




Contribution to the Themed Section: 'Decommissioned offshore man-made installations' Food for Thought

The past, present, and future of the regulation of offshore chemicals in the North Sea—a United Kingdom perspective

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The North Sea is one of the most studied and exploited ecosystems worldwide. The multiple uses from industrial, transport, as well as recreational activities have required researchers, regulators, and legislators to understand and, where possible, to minimize any expected negative environmental impacts. As with any international sea, assessing the current pressures and management actions resulting from these activities is centred on several national and international legislative instruments. This variety of co-existing legislations makes development processes and regulatory assessments cumbersome and time consuming. Hence there is a need to integrate environmental risk assessment and management across sectors, ensuring smart, cost-effective data generation, as well as supporting and standardizing environmental practices. This paper provides an overview of the changing regulatory frameworks regarding offshore chemicals used in the oil and gas industry, and the process of chemical risk assessment conducted under the Offshore Chemical Notification Scheme (ONCS) in the UK. Our view of methodological, research, and regulatory needs and challenges that should be addressed to ensure an adequate and sustainable assessment of offshore chemical use in the North Sea is discussed. Furthermore, we discuss the issues faced regarding chemicals used in the UK oil and gas sector with respect to declining hydrocarbon production.

Keywords: North Sea, offshore chemicals, regulations, regulatory frameworks.

The development of risk and hazard assessments for offshore chemicals in the North Sea

During the 1960–1970s, improved drilling technologies and knowledge of the local geology facilitated the exploitation of oil and gas in the North Sea, leading to a self-sufficient period in oil and gas up until the early 2000s for Britain (UK) and the Netherlands (NL) (Craig *et al.*, 2018).

These developments in the North Sea have required the use of chemicals on a large scale, combined with the need to

consider the risks to the marine environment posed by their discharge.

At the time the first wells were drilled, little thought was given to the potential environmental fate and hazard of chemicals used in drilling and the production of hydrocarbons. Drilling chemicals e.g. often included oil-based drilling muds that were discharged to sea. Although such discharges would be maintained for only a relatively short period required to drill each well, the subsequent production of oil and gas from successful wells would

normally entail the discharge of chemicals on an ongoing basis. This is due to the presence of water in each reservoir, which on production installations must be separated from the oil and gas and is normally discharged. This “produced water” (PW) inevitably contains many of the chemicals used by the installation. Increasing scrutiny by e.g. non-governmental organizations (NGOs), such as Greenpeace and Friends of the Earth, led to increased pressure on the government to regulate and monitor such chemical discharges. Eventually, this led to both national and international regulations on the types of chemicals discharged and the requirement for justifications for the use of chemicals that are considered environmentally problematic (Craig *et al.*, 2018).

In the UK, a voluntary offshore notification scheme (OCNS) was set up in 1979 under which oil companies report quarterly on their chemical use and discharge (Cefas-OCNS, 2018a). This system is even in operation today, but has been amended to include the international reporting and assessment systems (see further details below).

On a European level, monitoring and reduction of potential marine pollution from oil and gas production was initially included in regulation regarding pollution from land-based sources (Paris Convention, 1974). Since 1992, discharges from the offshore industry have been regulated separately through the OSPAR Convention (1992).

One important measure regarding the reduction of offshore chemical discharge was to introduce the so called substitution warnings that require chemical products with particularly hazardous properties to be replaced by less hazardous ones (Oslo, 1972; Paris Convention, 1974; UN, 1974).

In June 2000, the OSPAR Commission adopted Decision 2000/2 on a Harmonised Mandatory Control System (HMCS) for the Use and Reduction of the Discharge of Offshore Chemicals (OSPAR Decision, 2000/2). The aim of this framework was to reduce the use and discharge of harmful chemicals in the North-East Atlantic. Contracting parties to OSPAR, including the UK, subsequently incorporated the HMCS into national legislation.

For the UK, the HMCS (and OCNS) is enforced through the Offshore Chemicals Regulations (OCR, 2002). Chemicals are assessed and registered using a multidisciplinary approach involving chemical hazard and risk assessors, at the Centre for Environment, Fisheries and Aquaculture Science (Cefas), on behalf of the regulator, the Department for Business, Energy & Industrial Strategy (BEIS).

In 2007, the UK extended the service of OCR to the Netherlands on behalf of the State Supervision of Mines (SSM) Staatstoezicht op de Mijnen. Since then, Cefas has been contracted to assess and register offshore chemicals to be used in the UK or the NL waters, as well as to provide scientific and regulatory advice to the regulator, chemical suppliers, and offshore operators.

Also, in 2007, the REACH Regulation (Registration, Evaluation, Authorisation and restriction of Chemicals) came into force. REACH is the system for controlling all chemicals before production/use/import in the European Union (EU) (European Commission, 2013). REACH replaced several national and EU chemical Directives and Regulations (see supporting information Supplementary Table S1) with a new single system, harmonizing chemical regulation and risk assessments across the EU. OSPAR recommended in 2006 (OSPAR, 2006) that the two systems (REACH and HMCS) could run in parallel until the time

when they could successfully be merged. However, that merger remains an elusive goal.

Current regulation and assessment of offshore chemicals

The regulation of offshore chemical use and discharge in the UK follows a two-step process. Any chemical product registered for potential use and discharge is first assessed regarding its potential marine environmental hazard i.e. the potential severity of an impact based on the ecotoxicological properties of the substances within the product (see Section “Hazard assessment” for details) combined with information on the mode of use of the product. Secondly, for planned operations requiring chemical use, the marine environmental risk (hazard and likelihood of environmental exposure) of every individual product is assessed for the specific location and operation (see Section “Risk assessment” for details). The outcome of this risk assessment is used to inform the regulatory permitting (see Section “Permitting”). For both stages of the process, the standard means of assessment is the Chemical Hazard and Risk Management model (CHARM) (CIN, 2004).

In the UK (and the Netherlands), offshore chemicals are registered for 3-year periods after which chemical suppliers must apply for re-registration. This rolling registration and periodic re-evaluation are combined with product differentiation using substitution warnings and colour bands to help encourage the use of more environmentally friendly chemical products (La Vedrine *et al.*, 2015).

Hazard assessment

Hazard assessments are conducted for each substance in a chemical product submitted for registration, with the product assessment driven by the substance that is considered most hazardous. All registered products are collected on the Ranked List of Registered Products (ranked list) (Cefas-OCNS website, 2018a). The ranked list provides operators of offshore platforms in the UK/NL waters with information regarding the hazard assessment ranking (i.e. predicted environmental impact based on generic platform data) of all chemical products available for use in the UK and NL. Products that are expected to have the least environmental impact are assigned with Gold banding, Purple banding is reserved for the most hazardous products. Additionally, every registered product receives a “template,” containing information regarding the most hazardous substance in the product. This template enables operators to have the minimum information necessary to conduct their mandatory risk assessments without needing to know the full composition of the chemical product.

Much of the focus of the assessment is on how chemical hazards are characterized and measured. The OCNS hazard assessment focuses primarily on whether a substance is likely to be persistent, bioaccumulative and/or toxic in the marine environment, based on the OSPAR Pre-Screening Scheme (2017). This assessment strategy captures three of the most problematic characteristics of chemicals and provides a model for the comparison of dissimilar substances. The approach can be criticized for ignoring risks that fall outside of this triad (e.g. endocrine disruption). Expert judgement and separate initiatives are relied upon to compensate for such shortcomings in the hazard assessment.

Substances that are considered hazardous for the marine environment due to persistence and/or bioaccumulation potential and toxicity are assigned a so called “substitution warning.”

Figure 1. Lethal concentration 50% (LC50)/effect concentration 50% (EC50) in mg/l of the ten most commonly used offshore chemical product functions (as currently registered by Cefas). The black horizontal line represents the median value for the individual product function with the box representing the variability within the quartiles with error bars and outliers (black dots). The red line marks the regulatory threshold for a “highly toxic” classification (for organic substances) of 10 mg/l.

While substitutable chemicals are allowed to be used offshore, the operator must apply for a permit and write a justification for the use and/or discharge of the chemical.

Currently, the number of different substances recognized as distinct and registered for offshore use in the North Sea is just below 2000. The total annual chemical use (for the entire OSPAR region) is over 700 000 tonnes and the total annual discharge over 200 000 tonnes (OSPAR, 2018). The vast majority (>75%) of these substances are considered to pose little or no risk (PLONOR), but there are a number of applications where hazardous substances are still being used.

Identified hazards vary substantially based on individual substances and application types (Figure 1). Half of the most commonly used product types (biocide, cement, corrosion inhibitor, etc.) have median hazardous properties around the regulatory threshold for high toxicity for organic substances ($LC_{50} \leq 10$ mg/l) and around 20% have median hazardous properties around the regulatory threshold for high toxicity for inorganic substances ($LC_{50} \leq 1$ mg/l) (OSPAR Decision, 2000/2) (Figure 1).

To this day, most ecotoxicological testing still relies on animals, especially if the data are produced to inform regulatory assessment. Such test practices evoke ethical concerns and

regulators, industry and science alike strive to develop methods to replace or, at least, reduce animal testing wherever possible. Strategies to reduce the need for new animal tests include the use of data from various species, testing of mixtures as mixtures, rather than compound by compound, read-across data from test results for similar substances, as well as the use of computational simulations (Quantitative Structure–Activity Relationships, or QSARs). This variety of acceptable data sources (as well as the uncertainty inherent to any laboratory experiment) can lead to a large range of submitted data for any given endpoint used to assess a substance.

For quality assurance, the regulator can use independent testing to confirm submitted test results (for the given method). The results of such verification testing can help to identify which data/data sources are suitable and most reliable for the assessment of chemical hazard and marine environmental impact, if they are compared with data submitted by other registrants.

Risk assessment

For risk assessment, the information regarding the hazard of a chemical product is used to conduct a site- and operation-specific

assessment of the potential severity of a marine environmental impact and the likelihood for such impact to occur.

Different quantitative chemical risk assessment approaches are employed as part of the OCNS assessment, however all are based on the internationally accepted predicted environmental concentration (PEC): predicted no effect concentration (PNEC) ratio in which the PEC of a chemical in the water column is compared with the PNEC (Bascietto *et al.*, 1990). The PNEC can be regarded as the chemical concentration limit, below which no environmental impact is expected. If the $PEC > PNEC$, then the potential for an environmental risk exists.

In each approach, the PNECs are derived in a similar way, through the application of assessment factors that convert experimentally derived acute toxicity results, expressed as effect concentration (EC) or lethal concentration (LC) of 50% of the test organisms, to PNEC values. The main difference in the approaches relates to the calculation of the PEC.

Permitting

Following the registration of a product, any operator who wishes to use the product offshore must apply for a specific permit.

The permit application process involves the operator producing a chemical risk assessment of the proposed use and discharge. For proposed operations in English waters, the OCNS risk assessment team at Cefas critically evaluates the chemical permit applications to establish if the proposed use represents a significant risk to the marine environment. Activities in Scottish waters are assessed by Marine Scotland. Comments are then relayed to the regulator who can decide if the permit is approved.

For permitting, the information obtained from product-specific hazard assessments are combined with site-specific use and discharge information. Dilution factors which are selected based on the characteristics of the discharge, are then applied to the discharge concentrations to give PEC values at a distance of 500 m from the discharge point.

The assessment factors used in CHARM to convert the experimentally derived toxicity results to PNEC values are chosen based on the type of discharge, continuous or batch and the amount of available toxicity data. The resultant PEC:PNEC ratio is called the CHARM RQ (risk quotient). An RQ is calculated for each relevant chemical, with values greater than unity indicative of a potentially significant risk to the environment. Any such instance must be justified by the operator, along with the use of any chemical that carries a substitution warning. The permit application should include a technical reason why the chemical is being used, what characteristics it has that result in the substitution warning, if there are ways to mitigate the environmental hazard and what alternatives have been considered (OCR, 2002, as amended 2011).

Risk-based approach

In addition to the submission of permit applications, the UK requires that the risks associated with the ongoing discharges of PW are assessed in a risk-based approach (RBA). Operators of installations that discharge PW are therefore required to conduct RBA assessments, in line with an OSPAR initiative (OSPAR Recommendation, 2012/5).

RBA goes beyond the requirements of the HMCS and the simple CHARM model in requiring operators to take a holistic approach to the risk assessment of offshore discharges, which

comprise not only offshore chemicals but also the naturally occurring substances that are present in PW. The sensitivity of the local environment must also be taken into consideration. These requirements have led to the UK adopting a four-tiered approach (DECC, 2014b), with the third and fourth tiers stipulating the use of dispersion modelling, using sophisticated tools such as the DREAM (Dose-related Risk and Effects Assessment Model) modelling software developed by The Foundation for Scientific and Industrial Research at the Norwegian Institute of Technology (SINTEF) in collaboration with a number of operators (2013).

DREAM is a four-dimensional model which takes into consideration oceanographic data to predict the behaviour of each chemical upon discharge. The results are expressed in terms of volumes of PW in which the $PEC > PNEC$, and in terms of the percentage contribution that each chemical contributes to the risk. This allows key contributors to the risk to be identified and informs the PW management strategy.

Listed chemicals

For the OCNS scheme, several restriction lists apply. The most comprehensive of these is provided by REACH's Annex XVII list of restricted substances. OSPAR specific lists are the OSPAR List of Chemicals for Priority Action and List of Substances of Possible Concern which have a specific focus on potential marine environmental impacts.

The assessment of certain chemicals is truncated because they are considered benign. OSPAR provides a "green list" of chemicals referred to as the PLONOR list (OSPAR Agreement, 2013-06). These are permitted for use and discharge without the requirement for a formal risk assessment because they are considered to present a low risk to the marine environment. A measure of harmonization with REACH is provided by the consideration of Annex IV entries as PLONOR items. The same applies to certain categories of substances that are exempted from registration under Annex V of REACH.

Challenges for the current scheme

Chemical identification

For simple, well-defined chemical substances identification is a facile task but many substances are challenging to describe. Less easily classified substances are often referred to as "substances of unknown or variable composition, complex reaction products and biological materials" or UVCBs for short. In terms of offshore chemicals, these are often distillates, polymers or complex reaction products. For some, typically polymers and distillates, the chemical structure may be well-defined, but the size of the molecule may vary. In other cases, stochastic reaction processes and heterogeneous starting materials can generate a range of products that are not described by a single chemical structure. To assist identification the OCNS scheme requires as much information as possible from suppliers. Unambiguous chemical descriptions and molecular weight are required as well as CAS and EC numbers if available. Since this information is often not readily available, characterization and therefore assessment of UVCBs remains a challenge.

Substitution warning chemicals—challenges

As described in Sections "The development of risk and hazard assessments for offshore chemicals in the North Sea" and "Permitting," substitution warnings are applied to products that

contain one or more substances with hazardous environmental properties. It is important to note that chemicals with a substitution warning should be replaced where possible but are not banned from use.

While the number of substitution chemicals and their use has decreased since the inception of the UK National Plan, they are still being used and discharged in the North Sea (La Vedrine, 2015; Cefas-OCNS website, 2018b; OSPAR, 2018, described in the Supplementary Material).

A challenge for substitution of chemicals is that the characteristics that give a chemical a substitution warning are often the properties most sought after for a specific function. For example, corrosion inhibitors are often surface-active substances with a low molecular weight—and therefore suspected bioaccumulative—as well as highly toxic, two criteria for substitution, yet products with these properties provide the best protection against microbial sources of corrosion because they adhere to surfaces protecting them longer. Similarly, chemicals that are highly persistent are often used in cement mixtures to increase the life or resilience of plugs and casings allowing an installation to be used for decades.

The search for alternatives leads to the issue of potential “regrettable substitution” (Zimmerman and Anastas, 2015) i.e. that the environmental risk and impact of a non-substitutable chemical is increased compared with one carrying a substitution warning. Regrettable substitutions may include the use of a larger volume of chemical, or one which is highly toxic, and which causes a larger environmental risk in terms of the PEC:PNEC ratio (described in Section “Risk assessment”), than that of a substitutable chemical.

Assessment challenges

The current hazard and risk assessment strategies are based on standardized tests (Organisation for Economic Co-operation and Development; OECD) and established assessment criteria (PEC and PNEC). While these methods and assessment strategies are well researched and provide comparable results, they are not well suited to address issues outside the “classic” persistence, bioaccumulation potential, toxicity (PBT) realm. Issues that are not being addressed in the current assessment include endocrine disruptive properties, changes in hazard profiles due to sizes (nanoparticles), environmental hazards based on non-toxic properties (e.g. in case of plastics) and mixture effects.

A step forward—the future of offshore chemical assessment in the North Sea

Advances in scientific knowledge regarding the hazard and risk of chemicals, a movement towards decommissioning of installations and the continuous development of novel offshore chemicals with unknown environmental risks, challenge the established assessment methods. In this section, we present our view of methodological, research and regulatory needs and questions that should be addressed in order to ensure an adequate and sustainable assessment of offshore chemical use in the North Sea.

Methodological/research needs

The current processes in place have made it possible to establish a direct, credible and effective regulatory/advisory process for the management of offshore chemicals. However, with the novel challenges and recent events these current processes of legislation and

advice may change at a UK, OSPAR, EU or even wider level. Challenges can come from many sources, such as the reduction in hydrocarbons due to well ageing and loss of viability, requiring the use of new chemistry to enhance oil recovery using polymers and/or fracturing. These novel techniques and materials can include chemical substances with new/unknown hazardous properties—not all of which can be captured by the current hazard and risk assessment process.

Assessment and testing methods need to be reviewed and challenged to account for the potential environmental risk from novel chemical products (such as e.g. nanomaterials) or new identified environmental risks (e.g. endocrine disruption and chronic toxicity). For the UK and the Netherlands, Cefas has been tasked with this adaptation process by conducting research projects on behalf of BEIS and SSM. Regulatory research priorities include advice regarding plastics in offshore chemicals for potential regulatory measures to reduce marine plastic pollution, as well as on the potential leachate of endocrine disruptive materials (and how to test it). Longer range initiatives involving horizon scanning for potential issues is an ongoing and iterative process that Cefas and other agencies are constantly engaged in. Emerging issues are raised at international conferences and within academic and industry fora. The information gathered is assessed to provide informed decisions through projects including literature reviews, product reviews and experiments, to shape regulations to provide effective protection for the environment whilst providing time frames to allow industry to innovate and change their practices.

However, innovation is not only needed with regards to novel contaminants but also in ensuring that current assessment and OECD testing methods represent the environmental risk based on the latest scientific information and for new processes such as decommissioning. Questions that need to be addressed include:

- Do the currently used LC/EC50 endpoints represent the environmental hazard of chemicals or are further criteria (e.g. endocrine disruptive potential) needed?
 - While currently acute toxicity is assessed on a substance basis for hazard assessment and later risk assessment other issues such as endocrine disruption is not. Novel methods for the identification and assessment of endocrine disruptive substances are urgently needed. Some of the needed novel methods include the identification of sources for endocrine disruptors. Could leachate from applications e.g. partition to the wastewater from wells and enter the marine environment?
 - Methods are needed to identify chemicals that are leached during the breakdown of plastics at extremely low levels and determined by specialist spectroscopic techniques. Emerging contaminants often need to be identified at extremely low levels to be able to potentially identify plastic sources and areas or particular plastic pollutants, and potentially trace the pollutant through time and the environment. Monitoring is critical in measuring the health of the marine environment.
- How can complex mixtures be characterized and assessed? What level of detail is needed to achieve a representative assessment?
 - Regulators are concerned with how chemicals made from complex mixtures can be characterized and grouped. This is both a pragmatic effort to ensure that data are not held

separately for individual chemicals but also that the differences in toxicity results can be better understood. International collaborations to identify methods and provide guidelines for characterization of mixtures and how best to risk assess them are currently on going but need continuous engagement from regulators, academia and industry alike to be effective. If complex mixtures are not adequately characterized there is potential for unknown hazards and risks to go unnoticed.

- How can assessments be conducted with minimal or without need for animal testing?
 - QSARs can provide a surrogate for test data providing the source data are good quality and the methods employed are transparent. There are several freely available pieces of software that use transparent data sources and present it in such a way that it is compliant with both REACH and OSPAR requirements. However, stringent quality control of the derived data and clear information regarding the applicability domain and limitations of the individual methods are paramount for ensuring the regulatory acceptance of animal-alternative methods such as QSARs.
- What are the lessons learned from the current legislation of offshore chemicals and which improvements can be made—especially with regards to decommissioning?
 - Over the last few years, decommissioning of installations in the North Sea has been increasing. Since many of the wells were developed prior to the current chemical legislation, risk assessments must be made on the historic well contents from a data poor perspective. Chemicals in use prior to the OSPAR regulations may or may not be recorded and there may be little information regarding the composition. In these cases, the regulator may have to rely on the name of the chemical to identify what type of chemical could be present. Due to the lack of information, risk assessments can often only be conducted qualitatively based on similar types of chemicals and likelihood of substitution warnings and general risk.

The INSITE initiatives phase I was created to address some of these questions to fully understand the effects of man-made structures and how these installations could be evaluated in the context of decommissioning practices (<https://www.insitenorthsea.org/>). This targeted research has provided the evidence to support regulators and industry alike, but the development of internationally accepted regulatory guidelines remains a challenging and time-consuming task.

Assessment strategies for new activities

Decommissioning of offshore oil and gas facilities in the North Sea is likely to gain momentum over the next 30 years (Royal Academy of Engineering, 2013). In the UK, decommissioning activities are predicted to take place on 214 fields between 2017 and 2025 and cost approximately £17 billion. Around 5500 km of pipeline and 1624 wells are forecast to be abandoned during that period while 98 platforms will need to be removed (Oil and Gas UK, 2017). Overall, over 3000 pipelines and approximately 5000 wells will require decommissioning (Oil and Gas UK, 2016) which must be carried out according to the requirements specified in the Petroleum Act 1998 (<https://www.gov.uk/guidance/oil-and-gas-decommissioning-of-offshore-installations-and-pipelines>).

In addition, to comply with the Offshore Chemical Regulations 2002 (as amended 2011), these operations will be captured in the well intervention and decommissioning permit applications submitted to BEIS by the offshore oil and gas industry.

There are several challenges relating to carrying out risk assessments of chemicals discharged during decommissioning operations. One of the biggest challenges is the evaluation of the risk presented by legacy chemicals that were first used prior to the introduction of the OCNS scheme and are therefore often not registered.

Legacy chemicals are e.g. retained in a well from the point at which it was drilled, but must be handled (and often discharged) in order for the well to be decommissioned. While such chemicals do not appear on the permit application, they still need to be assessed. The current approach is, to use a contemporary surrogate chemical on which the risk assessment can be carried out. There are limitations to this approach because operators will often buy a bespoke chemical “package” from a specific chemical supplier who is not necessarily the producer for all the chemical components. This might mean that the chemical supplier has no information regarding the exact chemical composition of a legacy product or what could be a suitable modern equivalent for the risk assessment. Issues arise when surrogate chemicals are chosen inappropriately e.g. if the choice includes PLONOR listed substances instead of chemicals that are more hazardous.

To mitigate this problem, the formulation of a legacy chemical is compared with that of a contemporary surrogate and it is identified where inappropriate surrogate chemicals have been used. This information is used to give advice regarding a chemicals substitution status and to provide a fuller picture of the risks associated with legacy chemicals.

Regulatory needs

REACH and OSPAR—how can the two legislative frameworks be harmonized?

As detailed in Section “The development of risk and hazard assessments for offshore chemicals in the North Sea,” the use and discharge of chemicals in the North Sea are currently regulated by the Harmonised Mandatory Control Scheme developed by OSPAR (OSPAR Decision, 2000/2), as well as the EU REACH Regulation (European Commission, 2013).

Since registration and assessment processes are time consuming for both the industry and the regulator, efforts are being made to harmonize HMCS with REACH as much as possible. Some ideas even go as far as to abandon the HMCS and rely fully on the REACH registration for the assessment of offshore chemicals.

At a first glance, this idea seems attractive, as it has the potential to remove laborious and, apparently, duplicate assessments. However, the HMCS risk assessment focuses specifically on the risk for the marine environment, whereas REACH looks at the risk for human and environmental health in general. Furthermore, chemical substances with a production/import volume below a certain tonnage limit, as well as polymers, are exempt from REACH registration, while they must be registered and assessed under the HMCS. There is therefore concern that an assessment solely under REACH could reduce the current level of marine environmental protection.

Figure 2. Substances meeting the criteria for concern under HMCS-registration status under REACH.

Figure 3. Comparison of assessment results under REACH and HMCS.

This concern was reinforced by the results of a recent study (Anderson *et al.*, 2018). Here we compared the assessment results from offshore chemicals registered under the HMCS scheme with their assessments under REACH and found that the vast majority of assessments either could not be compared, because of the exemption criteria under REACH (Figure 2) or did not result in the same conclusions (Figure 3).

Particularly the exemption of polymers under REACH is an obstacle for a harmonization with HMCS assessments, because many polymers are considered as substitutable substances under HMCS due to their high persistence. The difficulties surrounding both polymers and substitution criteria are discussed in the following sections, along with a further issue, which concerns the assessment factors used to calculate the RQ (HMCS) or risk characterization ratio (REACH).

Assessment factors

As described in Section “Permitting,” the key parameter that is used to determine chemical risk is the RQ, which becomes a concern when the PEC of the chemical exceeds the predicted no-effect concentration (PNEC). The latter figure is derived from estimated or measured ecotoxicity values, suitably adjusted by an assessment factor that provides a measure of environmental protection based

on the level of uncertainty that exists in extrapolating the (usually lab-based) ecotoxicity data to a real-world scenario.

However, different assumptions have been applied in the development of the CHARM model chosen by OSPAR to those made by the European Union for REACH (ECHA, 2008), and this has led to a difference of (typically) two orders of magnitude in the assessment factors computed in each case. As a result, chemical risk assessments conducted under REACH lead to risk characterization ratios that are higher by the same proportion than those generated in accordance with CHARM. This presents a dilemma for the offshore industry, since the conditions that have been used to permit the use of large numbers of chemicals under the OSPAR framework for many years will be regarded as inconsistent with safe use under REACH. The issue is the subject of current debate between industry groups and regulators, and OSPAR’s Offshore Industry Committee agreed in March 2019 to convene an intersessional correspondence group (ICG-REACH) to address this issue, the outcome of which is expected to be announced in 2020.

Polymers/plastics: substances of low concern?

Under REACH, polymers are exempted from registration and evaluation since they are considered to represent a low concern based on their high molecular weight (ECHA, 2012). However,

whilst their molecular weight may restrict their ready uptake into organisms via transport across cell membranes, the increasing prevalence in the marine environment of plastics and microplastics can present additional risks (GESAMP, 2015, 2016; UNEP, 2016). These range from the potential for physical harm to marine mammals from large plastic fragments (UNEP Resolution 1/6, 2014), to the ingestion of microplastics (House of Commons, 2016) by a wider range of marine animals. The persistence of plastics in the marine environment (Lithner *et al.*, 2011) exacerbates the problem, whilst there are additional concerns created by the ability of plastics to adsorb other (potentially toxic) marine pollutants, thus facilitating their ingestion (Engler, 2012; DECC, 2014a). It must be stressed that the main source of such materials in the oceans is litter, with the discharge of offshore chemicals representing very minor quantities by comparison (OSPAR, 2017). However, as international concern over marine plastics mounts, the offshore industry faces increasing pressure to minimize its own contribution to a global environmental problem. Under the HMCS framework, plastics must be registered and are expected to be classified as substitutable based on their persistence, thereby facilitating regulatory control, but such action under REACH is hindered by the lack of registration data. This limitation does not prevent the regulatory control of plastics under REACH, since all substances potentially fall under the scope of the Restriction process. However, the progress of REACH in this area is currently limited, with a recent proposal under development for the restriction of microplastics (ECHA, 2019).

Substitution criteria

It should be noted that harmonization of REACH and OSPAR HMCS assessment of plastics would not be achieved by simply removing the exemption currently applied to polymers by ECHA. The reason for this is that although the OSPAR pre-screening scheme is based on the same elements of biodegradability, bioaccumulation potential and ecotoxicity that are used to highlight hazardous substances under the REACH Regulation, the scheme identifies persistence alone as sufficient qualification for a substitution warning. In contrast, REACH requires the existence of additional ecotoxicological issues to trigger the equivalent classification (PBT or vPvB). In addition, different thresholds for concern are employed under the two frameworks, with the overall outcome of far fewer substances being identified as candidates for substitution under REACH than under the OSPAR HMCS (Anderson *et al.*, 2018, Figure 2). As a result, any moves towards the abandonment of OSPAR's definition of hazardous substances in favour of the equivalent REACH criteria would risk the re-introduction of numerous substances already phased out under the OSPAR framework, along with jeopardizing the investment made by the chemical industry in the development of greener chemicals to replace them. To avert this dilemma, and impart a measure of harmonization, in theory additional restrictions could be imposed under REACH, to as noted in the context of plastics. However, this may not be a practical option given the number of substances involved, hence no immediate solution to this problem is in sight.

Can sophisticated location-specific modelling approaches (e.g. DREAM) be accommodated within REACH (and OSPAR) frameworks?

From the foregoing discussion, it is evident that REACH still has some way to go before the HMCS can be considered to be

redundant. A further complication in a post-HMCS scenario would be the status of one of the most significant developments introduced by OSPAR's Offshore Industry Committee in recent years, the RBA (see Section "Risk-based approach").

Under REACH, legitimate use of chemical substances relies upon the production of safety data sheets that include annexed Exposure Scenarios that cover the intended uses of the substance. These are required to demonstrate that if the prescribed conditions are followed, those uses will not present a risk to the environment (or human health). However, these Exposure Scenarios are essentially generic in nature (the use of CHARM is suggested; ECHA, 2016a, b), and make no allowance for site-specific parameters that could influence the risk. To address these, individual operators would need to produce their own Exposure Scenarios to demonstrate safe use. The use of such parameters is however also accommodated within the higher tier models (e.g. DREAM) that are a feature of UK RBA assessments. This factor may offer a future for the RBA initiative within REACH: however, in assessing the overall chemical risk of both synthetic and naturally occurring substances together, RBA has already taken a step beyond the requirements of both REACH and the HMCS, and for time being, it is more likely to remain as a stand-alone OSPAR initiative.

Brexit

On 23 June 2016, the British public voted to leave the European Union in a historic referendum. At the time of writing, the terms of the UK's future relationship with the EU have yet to be finalized, although it is known that the UK will be excluded from the REACH Regulation, which has led to the UK announcing that it will impose the measures of REACH on a national basis. Conversely, the UK's participation in OSPAR (as a non-EU body) will be unaffected. The ongoing debate with regards to Brexit still provides certain uncertainty and once the full situation has reached its closure, the new challenges associated with Brexit will have to be distilled with regards to the uses of the UKEEZ.

Conclusions

The regulatory assessment of environmental risk from offshore chemicals in the UK (and OSPAR region) is based on methods and strategies that have been developed and used over decades. The established criteria and methods are a robust foundation for environmental risk assessment and protection. However, newly gained understanding on hazardous properties of plastics, nanomaterials as well as the continuous development of chemicals with novel properties (nanomaterials and emerging contaminants) call for a re-evaluation of the established criteria and a development of new ways of addressing challenges ranging from the assessment of endocrine disruptive properties, decommissioning (potential release of legacy chemicals), to the harmonization of international regulatory frameworks.

In this article, we outlined some of the challenges we have encountered as a group of regulators and scientists within the UK regulatory framework. Furthermore, we described our strategies and views of how to address these challenges.

Much work still needs to be done to address the old and emerging risks posed by offshore chemicals to the marine environment. To address these, we need new methods and assessment criteria, but, most importantly, more cross-disciplinary communication and collaboration of academia, regulators and industry

to drive innovation and understanding of marine environmental protection.

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Supplementary data

[Supplementary material](#) is available at the *ICESJMS* online version of the manuscript.

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