substances, see Appendix A. None of the OSPAR priority substances previously used in PPPs had their authorizations revoked before 2009 (European Parliament 2009). None of the substances are authorised for use in biocidal products under the Biocidal Products Regulation (BPR) 2012/528/EU. Furthermore, pentachlorophenol (PCP), lindane and endosulphan are identified as POPs under the SC. All of them are included on Annex A of the SC and are thus to be phased-out globally. Certain exempted uses do apply, however only for countries on the Registry (Stockholm Convention 2004). In addition, dicofol is up for evaluation to be identified as a POP under the SC which might lead to more stringent usage globally (UN Environment 2018).

Regarding lindane, the OSPAR background document (last updated 2004) stated the "need to reduce atmospheric inputs of lindane into the marine area" and the need to continue the current monitoring and assessment of lindane (OSPAR Commission 2002b). The 2008 review statement concluded the need to continuously monitor lindane through the OSPAR monitoring programmes CAMP and RID (OSPAR Commission 2008). Today, lindane is only recommended for monitoring on a voluntary basis under the OSPAR programme RID (OSPAR Commission 2018).

A few of these active substances are being phased out globally, however a few only within the EU (i.e. methoxychlor, trifluralin and dicofol). It is a possibility that these substances reach the OSPAR marine environment indirectly via the use of imported products, waste incineration and leakage from historically polluted sites. This report did also not assess the risk of long-range transport for these substances. However, as none of the OSPAR priority substances which are used as active substances in biocidal products and in plant protection products substances can be placed on the European Market, and some even are restricted globally, it is concluded that there is currently no need for OSPAR to take further actions to move towards the cessation target in 2020. However, the voluntary monitoring of lindane under RID should continue as decided.

3.3.2 Short chain chlorinated paraffins

The background document on short chain chlorinated paraffins (SCCP) was last updated in 2009 (OSPAR Commission 2009a). No OSPAR measures are currently active for SCCPs (Annex X). SCCP are used as a metalworking fluid in paints, sealants and coatings as well as flame-retardants in textiles and rubber. Since 2017, SCCPs are identified as POPs under the SC and listed in Annex A of the Convention Text. Decision SC-8/11 states exempted uses of SCCPs is allowed for Contracting Parties on the Register of the Convention Text and applies for use as additives in rubber convoy belts, transmission belts, textiles, lubricants, tubes for outdoor decoration bulbs, paints, adhesives, plasticizers and metal plating. Furthermore, SCCPs are identified as SVHC under REACH, however not yet included on Annex XIV of REACH (ECHA 2018h). The substance is also identified as a PHS substance under the WFD (European Parliament 2013).

Noteworthy, is the potential problems of common SCCP alternatives. The OSPAR background document on SCCP presents several alternatives to using SCCPs. At the latest update of the background document, it was stated that long-chained chlorinated paraffins (LCCPs) had been used as alternatives in metalworking fluids in Sweden. LCCPs were also suggested as alternatives to SCCPs in the leather industry. Medium chain chlorinated paraffins (MCCP) have also been used as replacement substances to SCCP as extreme pressure additives in metalworking fluids and in sealants and as plasticizers in paints. The background document however noted the potential environmental risk of using MCCPs as substitutes for SCCPs a risk assessment performed under the framework of the Existing Substance Regulation. The risk assessment stated that risk reduction measures were required for some specific uses, e.g. for the use in production of PVC (OSPAR Commission 2009a). Recent research indicates that MCCPs and LCCPs are equally as problematic as SCCPs. A Swedish screening study investigating levels of chlorinated paraffins in terrestrial mammals and birds in Sweden reported relatively high concentrations of LCCP in certain bird species and concluded that both MCCPs and LCCPs have the potential to bioaccumulate through the terrestrial food chain (Yuan & de Wit 2018).

Although SCCP are being phased out globally, the list of exempted productions and uses of the substance are quite substantial for SC Contracting Parties. Nonetheless, as they have been classified as POPs and are decided to be phased out, it is suggested that no additional OSPAR actions are needed at this time. However, the use of MCCP and LCCP as a SCCP alternative should be taken with caution as MCCPs and LCCPs are found in mammalian terrestrial biota as well as in birds, OSPAR should consider supporting any further work that is being undertaken in the screening and investigation of the risk MCCP and LCCP pose to the environment. As a suggestion, screening for MCCP and LCCP within the OSPAR Maritime Area could be an important OSPAR action.

3.3.3 Musk xylene and other musks

The OSPAR background document on musk xylene and other musks was last updated in 2004. Synthetic musks have a typical musky scent and are thus used by the fragrance industry in consumer products such as fabric softeners, cosmetics, detergents and other household products. The OSPAR background document covers the most important nitromusks (musk xylene and musk ketone) and the most important polycyclic musks i.e. HHCB and AHTN. The background document further includes several macrocyclic musks as they were considered as possible substitutes to musk xylene (OSPAR Commission 2004a).

The main nitromusk musk xylene was identified as a SVHC substance and included on Annex XIV of REACH in 2009 and the only route for authorization to be granted is in accordance with Article 60(4) of REACH (the socio-economic route). The sunset date and last application dates were set to 21/08/2014 and 21/02/2013 respectively (European Parliament 2007). Musk xylene is thus not registered for use and or production under REACH. The nitromusk musk ketone is currently registered in full use under REACH as the final risk assessment under EEC 793/93 concluded that musk ketone did not pose a risk to human health nor to the environment. Furthermore, nitromusks musk tibitene and muskene, as included in the background document, are not currently registered for any usage on the European Market.

The polycyclic musks HHCB, ADBI, AHMI, AITI were registered for use under REACH, without being restricted or identified to cause concern under said EU legislation, nor under the SC. For information on the status of the polycyclic musk AHTN, see Section 3.5.2.

The macrocyclic musks muskone, cyclopentadecanolide, musk T and musk R1, as included in the background document are all registered for full usage under REACH without any restrictions or causes for concern. The macro cyclic musk musk natural, as mentioned in the background document, is not registered for use on the European Market.

Given the presented data on the nitromusks, excluding musk xylene, the polycyclic musks, excluding AHTN and the macrocyclic musks, there is currently no reason to believe that these synthetic musks pose a risk to the marine environment. Although musk xylene is subjected to authorization under REACH, it is not registered for use on the European Market. It is thus suggested that OSPAR does not need to take further action in limiting the risk of synthetic musks other than those that already exist within the European Community.

3.3.4 Certain phthalates

The OSPAR background document on phthalates was last updated in 2006. The phthalates that are highlighted in the background document are di-n-butyl phthalate (DBP), butylbenzyl phthalate (BBP), di(2-ethylhexyl) phthalate (DEHP), di(isononyl) phthalate (DINP) and di(isodecyl) phthalate (DIDP). Phthalates are commonly used as plasticizers in PVC in the polymer industry, though as a family of industrial chemicals they can be used as adhesives, solvents and softeners by a variety of industries. It was concluded in the background document that neither of the mentioned phthalates met the PBT-criteria nor did they in general present a risk to the marine environment, given the present level of exposure. However, the background document also concluded that DBP, DEHP and BBP are potential endocrine disruptors but the risk in this regard should be considered in the context of a general approach to endocrine disrupting substances (OSPAR Commission 2006b).

DBP, BBP and DEHP are all identified as SVHC substances and included on Annex XIV of REACH. Authorization for use of either named substance may be granted if the risk to human health arising from the use of these phthalates are adequately controlled in accordance with Section 6.4 of Annex I of REACH; if not, authorization may be granted in accordance with Article 60(4) of REACH. These phthalates are further exempted for use in the immediate packaging of medicinal products covered under Regulation 2004/762/EC, Directive 2001/82/EC and/or Directive 2001/83/EC. The sunset date and last application dates are 2015/02/21 and 2013/08/21 respectively (ECHA 2009a, ECHA 2009b, ECHA 2009c). All three phthalates are currently registered for both full usage and intermediate usage under REACH, with various volumes on the European Market. DEHP has a yearly tonnage band of 10 000 to 100 000 tonnes per annum, DBP has a yearly tonnage band of 1000 to 10 000 tonnes per annum and BBP has an annual tonnage band of 0 to 10 tonnes per annum and has the same restricted usage under REACH. The restriction states that DBP, BBP and DEHP shall not be used as a plasticized material in toys and childcare articles, as a substance or as a mixture, in concentrations greater than 0.1% by weight of the material nor shall they be placed in childcare articles and toys containing these phthalates in concentrations greater than 0.1% by the weight of the plasticized material shall not be placed on the market (European Parliament 2007). Furthermore, DEHP is identified as a PHS under WFD and is thus

incorporated in national screening programmes on water quality in EU Member States (European Parliament 2013).

DINP and DIDP are also restricted under REACH, where the restriction states that said substances shall not be used as a substance or in mixtures in toys and childcare articles which can be placed in the mouth by children, in concentrations greater than 0.1% by weight of plasticized materials. The toys and childcare articles, as mentioned, shall not be placed on the European Market (European Parliament 2007). Both have undergone risk assessments under EEC 793/93 with the conclusion that neither of the substances poses any risk on any of the environmental compartments and that there was at the time (2005) not needed to act in reducing the risk. However, there was a need to limit the risk DIDP poses on consumers if the intended use was for substitution of other phthalates in consumer products. Both DINP and DIDP are registered for use under REACH with a total tonnage band of 100 000 to 1 000 000 and 10 000 to 100 000 tonnes per annum respectively.

Although, specifically DEHP and DBP, are used in substantial volumes, the use and production are restricted and subjected to authorization. It is thus believed that the risk these substances pose on human health and the environment is sufficiently controlled by current EU legislation. On this basis, it is suggested that OSPAR does not need to take further action in limiting the risk by said substances. As both DINP and DIDP are restricted and are previously assessed not to pose any risk to the environment, it is suggested that no further OSPAR actions are needed. It should however be noted that phthalates are a sizeable group of substances with many possible substitutes. Björkblom *et al.* (2018) investigated what substances may be used as substitutes to restricted plasticizers, with focus on phthalates. Out of the 152 potential candidates 11 individual plasticizers where prioritized and recommended for screening in Sweden, with prioritization based on production volumes (as registered under ECHA), on whether substances were included on ECHA's Restriction List or CoRAP and on whether the substances were classified as hazardous or not (Björkblom *et al.* 2018). Due to the large number of possible substitutes of plasticizers, OSPAR should consider supporting any further work that is being undertaken in the investigation and screening of substances which are potentially used as substitutes to phthalates.

3.3.5 Nonylphenol and nonylphenol ethoxylates (NP/NPE)

The OSPAR background document on nonylphenols and nonylphenol ethoxylates (NP/NPEs) was last updated in 2009. NPEs are used as dispersive agents, emulsifiers, surfactants and/or wetting agents; these are the main input sources of NP/NPEs to the sea (OSPAR Commission 2009b).

The background document on NPs/NPEs focused on these phenols as a group rather than individual substances, while noted that the most common NPs/NPEs carried the CAS numbers are 25154-52-3 and 9016-45-9 respectively (OSPAR Commission 2009b). The current legislative status on NPs/NPEs is not straight forward as changes of CAS are currently undertaken by ECHA. However, the Swedish Chemicals Agency (KemI), has kindly assisted with the mapping of the substances. Both 4-nonylphenol, branched and linear and 4-nonylphenol, branched and linear, ethoxylated are identified as SVHC and included on the Candidate List under REACH. Only 4-nonylphenol, branched and linear, ethoxylated are not yet included on Annex XIV of REACH as the wide dispersive use of the non-ethoxylated 4-

nonylphenol, branched and linear, is not large enough to be subjected to authorization (European Parliament 2007). This does not exclude a potential prioritization for named NPs to be included on Annex XIV in the future. Furthermore, the NPs/NPEs with CAS numbers as mentioned in the background document are restricted under REACH (European Parliament 2007). NPs are also identified as PHS under WFD (European Parliament 2013). For a detailed description on the current legislative status of the NPs/NPEs under REACH and WFD, see Appendix B.

NPs/NPEs are not included in OSPAR CEMP monitoring but as the substances are included as a PHS under WFD they are included in many national monitoring programmes. NPs have also been screened in Swedish monitoring surveys. In 2016-2017 phenolic compounds were analyzed in 10 Swedish rivers over four different seasons. The daily fluxes of phenolic compounds were estimated to be 16 000 g d^{-1} (5700 kg $year^{-1}$) for all 10 investigated rivers. The EQS of the WFD was exceeded in 13% (n = 5) of the surface water samples for 4-NP (Ahrens *et al.* 2018). This indicates that there is a potential risk for the limnic environment. In 2008, NPs were measured but not detected in marine offshore sediments but high concentrations in fish liver (<1 – 44 µg kg^{-1} ww^{-1}) and in blue mussels (<1-37 µg kg^{-1} ww^{-1}) were reported by other Scandinavian countries in urban areas in 2008 (Naturvårdsverket 2014). Nonylphenols are also regularly monitored in WWTP effluents in Sweden since 2010. In 2015 4-NP was found above the detection limit in four out of nine effluents (100-243 µg l^{-1}) (Haglund 2017). Furthermore, early 2018 Helcom Pressure launched a data call to investigate data availability on riverine loads of pollutants and micropollutants in WWTP effluents in the Baltic Sea area, NP/NPEs being one substance group for which data was requested. Initial results suggest that NP/NPEs are often found in effluents of WWTPs as well as riverine or coastal water, sometimes exceeding the EQS. The data will be compiled and further analyzed in a brief report and possibly NP/NPEs could be of interest for indicator development within Helcom.

NPs/NPEs are today, to a large extent, covered by restrictions and are subjected to authorization under REACH. The OSPAR background document on NPs/NPEs concluded that additional actions might be needed in order reach the OSPAR 2020 target. Such actions were suggested to be based on the work made in the EU risk reduction strategy and risk assessment (OSPAR Commission 2009b). Monitoring data suggests that nonylphenols are present in riverine waters and WWTP effluents, this implies that they might also still pose a risk for the marine environment. It is suggested that OSPAR awaits the coming Helcom report on riverine pollutants and micropollutants in WWTP effluents in order to decide on future actions that could include screening in OSPAR waters. There is thus no need to include additional OSPAR actions at this time.

3.3.6 Octylphenol

The background document on octylphenols were last updated in 2006, and a review statement to the background document was adopted in 2009. The background document includes several isomeric compounds of the general formula $C_8H_{17}.C_6H_4(OH)$, however focus is on 4-tert-octylphenol (CAS no 140-66-9) as it is of most commercial importance. The substances are primarily used as intermediates in the production of formaldehyde/phenol resins and in the manufacture of octylphenol ethoxylates. They can however be found as impurities in commercially used nonylphenols which is believed to add to the environmental

exposure of OPs. 4-tert-octylphenol only meet two of the PBT-criteria in the marine risk assessment (P or vP and T-criteria; classification against the EC Technical Guidance Document PBT-criteria, in the background document). The background document also states that 4-tert-octylphenol exhibits endocrine disruptive properties (OSPAR Commission 2003).

Octylphenol is registered, in full, under REACH with a tonnage band of 10 000 to 100 000 tonnes per annum. The priority substance was in late 2011 identified as a SVHC and included on the Candidate List under REACH yet awaiting to be recommended for inclusion on Annex XIV of REACH. No restrictions apply for the use and production of octylphenol on the European Market. Additionally, the background document states the fact that more stringent regulations regarding the use and production of nonylphenols could simultaneously decrease the exposure of octylphenol to the environment (OSPAR Commission 2003). Octylphenol is identified as a PS under WFD and is thus often incorporated in national screening programs on water quality in EU Member States (European Parliament 2013). Sweden reported in 2014, elevated, and occasionally levels exceeding the environmental impact standards (EIA), in water at point sources, around urban areas and WWTP influent (Naturvårdsverket 2014). Octylphenols are also regularly monitored in WWTP effluents in Sweden since 2010. In 2015 4-OP was found above the detection limit in five out of nine effluents (11-48 ng l^{-1}) (Haglund. P 2017). Data on octylphenol is also included in the above-mentioned Helcom Pressure data call on riverine pollutants and micropollutants in WWTPs in the Baltic Sea area. There is less data for the OPs compared to NPs but the initial presentation of the data compilation suggests that the levels in WWTP effluents around the Baltic sometimes exceed the EQS. OPs were also included in the Swedish study of phenolic compounds in rivers, however 4-OP was rarely detected and the EQS was not exceeded in any surface water sample (Ahrens *et al.* 2018).

The published review statement on octylphenol from 2009 concluded that any further measures or work for the control of octylphenols would best be taken in the European Commission framework, rather than by OSPAR (OSPAR Commission 2009c). The review statement suggested that OSPAR instead should keep a watching brief on future developments to ensure that any possible risk to the marine environment that might arise are noted and taken into account and then act upon if needed. Although octylphenol is only identified as a SVHC and listed on the Candidate List and not subjected to authorization under REACH, stronger constitutive restrictions might be needed in order to minimize the risk octylphenol poses on the environment. Monitoring data suggests that octylphenols are present especially in WWTP effluents. This implies that they might also still pose a risk for the marine environment. It is suggested that OSPAR awaits the coming Helcom report on riverine pollutants and micropollutants in WWTP effluents in order to decide on future actions. These could include screening in OSPAR waters. As suggested in the review statement, OSPAR could also keep a watching brief on future developments concerning octylphenols on the European Market.

3.3.7 Trichlorobenzenes (TCB)

The OSPAR background document on trichlorobenzenes investigates the risk of three individual trichlorobenzenes: substances 1,2,3-trichlorobenzene (1,2,3-TCB), 1,2,4-trichlorobenzene (1,2,4-TCB) and 1,3,5-trichlorobenzene (1,3,5-TCB). The background document was last updated in 2005, however a review statement to the background

document was adopted in 2010. Trichlorobenzenes (TCBs) are used as intermediates in chemical synthesis, as a coolant, as a solvent, a heat-transfer medium and as a lubricant; additional uses of TCB also exist, e.g. in termite-control preparations, in polyester dying and as an insecticide. Previous production of hexachlorocyclohexane (HCH), which can be found in the insecticide lindane, commonly used TCB as a chemical intermediate. Furthermore, TCB can also be formed in degradation process of higher chlorinated benzenes such as pentachlorobenzenes and hexachlorobenzenes (OSPAR Commission 2005).

The TCBs underwent a Risk Management Option Analysis (RMOA) in 2010 which suggested to propose the substances as SVHC due to their endocrine disruptive properties. However, this identification has not been prioritized and the substance was thus not identified as a SVHC and not included on the Candidate List (Swedish Chemicals Agency, personal communication, 2018-10-26). The TCBs are registered for intermediate use only. 1,2,4-TCB is the only TCB which has restricted usage under REACH thus the substance shall not be used, or placed on the market, as a substance or in mixtures in a concentration equal to, or greater than, 0.1% by weight by any use. The only exempted uses are as an intermediate of synthesis or as process solvent in closed chemical application for chlorination reactions or in the production of 1,3,5-triamino-2,4,6-trinitrobenzene (TATB) (European Parliament 2007). Furthermore, TCBs are identified as a priority substance (PS) under WFD (European Parliament 2013). The review statement on TCB reported that there was only one producer in Europe (located in Germany) which sells and uses TCB, only as intermediates; the expected release to water from production was estimated at about 30 kg/year. The review statement further noted that TCB has been phased out in a number of uses; as dielectric fluids, lubricants and heat transfer fluids, as solvents, as components in synthetic oils, in abrasive formulations, in degreasing agents and cleaning agents for septic tanks. TCB are now used mainly as a chemical intermediate for the production of pigments, dyes and herbicides (OSPAR Commission 2010b).

Swedish monitoring data on TCB, as a part of the WFD screening in 2014, showed low levels in water and in several cases below the detection limit for used analytical methods. 1,2,4-TCB was found in sludge from all waste water treatment plants (WWTP), which indicated a local need for monitoring. Nonetheless, it was concluded that there was currently no need to increase monitoring of TCBs in water. TCBs are also found in marine offshore sediments, albeit levels are decreasing (Naturvårdsverket 2014).

Considering that 1,2,4-TCB is restricted under REACH and as TCBs are only allowed for intermediate use it is suggested that the risk of TCBs are adequately controlled. This assumption is strengthened by the low levels of TCB in Swedish waters; no additional OSPAR actions are therefore suggested. The revised background document on TCBs from 2010 however suggests for OSPAR to identify historical sites and sinks of TCB and to investigate remediation needs if required. These sinks are likely connected to TCB formed via degradation processes from hexa- and pentachlorinated benzenes. Whether this action is still relevant is, in this evaluation, is difficult to conclude.

3.4 Substances which are not considered fulfilling the criteria as hazardous substances and should be removed from the LCPA

Three OSPAR priority substances are suggested to be either demoted to the LSPA, as they are no longer considered to need priority actions prioritization, or removed from both lists as they are no longer considered to fulfil the criteria for OSPAR The evaluation is essentially based on the differences in hazard assessments between OSPAR and REACH and whether the European Commission interprets the use and production of said substances as problematic from a human health and environmental point of view.

3.4.1 Clotrimazole

The OSPAR background document on clotrimazole was last updated in 2013. The pharmaceutical clotrimazole is used in the treatment for gynecological and dermatological fungal infections and can be found in prescription drugs as well as non-prescription drugs. The OSPAR background document on clotrimazole stated that the pharmaceutical is a borderline PBT-substance as it does not fully fulfil the OSPAR DYNAMEC PBT-criteria, while the P- and T-criteria were fulfilled the B-criteria was only almost fulfilled. Clotrimazole is not considered a PBT-substance in accordance with REACH as only the P and T criteria are fulfilled. Bayer (manufacturer of clotrimazole) conducted a risk assessment for "The Guideline on Environmental Risk Assessment of Medicinal Products for Human Use" (EMEA) and reached the conclusion that the pharmaceutical was not a PBT-substance (it fulfilled the P and T criteria, however not B) and that there was no environmental risk for the use of clotrimazole. Furthermore, the OSPAR risk assessment on clotrimazole, as stated in the background document, indicates that there was at present no risk for the different environmental compartments from the use of clotrimazole. The background document concluded that given the data on European production and use (data from 2010) there was no need for OSPAR to take actions to move forward towards cessation of discharges, emissions and losses of clotrimazole. In case of changes to production/use figures, the monitoring strategy suggests a review of the risk of clotrimazole to the marine environment and to suggest a subsequent monitoring strategy (OSPAR Commission 2013a).

No information on the current production and use figures of clotrimazole for the EU has been obtained for this report. However, by reviewing the sales statistics for the defined daily doses (DDD) sold for prescription drugs containing clotrimazole in Sweden, the sales figures have more or less stagnated since 2012 (Socialstyrelsen 2018). Given the presented risk of clotrimazole, it is concluded that there is currently no need for OSPAR to take further actions to move towards the cessation target in 2020. As the pharmaceutical does not fulfill the DYNAMEC PBT-criteria, it can further be suggested to demote clotrimazole as an OSPAR priority hazardous substance to the OSPAR LSPA. Although sale statistics on prescription drugs containing clotrimazole in Sweden has not changed, the situation may be different in other countries as well as for non-prescription drugs. If additional data on production and use of clotrimazole emerges, it might be important to re-evaluate the risk clotrimazole poses on the marine environment.

3.4.2 Neodecanoic acid, ethenyl ester (vinyl neodecanoat)

The OSPAR background document on neodecanoic acid, ethynyl ester, was last updated in 2011. Neodecanoic acid, ethenyl ester, goes also under the name vinyl neodecanoate, and is

mostly used as an intermediate in the production of polymeric binding agents. The polymeric binding agents are later used in latex coatings. Note that no monitoring strategy for vinyl neodecanoat has been proposed and no measures have been taken to date (OSPAR Commission 2013b). The substance is registered for use on the European Market, with a total tonnage band of 10 000 to 100 000 tonnes per year. Vinyl neodecanoat is not restricted or identified (nor currently intended to be identified) as a SVHC under REACH or as a PS/PHS under WFD (European Parliament 2013).

According to the OSPAR background document, vinyl neodecanoat is not identified as a PBT-substance in accordance with REACH-criteria as it only meets the T-criterion. The compound was identified as a PBT-substance in accordance with OSPAR cut-off PBT values, but there were great uncertainties in the assessment. Although all criteria were met, the P-criterion assessment was based on data from laboratory studies which had shortcomings that lead to uncertainty in the conclusion on the compound's persistence. Moreover, the QSAR-predictions indicated that vinyl neodecanoate potentially would degrade rapidly in the marine environment (OSPAR Commission 2013b). The background document further concluded that the initial results from the marine risk assessment indicated that the use of vinyl neodecanoate and the use of latex polymer products containing said substances might be of concern. However, it was additionally noted that the majority of the PEC-values were derived from default "reasonable worst case" emission estimates which should be taken into account when considering future measures. The background document did not present any of the locations of the sites involved in the polymerization of vinyl neodecanoate in the EU; this information ought to be sought together with information on marine releases as current information was lacking in the refinement of the marine assessment (OSPAR Commission 2013b). The OSPAR background document further included information from, the then yet to be released, risk evaluation on vinyl neodecanoate as carried out by the UK Environment Agency; the risk evaluation concluded that vinyl neodecanoate presented a substantial risk on the marine environment but that there were great uncertainties and the risk assessment needed to be refined with further information and/or testing.

The presented information on vinyl neodecanoate is equivocal. From a purely legislative point of view, vinyl neodecanoate is not considered to be a substance of concern under the current EU regulations as it is not restricted, intended to be subjected to, nor subjected to authorization under REACH. This suggests that the substance in fact does not raise concern from current use and should consequently not be prioritized within the OSPAR framework of prioritized substances. On the other hand, the OSPAR background document stresses the need to further investigate both the persistency of vinyl neodecanoate but also the need to collect additional information on the marine exposure as well as refine PEC-values of said substance as there is a great uncertainty in the estimations of the risk. Given the presented information on the current legislative status under European Commission regulations, no additional OSPAR actions are needed for vinyl neodecanoate. Subsequently, if the substance is not considered to be of concern, vinyl neodecanoate is suggested to be demoted as an OSPAR priority substance. If, however, OSPAR believes that there is reason to investigate the discrepancy between the status within REACH and the UK risk assessment it is suggested for OSPAR to help fill in the knowledge gaps as previously mentioned.

3.4.3 4-(dimetyhylbutylamino)diphenylamine (6PPD)

The OSPAR background document on 4-(dimethylbutylamino)diphenylamine (6PPD) was latest updated in 2006, and no review statement has been adopted for the substance. 6PPD is mainly used as a protective agent (anti-oxidant and anti-ozonat) in the rubber industry where the substance is commonly found in tyres. However, the substance can also be found in consumer products, e.g. in the seals of pressure cockers (OSPAR Commission 2006c).

6PPD is presently registered under REACH with a yearly tonnage band of 10 000 to 100 000 tonnes (ECHA 2018i). The substance is not restricted, nor identified as a substance of very high concern under REACH. 6PPD is further not identified as a POP under SC. It is neither identified as a PS/PHS under the WFD (European Parliament 2013).

The OSPAR background document on 6PPD states that the priority substance does not present an unacceptable risk to humans with respect to CMR properties. 6PPD is not classified as a PBT-substance either as it only fulfills the P and T-criteria. 6PPD is not classified as a PBT/vPvB substance under the former EU chemicals legislation. Additionally, the background document concluded, at time of publication (2006), that the environmental exposure and transport of 6PPD to the sea was considered low and consequently risks to marine organisms were expected to be negligible. Although the risk to the marine environment is considered low, the background document concluded that the high production volume and the limited knowledge concerning the degradation of 6PPD in soil and the environmental fate of its metabolites still justified continuous attention towards 6PPD. Production of 6PPD was located to one facility in Germany with volumes ranging between 10 000 – 25 000 tonnes per annum (OSPAR Commission 2006c).

The ECHA registration dossier on 6PPD only presents one study on biodegradation in soil; noteworthy is that the structurally similar 1,4-Benzenediamine, N-(1,4 -dimethylpentyl)-N'-phenyl (7PPD) is used instead of 6PPD. The study concluded that under aerobic conditions metabolism is proposed to proceed via the formation of minor transient metabolites and mineralization while the main proportion of the residue binds to the soil matrix making it unavailable for further mineralization/degradation (ECHA 2018i).

The background document concluded that the risk of 6PPD to the marine environment was dependent on the aggregated production volumes. Production volumes, since time of publication in 2006, seem to be the same or higher. Whether the large production volumes are sufficient reason to prioritize 6PPD within the work of OSPAR is questionable due to its presented low risk. From a strictly legislative point of view, the use of 6PPD does not seem to raise a level of concern equivalent of any restriction regulation on the use and production of said substance. It is thus recommended to demote 6PPD from the LCPA to the LSPC as the high aggregated volumes still raises a level of concern, however not high enough to be prioritized within the OSPAR framework.

3.5 Substances for which additional actions may be needed

Three of the LCPA substances may need additional OSPAR actions or measures. All three substances are currently enrolled in the CoRAP-process, however at different stages of the process. Depending on what new information that is being enlightened in this process,

OSPAR may, evaluate the need for additional actions in order to protect the marine environment in the North-East Atlantic.

3.5.1 Tetrabromobisphenol-A (TBBP-A)

The OSPAR background document on tetrabromobisphenol-A was last updated in 2011. Tetrabromobisphenol-A (TBBP-A) is mainly used as a reactive intermediate in the production of flame-retarded polycarbonate and epoxy resins (OSPAR Commission 2011a).

TBBP-A is registered, in full, under REACH with a tonnage band of 1000 to 10 000 tonnes per annum on the European Market. The substance is not restricted nor labelled as a PS/PHS under WFD or as a POP under the Stockholm Convention (European Parliament 2013, Stockholm Convention 2004). The OSPAR background document had classified TBBP-A as a PBT-substance (borderline case for the fulfillment on the B-criterion) in accordance with the OSPAR-criterion, while noted that the same data would not fulfill the REACH criteria as stated in the EC Technical Guidance Document. Furthermore, the detailed risk assessment under the previous EU chemical legislation 793/93 stated the need to limit the risk of TBBP-A on surface waters and sediments around sites where TBBP-A is used as an additive flame retardant in the manufacturing of acrylonitrile-butadiene-styrene (ABS) resins (OSPAR Commission 2011). In 2015, TPPB-A underwent a CoRAP process due to the raised concerns about its potential endocrine disrupting effects, the suspected reproductive toxic effects and its suspected PBT/vPvB properties, to name a few. The process is presently awaiting more information in order for Member States to complete the evaluation on whether TBBP-A constitutes any concern to both human health and the environment.

As no conclusive information has surfaced on the potential hazardousness of TBBP-A, it is concluded that the substance yet remains a priority for OSPAR; additional OSPAR actions might be needed, e.g. in the form of screening to evaluate if the substance poses a potential risk to the marine environment in the North-East Atlantic.

3.5.2 AHTN (synthetic musk)

The background document on synthetic musks and musk xylene, as previously presented in section *3.3.3* of this report, contained numerous synthetic musks which were included in this report. The polycyclic musk AHTN, unlike the other individual musks presented, was one of the musks which stood out. AHTN is presently registered under REACH, with a total tonnage band of 1000 to 10 000 tonnes per annum. The risk assessment on the polycyclic musk AHTN under EEC 793/93 concluded in 2005 the need to limit the risk via occupational exposure of AHTN. At the time being, AHTN was considered not to pose a risk to any of the environmental compartments (European Communities 2008). AHTN is to additionally undergo a CoRAP process in 2020 to investigate the initial grounds of concerns regarding its potential endocrine disrupting properties and due to its high aggregated tonnage in the EU. Depending on the CoRAP outcome, AHTN can be of future interest of OSPAR within its work with prioritized substances. Additional actions may be in the form of screenings in order to evaluate if the substance poses a potential risk to the marine environment in the North-East Atlantic.

3.5.3 2,4,6-tri-tert-butylphenol

The OSPAR background documents on 2,4,6-tri-tert-butyl-phenol was last updated in 2006, however a review statement for the background document was adopted in 2009. 2,4,6-tri-tert-butyl-phenol is used as a chemical intermediate for the manufacturing of antioxidants used in plastics and rubber; as an additive for gasoline and fuel oil distillate; as a lubricant agent in the transport sector; as a by-product in the manufacturing of 4-tert-butylphenol; and used in the offshore sector. The background document however noted that there still exists some ambiguity in the exact use pattern of the substance (OSPAR Commission 2006d).

The OSPAR background document on 2,4,6-tri-tert-butylphenol stresses the lack of knowledge on the sources of the substance and a lack of monitoring data, at point of publishing of the monitoring strategy in 2004 (OSPAR Commission 2006d). Since then an exploratory one-off survey has been carried out in sediments in industrial estuaries in the United Kingdom with a number of samples ranging under the detection limit however a few above as well (OSPAR Commission 2009d). The substance is believed to reach the marine environment by a single main route, specifically via the discharge of wastewater from land-based production processes. Diffuse emissions were believed to occur from "releases due to its presence as an impurity in, or degradation product of, final formulations and/or articles, and use of products in the transport industry"(OSPAR Commission 2006d). The background document points out that 2,4,6-tri-tert-butylphenol might not be manufactured at sufficient quantities to pose a risk to the marine environment, but rather cause local problems (OSPAR Commission 2006d). By the time of publication of the review statement, this view had not changed as no new information on this matter had emerged. The review statement indicates that very little information has surfaced since the last update of the background document (OSPAR Commission 2009d).

2,4,6-tri-tert-butylphenol is currently registered under REACH on the European Market, with a yearly use/production volume of 100 to 1000 tonnes. The priority substance is currently not restricted under REACH, nor labelled as a PS/PHS under the Water Framework Directive and/or as a POP under the Stockholm Convention (European Parliament 2013, Stockholm Convention 2004). The substance is currently undergoing a CoRAP evaluation under REACH, where the conclusion is under preparation. Depending on the outcome of the evaluation, OSPAR may need to consider additional actions to limit the potential risk of 2,4,6-tri-tert-butylphenol in the marine environment.

3.6 Substances which require continuous monitoring and potentially evaluation of needs for additional measures

This report presents several prioritized substances which require continuous monitoring, and which may need additional measures in order to reach the OSPAR 2020 cessation target. Most of these substances are included in one or several OSPAR monitoring programmes and have the status and trends of the substances are thus assessed in the OSPAR IA 2017. Although constitutive regulatory work has been undertaken on both a global scale, as well as within the European Community, the presence of these substances in the environment is in one way or the other, inevitable; a few of these substances are very persistent and will thus remain in the environment long past cessation of emissions, some are produced unintentionally as by-products while others are naturally occurring in the environment.

3.6.1 Polycyclic aromatic hydrocarbons (PAH)

The OSPAR background document on polycyclic aromatic hydrocarbons (PAH), was last updated in 2009. The background document on PAHs deals with PAHs as a group and not individual PAH compounds. The OSPAR background document on PAHs concluded that emissions of PAHs are impossible to eliminate as production is to a large extent unintentional. It was stated that sources of PAH are incomplete combustion of wood and fossil fuels, though the sources of greatest significance differ between countries (OSPAR Commission 2009e). 5-6 rings PAHs are identified as PHS under WFD, where 3 EQS values are reported for the substance benzo[a]pyrene (BaP), sum of benzo[b]fluoranthene (BbFA) and benzo[k]fluoranthene (BkFA) and sum of benzo[g,h,i]perylene and indeno[1,2,3-cd]pyrene (European Parliament 2013). As the group of substances is not used as a product, they are not registered nor regulated under REACH. The OSPAR background document however included several regulations which in some way restricted the losses of PAH to the environment, e.g. Council Directive 96/61/EC, now repealed by Directive 2010/75/EU, regarding industrial emissions (OSPAR Commission 2009c). Relevant regulations important for the regulation of PAH emissions are not investigated further at this point.

Within the OSPAR monitoring programme CEMP the Contracting Parties monitor the trends and status of PAH in both shellfish (mussles) and sediments. The OSPAR IA 2017 assessed that the mean concentrations for each measured PAH in shellfish were below the EAC but above the BAC in all 10 assessment areas. Regarding the temporal trends of PAH, the concentration in shellfish were assessed in several areas where at least five years of data was available. In four of the assessment areas (English Channel, Irish and Scottish West Coasts, Southern North Sea and the Iberian Sea), concentrations were declining with a mean annual decrease in concentrations between 6.5% and 3.2%. No statistically significant changes in PAH concentrations were seen at four of the assessment areas (Irish Sea, Northern Bay of Biscay, Skagerrak and Kattegat and the Northern North Sea). To fill in existing knowledge gaps, the IA 2017 suggested to potentially extend the monitoring in biota to fish, as it could then include open waters as well. It was further suggested to develop EACs for alkylated PAHs in shellfish (OSPAR Commission 2017b).

The 2017 IA reported for all assessment areas mean PAH concentrations in sediments bellow the ERL (the USEPA's Effects Rang-Low Criteria). In the Irish and Scottish West Coast and the Gulf of Cadiz, PAH sediment concentrations were below BAC and for four of the assessment areas mean concentrations where not statistically significant below the BAC but below the ERL. The assessment reported decreasing concentrations of PAH in the sediments in the English Channel and the Gulf of Cadiz. For the other four contaminants assessment areas, concentrations showed no statistically significant trends. To fill in existing knowledge gaps, the IA 2017 suggested cooperation between the Arctic Monitoring and Assessment Programme (AMAP) and OSPAR as there are presently insufficient monitoring data for PAHs, particularly in Arctic Waters and some parts of the Celtic Seas, the Great North Sea and Bay of Biscay and Iberian Coast. As the US EPA ERL was used for the environmental assessment of PAHs in sediments, there exists a need for OSPAR to develop EACs, for both parent and alkylated PAH (OSPAR Commission 2017c).

The 2017 IA presented PAH concentrations in shellfish to unlikely cause adverse effects on the marine environment and decreasing trends at four OSPAR contaminants assessment

areas. Similarly, PAH concentrations in sediments were for all sites below ERL and thus unlikely to cause adverse effects on the environment. Although, the concentration of PAH in sediments were at background levels at two sites, this was not the case for the four other assessment areas. It is thus suggested for OSPAR continue the current monitoring of PAH as well as consider filling the knowledge gaps as presented in IA 2017. As downwards trends are not seen for all assessment sites, OSPAR could consider if and what additional actions that might be needed in order to reach the OSPAR 2020 cessation target. As the sources of PAH to the environment are so diverse, the background document does indeed play an important role in presenting an overview of both the environmental and legislative status. It is thus further suggested of OSPAR to update the background document on PAH.

3.6.2 Organic tin compounds (OTC)

The OSPAR background document on organic tin compounds was last updated in 2011, including the monitoring strategy. Organic tin compounds have frequently been used as antifouling agents on ship hulls, which also has been the major pollution source (OSPAR Commission 2011b).

The background document on organic tin compounds focuses on organotins as a group rather than individual substances. However, the annexed monitoring strategy addresses primarily the groups tributyltins (TBT), triphenyltins (TPT) and mono- and dibutyltins (MBT/DBT), which have been considered in this report. Detailed information on the current legislative status of the organic tin compounds that were individually mentioned in the background document are found in Appendix C. Noteworthy is that neither of the organic tin compounds in Appendix C are allowed for usage as active substances in biocidal products and plant protection products under the BPR (2012/528/EU), or the Council Regulation 2009/1107/EC concerning the placing of plant protection products on the market. Bis(tributyltin)oxide is registered for intermediate use under REACH and is identified as a SVHC awaiting eventual inclusion on Annex XIV of REACH. The substance has yet to be recommended for inclusion on Annex XIV. Organostannic compounds, as a group, are not registered but restricted under REACH. The restriction applies to organostannic compounds in general with more specific restrictions for the groups of tri-substituted organostannic compounds, dibutyltin (DBT) and dioctyltin (DOT) compounds. The restriction severely restricts the usage of organostannic compounds in general and the use/production volume of these compounds is too small to be registered under REACH (European Parliament 2007). Furthermore, OTCs are not identified as POPs under the Stockholm Convention but TBT compounds (including the tributyltin-cation) are identified as a PHS under the WFD (Stockholm Convention 2004, European Parliament 2013). The International Maritime Organization (IMO) and the International Convention on the Control of Harmful Antifouling Systems on Ships (AFS), entered into force 17 September 2008, introduced a ban on organic tin compounds which in 2011 covered 75% of the worlds shipping fleet (OSPAR Commission 2011b).

TBT is included in the OSPAR monitoring programme CEMP. Other organostannic compounds are not monitored by OSPAR as the sources of these compounds are mainly land-based and thus not suitable for monitoring in the marine environment. The OSPAR IA 2017 assessed the status and trends of organotin compounds in sediments. Most countries have stopped monitoring OTCs in sediments and as no EAC is established, it is not possible to

assess the environmental significance of the observed OTC concentrations. As a result, this report does not include any environmental monitoring data of OTC in sediments. Most countries instead monitor the biological effect of OTCs, i.e. the presence of imposex in marine gastropods. However, the IA 2017 stated the need to monitor OTCs in the marine environment as the substance is still used as an antifouling agent in countries outside of Europe. It was further suggested to consider establishing BAC and EACs for sediment (OSPAR Commission 2017d).

In six of ten assessment areas, levels of imposex in the three species monitored were significantly below the EACs for each species over the period 2010-2015. However, in the assessment areas of Skagerrak and Kattegat, Celtic Sea and Nothern Bay of Biscay, the VSD was at level with EAC and in the Iberian Sea levels were more than five times higher than the EAC. None of the assessment areas had imposex levels significantly below the BAC. Temporal trends in imposex levels varied between the 174 analyzed sites. Over the period of 2010-2015, no increase of imposex levels was observed at any of the sites however, no statistically significant changes in imposex was detected at 52% of the sites. An improvement in imposex levels was detected at 48% of the sites where the percentage of improvement was lowest at the Irish and Scottish West Coasts. The IA 2017 suggested monitoring the use of alternatives to TBT in order to avoid adverse effects of the used substitutes, e.g. copper-based paints, which can have other chemical additives as well (OSPAR Commission 2017e).

Presented data showed, at large, improvements of levels of imposex induced by TBT as the majority of the sites had VDS levels at, or below, the EAC level. Some areas are still subject to high levels of imposex although TBT is banned for use in antifouling paints under the IMO AFS Convention. As the substances are not close to background levels, continuous monitoring should help identify future developments on levels of imposex. The 2017 assessment concluded that continuous monitoring will help identify losses of TBT from marinas, dockyards and vessel maintenance activities as well as illegal use of TBT. No additional action is suggested besides the previously suggested ones.

3.6.3 Heavy metals

The OSPAR LCPA contains the three heavy metals mercury, lead and cadmium, all with individual background documents. The legislative overview, with suggested OSPAR actions, of the heavy metals are presented separately under subheadings 3.6.4.1 to 3.6.4.3. However, as the OSPAR IA 2017 on mercury, lead and cadmium was analysed and reported jointly, many of the suggested needs in order to fill in current knowledge gaps apply for all heavy metals. Suggestions made by the OSPAR IA 2017, that apply for all three heavy metals, are collected below whereas suggestion made by the OSPAR IA 2017 that only apply to the individual heavy metal are accounted for under the associating subheading.

The OSPAR IA 2017 on the status and trends of heavy metals in marine biota addressed the need to develop EAC for the assessment of heavy metal concentration in fish and shellfish as current assessment criteria are not based on environmental limits, but on the European Commission maximum limits in foodstuff and on background concentrations (OSPAR 2017e). Furthermore, the European Commission has derived an environmental quality standard for

only mercury in fish, however as it is lower than existing background concentrations, there is a need to discuss if and how this EQS can be applied for OSPAR data (OSPAR 2017f)

The OSPAR IA 2017 on the trends and status of heavy metals in sediments addressed the need for additional ecotoxicological data for the development of new assessment criteria based on the OSPAR Environmental Assessment Criteria (EAC) principles or on the EU Water Framework Directive. These EAC should thus replace the ERL criteria. It was additionally noted that there are too few monitoring sites in Arctic waters to carry out an area assessment (OSPAR 2017g).

The OSPAR IA 2017 on inputs of the heavy metals via air and water to the Greater North Sea focused on the need for strict quality controls of laboratories analyzing heavy metals in order to correctly detect changes. The assessment also reported the need to assess the effect on quantification limits whenever a change in analysis laboratory is considered. There is also a need to comprehend the retention and export of heavy metals in estuaries to gain knowledge of the proportion of heavy metals that reach the environment. Additionally, the knowledge of the losses of heavy metals from shipping, harbors, historical dumping sites and other potential sources are limited. There is currently a mismatch between the OSPAR Agreement to quantify total heavy metal inputs and the EU WFD to measure metal concentrations in the dissolved fraction which needs to be addressed (OSPAR 2017h).

3.6.3.1 Mercury and organic mercury compounds

The OSPAR background document on mercury was last updated in 2004, however a review statement to the background document was adopted in 2009 (OSPAR Commission 2004b).

As a heavy metal, the presence of mercury in the environment is inevitable. However, there exists stringent restrictions and bans, both within REACH and in other legislation, to minimize the anthropogenic dispersion of mercury. The most important legislative tool is the Minamata Convention that solely focuses on minimizing the anthropogenic uses of mercury. The Convention entered into force on 16 August 2017 and it limits and prohibits the use of mercury in industrial processes and in products as of 2020. Major highlights of the Minamata Text includes, for Contracting Parties to phase-out existing mercury mines while prohibiting new mercury mines, phase-out and phase-down the use of mercury in several products and processes, control measures on emissions to air and releases to land and water and regulate the informal sector of artisanal and small-scale gold mining. Interim storage of mercury and mercury disposal is also covered by the Convention. Within the European Union, mercury is already regulated to certain extents (UN Environment 2017). Alkyl mercury and alkyloxyl and aryl mercury compounds intended as active substances in pesticides have been banned under Regulation (EC) No 1107/2009 since 2009 with no possibility for authorization. Additionally, mercury is also registered both in full and for intermediate usage under REACH. The use of mercury in products in the EU is restricted, with certain exemptions which are accounted for in Appendix D of this report. Furthermore, mercury is identified as a PHS under WFD (European Parliament 2013).

Mercury is presently included in the OSPAR monitoring programmes CAMP, CEMP and RID. The OSPAR 2017 IA assessed the trends and status of mercury in marine biota (fish and shellfish), sediments as well as the inputs of mercury via water and air to the Great North

Sea. The 2017 IA reported mercury concentrations at, or above, the BAC in biota for all OSPAR contaminants assessment areas. Concentrations as much as twice the background concentrations where found in the Northern North Sea, Southern North Sea, Norwegian Trench and Irish Sea. The maximum EC levels for mercury concentrations in marine biota are five times greater, or more, than the existing background concentration however still below the maximum EC levels in foodstuffs. For most of the assessment areas, there is no significant change or downward trend in mercury concentrations in biota. The assessment further addressed the need to discuss if and how the EQS for mercury (as derived by the European Commission) can be applied for OSPAR data as they are currently lower than the background concentrations (OSPAR 2017f).

Regarding the temporal trends of mercury in sediments, the concentration of mercury in sediments where decreasing in five out of six OSPAR contaminants assessment areas, with no statistically significant change in concentrations in the English Channel (OSPAR 2017g).

Regarding the OSPAR IA 2017 on inputs of mercury via air and water to the Great North Sea, it was assessed that the inputs via air had reduced with approximately a third while the inputs of mercury via water have approximately halved between 1990-1995 and 2010-2014. However, it was noted that this downward trend was, to some extent, the result of improved more sensitive technology although it is not possible to determine the size of the overestimation (OSPAR 2017h).

A heavy metal like mercury will always be present in the environment. To limit anthropogenic dispersion of mercury is thus vital to reach background levels of the metal in the environment. As more than half of the assessment areas the concentration of mercury in the marine biota was at, or above the ERL, concluding that adverse ecological effects cannot be ruled out for these areas. Additionally, concentrations in marine biota was at, or above, the BAC for all assessment areas. Although the Minamata Convention entered into force in 2017, the use of mercury in products and industry will only be prohibited by 2020, with certain exempted uses. OSPAR should continue monitoring, as well as fill in all knowledge gaps as mentioned in the OSPAR IA 2017, in order to see whether the concentrations of mercury in marine biota, sediments and the inputs of mercury from air and water decreases in parallel to the global ban.

3.6.3.2 Lead and organic lead compounds

The OSPAR background document on lead and organic lead compounds was last updated in 2009. The heavy metal is used in a wide variety of products, e.g. batteries, microelectronics, radon gas shielding and in superconductors (OSPAR Commission 2011c).

Lead and organic lead compounds are registered under REACH in full, and for intermediate use only as well, with a total tonnage band of 10 000 to 100 000 tonnes per annum. Lead is restricted under REACH; the specific restrictions can be found in Appendix E. The heavy metal is both identified as a PHS under WFD and as a SVHC under REACH and included on the Candidate List in June 2018 (European parliament 2013). The substance has not yet been recommended for inclusion on Annex XIV of REACH.

Lead is monitored under the OSPAR monitoring programmes CEMP, CAMP and RID. The OSPAR 2017 IA assessed the trends and status of lead in fish and shellfish and sediments as well as the inputs of lead via air and water to the Great North Sea. For three of the assessment areas, the concentration of lead in biota was a 2-5 times the BAC level, while for two of the assessment areas, the concentration was below the BAC. For the remaining three assessment areas, the mean concentration of lead was below the BAC, however the upper confidence limit was above the BAC in all these three cases. Regarding the temporal trends, lead concentrations in biota are declining in seven out of ten OSPAR contaminant assessment areas while no significant changes were seen in the Northern North Sea, Celtic Sea and Irish and Scottish West Coast (OSPAR Commission 2017f).

No significant changes in lead concentration trends were seen in the sediments of the Norther North Sea, English Channel, Irish and Scottish West Coast and the Irish Sea. A downwards trend was recorded for the Southern North Sea while there was an upward trend in the Gulf of Cadiz. Regarding the status of lead in marine sediments, the 2017 IA reported all OSPAR contaminant assessment areas had concentrations of lead above the background concentration. On the Irish and Scottish West Coast concentrations were below ERL while for the other five assessment areas (Northern North Sea, Southern North Sea, English Channel, Irish Sea and Gulf of Cadiz) the mean lead concentrations in lead was above the ERL (OSPAR Commission 2017g).

Regarding the OSPAR 2017 IA on inputs of lead via water and air to the Great North Sea, it was assessed that the inputs via water had more than halved and airborne inputs of lead reduced with less than a third of the level it was in 1990 between 1990-1995 and 2010-2014. However, the input estimates are very uncertain due to varying quantification limits between laboratories within countries, as well as methodological and laboratory changes which results in substantial changes in the estimated inputs (OSPAR Commission 2017h).

Lead has restricted usage under REACH, although several exemptions do apply. Although lead concentrations in biota, for most of the areas are decreasing, the concentrations are above the background levels in most of the assessment areas. Additionally, for five out of six assessment areas, the lead concentration in sediments is above the ERL indicating that adverse ecological effects can occur. There still exists a need to limit the levels of lead in several OSPAR contaminant assessment areas. It is thus suggested that OSPAR should continue monitoring the presence and input of lead to the OSPAR Maritime Area and continue the work on addressing the limitations that have been presented above.

3.6.3.3 Cadmium

The OSPAR background document on cadmium was last updated in 2004, however a review statement to the background document was adopted in 2010. The heavy metal is used in several different products and processes, e.g. production of catalysts and intermediates for electroplating, as a stabilizer for plastics and used in the production of batteries(OSPAR Commission 2004c).

Cadmium is registered in full under REACH with a tonnage band of 1000 to 10 000 tonnes cadmium per annum. The heavy metal underwent a risk assessment under the previous EU chemicals legislation (EEC 793/93), which in 2007 concluded the need to limit the risk

cadmium poses to the environmental compartment in general, although the existing measures already being applied were to be considered. The risk assessment on the aquatic compartment concluded the need for better information on the bioavailability of cadmium in sediments as well as better information on the toxic effects of cadmium to aquatic organisms under low water hardness conditions (European Chemicals Bureau 2007). Cadmium is currently restricted under REACH; restrictions are explained in Appendix F. Furthermore, cadmium is identified as SVHC under REACH and included on the Candidate List in 2013 (European Parliament 2007). The heavy metal is additionally identified as PHS under WFD (European Parliament 2013).

Cadmium is monitored under the OSPAR monitoring programmes RID, CEMP and CAMP. The OSPAR IA 2017 assessed the trends and status of cadmium in marine biota (fish and shellfish) and sediments as well as the inputs of cadmium via water and air to the Great North Sea. Much like for mercury, the assessment criteria is based on the EC maximum levels in foodstuff and background concentrations of the metal. The assessment presented maximum levels for cadmium concentration in fish and shellfish which were greater than the background concentration. For three of the OSPAR contaminant assessment areas, the cadmium concentrations were significantly below the BAC, while for the other nine sites this was not the case. Cadmium concentrations, as much as two to five times the background concentration, where found in marine biota from the Barents Sea and Southern North Sea. However, the average cadmium concentration in marine biota still below the European Commission's maximum levels in food stuffs and have been since 2009 for all assessed OSPAR regions. For the temporal trends of cadmium in the OSPAR regions, the assessment used data from the years 1996 to 2015. A downwards trend in cadmium concentrations were seen in the in four of the assessment sites while no significant changes were seen in the remaining five assessment sites. However, a yearly increase of approximately 2% was seen in one of the assessment sites (the Southern North Sea). As a result of the 2017 IA, OSPAR addressed the future needs within the work of limiting cadmium. It was suggested to identify the sources of cadmium in biota in the Southern North Sea, as concentrations are increasing. (OSPAR Commission 2017f).

For three of the assessment areas, the mean cadmium concentration in sediments was below the BAC, while the mean concentration was above BAC for the remaining three assessment areas. The mean cadmium concentration was below the ERL for all assessment areas. Regarding the temporal trend analysis of cadmium in marine sediments, no statistically significant changes were seen in five of the six OSPAR contaminant assessment areas, while decreasing concentrations where seen in the Southern North Sea (OSPAR Commission 2017g).

Regarding the OSPAR 2017 IA on inputs of cadmium via air and water to the Great North Sea, it was assessed that the inputs via air and water had both significantly been reduced by two-thirds between 1990-1995 and 2010-2014. However, the input estimates are very uncertain due to varying quantification limits between laboratories within countries, as well as methodological and laboratory changes which results in substantial changes in the estimated inputs (OSPAR Commission 2017h).

The presence of cadmium in the environment is inevitable. Although the cadmium concentration in marine biota is below European Commission's maximum levels in food stuff, the concentrations are above background levels. Similarly, decreasing trends of cadmium concentrations are seen in three out of twelve assessment areas, no temporal trends in nine out of twelve assessment areas while for the Southern North Sea, the concentrations in marine biota was increasing. On the contrary, a decreasing trend of cadmium in sediments was reported in the Southern South Sea and no temporal changes in other sites. As the concentrations are still not at, or below the background level for cadmium, and as there is an increase in cadmium concentration in the sediments of the Southern North Sea, additional work needs to be done. As cadmium is regulated by REACH, OSPAR should suggestively continue monitoring the presence and input of cadmium to the OSPAR Maritime Area, as well as fill in all knowledge gaps as mentioned, in order to help gain a clear picture if additional actions are needed.

3.6.4 Polychlorinated biphenyls (PCBs)

The background document on polychlorinated biphenyls (PCBs) was last updated in 2004, however a review statement to the background document was adopted in 2008. The large group of PCBs have been produced since 1928, and they have been used both in "closed" systems, e.g. as an insulating agent, as well as in "open" uses, e.g. as a plasticizer in paints. The background document stated that since the 1980s, production of PCB has ceased in Europe and the largest sources have been losses from waste disposal, PCB-containing units, remobilization of PCB-contaminated sediments as well as via formation as by-product in various chemical and thermal processes (for the latter; unknown as to what extent this occurs) (OSPAR Commission 2004d).

PCBs are identified as POPs under the Stockholm Convention and are included on both Annex A and C of the Convention Text. Exempted uses apply for the decision on including PCBs on the Stockholm Convention; Contracting Parties have been banned from manufacturing and usage of PCBs since 2004, however products already contaminated with, or containing, PCBs are allowed to be used until 2025 (Stockholm Convention 2004). PCBs are thus not regulated under REACH, but by Regulation (EC) 850/2004 on persistent organic pollutants (European Parliament 2004). Moreover, PCBs are not identified as PS/PHS under the WFD (except the linear PCBs as part of the WFD PHS dioxin and dioxin-like PCBs) (European Parliament 2013).

PCBs are included in the OSPAR CEMP monitoring program. In the OSPAR IA 2017, status and trends of PCBs were assessed in sediment, fish and shellfish. It was concluded that for most of the assessment areas the PCB concentrations in fish and shellfish have decreased to acceptable ecological concentrations, except for the most toxic PCB congener CB118 in which case the concentrations could pose an unacceptable risk to the environment. The IA further highlighted suggestable fields in which to fill in the knowledge gaps of PCBs; it was stated that further research is needed in order to identify and quantify the diffuse inputs from terrestrial sources. It was further suggested to develop EACs for the purpose of protection of secondary poisoning, as this had not been considered when EACs were developed initially (OSPAR Commission 2017i).

Regarding the presence of PCBs in sediments, it was concluded that while PCBs are found in all marine sediments; concentrations are decreasing in the Greater North Sea and the Gulf of Cadiz and no significant changes where seen in the Celtic Seas, except for CB118 which could pose an unacceptable risk to the marine environment (OSPAR Commission 2017j).

The OSPAR 2017 IA presented a general decreasing trend of PCBs in fish and shellfish and in sediments, with certain exceptions for PCB congener CB118. PCBs are persistent and have a potential to bioaccumulate in the food chain prolonging their existence in the environment long after cessation of uses and discharges. It is thus suggested that OSPAR continues the current monitoring of PCBs and act if concentrations are not decreasing.

3.6.5 Brominated flame retardants (BFR)

The OSPAR background document on brominated flame retardants (BFR) was last updated in 2009. The background document contains several individual substances but only the following five substances were included in the annexed monitoring strategy; octabrominated diphenyl-ether (octaBDE), pentabrominated diphenyl-ether (pentaBDE), decabrominated diphenyl-ether (decaBDE), decabromobiphenyl (decaBBP) and hexabromocyclododecane (HBCDD). At point of publication of the background document in 2004, octaBDE and pentaBDE had been banned in the European Union and alternative BFRs had not yet gained commercial importance. If these alternatives indeed did become of commercial importance, the background document stated that OSPAR might choose to include these substances in the background document (OSPAR Commission 2009f).

The ban of certain BFRs lead to the introduction of several other flame retardants on the global market, which in a few cases led to the replacement of substances with similar physicochemical properties as the banned flame retardants. In a screening study on flame retardants, replacements for PBDE, HBCDD and TBBP-A were analyzed in different types of Swedish waters f. A wide range of flame retardants was found; organophosphorous flame retardants (OPFR), halogenated flame retardants and polybrominated flame retardants (PBDE), where the highest average number of detected flame retardants were found in waters from waste treatment facilities (WTFs) followed by waters from waste water treatment plants (WWTP) (Gustavsson *et al.* 2018). If the work with the LCPA is continued it is suggested that OSPAR includes additional flame retardants in the background document on BFR or in a new document.

Although several BFRs were mentioned in the background document, only decaBDE and HBCDD were of enough commercial importance to be subjected to further measures by OSPAR, as they jointly constituted 97% of the BFRs used in Europe in 2003 (OSPAR Commission 2009e). This report thus focuses solely on the current legislative status of decaBDE and HBCDD. Both decaBDE and HBCDD are identified as POPs under the Stockholm Convention and included in Annex A of the Convention Text (Stockholm Convention 2004). Both are identified as SVHC under REACH, however only HBCDD is included in Annex XIV of REACH. Both substances are registered in full under REACH and both are additionally restricted under the same legislation (European Parliament 2007). HBCDD is furthermore identified as a PHS under WFD (European Parliament 2013). An overview of the status of decaBDE and HBCDD can be found in Appendix G.

The BFR that are included in the OSPAR monitoring strategy are pentaBDE, octaBDE, decaBDE, HBCDD and decaBBP, which have been monitored under CEMP. The OSPAR 2017 IA could only determine and not assess the environmental significance of the BFR in marine biota and in sediments as no assessment criteria had been developed. The concentrations of BFR where measured and determined for the OSPAR regions the Great North Sea, Celtic Seas, Bay of Biscay and Iberian Coast, and they were used to examine the temporal trends of BFR concentrations and to equate patterns and concentrations between the assessment areas. The concentrations of BFRs were measured in fish, mussels and oysters and the temporal trend assessment was carried out in seven assessment areas which had more than five years of data. Six out of seven OSPAR contaminant assessment areas (Northern North Sea, Southern North Sea, English Channel, Irish and Scottish West Coast, Irish Sea and Iberian Sea), there was a downwards trend in mean concentration of BFRs in marine biota, while no significant changes where seen in Skagerrak and Kattegat. The assessment concluded that the concentrations of BFRs have decreased for the majority of the assessment areas since the substances were regulated and that the temporal trends are decreasing with approximately 10% per year in six out of seven assessment areas. Regarding the concentration of BFRs in biota, the concentrations varied between the assessed areas where the highest concentrations can be found in the Irish Sea and English Channel and the lowest in the Iberian Sea. As different species are monitored in different assessment areas, it was not possible to draw any conclusion of the contamination load in the respective assessment areas. The IA 2017 addressed the need to develop assessment values which are applicable to the OSPAR monitoring data for the status of and the temporal trends of BFRs. The assessment also reported a lack of monitoring data, particularly in Arctic Waters, which is believed to aided by cooperation between the Arctic Council's Arctic monitoring and Assessment Programme (AMAP) in order to improve access to data for Arctic Waters. Additionally, in order to use the WFD EQS in the OSPAR Maritime Area, further investigations are required (OSPAR Commission 2017k).

In the OSPAR 2017 IA the mean BFR concentration in the Northern North Sea showed no significant change while for the Irish Sea, there was a decrease of BFR in sediments. It was reported that the BFR concentrations in sediments were low (<1 µg/kg dry weight) and often below the detection levels. The highest concentrations of BFR in sediments were found in the Irish Sea and Southern North Sea, while the Gulf of Cadiz had the lowest concentrations (<1 µg/kg dry weight). The 2017 IA on status and trends of BFR in sediments concluded that given the few monitoring sites for the assessment, the temporal trends could not be considered representative for the OSPAR Maritime Area as a whole. In order to assess the environmental significance of the observed concentrations, the OSPAR assessment addressed the need to develop BACs and EACs. To improve the limited access of data for Arctic Waters, cooperation between the Arctic Monitoring and Assessment Programme (AMAP) and OSPAR was again suggested (OSPAR Commission 2017l).

The BFR mentioned are all regulated under REACH, a few are even up for elimination under the Stockholm Convention. Although, it is not possible to assess the environmental significance of the measured concentrations in both marine biota and sediments, the concentrations of BFR in marine biota has been seen to decrease over time in a majority of the OSPAR contaminant assessment areas. As alternative used flame retardants might present a potential problem, OSPAR could suggestively decide to investigate and include

new additional flame retardants in the background document on BFR. OSPAR should develop BACs and EACs, as previously mentioned, and continue to monitor and develop the monitoring of BFRs in order to gain a full comprehensive view of the status of these substances in the North-East Atlantic.

3.6.6 Perfluorooctanyl sulphonic acid and its salts (PFOS)

The OSPAR background document on perflurooctane sulphonante (PFOS) and its salts was last updated in 2006, while a review statement to the background document was adopted in 2011. PFOS is a group of organic substances belonging to the large family of perfluoroalkyl substances (PFAS). PFOS and its related substances have good water and oil repellant effects and are thus used in a number of industries and products (OSPAR Commission 2006e).

PFOS is identified as a POP under the SC and is included on Annex B, which restricts the use of the substance for Contracting Parties. Several acceptable purposes for the use of POFS includes, but is not limited to, metal plating, chemical driven oil production, carpets, textiles and upholstery etc. Further details regarding acceptable purposes and specific exemptions are stated in decision SC-4/17 (Stockholm Convention 2004). PFOS was previously restricted under REACH (included in Annex XVII) but was demoted when included in the Stockholm Convention as a POP substance (deleted by Commission Regulation (EU) No. 207/2011) and is thus currently regulated under Regulation (EC) no. 850/2004 on persistent organic pollutants. PFOS is also identified as a PHS under WFD (European Parliament 2013).

The National Swedish Contaminant Monitoring Programme on Marine biota reported decreasing temporal trends of PFOS in herring liver in the sampling site Fladen, a site within the OSPAR Maritime Area, over the period 2004 to 2016. The concentration was below the suggested target value at 9.1 ng/g for PFOS in fish muscle (wet weight) (Bignert *et al.* 2017). The 2010 review statement on PFOS stated that OSPAR had focused its actions on monitoring of PFOS and how it should be addressed in the OSPAR monitoring programme CEMP (OSPAR Commission 2011d). Included in the pre-CEMP in 2007, PFOS is currently monitored as stated in OSPAR Agreement 2016-01 (amended in 2018) (OSPAR Commission 2018).

The OSPAR review statement stated the belief that any additional work and measures should not be taken by OSPAR but rather within the EU frameworks (OSPAR Commission 2011d). Additionally, the PFOS concentrations seems to be decreasing on the Swedish west coast and the use and production of said substance is currently restricted globally. As PFOS is highly persistent and will remain in the environment even though the exposure is restricted, it is thus suggested for OSPAR to continue the current monitoring of PFOS and in light of new information act additionally if needed. However, PFOS is no longer the only cause of concern among the PFAS family. In a screening of the presence of PFAS in the Swedish Environment, including biota as well as ground and surface waters, up to 40 different types of PFAS were found collectively in biota as well as ground and surface waters (Naturvårdsverket 2016). As a proactive measure, OSPAR could encourage/screening studies of other PFAS in the marine environment and flag for eventual discoveries in the OSPAR Maritime Area. Furthermore, OSPAR could take action in evaluating and compiling information on environmentally friendly alternatives to use as substitutes for PFAS.

3.6.7 PCDDs and PCDFs

The OSPAR background document on dioxins, including polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) was last updated in 2007, and no review statement has been adopted to the background document. PCDDs and PCDFs are large groups of substances, with theoretically 75 and 135 possible congeners respectively. Dioxins are unintentionally produced in processes revolving combustion and heating of chlorine compounds and organic matter, as well as by pulp bleaching and in the production of certain chlorinated chemicals (OSPAR Commission 2007b).

As production is unintentional, PCDDs and PCDFs cannot be regulated through REACH. These substances are identified as POPs under the SC and included on Annex C of the Convention Text (Stockholm Convention 2004). PCCD and PCDEs are further identified as PHS under the WFD (European Parliament 2013). The releases and production of dioxins are however addressed and regulated under numerous directives and conventions and under other EU regulations, such as Council Directive 96/61/EC, now repealed by Directive 2010/75/EU to name one (OSPAR Commission 2007). Since the update of the background document, PCDDs and PCDFs are included in the pre-CEMP for voluntary monitoring in biota and sediments on temporally basis. However, monitoring should only be considered if stated levels of marker PCBs are a certain time higher than the BAC or if an area are known for having high concentrations of PCDDs and PCDFs (OSPAR Commission 2018).

Swedish monitoring data reported concentrations below EQS, and at times, decreasing trends of PCCDs and PCDFs in marine biota from the O area which indicates concentrations below the level of concern for further actions. Additionally, as PCDDs and PCDFs are included in the SC, measures are already undertaken on a global level. However, as the presence of PCDDs and PCDFs in the environment is inevitable and will remain as a priority substance of concern, OSPAR should suggestively update the background document and investigate what measures are undertaken within the current regulations in order to identify potential areas of contributions in order to protect the marine environment in the North-East Atlantic.

4. General discussion of results

Whether or not OSPAR should update the background documents for the prioritized substances cannot be generally stated for all documents. As seen, this report presents different conclusions and suggestions for future OSPAR actions which are based on the current legislative status under important EU regulations as well as global treaties. This evaluation has several limitations which are important to bear in mind. In this report it is not evaluated whether the restrictions and bans set up by the European Commissions, together with the Stockholm Convention, are sufficient in the protection of the marine environment in the North-East Atlantic. It is important to recognise that the REACH regulation does not only aim to protect the human health and the environment against harmful chemicals but also to strengthen the market for chemicals in Europe (European Parliament 2007). It should be added that almost all applications for authorizations have been approved by ECHA, with the exception of a few inadequate applications (Swedish Chemicals Agency, personal communication, 2018-10-26). Additionally, other regulations than those mentioned here may be of importance for the evaluation of whether the substances are sufficiently regulated or not, as is seen for e.g. the PAHs.

As prioritization of particularly hazardous substances which require actions and measures in order to reach the 2020 cessation target has not occurred since early 2000, and as many of the background documents have not been frequently updated, it is important to decide whether or not OSPAR will again take an active role in the protection of the marine environment, within the OSPAR strategy for hazardous substances. In some background documents and review statements, such as the ones for the octylphenols and PFOS, it is clearly stated that future measures would be best taken within the European Commission framework rather than by OSPAR (OSPAR Commission 2009c, OSPAR Commission 2011d). It is important that OSPAR decides on whether or not they believe the constitutive regulations within existing international forums are adequate in the protection of the marine environment and if so, what additional contributions may OSPAR present within the field of hazardous substances. If the EU measures already undertaken are considered sufficient, OSPAR could instead take a more pro-active role in the screening of, as well as monitoring of substances which yet does not raise a high level of concern within the European Commission framework. This could be a valuable contribution given the presented problematics of hazardous substances being replaced with substances which potentially give raise to an equivalent level of concern, e.g. MCCP and LCCP as substitutes for SCCP, other PFAS as substitutes for PFOS and the substitution of phthalates and BFRs (Yuan & de Wit 2018, Gustavsson *et al.* 2018, Naturvårdsverket 2016). OSPAR could thus act as a safety net to substances which fall between the implementation of the REACH regulation in order to prevent concentrations of contaminant in reaching unacceptable concentrations in the North-East Atlantic.

In 2007 OSPAR conducted a review of the progress of actions for the prioritised substances within the OSPAR strategy of hazardous substances. The reviewed actions where collected from the background documents, as agreed between the years 2000 and 2005 (OSPAR Commission 2007a). This review gave a good understanding on the current progress of adopted actions, as well as measures, for each prioritized substance and it is thus suggested for OSPAR to conduct a new, or add to the current review, new information. This is especially of interest for substances in the category *substances which require continuous monitoring and potentially evaluation of needs for additional measure,* as they of today still pose a risk to the marine environment in the North-East Atlantic.

5. Conclusion

This report presents a summary of the current legislative status of the prioritized substances within the OSPAR strategy for hazardous substances, for which background documents have been adopted. Given the information in each background document, the status under the EU regulation REACH, the Stockholm Convention on Persistent Organic Pollutants, the EU Water Framework Directive, relevant EU regulations which regulate substances that are used as active substances in biocidal products and plant protection products and, for some of the prioritized substances, monitoring data and assessments, suggestions concerning the need to update each background documents as well as further needs for additional actions and measures where stated. The suggestions differ between each substance or substance group; however, this report still grouped the substances depending on the general direction in which OSPAR is suggested to pursue. The groupings are as follows: substances which

require no additional action, substances which are not considered fulfilling the criteria as hazardous substances and should be removed from the LCPA, substances which may need additional OSPAR actions and substances which require continuous monitoring and potentially evaluation of needs for additional OSPAR measures. It is recommended that OSPAR decides on whether or not prioritization should continue within the OSPAR strategy for hazardous substances or if OSPAR best can protect the marine environment through other measures than what is, and has previously been, undertaking. It is suggested that OSPAR may take on a more active role and act as a safety net to the European Commission in the identification of future hazardous substances in the marine environment of the North East-Atlantic.

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Appendix A – Legislative status of OSPAR LCPA substances used as active substances in biocidal and plant protection products

This appendix contains comprehensive information on the legislative status of the OSPAR LCPA compounds used as active substances in biocidal and plant protection products, as mentioned in the OSPAR background documents on trifluralin, lindane, endosulphane, mthoxychlor, dicofol and pentachlorophenol and its salts and esters. Apart from pentachlorophenol and its salts and esters (PCP), the scope for which the substances are used falls under the Regulation (EC) No. 1107/2009, concerning the placing of plant protection products on the EU market, as well as EU Directives 98/8/EC (the Biocidal Products Directive) and 2012/528/EU (The Biocidal Products Regulation), which will be accounted for in Table 1. Furthermore, Table 1 contains additional information on the status of each substance under the Stockholm Convention and whether the substances are identified as priority substances (PS) or priority hazardous substances (PHS) under the EU Water Framework Directive (WFD).

Table 1. Legislative status of lindane (including HCH isomers), endosulphan, methoychlor, dicofol, trifluralin and pentachlorophenol and its salts and esters under the Stockholm Convention, the EU Regulations REACH and (EC) No 1107/2009, the EU Water Framework Directive (WFD) and the EU Directives 98/8/EC and 2012/528/EU.

CAS No	Substances name	Status under the Stockholm Convention, EU Regulation REACH, EU Regulation (EC) No. 1107/2009, EU Directives 2013/39/EC, 98/8/EC and 2012/528/EU	References
58-89-9 (319-84-6) (319-85-7) (319-86-8) (608-73-1)	Lindane g HCH (a HCH) (b HCH) (d HCH) (sum HCH)	**<u>The Stockholm Convention:</u>** Identified as a POP and included in Annex A of the Convention Text since 2009. The substance is up for elimination, with specific exemption as some human health pharmaceuticals for control against headlice and scabies as second-line treatment (as stated in decision SC-4/15).	Stockholm Convention 2004
		<u>EU Regulation (EC) No. 1107/2009:</u> Lindane is banned as an active substance in plant protection products, by the amending legislation 00/801/EC.	European Commission 2000
		Sum-HCH and g-HCH (including lindane) is banned for production/use, with the amended legislation 2004/850/EC. Excepted uses pertain where Member States may allow the following uses: - Until 2006/09/01; industrial treatment and professional remedial of timber,	European Parliament 2004

		lumber and logs and for residential and indoor industrial applications. - Until 2007/12/31; technical HCH fmay be used as an intermediate in chemical manufacturing; and for products which contains at least 99 % of the HCH isomer is in the gamma form (lindane) are restricted for use as a topical insecticide for public health and veterinary applications.		
		WFD: Identified as a PHS	European Parliament 2013	
		EU Directives 98/8/EC and 2012/528/EU: Not approved as active substances in biocidal products		
115-29-7	Endosulphan	**The Stockholm Convention:** Identified as a POP and included in Annex A of the Convention Text, since 2011. Certain exemtions to both production and use of endosulphan exist (as stated in Decision SC-5/3). The decision states that production is allowed for Contracting Parties listed in the Register of specific exemptions and the exempted uses for endosulphan are as crop-pest complexes as listed in accordance with the provisions of par VI of Annex A of the Convention Text.	Stockholm Convention 2004	
		EU Regulation (EC) No. 1107/2009: Banned for use as an active substance in plant protection products, by the amending Decision 2005/864/EC for the non-inclusion of endosulphan as an active substance in plant protection products. Authorizations for plant protection products containing endosulphan as an active substance where withdrawn by 2 June 2006 however two grace periods where included for certain Member States to keep existing authorizations, the latest, until 31 December 2007.	European Commission 2005	
		EU Directives 98/8/EC and 2012/528/EU:		

		Not approved as active substances in biocidal products	
		WFD: Identified as a PHS	European Parliament 2013
72-43-5	Methoxychlor	**The Stockholm Convention:** Not identified as a POP	
		EU Regulation (EC) No. 1107/2009: Not approved for as an active substance in plant protection products, by the amending Regulation (EC) No. 2076/2002.	European Commission 2002
		EU Directives 98/8/EC and 2012/528/EU: Not approved as an active substance in biocidal products	
115-32-2	Dicofol	**The Stockholm Convention:** Under review to potentially be identified as a POP	UN Environment 2018
		EU Regulation (EC) No. 1107/2009: Not approved as an active substance in plant protection products, as amended by legislation 2008/764/EC; no authorizations for usage are renewed or granted as of October 2008 and any existing authorization was withdrawn by March 2009.	European Parliament 2008
		EU Directives 98/8/EC and 2012/528/EU: Not approved as an active substance in biocidal products	
		WFD: Identified as a PHS	European Parliament 2013

	Trifluralin	**The Stockholm Convention:** Not identified as a POP **EU Regulation (EC) No. 1107/2009:** Not approved as an active substance in plant protection products, by the amending legislation 2010/335/EU; no authorizations for usage where renewed nor grated from September 2007 and any existing authorizations were withdraw by March 2008. **EU Directives 98/8/EC and 2012/528/EU:** Not approved as an active substance in biocidal products **WFD:** Identified as a PHS	European Commission 2010 European Parliament 2013	
87-86-5	Pentachlorophenol (PCP) and its salts (NaPCP) and esters (PCPL)	**The Stockholm Convention:** PCP and its salts and esters (NaPCP and PCPL) are identified as a POP and included in Annex A of the Convention Text, with inclusion in 2015. Certain exemptions for production and usage applies, as stated in Decision SC-7/13; production is allowed for parties registered in the Register, according with the provisions of part VIII of Annex A and exempted uses includes for the use of PCP in cross-arms and utility poles, according with the provisions of Annex A. **EU Regulation (EC) No. 1107/2009:** Not approved as an active substance in plant protection products, by the amending legislation 2076/2002/EC. **EU Directives 98/8/EC and 2012/528/EU:** Not approved as an active substance in biocidal products	Decision SC-7/13 European Commission 2002	

WFD:		
Identified as a PHS	European 2013	Parliament
REACH:		
Registered: Not registered		
Authorization process: Not identified as a SVHC		
Restriction: Usage of PCP and its salts and esters are restricted under REACH with the following conditions (Entry 22): - Shall not be used, nor placed on the market, as a substance or as a component in mixtures and other substances, in a concentration ≥0.1% by weight. No exemptions apply.	European 2007	Parliament

References

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European Commission. 2002. Commission Regulation (EC) No 2076/2002 of 20 November 2002 extending the time period referred to in Article 8(2) of Council Directive 91/414/EEC and concerning the non-inclusion of certain active substances in Annex I to that Directive and the withdrawal of authorisations for plant protection products containing these substances. 32002R2076: P. 0003-0011.

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European Parliament. 2004. Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC. 32004R0850. P. 7-49.

European Commission. 2010. Commission Decision of 25 June 2010 concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414/EEC. 32010D0355: 30–31.

European Parliament. 2007. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. 02006R1907-20140410: OJ L 396.

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Appendix B – Legislative status of substances as included in the OSPAR background document on nonylphenols and nonylphenol ethoxylates

This appendix contains comprehensive information on the legislative status of nonylphenols and nonylphenol ethoxylates (NP/NPE) as mentioned in the OSPAR background document on nonylphenols and nonylphenol ethoxylates under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive (WFD) (Table 1). The presented information explains if the substances is identified as Persistent Organic Pollutant (POP), and whether or not it is included in the SC Convention Text. Information on the production and use volumes on the European Market (if registered under REACH) is presented, together with the status, if any, under the REACH Authorization Process. As some NP/NPEs are restricted under REACH, the conditions and exemptions to stated conditions are accounted for, in detail, in Table 1. As NP/NPEs are not intended to be used as active substances in biocidal and plant protection products, the status under Information on the status of EU Regulation (EC) No. 1107/2009 as well as under EU Directives 98/8/EC and 2012/528/EU is considered irrelevant to present.

Table 1. Legislative status of nonylphenols and nonylphenol ethoxylates under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive (WFD).

CAS No	Substances name	Status under the Stockholm Convention, the EU Regulation REACH and EU Directive 2013/39/EC	References
Not applicable	4-nonylphenol, branched and linear	**The Stockholm Convention:** Not identified as a POP	Stockholm Convention 2004
		REACH: **Registered:** Not registered	
		Authorization process: Identified as a SVHC and included in the Candidate List in 19 December 2012; not yet recommended for inclusion on Annex XIV of REACH	ECHA 2012
		Restriction: Usage not restricted	European Parliament 2007
		WFD: Isomers of 4-nonylphenol (CAS 104-405) and 4-nonylphenol (branched) (CAS 84852-15-3) are identified as PHS	European Parliament 2013
Not	4-Nonylphenol,	**The Stockholm Convention:**	

applicable	branched and linear, ethoxylated	Not identified as a POP	Stockholm Convention 2004
		REACH: **Registered**: Not registered	
		Authorization process: Identified as a SVHC an included in the Candidate List in 20 June 2013; included in recommendation round 2013, to Annex XIV (Entry 43). *Last application date*: 2019/07/04 *Sunset date:* 2021/01/04	ECHA 2013 European Parliament 2007
		At the recommendation for inclusion, ECHA did not recommend a review period nor any exemptions for uses for said ethoxylated nonylphenols. No recommendations to exempt the use in PPROD.	ECHA 2006
		WFD: Not identified as a PS/PHS	European Parliament 2013
25154-52-3	Nonylphenol	**The Stockholm Covention:** Not identified as a POP	Stockholm Convention 2004
		REACH: **Registered**: Not registered **Authorization process:** Not identified as a SVHC	
		Restriction: Nonylphenol (including nonylphenol ethoxylates ($C_2H_4O)_nC_{15}H_{24}O$) is restricted under REACH with the following conditions (Entry 46): - Shall not be used, nor placed on the market, in mixtures or as substances with concentrations ≥0.1% by weight, for the purpose as industrial and institutional cleaning o This condition does not apply where the washing liquid is	European Parliament 2007

incinerated or recycled for cleaning systems with special treatment and for controlled closed dry-cleaning systems.

- Shall not be used, nor placed on the market, in mixtures or as substances with concentrations ≥0.1% by weight for domestic cleaning, manufacturing of pulp and paper, emulsifier in agricultural teat dips, cosmetics products and
- Shall not be used, nor placed on the market, in mixtures or as substances with concentrations ≥0.1% by weight for leather processing's and textiles
    - This condition does not pertain for degreasing of sheepskin and for processing with no release into waste water
- Shall not be used, nor placed on the market, in mixtures or as substances with concentrations ≥0.1% by weight in metal working.
    - This condition does not apply to uses in closed controlled systems where the washing liquid is incinerated or recycled

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European Parliament. 2007. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation,

Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. 02006R1907-20140410: OJ L 396.

European Parliament. 2013. Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. 32013L0039: P. 1-17.

Stockholm Convention. 2004. Convention text - The Stockholm Convention on Persistent Organic Pollutants.

Appendix C - Legislative status of substances as included in the OSPAR background document on organic tin compounds

This appendix contains comprehensive information on the legislative status of organic tin compounds as mentioned in the OSPAR background document on organic tin compounds, under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive (WFD) (Table 1). The presented information explains if the substances is identified as Persistent Organic Pollutant (POP), and whether or not it is included in the SC Convention Text. Information on the production and use volumes on the European Market (if registered under REACH) is presented, together with the status, if any, under the REACH Authorization Process. As organostannic compounds are restricted under REACH, the conditions and exemptions to stated conditions are accounted for, in detail, in Table 1. Information on the status of specific organostannic compounds under EU Regulation (EC) No. 1107/2009 as well as under EU Directives 98/8/EC and 2012/528/EU is further stated.

Table 1. Legislative status of organic tin compounds under the Stockholm Convention, the EU Regulation REACH, the EU Water Framework Directive (WFD), EU Regulation (EC) No. 1107/2009 and EU Directives 2013/39/EC, 98/8/EC and 2012/528/EU.

CAS No	Substance name	Status under the Stockholm Convention, the EU Regulations REACH, (EC) No 1107/2009 and EU Directives 2013/39/EC, 98/8/EC and 2012/528/EU	References
36643-28-4	Tributyltin-cation	**REACH:** Not registered under REACH **The Stockholm Convention:** Not identified as a POP	Stockholm Convention 2004
		WFD: Identified as a PHS	European Parliament 2013
		EU Directives 98/8/EC and 2012/528/EU: Substances is not approved as an active substance in biocidal product	
56-35-9	Bis(tributyltin) oxide	**REACH:** Registered for intermediate use only.	ECHA 2018
		Authorization process: Identified as a SVHC and included on the Candidate List in 2008; not yet	ECHA 2008

		recommended for inclusion of Annex XIV of REACH **Restriction:** No restrictions apply **The Stockholm Convention:** Not identified as a POP	Stockholm Convention 2004
		WFD: Not identified as a PS/PHS	European Parliament 2013
		EU Directives 98/8/EC and 2012/528/EU: Not approved as an active substance in biocidal product	
		EU Regulation (EC) No. 1107/2009: Not approved as an active substance in plant protection products under Commission Regulation (EC) No 2076/2002	European Commission 2002a
56-36-0 4027-18-13 4342-30-7 4342-36-3 Not applicable	tributyltin acetate tributyltin maleate tributyltin salicylate tributyltin benzoate TBT-coPolymer	**REACH:** Not registered under REACH **The Stockholm Convention:** Not identified as POPs	Stockholm Convention 2004
		EU Directives 98/8/EC and 2012/528/EU: Not approved as an active substance in biocidal product	
668-34-8	Fentin acetate	**REACH:** Not registered under REACH	
		The Stockholm Convention:	

		Not identified as POPs	Stockholm Convention 2004
		EU Regulation (EC) No. 1107/2009: Not approved as an active substance in plant protection products as the substance, as amended by Commission Regulation (EC) No 478/2002	European Commission 2002b
76-87-9	fentin hydroxide	**REACH:** Not registered under REACH	
		The Stockholm Convention: Not identified as POPs	Stockholm Convention 2004
		EU Regulation (EC) No. 1107/2009: Not approved as an active substance in plant protection products as the substance, by amendment Commission Decision (EC) 479/2002.	European Commission 2002c
Not applicable	Organostannic compounds	**The Stockholm Convention:** Not identified as POPs	Stockholm Convention 2004
		REACH: Not registered under REACH. **Authorization process:** Not identified as SVHC	
		Restrictions: The use of organostannic compounds are restricted under REACH, with specific restrictions as specified for tri-substituted organostannic, dibutyltin (DBT) and dioctyltin (DOT) compounds, with the following conditions (Entry 20); - Organostannic compounds shall not be used, nor placed on the market, as	European Commission 2007

biocides in free association paint, neither as substances nor as mixtures.

- Organostannic compounds shall not be used, nor placed on the market, in mixtures or as substances with the intention to act as antifouling agent to plants, animals or micro-organisms for all crafts (regardless of intended use or length) in costal, marine, inland and estuarine waterways and lakes or in appliances or equipment used for fish and shellfish farming (i.e. cages, floats, nets etc) or in any partly or totally submerged equipment or appliance.
- Organostannic compounds shall not be used, nor placed on the market, with the intended use of treatment of industrial waters, neither as substances nor as mixtures.
- Tri -substituted organostannic compounds, such as triphenyltin (TPT) and tributyltin (TBT) shall not be used, in articles where the concentration in the article, or any of the article's parts, is greater than the equivalent of 0.1% by weight of the tin, after 1 July 2010. This does not apply to articles which were already in used in the European Community before 1 July 2010.
- Dibutyl tin compounds (DBT) shall not be used, in articles or mixtures where the concentration in the article, or any parts of the article, is greater than the equivalent of 0.1% by weight of the tin, after 1 January 2012. This does not apply to articles and mixtures which were already in use in the European Community before 1 January 2012.
    - These conditions does not apply until 1 January 2015 for the following articles and mixtures which are aimed to the general public: paints and coatings containing where DBT compounds acts as catalysts when applied to articles, fabrics coated with PVC where DBT compounds acts as stabilizers when intended for outdoor applications, RTV-1 and RTV-2 sealants and adhesives, in PVC profiles (by itself or coextruded with hard PVC), outdoor gutters, fittings and rain water pipes, as well as, covering material

	for façades and roofing. o These conditions do not pertain to articles and materials as regulated under Regulation (EC) No. 1935/2004. - Dioctyl tin (DOT) compounds shall not be used by, or supplied to, the general public where the articles, or any parts of the article, contains a DOT concentration greater than the equivalent of 0.1% by weight of tin, after 1 January 2012. This condition applies for the following articles: gloves, female hygiene products, childcare articles, nappies, textile articles with the intention to come in contact with the skin, RTV-2 moulding kits and wall and floor coverings. This does not apply to articles which were already in use in the European Community before 1 January 2012.	

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European Commission. 2002b. 2002/478/EC: Commission Decision of 20 June 2002 concerning the non-inclusion of fentin acetate in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. 32002D0478: P. 0041-0042.

European Commission. 2002c. 2002/479/EC: Commission Decision of 20 June 2002 concerning the non-inclusion of fentin hydroxide in Annex I to Council Directive

91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (Text with EEA relevance) (notified under document number C(2002) 2207). 32002D0479: P. 43-44.

European Parliament. 2007. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. 02006R1907-20140410: OJ L 396.

European Parliament. 2013. Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. 32013L0039: P. 1-17.

Stockholm Convention. 2004. Convention Text - The Stockholm Convention on Persistent Organic Pollutants.

Appendix D – Legislative status of substances as included in the OSPAR background document on mercury and organic mercury compounds

This annex contains comprehensive information on the legislative status of mercury and organic mercury compounds, as mentioned in the OSPAR background document on lead, under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive (WFD) and the Minamata Convention (Table 1). Due to the very comprehensive and detailed nature of the Minamata convention Text, only highlights of limitations and prohibitions under the Convention is accounted for. The presented information explains if the substances is identified as Persistent Organic Pollutant (POP), and whether or not it is included in the SC Convention Text. Information on the production and use volumes on the European Market (as registered under REACH) is presented, together with the status, if any, under the REACH Authorization Process. As mercury is restricted under REACH, the conditions and exemptions to stated conditions are accounted for, in detail, in Table 1. Information on the status of specific mercury compounds under EU Regulation (EC) No. 1107/2009 is further stated.

Table 1. Legislative status of lead and organic lead compounds under the Minamata Convention, the Stockholm Convention, the EU Regulation REACH, the EU Water Framework Directive and EU Regulation (EC) No. 1107/2009.

Substance name	Mercury	**References**
CAS No	7439-97-6 (not applicable in the Minamata Convention Text)	
Minamata Convention	Anthropogenic uses of mercury (and organic mercury compounds) are covered by the Minamata Convention. The Convention entered into force on 16 August 2017 and it limits and prohibits the use mercury in industrial processes and in products as of 2020. Major highlights of the Minamata Text includes phasing-out of existing mercury mines while prohibiting new mercury mines, phase out and phase down the use of mercury in several products and processes, control measures on emissions to air and releases to land and water and regulate the informal sector of artisanal and small-scale gold mining. Interim storage of mercury and mercury disposal is also covered by the Convention.	UN Environment 2017
Status under the Stockholm Convention	Not identified as a POP	Stockholm Convention 2004

Status under REACH	**Registered** for both intermediate use and full use, whereas the latter has a yearly tonnage band of 1 000– 1000 tonnes per annum **Authorization process:** Not identified as a SVHC **Restriction:** The use of mercury is restricted under REACH, with the following conditions (Entry 18a): - Mercury shall not be placed on the market in the following specified products: fever thermometers and in measuring devices, with the intention to be sold to the general public, i.e. barometers, manometers, sphygmomameters and thermometers which are not used as fever thermometers. o This condition does not apply to measuring devices which were used before 3 April 2009; Member States may however restrict or prohibit the placement on the market of such devices. o This condition does not apply to measuring devices older than 50 years on 3 October 2007 and to barometers, which are not older than 50 years old, until 3 October 2009. - Hygrometers, barometers, sphygmomameters, manometers, tensiometers, strain gauges to be used with plethysmographs and thermometers and other non-electrical, with the intended use within the professional and industrial sector, shall not be placed on the market after 10 April 2014. This also applies for said empty measuring devices intended to be filled with mercury. o This condition does not apply; to sphygmomameters used as reference standards in clinical validation studies of mercury-free sphygmomameters or in epidemiological studies which are continuing on 10 October 2012; to mercury triple point cells used for calibration of platinum resistance thermometers and to thermometers intended to be used in tests according to standards which require mercury thermometers (until 10 October 2017).	ECHA 2018a, ECHA 2018b European Parliament 2007

	o This does not apply to measuring devices older than 50 years on 3 October 2007 and in measuring devices displayed in public exhibitions for historical and cultural purposes. - Mercury pycnometers and mercury metering devices for determining the softening point, which are intended to be used by professionals and the industry, shall not be placed on the market after 10 April 2014. o This does not apply to measuring devices older than 50 years on 3 October 2007 and in measuring devices displayed in public exhibitions for historical and cultural purposes.		
Status under WFD	Identified as a PHS	European Parliament	2013
Status under Regulation (EC) No 1107/2009	Alkyl mercury compounds intended as an active substance in pesticides is banned with no possibility for authorization since 2009.	European Parliament	2009
	Alkyloxyl and aryl mercury compounds intended as an active substance in pesticide is banned with no possibility for authorization, since 2009.	European Parliament	2009

References

ECHA. 2018a. Registration dossier – Mercury. WWW document 2018: https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/5169.
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European Parliament. 2007. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. 02006R1907-20140410: OJ L 396.

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Appendix E – Legislative status of substances as included in the OSPAR background document on lead and organic lead compounds

This annex contains comprehensive information on the legislative status of lead and organic lead compounds, as mentioned in the OSPAR background document on lead, under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive (WFD) (Table 1). The presented information explains if the substances is identified as Persistent Organic Pollutant (POP), and whether or not it is included in the SC Convention Text. Information on the production and use volumes on the European Market (as registered under REACH) is presented, together with the status, if any, under the REACH Authorization Process. As lead is restricted under REACH, the conditions and exemptions to stated conditions are accounted for, in detail, in Table 1.

Table 1. Legislative status of lead and organic lead compounds under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive.

Substance name	Lead and its compounds	References
CAS No	7439-92-1	
Status under Stockholm Convention	Not identified as a POP	
Status under REACH	**Registered** for both intermediate use and full use, whereas the latter has a yearly tonnage band of 1 000 000 – 10 000 000 tonnes per annum	ECHA 2018a, ECHA 2018b
	Authorization process: Identified as a SVHC substances and included on the Candidate List on 27th June 2018; not yet included, nor recommended to be included on Annex XIV of REACH.	ECHA 2018c
	Restrictions: The use and production of lead and its compounds are restricted under REACH with the following conditions (Entry 63): - shall not be placed on the market or used in any individual part of jewelry if the concentration of lead (expressed as a metal) is equal to or greater than 0.05% by weight; this applies for brooches, cufflinks, bracelets, rings, necklaces,	European Parliament 2007

	wristwatches, wrist wear and piercing jewelry as well as for individual parts used in jewelry or from materials which the jewelry is made from. This further includes individual parts used or placed on the market or jewelry making. o This condition does not apply to individual parts which are inaccessible to consumers in watch timepieces, to crystal glass (as defined in Annex I of Directive 69/493/EEC), to lead untreated enamels and to reconstructed or non-synthetic precious or semi-precious stones (as defined by Regulation 87/2658/EEC). Furthermore, this condition does not apply to jewelry articles produced before 10 December 1961 or if it was placed for the first time before 9 October 2013. - Shall not be used in, or placed on the market, for the general public in articles or, accessible parts of articles, which can be placed in the mouth by children under foreseeable conditions of use at a lead (expressed as metal) concentration equal to or greater than 0.05% by weight. This limit only applies if it is demonstrated that the lead release rate from the article (coated or uncoated) does not exceed 0.05μg/cm per hour, or for coated substances which during normal wear and tear or a period of 2 years does not exceed this limit. o This condition does not apply to jewelry articles (as above mentioned) crystal glass (as defined in Annex I of Directive 69/493/EEC), to lead untreated enamels, to reconstructed or non-synthetic precious or semi-precious stones (as defined by Regulation 87/2658/EEC), to musical instruments, to keys and locks, including padlocks, to religious articles, to the tips of writing instruments, to button cell batteries and portable zinc carbon batteries and to articles within the scope of Directive 94/62/EC, Directive 2009/48/EC, Directive 2011/65/EU and Regulation (EC) No1935/2004. Furthermore, this condition does not apply to articles placed on the market, for the first time, before 1 June 2016.	
Status under WFD	Identified as a PS	European Parliament 2013

References

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ECHA. 2018b. Registration dossier – Lead. WWW document: https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/23174 Accessed: 21 November 2018

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European Parliament. 2007. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. 02006R1907-20140410: OJ L 396.

European Parliament. 2013. Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. 32013L0039: P. 1-17.

Appendix F - Legislative status of substances as included in the OSPAR background document on cadmium

This annex contains comprehensive information on the legislative status of cadmium, as mentioned in the OSPAR background document on cadmium, under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive (WFD) (Table 1). The presented information explains if the substances is identified as Persistent Organic Pollutant (POP), and whether or not it is included in the SC Convention Text. Information on the production and use volumes on the European Market (as registered under REACH) is presented, together with the status, if any, under the REACH Authorization Process. As cadmium is restricted under REACH, the conditions and exemptions to stated conditions are accounted for, in detail, in Table 1.

Table 1. Legislative status of cadmium under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive.

Substance name	Cadmium	References
CAS No	7440-43-9	
Status under the Stockholm Convention	Not identified as a POP	Stockholm Convention 2004
Status under REACH	**Registered**, in full: 1000 – 10 000 tonnes per annum	ECHA 2018
	Authorization process: Identified as a SVHC and included on the Candidate list in 2013; not yet included, nor recommended to be included on Annex XIV	ECHA 2013
	Restricted: Cadmium is restricted under REACH with the following conditions (Entry 23); - shall not be used in articles and mixtures produced from certain synthetic organic polymers (16 specific polymers as defined in Annex XVII, entry 23), where these mixtures and articles containing more than, or equal to 0.01% cadmium per weight are not allowed to be placed on the market. o This does not apply to articles placed on the market before 10 December 2011,	European Parliament 2007

nor does it apply to mixtures and articles containing recovered PVC, if the concentration if the cadmium concentration (expressed in cadmium metal) does not exceed 0.1% by weight of the plastic material for the use of specific rigid PVC applications (as stated in Annex XVII, entry 23).
    - Furthermore, this condition does not apply to articles which have been colored, for safety reasons, with mixtures containing cadmium.
- Cadmium (expressed as metal), shall not be placed on the market, or used in paints (with codes [3208] [3209]) at a concentration equal to or greater than 0.01% by weight.
    - This condition does not apply to said paints, with a zinc concentration surpassing 10 % by weight of the paint, for which said paints cadmium metal concentration shall not be equal to, or greater than 0.1% by weight.
    - Painted articles, containing cadmium expressed as metal, shall not be placed on the market if the concentration is equal to, or exceeds, 0.1% by weight of the paint of the painted articles.
    - This condition does not apply to articles which have been colored, for safety reasons, with mixtures containing cadmium.
- shall not be used for cadmium plating of metallic articles or components of these articles used in machinery and equipment for certain sectors (food production, cooling and freezing, agriculture and printing and book-binding) and for certain applications (furniture, household goods, sanitary wear and central heating and air conditioning plating).
    - This condition does not apply to components of articles or articles used in sectors, whose applications requires high safety standards; in the sectors in the mining, aerospace, offshore, aeronautical and nuclear sectors, as well as in articles/compontents of articles used in safety devices in agricultural vehicles and road, rolling stock.
    - This condition additionally does not apply to electrical conducts, in any sectors.
- Shall not be used in brazing fillers, or be placed on the market, in concentrations equal to or greater than 0.01% by weight.

	o This condition does not apply to brazing fillers used in aerospace and defense applications, nor to brazing fillers for safety reasons. - Shall not be placed on the market if the concentration is equal to or greater than 0.01% by weight in metal goods such as metal components in jewelry or in metal parts and imitation jewelry accessories. o This condition does not apply for jewelries placed on the market before 2011 or if jewelries are older than 50 years.	
Status under WFD	Identified as a PHS	European Parliament 2013

References

ECHA. 2013. MEMBER STATE COMMITTEE SUPPORT DOCUMENT FOR IDENTIFICATION OF CADMIUM AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS CMR1 PROPERTIES AND BECAUSE OF ITS ADVERSE EFFECTS ON KIDNEY AND BONE TISSUES AFTER PROLONGED EXPOSURE, WHICH CAUSE PROBABLE SERIOUS EFFECTS TO HUMAN HEALTH WHICH GIVE RISE TO AN EQUIVALENT LEVEL OF CONCERN TO THOSE OF CMR AND PBT/vPvB2 SUBSTANCES. WWW document 12 June 2013: https://echa.europa.eu/documents/10162/a048359b-de39-4b7e-8602-51272a55aeae. Accessed: 21 November 2018.

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European Parliament. 2013. Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy. 32013L0039: P. 1-17.

Stockholm Convention. 2004. Convention Text - The Stockholm Convention on Persistent Organic Pollutants.

Appendix G – Legislative status of substances as included in the OSPAR background document on brominated flame retardants

This appendix contains comprehensive information on the legislative status of DecaBDE and HBCDD as mentioned in the OSPAR background document on brominated flame retardants under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive (WFD) (Table 1). The presented information explains if the substances is identified as Persistent Organic Pollutant (POP), and whether or not it is included in the SC Convention Text. Information on the production and use volumes on the European Market (if registered under REACH) is presented, together with the status, if any, under the REACH Authorization Process. DecaBDE is restricted under REACH, the conditions and exemptions to stated conditions are accounted for, in detail, in Table 1. As neither DecaBDE or HBCDD are not intended to be used as active substances in biocidal and plant protection products, the status under Information on the status of EU Regulation (EC) No. 1107/2009 as well as under EU Directives 98/8/EC and 2012/528/EU is considered irrelevant to present.

Table 1. Legislative status of the brominated flame retardants DecaBDE and HBCDD under the Stockholm Convention, the EU Regulation REACH and the EU Water Framework Directive

CAS No	Substance name	Status under the Stockholm Convention, the EU Regulations REACH, (EC) No 1107/2009 and EU Directives 2013/39/EC, 98/8/EC and 2012/528/EU	References
1163-19-5	DecaBDE	**The Stockholm Convention:** Commercial mixture of c-decaBDE is identified as a POP under SC; listed in Annex A of the Convention Text in 2017. The decision has not yet been published (October 2018). Specific exemptions apply for parties listed in the Registry; use of c-decaBDE in vehicles, textile, aircrafts, additives in plastic housings etc., polyurethane foam for building insulation in accordance with part IX of Annex A. **REACH:** **Registered:** In full, 1000 – 10 000 tonnes per annum **Authorization process:** Identified as a SVHC and included on the Candidate List; not yet recommended for inclusion on Annex XIV of REACH **Restriction:** DecaBDE is restricted under, with the following conditions (Entry 67); - Shall not be used, nor produced, on its own or as a substance after 2	Stockholm Convention 2008 ECHA 2018a ECHA 2012 European Parliament 2007

		March 2019. - Shall not be placed on the market in, or used in the production of, other substances (as a constituent), in mixtures, any parts of any other articles at concentrations which are ≥ 0.1 % by weight, after 2 March 2019. - These two conditions does not apply if decaBDE is used as a substance, component of another substance or as a mixture which is supposed to be used in the production of aircrafts, or aircraft spare parts, that are produced before 2 March 2027. Similarly, the above-mentioned conditions do not apply to articles placed on the market before 2 March 2017, as well as for electronic and electrical equipment within the scope of Directive 2011/65/EU	
25637-99-4 3194-55-6	HBCDD	**WFD:** Not identified as a PS or PHS **The Stockholm Convention:** Identified as a POP under SC; included on Annex A of the Convention Text in 2013. Specific exemptions apply, as stated in Decision SC-6/13: - Production; as allowed by the parties listed in the Registry of specific exemptions - Use; extruded polystyrene in buildings and expanded polystyrene in accordance with the provisions of part VII of Annex A **REACH:** **Registration:** in full, 1000 – 10 000 tonnes per annum **Authorization process:** Identified as SVHC and included on the Candidate List; included in recommendation round 2009, to Annex XIV. *Last application date*: 2014/02/21 *Sunset date:* 2015/08/21 At the recommendation for inclusion, ECHA did not recommend a review period nor any exemptions for uses of HBCDD. No recommendations to exempt the use	Decision SC-6/13 ECHA 2018b European Parliament 2007 ECHA 2009

	of HBCDD in PPROD. The only possible route for authorization can be granted in accordance with Article 60(4) of REACH (the socio-economic route). **Restrictions:** Not restricted **WFD:** Identified as a PHS	European Parliament 2013

References

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ECHA. 2009. Recommendation of the European Chemicals Agency (ECHA) of 1 June 2009 for the inclusion of substances in Annex XIV (the list of substances subject to authorization of Regulation (EC) 1907/2207. WWW document 1 June 2009: https://echa.europa.eu/documents/10162/13e903f2-5aba-41b7-b513-59c4388083af. Accessed: 20 November 2018.

ECHA. 2012. MEMBER STATE COMMITTEE SUPPORT DOCUMENT FOR IDENTIFICATION OF BIS(PENTABROMOPHENYL) ETHER AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS PBT/vPvB PROPERTIES. WWW document 29 November 2012: https://echa.europa.eu/documents/10162/b41b5e85-68c6-4522-980f-75f3e0f7f21d. Accessed: 21 November 2018.

ECHA. 2018a. Registration dossier – Bis(pentaomophenyl) ether. WWW document 2018: https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/14217. Accessed: 20 November 2018.

ECHA. 2018b. Registration dossier – Hexabromocyclododeane. WWW document 2018: https://echa.europa.eu/sv/registration-dossier/-/registered-dossier/15003. Accessed: 20 November 2018.

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