Regulatory Compliance of Biocides in the Offshore Oil and Gas Industry

Regulatory Requirement for North Sea Operations

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Regulatory Requirements for North Sea Operations

Biocides used in the offshore oil and gas industry can help maximise the oil and gas production while protecting asset integrity through the inhibition of microbial induced corrosion and biofilm. In the European Union, the regulatory process to authorise and permit the use of a biocidal product can be complex, lengthy and expensive. The following white paper provides an overview of biocides used in the industry, followed by a description of the key regulatory requirements applicable to the use of biocides in offshore oil and gas operations in the North Sea, including the Biocidal Products Regulation (BPR) and the OSPAR Convention (OSPAR). Recommendations to reduce the cost and time associated with regulatory compliance of biocidal products are provided.

1.0 Use of Biocides in the Offshore Oil and Gas Industry

Biocides are used in relatively small quantities in the offshore oil and gas industry, but are an essential component of their operations. Biocides are substances that control bacteria and other harmful organisms, and in offshore oil and gas applications they can protect equipment and increase operational efficiency by controlling microbially induced corrosion, and mitigating the generation of by-products from bacterial metabolism, such as poisonous gases, acids, slime and scales. Biocides can also be used to treat topside structures to prevent marine growth, and can be applied in pipelines to help decontaminate injection wells and protect the reservoir from microbial activity. For example, biocidal products can be added to hydrostatic testing water to prevent internal corrosion of equipment and pipelines during the testing of offshore equipment and marine pipelines. Small quantities of biocides can also be added to the water injected in wells during offshore hydraulic fracturing operations (IFC 2015). Similarly, biocides can be added to produced water prior to being reused. Some of the most frequent types of bacteria present in systems used in offshore oil and gas, and the potential effects they can have on those systems, are presented in Table 1.1.

Table 1.1 *Common types of bacteria present in offshore oil and gas systems*

Bacteria Type	By-product from metabolism	Potential effects of bacteria presence
Sulphate-reducing bacteria	Hydrogen sulphide (H_2S)	Corrosion Health and safety risks Scale deposits Reservoir souring
Acid-producing bacteria	Organic acids Inorganic acids	Corrosion
Slime-forming bacteria	Long chain polymers (e.g. exopolymer)	Biofilm Support growth of sulphate-reducing and acid-producing bacteria

The presence of sulphate-reducing bacteria can result in corrosion through the removal of the hydrogen layer and creation of localised indentation on the metal surface. In addition, this type of bacteria produces hydrogen sulphide as a by-product of its metabolism, which poses health and safety risks and can also result in scale deposits. Sulphate-reducing bacteria are typically found in water injection systems and production systems with seawater breakthrough through natural or induced fractures. They can also be found in reservoirs, where cold, sulphate-containing seawater and hot hydrocarbon-containing formation water creates ideal conditions for the proliferation of this bacteria. The presence of this bacteria in the reservoir can result in reservoir souring, which is caused by the gradual increase of H_2S concentration in the oil reservoir.

Acid-producing bacteria generate organic and inorganic acids through their metabolic activities, which can result in corrosion. Through their metabolic activities, slime-forming bacteria produce long chain molecules, such as exopolymer. These molecules act as the foundation for biofilms, which build up on surfaces and pipelines and can block filters, lines and injection pores. The slime forming bacteria are also influential in the microbial influenced corrosion process, since they provide environmental conditions which support the growth of sulphate-reducing and acid-producing bacteria.

Every offshore oil and gas project is unique and there are several types of biocidal active substances that can be used to manage microbial activity in various environments, such as topsides or pipelines. For this reason, biocidal products are often formulated specifically to function in the unique environment targeted, such as high pressure, high salinity or high temperature environments.

2.0 Regulatory Compliance of Biocides

There are two key regulatory frameworks which are directly applicable to the use of biocides in the offshore oil and gas industry in the North Sea: the EU Biocidal Product Regulations (BPR) and the OSPAR Convention.

EU Biocidal Product Regulations

The EU BPR came into force on 1st September 2013. The BPR aims to improve the internal market for biocidal products across the EU and affects EU importers and EU manufacturers of biocidal products, the active substances used in biocidal products, and treated articles treated with, or incorporating biocidal products.

The BPR sets out to evaluate the safety of active substances for use in biocidal products, and to authorise the use of biocidal products. Biocidal products containing active substances under evaluation in the Review Programme can be placed on the market according to individual Member States biocides legislation, however, eventually, all biocidal products containing approved active substances will need to be authorised according to the BPR before being placed on the market. In addition, as of 1st March 2017 it is only possible to place treated articles on the market if they contain approved active substances, or active substances under evaluation in the Review Programme in cases where the approval application was submitted before 1st September 2016.

Table 2.1 *Useful definitions*

Term	Definition	BPR Reference
Active Substance	A substance or a micro-organism that has an action on or against harmful organisms. Existing active substances are those that were identified as being on the market for use in biocidal products prior to 14th May 2000. New active substances are those introduced after 14th May 2000, or not identified as being on the market for use in biocidal products by 14th May 2000. It should be noted that the status of active substances should always be considered in relation to a named product-type.	BPR Article 3(1)(c)
Biocidal Product	— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, — any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action. A treated article that has a primary biocidal function shall be considered a biocidal product.	BPR Article 3(1)(a)
Treated Article	Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.	BPR Article 3(1)(a)

The BPR process begins with the approval of a biocidal active substance, followed by the authorisation of biocidal products containing those active substances. This process is described below. In addition, information on treated articles, biocides suppliers and biocidal product-types is provided to help gain an understanding of the real-life applications of the BPR for biocides used in the offshore oil and gas industry.

Active Substance Approval

Active substance approval involves the evaluation of active substances for use in named product-types to determine whether they can be safely used in biocidal products and treated articles, and whether the substance demonstrates a sufficient level of efficacy (Article 4). If approved, an evaluated active substance will be included in the Union list of approved active substances maintained by the EU Commission (Article 9(2)). Active substance approvals are granted for a maximum period of 10 years, with an expiry date provided in the EU Commission's decision documents (Article 4(3)(h)). Eventually, only approved active substances will be able to be used in biocidal products, with the exception of active substances which are under evaluation in the Review Programme, or new active substances in biocidal products for which a provisional authorisation has been granted.

Biocidal Product Authorisation

The BPR ensures that eventually, only authorised biocidal products can be placed on the EU market (Article 17(1)). However, whilst the Review Programme is ongoing, biocidal products containing only *existing* active substances still under evaluation can be placed on the market in accordance with Member State National Legislation (Article 89(2)). Once all active substances in the biocidal product have been approved, full BPR product authorisation will be needed. A number of product authorisation options are available, each with different eligibility criteria. Biocidal products are assessed to determine whether they can be used safely and are sufficiently efficacious before they can be authorised. Product authorisations are granted for a maximum period of 10 years, and an application for renewal must be made at least 550 days before the expiry date (Articles 31 and 45).

Treated Articles

A treated article is any substance, mixture or article that has been treated with, or incorporates one or more biocidal products. A treated article that has a ***primary*** biocidal function is defined as a biocidal product (Article 3(1)(a)) and the requirements for authorisation of biocidal products will apply. Requirements for labelling of treated articles are covered in Article 58 of the BPR. The treated article should be labelled with any relevant instructions for use, including any precautions to be taken, if this is necessary to protect humans, animals and the environment.

Biocides Suppliers

Article 95 of the BPR introduces the concept of sharing the costs associated with the generation of data required for evaluation of an active substance by all manufacturers and importers who place the active substance on the EU market, either as an active substance on its own, or in a biocidal product. As of 1 September 2015, biocidal products cannot be made available on the EU market unless the substance supplier or product supplier is included in the Article 95 list for the product-type to which the product belongs. The companies listed on the Active Substance Supplier list are designated as 'substance suppliers' or 'product suppliers'.

The requirements of Article 95 do not apply to active substances used only in treated articles, however they do apply to the biocidal products used to treat the articles. It should be noted that Article 95 obligations apply from the date when an active substance approval application is accepted and validated.

Biocides Product-Types

A biocidal product application cannot be authorised under the BPR until the following conditions are met:

all the active substances in the product are evaluated and approved for inclusion in the Union List (or Annex I of the BPR), and; the entry covers the product-type appropriate for the product.

There are 22 product-types specified in Annex V of the BPR, which are grouped into four main groups: disinfectants, preservatives, pest control and other biocidal products. Common biocidal product-types for offshore oil and gas biocides are shown in Table 2.2 below. Examples of biocidal active substances used in offshore oil and gas products with their associated BPR status are shown in Table 2.3.

Table 2.2 *Common biocidal product types for biocides used in the offshore oil and gas sector*

Main Group	Product-type	Description
Disinfectants	2	Disinfectants and algaecides not intended for direct application to humans or animals
Preservatives	6	Preservatives for products during storage
	11	Preservatives for liquid-cooling and processing systems
	12	Slimicides
	13	Working or cutting fluid preservatives

Table 2.3 *Examples of biocidal active substances used in the offshore oil and gas products with associated BPR status, as of 19 February 2018*

Active Substance	CAS	BPR Status	Key Functions
3,3'-Methylenebis[5-methyloxazolidine] (MBO)	66204-44-2	Under review for PT 2, 6, 11, 12, 13	Broad spectrum microbial control, including sulphate-reducing bacteria Prevents microbially influenced corrosion
N-alkyl-N,N-dimethyl-N-benzylammonium chloride (ADBAC)	68424-85-1	Under review PT 1, 2, 3, 4, 10, 11, 12, 22 Approved PT 8	Rapid microbial control Biofilm penetration properties
Tetrakis (hydroxymethyl) phosphonium sulfate (THPS)	55566-30-8	Under review for PT 6, 11, 12	Decontamination of downhole environment
2,2-dibromo-3-nitrilopropionamide (DBNPA)	10222-01-2	Under review for PT 2, 4, 6, 11, 12, 13	Control microbial activity before injection of water downhole
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride (CTAC)	51229-78-8	Under review for PT 6, 13	Long-term reservoir protection Performance at high temperature and salinity
C(M)IT/MIT	55965-84-9	Approved for PT 2, 4, 6, 11, 12, 13	Control microbial activity Injection in pipelines

The following points outline scenarios for obtaining a biocidal product authorisation:

1. If all the active substances contained in the product have been approved for the relevant product-type, you may apply for a Biocidal Product Authorisation under the BPR.
2. If some of the active substances have been approved, but are not approved for the relevant product-type, you need to get the product-type approved prior to applying for a Biocidal Product Authorisation. This can be done by submitting an active substance approval application to the European Chemicals Agency (ECHA). Once your product-type is approved, proceed with the submission of the Biocidal Product Authorisation.
3. If the active substances are under review for the relevant product-types, you should monitor the status of your active substance and prepare an application for a Biocidal Product Authorisation, to be submitted after approval of the active substance. During that time, you may need to apply for marketing approval under the national biocides legislation of the Member State where you are placing the product on the market.

4. If the active substances have not been notified, you need to submit an application for an active substance approval to ECHA. Once the active substance is approved, proceed with the submission of the Biocidal Product Authorisation.

2.2 OSPAR Convention

Even if a biocidal product is authorised under the EU BPR, it is not automatically approved for use in offshore oil and gas operations. The use of chemicals in the offshore oil and gas industry in the North Sea is also regulated under the OSPAR Convention. The regulatory requirements for offshore oil and gas activities are set out in the OSPAR Recommendation 2000/2 for a Harmonised Mandatory Control System (HMCS), which aims to reduce the impact of offshore chemicals on the marine environment. Under the HMCS, chemicals used and expected to be discharged offshore, as well as chemicals generated offshore, are required to be registered. The HMCS system also promotes the substitution of chemical with certain characteristics by less hazardous alternatives.

In the United Kingdom and the Netherlands, HMCS requirements are incorporated in the Offshore Chemical Notification Scheme (OCNS). To register a product with the OCNS, companies must complete a Harmonised Offshore Chemical Notification Format (HOCNF). Chemicals have to meet requirements regarding their biodegradation in seawater, bioaccumulation and toxicity to aquatic organisms. The Centre for Environment, Fisheries and Aquaculture Science (Cefas) OCNS team evaluates the HOCNF form and conducts a hazard assessment, using the Chemical Hazard and Risk Management (CHARM) model, when possible. The CHARM model uses the biodegradation, bioaccumulation and toxicity information provided in the HOCNF form, and the result is expressed as a Hazard Quotient (HQ), which is used to rank the product (Figure 2.1). The gold colour band is assigned to products with the lowest hazard, whereas the purple colour band is assigned to those with the highest hazard.

Minimum HQ value	Maximum HQ value	Colour banding	
>0	<1	Gold	
≥1	<30	Silver	
≥30	<100	White	Lowest hazard ↓
≥100	<300	Blue	
≥300	<1000	Orange	Highest hazard
≥1000		Purple	

Figure 2.1 *OCNS HQ and Colour Bands*
Source: Cefas 2018

The CHARM model does not apply to all types of products. Some products, such as inorganic substances, hydraulic fluids and chemicals used only in pipelines cannot be assessed with the CHARM model. In the UK, those products are assigned an OCNS letter grouping of A to E, where A represents the highest potential environmental hazard and E represents the lowest potential environmental hazard (Figure 2.2). The letter groupings are assigned based on toxicity, and they are adjusted depending on the biodegradation and bioaccumulation of the chemicals (Figure 2.3).

Initial grouping	A	B	C	D	E
Result for aquatic-toxicity data (ppm)	<1	>1-10	>10-100	>100-1,000	>1,000
Result for sediment-toxicity data (ppm)	<10	>10-100	>100-1,000	>1,000-10,000	>10,000

Figure 2.2 *OCNS Grouping for Non-Charmable Products*
Source: Cefas 2018

Increase by 2 groups (e.g. from C to E)	Increase by 1 group (e.g. from C to D)	Do not adjust initial grouping	Decrease by 1 group (e.g. from C to B)	Decrease by 2 groups (e.g. from C to A)
Substance is readily biodegradable and is non-bioaccumulative	Substance is inherently biodegradable and is non-bioaccumulative	Substance is not biodegradable and is non-bioaccumulative or	Substance is inherently biodegradable and bioaccumulates	Substance does not biodegrade and bioaccumulates
		Substance is readily biodegradable and bioaccumulates		

Figure 2.3 *Adjustment Criteria for OCNS Grouping*
Source: Cefas 2018

At the end of the registration process, a Cefas Template is issued to the chemical supplier and the chemical is added to the Definitive Ranked Lists of Registered Products. The Cefas Template shows the product name, expiry date, and CHARM type or OCNS letter grouping representing the environmental hazard of that particular product. Substitution warnings can be issued on the Cefas Template and added to the list. To remain in line with the objective of the OSPAR Convention, chemical suppliers are advised to replace any candidates for substitution in chemical products by reformulating products which are assigned substitution warnings, when possible. Operators must provide a robust defence for the continued use of products with a high HQ or those that contain candidates for substitution.

3.0 Summary and Recommendations

Biocidal products are subject to stringent regulations. To limit the cost of regulatory compliance and expedite the approval process, it is recommended to use products that contain biocidal active substances which have been approved or are currently under review pursuant to the BPR, for the relevant product-types. The chemical suppliers and operators must also ensure that their uses of the active substances are covered within the relevant product-types and that those active substances are obtained from Article 95 suppliers. Once the biocidal product has been selected and is identified as compliant under the BPR, the chemical supplier can submit the HOCNF form to get the product approved by Cefas. The Cefas review process generally takes eight weeks to be completed.

As a summary, to expedite the regulatory compliance process, some of the key properties of biocides for use in the offshore oil and gas industry include:

- Active substances approved or under review pursuant to the BPR
- Cefas Gold and Silver banding classification
- Low toxicological profile
- Biodegradable according to OECD 306
- Non bioaccumulating
- Stability and proven efficacy at high temperature and high pH

4.0 References

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