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Comments on the Proposed Changes to the Norwegian Activities Regulations

EOSCA would like to put forward the following comments regarding the proposed changes to the Norwegian Activities Regulations and the corresponding Guidelines:

Re Section 63 Categorisation of substances and chemicals – seventh paragraph

The paragraph currently reads: 'When assessing the properties of degradation products for substances with moderate degradation, results from testing of inherent biodegradability, among other things, may be used together with other available information on substances. The assessment should be documented.' It is suggested that the following be added to the paragraph: 'The industry often uses the terms Y1, Y2 and Y3 and yellow subcategories 1, 2 and 3 respectively.'

To understand the degradation of a substance we need to understand the definition of a substance, and how substances are identified:

- A substance is defined in REACH as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

- The objective of the Guidance for identification and naming of substances under REACH is to give clear guidance for Manufacturers and Importers on identifying and recording the identity of a substance within the context of REACH. As an important key element of substance identification the document provides guidance on how to name the substance.

- The approach to identify a substance depends on the substance type. Substances can be divided into two main groups:

"Well defined substances": Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex VI Section 2. Rules for identification and naming differ for "well defined substances" with one main constituent (in principle > 80%) and for substances with more than one main constituent (in principle each constituent > 10%): the so called "mono-constituent" versus "multi-constituent" substances.

"UVCB substances": Substances of Unknown or variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified based on composition like it is the case for well-defined substances. For the various substance types under the umbrella of "UVCB", different identification and naming rules are described in the "Guidance for identification and naming of Substances under REACH".

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Many of the chemicals used in the offshore oil & gas industry are a combination of “well defined substances” and “UVCB substances”. In many cases the chemicals supplied to end-users are mixtures and combinations of both types.

As such a substance may be variable in composition, or comprise of a distribution of molecule sizes or molecular weights. Rather than being engineers to meet one classification or another, these complex mixtures are a result of the complex or variable nature of the reactants used, and are chosen to derive products with specific properties intended for use in oilfield applications.

It should be remembered that the HMCS requires a biodegradation screen test study to be conducted and reported. The nature of such tests and their design is to minimise the chance of false-positives results; ensuring that no substance should achieve a positive result in a degradation screening test when the substance is unlikely to degrade in the environment. Because of this, substances that only partially degrade in a screening test may biodegrade to a greater extent in the environment. Furthermore, the biodegradation screening test is only testing for one degradation route, when in the environment there are a number of degradation paths that may all contribute to a greater or lesser extent to the total degradation profile of a substance, e.g. photolysis, hydrolysis as well as aerobic and anaerobic degradation.

EOSCA believes that the current situation where there is no guideline for assessing the properties of the degradation products for partially degraded susbtance, combined with the Norwegian system set-up where HOCNFs are registered with the operators not the regulators, has led to, and will continue to lead to, unfortunate situations where disagreements on evaluations occur as individual opinions are allowed to play a part and the playing field is uneven.

The issues arise when full biodegradation over time cannot be documented. There is no current guideline how to identify the breakdown products, how far down the breakdown chain the identification of degradation products is supposed to go, nor how to assess the breakdown products. This uncertainty may also open an infinite number of possible permutations. Breakdown pathways and products will also depend on the presence of bacteria, is the degradation aerobic or anaerobic, and other conditions such as temperature and time frames involved.

A consequence of the above unclear evaluation process, combined with the Norwegian set-up where HOCNFs are registered with the operators not the regulators, is also that an evaluation may be accepted by most operators, but not by some/one operator(s). There is no concluding body and as there is no evaluation process to follow, the decision is open to opinions, as the operator, by nature, in this process also has the casting vote, the playing field is by nature uneven.

The above has been the situation since the introduction of the requirement. The previous guideline that was a part of the system for a while did not cover the above issues.

EOSCA would like the Norwegian Environment Agency to provide clear guidance on acceptable approaches to responding to concerns regarding partial degradation. Including what may be accepted as documentation for substances where documentation of full biodegradation over time cannot be provided. The guidance needs to be easy to follow, practical, and if pathways are proposed, they need to be common and inexpensive.

Yours faithfully on behalf of EOSCA,

Dr Nik Robinson
Executive Secretary