THE DEVELOPMENT OF THE EOSCA GENERIC EXPOSURE SCENARIO TOOL (EGEST) – WHY WE NEED IT?
THE DEVELOPMENT OF A METHOD TO CONDUCT A GENERIC EXPOSURE SCENARIO FOR OFFSHORE CHEMICAL USE TO ENABLE REACH REGISTRATION

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1 ABSTRACT

REACH is the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals. It requires manufacturers and importers of substances to provide a defined set of information, in the form of a registration dossier, to the European Chemicals Agency (ECHA).

Once substances have been registered, downstream users will receive safety information from their suppliers for dangerous substances and preparations. This information, presented in new, extended safety data sheets will include risk mitigation measures for the notified uses of the chemicals. Some safety data sheets will have an annex, called an exposure scenario which will give more specific information on how to use the substance or preparation safely and how the users can protect themselves and their customers, and minimise environmental risk. Information on use needs to be shared up and down the supply chain to ensure that all uses are included in the Registration Dossier submitted to ECHA. Many of the substances used offshore by the Oil & Gas industry are expected to be used onshore in similar use categories, for which exposure scenarios will be generated. There are however, likely to be some substances that are used differently or even exclusively offshore, and some of these are used in relatively large quantities. The European Oilfield Speciality Chemicals Association (EOSCA) represents chemical suppliers for both onshore and offshore uses and has developed a standard approach to use and exposure scenarios for the offshore industry which can be used in REACH chemical safety assessments. This paper outlines the development of this generic approach to exposure scenario modelling and demonstrates the EOSCA generic Exposure Scenario tool (EGEST).

2 EXPOSURE SCENARIOS, THE REQUIREMENT

REACH is the Regulation[1] for Registration, Evaluation, Authorisation and Restriction of Chemicals. A major requirement of the Regulation is registration of substances manufactured or imported into the EU. An initial pre-registration step allowed phase-in substances just to be notified to the European Chemicals Agency (ECHA). The requirement to submit a dossier of a defined set of information to ECHA depends on the volume of manufacture or import with first registrations of all existing substances over 1,000 tonnes/yr, along with those with risk phrases R50/ 53 and over 100 tonnes/yr, and those with CMR properties 1 or 2 over 1 tonne/yr becoming due by December 2010.. Existing substances used at lower tonnages will become due for registration at later dates. All new substances must be registered prior to being placed on the market within the EU.

After registration, downstream users (DU) will receive safety information from their suppliers for dangerous substances and preparations. A Chemical Safety Assessment (CSA) will have to be done for all substances manufactured or imported > 10 tonnes/year and a "Chemical Safety Report" (CSR) must be produced. It will serve as an evaluation and attestation of chemical, physical, health and environmental hazards of a substance, in relation to the potential for exposure to man and the environment. For substances classified as dangerous, or found to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), then an Exposure Scenario and Risk Characterisation will be required. The information from the CSR will be presented in new, extended safety data sheets which will include the risks presented by the chemicals and measures to control these risks. Where an ES is required it will be summarised and communicated in the form of Annexes to SDSs.

The extended safety data sheets will give more specific information on how to use the substance or preparation safely and how the users can protect themselves and their customers, and how to minimise environmental risk. This information on what are termed "identified uses" needs to be shared up and down the supply chain to ensure that all uses are included in the Registration Dossier submitted to ECHA. Downstream Users must only use substances for identified uses and must apply any recommended controls to limit risks to human health and the environment, unless they prepare and submit to ECHA their own chemical safety assessment and report. If a use is not covered in the exposure scenario then it will not be allowed. It must be recognised here that use does not mean just application e.g. used as a corrosion or scale inhibitor. Rather it includes how the chemicals are physically handled and administered to the system.

Many of the substances used offshore by the Oil & Gas industry are expected to be handled in the same way onshore. So the exposure scenario for offshore use could be essentially the same for onshore from a human health point of view, but the environmental exposure will be quite different. This is due to offshore discharges being made direct to the sea without any mitigation (3rd party as in a Municipal waste water treatment plant) measures. Environmental exposure in this case is therefore best assessed by looking at data sets from tests conducted on marine species or under marine conditions. Onshore environmental exposure will generally be assessed for effects in the freshwater domain. However, it should be noted that there will be some substances that are used differently or have unique uses offshore, and some of these may be used in relatively large quantities.

The European Oilfield Speciality Chemicals Association (EOSCA) represents chemical suppliers for both onshore and offshore uses. As a trade association, EOSCA examined ways in which it might, be able to provide some assistance to its members regarding the implementation of REACH. It decided to develop a tool so that a standard approach could be taken for exposure scenarios for offshore uses of chemicals for the oil and gas industry which can be used in REACH chemical safety assessments. A generic approach would be taken in order to identify, hopefully, the majority of uses which are relatively benign from either a human health or effect on the environment. If this could be achieved, then companies supplying and or using chemicals would only need to spend effort on the more challenging ones for which higher tier assessments would then be necessary.

So, where does EGEST fit into the overall risk assessment process? The intrinsic hazards of a chemical substance are determined by testing, read across, QSARS, etc. This work is normally done by the manufacturer or importer, and enables them to calculate DNELs and PNECs.

The first measure of potential exposure comes from a definition of the end–uses. ECHA have defined a system of standard phrases[2], called use descriptors and environmental release categories, which enables basic information to be collected from downstream users. The EGEST tool makes some recommendations related to oilfield uses.

The next step in the process is to collect exposure data that is generic to specific uses, and this is what the EGEST tool does. In fact the tool also allows the DNEL and PNEC from the hazard data to be entered, thus enabling the first tier of risk assessment calculations.

If the first risk assessment calculations suggest insufficient control of risk, it may be necessary to then obtain data which is more specific to the substance in question. This may lead to the development of specific exposure scenarios and more sophisticated higher tier risk assessments. This step is outside the scope of the EOSCA project.

3 THE PROCESS

3.1 Project Initiation

The challenges facing EOSCA were deciding what the overall task would be and who would actually develop the tool. The decision to develop the tool was taken at the EOSCA AGM in December 2007. It was recognised at that time that exposure scenarios could not be completed by the suppliers of chemicals alone. The users of chemicals determine how the chemicals are actually handled and in what situations. The process equipment of the user also determines what if any discharges are made to the environment. A meeting was called early in 2008 between chemical suppliers, EOSCA members, and the chemical end users the Oil and Gas operators. The latter were approached through contact with the International Association of Oil & Gas Producers (OGP). It had been hoped that joint funding could be secured for the project between the stakeholders, however when this did not come to fruition EOSCA felt that the merits of the project were sufficient to fund it solely from the membership contributions.

A steering committee of 7 members was convened. This allowed enough input to cover all the Membership interests and to allow the project to meet the deadlines set for completion to enable the tool to be available for use by the industry.

The exact requirements for generic exposure scenarios were not known at the time as the relevant REACH guidance on the REACH Implementation Project[3] (RIP) had not been finalised. It was difficult to set a comprehensive scope of work, but it was decided to offer an outline scope to a number of suitable consultant organisations to get their ideas and costs for how the work might progress. Three organisations were chosen following suggestions from EOSCA Members. Each company was invited to present themselves and their proposals to the steering committee. A scoring system was used to rank the companies on various aspects of their expertise and knowledge in the required areas, together with anticipated costs. From this, BMT Cordah was chosen to develop a final scope of work. This was agreed by the membership at the following EOSCA meeting in June 2008.

3.2 Project Scope

By this time the RIP[3] had been published and a better idea of the requirements was known.

The main objectives of the project were identified as:

To identify and agree on a number of generic human health and environmental exposure scenarios (ESs) which were to be modelled and serve to aid EOSCA members (and their customers) in their REACH obligations;

To collate the relevant data that will be required to produce generic exposure scenarios, from chemical suppliers and oil and gas operators; and

To generate generic ESs for the agreed scenarios that can be used in the form developed, or tailored to suit individual chemical suppliers' requirements.

The Project was arranged into a number of tasks as described in Table 1.

Table 1 *Project programme stages*

Project Task
Task 1 – Identify and agree Exposure Scenarios and collate data a) Human Health Scenarios b) Environmental Scenarios
Task 2 – Compare models and tailor for offshore generic modelling
Task 3 – Develop generic exposure scenarios
Task 4 – Presentation of robust case to support approach to exposure scenarios

To start the project the EOSCA Executive Secretary produced a list of a number of typical use scenarios for chemicals offshore. The list consisted of only 8 scenarios. Chemicals are shipped offshore in only a limited number of ways and are then either applied directly from the shipping container or transferred to platform storage from where the chemical is pumped into the process system. Direct exposure to chemicals is generally quite limited.

The starting description of these scenarios is given in Table 2.

Table 2 *Starting Chemical Use Descriptions*

Scenario	Description
1	Chemical shipped to offshore installation in tote tanks. Chemical subsampled from tote tank for quality check. Tote tank connected by hose to installation storage tank. Hose disconnected. Empty tank shipped onshore. Chemical applied by fixed dosing pump.
2	Chemical shipped to offshore installation in tote tanks Chemical subsampled from tote tank for quality check. Tote tank connected by hose to transfer pump Chemical transferred/ injected Hose disconnected. Empty tank shipped onshore.
3	Chemical shipped to offshore installation in drums. Dosing pump connected to drum Chemical dosed directly from drum. Dosing pump disconnected. Empty drum shipped onshore
4	Chemical shipped to offshore installation in drums. Transfer pump connected to drum Chemical pumped/poured from drum into system or dosing jug. Transfer pump disconnected. Empty drum shipped onshore
5	Bulk mud/brine/weighting agent/base oil shipped offshore in offshore support vessel tanks Transfer hose connected from vessel to installation storage tank. Mud/brine/weighting agent pumped from vessel Transfer hose disconnected. Mud/brine/weighting agent/base oil pumped from storage tank to well/ mud pits Also applies to shipping mud etc back onshore from installation.
6	Solid chemical shipped to offshore installation in sacks. Chemical emptied from sack into hopper /mud pit Chemical emptied from hopper into mud pit Empty sack shipped onshore
7	Chemical shipped to offshore installation in tubs. Tub opened Chemical applied by spatula from tub. Empty tub shipped onshore
8	Maintenance of pumps used for dosing chemicals Pump priming – chemist checks dose rate of chemical by isolation of main feed and dosing from a small reservoir with measurement points to side

Table 3 *OSPAR Functions of Chemicals*

Acidity Control Chemical	Hydraulic Fluid
Antifoam (Hydrocarbons)	Hydrogen Sulphide Scavenger
Antifoam (Water Injection)	Jacking grease
Asphaltene Dissolver	Lost Circulation Material
Asphaltene Inhibitor	OPF Additive
Biocide	OPF Base Oil
Brine (Completion)	OPF Base Synthetic
Carrier Solvent	OPF Oil based Drilling fluid
Cement or Cement Additive	OPF Synthetic-based Drilling Fluid
Coagulant	Oxygen Scavenger
Coolant or Coolant Additive	Pipe Dope
Corrosion Inhibitor	Pipe Release Chemical
Crosslinking Chemical	Pipeline Hydrotest Chemical
Cuttings Wash Fluid	Pipeline Pigging Chemical
Defoamer (Drilling)	Proppant
Demulsifier	Scale Dissolver
Deoiler	Scale Inhibitor
Detergent / Cleaning Fluid	Shale Inhibitor / Encapsulator
Dispersant	Thinner
Drilling Lubricant	Tracer chemical
Dye	Viscosifier
Emulsifier	Water Based Drilling Fluid Additive
Filter Cake Removal Chemical	Water Based Drilling Fluid
Filter Media or Filter Media Additive	Water Clarifier
Filtrate Reducer	Wax Inhibitor
Flocculant	Wax Dissolver
Fluid Loss Control Chemical	Weighting Chemical
Gas Hydrate Inhibitor	Well Stimulation Chemical
Gelling Chemical	Well Bore Clean-up Chemical

This was then combined with the Chemical Applications listed in the OSPAR Function list (Table 3) to produce a matrix of uses and applications. This was done mainly to ensure that most if not all typical offshore use/applications were covered. This matrix was then reviewed by EOSCA Members and some oil and gas operators to again ensure that nothing obvious was missing. The review process highlighted a number of scenarios which were not covered but after discussion these were generally not added as they were not considered to be generic uses. The project always intended to cover the majority of scenarios, but accepted that it would be impractical to cover all uses and handling situations.

4 EXPOSURE ASSESSMENT

4.1 Human Health

Rather than develop a completely new occupational exposure model BMT Cordah reviewed and evaluated the models and semi-quantitative exposure estimation tools already in common use. Algorithms and software were examined from various sources, including the following:

- POEM (Predictive Operator Exposure Model; UK Pesticide Safety Directorate, estimates exposure during pesticide mixing)
- EUROPOEM (a model based on the above, but including functions from a German model and US system)
- PHED (Pesticide Handlers Exposure Database; US EPA)
- CLEA (Contaminated Land Exposure Assessment; UK Environment Agency, human exposure modules)
- EU Technical Guidance Document (TGD); Exposure Scenario algorithms for biocides;
- EASE (Estimation and Assessment of Substance Exposure; developed by the UK Health and Safety Executive for chemicals)
- RISKOFDERM (European higher tier dermal exposure model)
- TRA (Targeted Risk Assessment; developed by European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC))

The models were evaluated against the following criteria, in order to establish their suitability for use with offshore chemicals:

- Compatibility with substances used offshore i.e. justifiably could be used with this diverse group of chemicals
- Relatively simple and transparent, allowing user manipulation of data to generate refined estimates
- Validation status, what level of validation or verification was available to justify the output of the model?
- Regulatory use, what and where were models used, and with what level of regulatory acceptability?

From the above criteria, the model identified as being most suitable was the EASE model and its further development in the ECETOC TRA model. This outcome was also in agreement with the REACH Guidance[4], which favoured ECETOC TRA as one of the early assessment tools. The ECETOC TRA tool describes likelihood of exposure and effects in a Tiered Scheme, filtering out non-hazardous chemicals / chemicals with low potential exposure, which require a simpler assessment to demonstrate low risk, than those that are hazardous and / or have high potential exposure.

As REACH identified the TRA as a preferred tool, it was considered that an analogous tool, based on the same underlying principles and validation set of the TRA, would be a sound basis in terms of regulatory compliance and acceptability as there were no measured occupational exposure values readily available for offshore chemicals with which to construct a new model.

To assess risk adequately in the absence of measured data, an initial risk assessment must rely on surrogate values for exposure which, to be acceptable, must generally conform to the following principles:

- Be based on a validated data set or accepted measurement
- Be precautionary, assuming that possible exposure will lead to actual exposure
- Be conservative and always overestimate exposure

REACH guidance recognises the use of such models as initial and first Tier tools as being useful for screening out chemicals and substances that essentially present little or no-risk and are not of immediate concern. It is EOSCA's view/ hope that this will be the case for the majority of chemicals used offshore and that screening out chemicals of low concern enables targeted assessments for those chemicals where risk cannot be ruled out.

4.2 Environment

The REACH Guidance on environmental exposure is in the main unchanged from its predecessor the EU Technical Guidance Document on Risk Assessment[5] (EU TGD). Neither of the documents specify an approach to marine discharges or those from offshore oil and gas production which would satisfactorily assess chemicals used in the oilfield industry. The REACH Guidance does however mention Chemical Hazard Assessment and Risk Management[6] (CHARM) which is an established model which has been used to assess offshore discharges since 2001.

Environmental assessment cannot necessarily be broken down by function type according to the OSPAR functions list. CHARM has a number of defined of assessment scenarios and some chemicals may be discharged via a number of possible routes specific to the actual chemical and the point of application of them. Topside discharges are assumed by CHARM to be at the sea surface although many discharges are from caissons emitting below the surface. Environmental exposure from mid-water-column discharges are largely determined by dispersion, which in turn depends on the depth of the discharge, depth of water to seabed, as well as the discharge temperature, salinity and other physico-chemical properties. Because of the amount of scenario specific data required, this type of scenario is unsuitable for generic assessment. This is why all topside discharges are assumed to be at the sea surface using worse case assumptions.

The discharge scenarios included are;

- Subsea, and two topside discharge types, consideration being given to whether exposure would occur during the main operational/activity phases: production, drilling, cementing, work-over, decommissioning and pipeline work.
- Subsea production discharge – Hydraulic fluids are believed to be the main chemical function group that are used as part of production operations that may result in a subsea discharge.

- Subsea (other processes) – Drilling, cementing, work-over operations, and pipeline operations may all result in subsea discharges.
- Topside direct discharges – Production, drilling and cementing can result in direct marine discharge of substances.
- Topside produced water discharge – Production, pipeline and work-over operations may all result in substances being discharged via the produced water stream.

All of these scenarios were identified as requiring generic ESs

5 THE EOSCA GENERIC EXPOSURE SCENARIO TOOL (EGEST)

EGEST is a Microsoft Excel spreadsheet based model with assessment being carried out using a series of linked sheets. The user is required to enter physico-chemical data, hazard data and data regarding the use based on one of nine defined occupational exposure scenarios and eleven discharge scenarios.

EGEST uses this data to derive endpoints which describe the availability of the substance for worker exposure and the potential for exposure, based on use. The values are then used to pick appropriate values from set look-up tables. The values in the look-up tables are based on those developed for EASE and subsequently amended where appropriate for TRA (i.e. a validated and accepted data set) for human health assessment.

This tiered approach is similar to the TRA process, with the exception that there are two sections to Tier 1, A and B. Tier 1 A is based on generic values, whereas Tier B allows the user to add additional information to refine the estimates where appropriate. Tier B is not intended to replace any in-depth Tier 2 assessment which must be conducted following the methodology outlined in the TGD and as such is outside the scope of this project, but allows the use of measured data, where available to further refine the assessment.

Data required for some of the eleven discharge scenarios includes that of Predicted No Effect Concentration (PNEC). The source of the PNEC used is recorded in EGEST and this may be derived from assessment criteria used within CHARM or the TGD using the New CHARM Calculator Software[7] (NECCS) or other source eg data agreed within a SIEF. The assessment for environmental exposure is then based on the PEC:PNEC ratio which is the accepted method in both the TGD and CHARM.

Whilst EOSCA has been developing its own tool other organisation have also been developing or refining others. Cognisant of this the raw tool as developed by BMT Cordah has also been refined by EOSCA. A user guide was felt necessary to lead users through the sheets indicating what input is required. This is now incorporated into the tool. Also sector and use descriptors for process and environmental release codes have been added to bring the tool into line with other tools.

Earlier it was stated that *exposure scenarios could not be completed by the suppliers of chemicals alone*. The tool will help to communicate identified uses between suppliers and the users (O&G operators) and the nature of the supply and use of chemicals offshore is such that the suppliers do in fact provide much information as well as chemicals to their customers. It is quite likely that much of the input for exposure scenarios

will fall to being provided by the suppliers. With this in mind and to encourage and maximise the general uptake of a standardised approach, EOSCA decided that the tool when it was developed would be offered not only to its own members, but to the whole of the industry as a free download from its website. Accordingly EGEST can be downloaded from http://www.eosca.com/EGEST/Download.htm. To try to keep track of potential uptake a short questionnaire needs to be completed before the download is allowed.

EOSCA will monitor the uptake of the tool and any future requirements for exposure scenarios. Any future enhancement to the tool will be considered and implemented if felt appropriate and funding allows.

6 SUMMARY

Exposure scenarios will become a feature of supply for many chemicals used offshore as REACH is implemented. These will need to address not only the exposure of workers to the effects of chemicals but also the effects of the chemicals on the environment. Whilst these are already being done to a large extent a more standardised approach will be required in the future. With this in mind EOSCA developed a tool for the industry to use. The tool offers generic assessment which it is hoped will be sufficient for the majority of chemicals currently in use. However, only time will tell whether or not this is the case. EOSCA will continue to review any new exposure scenario guidance issued by ECHA and CEFIC, as it is expected that further EOSCA guidance for use by the Chemical suppliers to ensure that they comply with all REACH requirements will become necessary.

7 REFERENCES

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