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# ERA Acute

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The ERA Acute methodology will be the new industry standard environmental risk assessment (ERA) method on NCS in 2019, replacing the currently used MIRA method.

ERAs are carried out with the purpose to assess and ensure acceptable environmental risk for oil and gas offshore operations, aiming to minimize the risk to the environment. ERA Acute has been developed by leading ERA experts, and provides the mean to evaluate the potential risk from an acute oil spill in the marine environment.

The ERA Acute method includes four environmental compartments: the sea surface, shoreline, water column and seafloor. ERA Acute uses input data from an oil spill trajectory model and biological resource data, and calculates the potential environmental risk (impact and recovery time) for biological resources in all compartments.

The ERA Acute software tool provides relevant visualization of the output results from the ERA Acute method, such as maps, graphs and tables. The tool has applications for environmental risk management, such as a risk matrix and a comparison tool which may support a spill impact mitigation analysis (SIMA).

Report 2: Threshold values and exposure to risk functions for oil components in the water column to be used for risk assessment of acute discharges (EIF Acute)

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The report (2006) presents biological effect threshold values and damage functions for oil in the water column. The results were included in the later developed ERA Acute method.







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### Threshold values and exposure to risk functions for oil components in the water column to be used for risk assessment of acute discharges (EIF Acute)

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Threshold values and exposure to risk functions for oil components in the water column to be used for risk assessment of acute discharges (EIF Acute)

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#### 1 Introduction

Threshold values and exposure to

the water column to be used for

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risk functions for oil components in

The oil industry is required to assess the risks to the environment for both regular discharges and accidental oil spills. In order to compare assessments carried out by different assessors, compare alternative technologies, compare risk assessments of different fields, as well as to select the best available technology (BAT) or best environmental practice (BEP), a generally accepted method for establishing a common risk measure is needed. For this reason the Environmental Impact Factor (EIF) was introduced for assessing the environmental risks of discharges of produced water. For assessing the risks related to marine oil spills, the EIF Acute Model is currently under development.

As part of the project, methodology for calculating threshold values for toxic effects of hydrocarbons has been proposed in the following reports:

- Calculation of PNEC values for the water column applied in environmental risk management for accidental discharges (1).
- Establishment of PNEC limits for EIF-Acute; Sea-surface and coastal habitats (2).

The PNEC report for the water column (1) suggests a methodology for calculating PNEC values for dissolved hydrocarbon components in the water column. However, the report does not suggest a methodology for calculating PNEC values for *dispersed oil* in the water column.

In the PNEC report for the sea-surface and coastal habitats (2) theoretical considerations and modelling has been applied in combination with literature findings, to identify possible PNEC values of oil in the environment. However, the report discusses the suitability of the PNEC method, and recommends that further work should focus on the establishment of *"effect limits"* in stead of PNECs for the various species and habitats.

Thus, after finalising the PNEC report for the water column (1), and the PNEC report for the sea-surface and coastal habitats (2) the EIF Acute project team made a decision to establish

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*threshold values* in stead of PNEC values to be used in EIF Acute level I and II. In addition, according to the definition of risk, the endpoint of a risk assessment should include a quantification of the likelihood and a characterization of the severity of biological effects. Thus in EIF Acute Level III *damage functions* or "exposure to risk" functions should be established to be able to quantify the effect caused by the pollution.

The present report covers a suggested methodology for establishment of such threshold values and damage functions for both dissolved oil components and dispersed oil in the water column. Chapter 2.1 describes a suggested method for establishing threshold values and damage functions for **dissolved components**, while **dispersed oil** is covered in chapter 2.2. Chapter 2.1 includes a comparison of the resulting *threshold values* against the established *PNEC-values* from the PNEC report for the water column (1).

Lastly, this report discusses the main differences between these new methods and methods currently in use by other researchers and projects (Chapter 3).



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#### 2 Establishment of threshold values for effect

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risk functions for oil components in the water column to be used for

The true "no-effect" level cannot be determined directly. However, a predicted no effect level (PNEC) can be estimated. The European Commission describes in the second edition of the Technical Guidance Document (TGD) on Risk Assessment (3) two PNEC calculation methods:

- Calculation of PNEC using assessment factors
- Calculation of PNEC using statistical extrapolation techniques ("SSD method")

The TGD (3) states that for most substances, the pool of data from which to predict ecosystem effects is very limited as in general, only short-term toxicity data are available. In these circumstances, it is recognised that, while not having a strong scientific validity, empirically derived assessment factors must be used. The size of the assessment factor depends on the confidence with which a PNEC can be derived from the available data. This confidence increases if data are available on the toxicity to organisms at a number of trophic levels, taxonomic groups and with lifestyles representing various feeding strategies. Thus, lower assessment factors can be used with larger and more relevant datasets than the base-set data. Calculation of PNEC for dissolved oil components using assessment factors is described in the PNEC report for the water column (1). However, the decision made in the EIF project to establish threshold values instead of PNEC values have suggested the SSD method as the preffered method for establishing these threshold values.

As discussed in the PNEC report for the water column (1), the results from laboratory toxicity tests, with organisms exposed to a substance for a fixed period of time, are usually expressed as a LC50 or an EC50. In principle, the PNEC is calculated by dividing the calculated LC50/EC50 by an appropriate assessment factor. The assessment factors are applied to extrapolate from laboratory single-species laboratory toxicity data to multi-species ecosystem effects etc. For some of the individual petroleum components there are no acute toxicity data available for marine organisms. In EIF acute a QSAR-based (Quantitative Structure Activity Relationship) approach using available toxicity data and modelling for chemicals acting by



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narcosis, is recommended in the PNEC report for the water column (1) for assessing toxicity (LC50/EC50 values) and establishing PNECs for dissolved oil components in the water column for components where no toxicity data is available.

If a large data set from long-term tests for different taxonomic groups is available statistical extrapolation methods may be used to derive a PNEC (3). This method is called the Species Sensitivity Distributions (SSDs) method. The main underlying assumptions of the statistical extrapolation methods are as follows:

- The distribution of species sensitivities follows a theoretical distribution function;
- The group of species tested in the laboratory is a random sample of this distribution.

In general, the method works as follows: long-term toxicity data are log transformed and fitted according to the distribution function and a prescribed percentile of that distribution is used as criterion. For pragmatic reasons it has been decided that the concentration corresponding with the point in the SSD profile below which 5% of the species occur should be derived as an intermediate value in the determination of a PNEC. A 50% confidence interval (c.i.) associated with this concentration should also be derived. The PNEC is calculated as:

PNEC = 5% SSD (50% c.i.) / AF.

The AF is an appropriate assessment factor between 5 and 1, reflecting the further uncertainties identified. The approach of statistical extrapolation is still under debate and needs further validation. An advantage of this method is that it uses the whole sensitivity distribution of species in an ecosystem to derive a PNEC instead of taking always the lowest long-term NOEC. However, such methods could also be criticised. Among the most common drawbacks, the reasons put forward are: the lack of transparency by using this method compared to the standard approach, the question of representativity of the selected test species, the comparability of different endpoints, the arbitrary choice of a specific percentile and a statistical confidence level etc. In response to these concerns it has been seen as necessary to provide some guidance on when and how to use such methods. The TGD (3) gives advice on which input data should be used (at least 10 chronic/long term NOECs, preferably more than

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15 for different species covering at least 8 taxonomic groups). These advices will exclude the SSD method for use in the EIF Acute concept. However, since the EIF project team has decided to establish *threshold values* instead of PNEC values to be used in EIF Acute level I and II, and damage functions or "exposure to risk"<sup>1</sup> functions to be used at level III, the SSD method could be evaluated and compared with the assessment factor approach for its suitability.

The method for establishing the *threshold values* in stead of PNEC values is based on species sensitivity distributions to dissolved oil components. However, it is based on distributions of *LC50 values*, not on long-term NOEC values, and of *zooplankton and fish* only. The concept is further described in chapter 2.1. A comparison of the resulting *threshold values* based on the SSD methodology against the established PNEC-values from the PNEC report for the water column (1) is given in chapter 2.1.

## 2.1 Establishment of *threshold values for effects* and *damage functions* based on species sensitivity distributions to dissolved oil components

In the PNEC report for the water column (1) distribution curves of  $LC_{50}$  for zooplankton and fish is established for dissolved oil components. These curves show the sensitivity variation among zooplankton and fish species, expressed as LC-50 values from toxicity tests. Based on these LC-50 distributions, the 5% lowest value ("5% percentile LC50") can be selected as being representative for a particular sensitive organism, and used as basis for constructing a dose-response curve for such an organism.

The threshold value for acute effects used in EIF acute is in line with the considerations made in the previous report (1):

• In the previous report (1) a correction factor of 0.5 was introduced due to an apparent difference between the theoretically calculated LC50 by the model and the reference data from tests with *Acartia tonsa* and *Calanus finmarchicus*. The average ratio between model

<sup>&</sup>lt;sup>1</sup> The damage function is called "plet" function in the OSCAR model.



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and observed data was 0.53 (SD=0.28) log units. Ongoing testing of individual chemicals with *C. finmarchicus* at Statoil also confirms this. It appears that *C. finmarchicus* is a less sensitive than the "average crustacean" according to data derived from various databases. Preliminary data from benzene, toluene and ethylbenzene indicate a mean ratio between averaged data of the individual chemicals of 0.55 (SD = 0.14) relative to the QSAR, and 0.73 (SD = 0.32) relative to the available literature data (N = 50) for the same chemical components. According to the theory behind the unit toxicity model we assume that this is also the case with the mixture toxicity. In conclusion, there are currently no indications that the model underestimates the toxicity.

• Considerations of dose/response curves (risk curves) for various combinations of species and chemical substances made us change the slope of the "typical" risk curve for individual species. The risk curve, or damage function, now used is thus steeper than the one used in the previous report. Thus, the so called "assessment factor" derived from the calculations is now 11 compared to the tentative value of 36 used in the previous report. However, the use of the notation "assessment factor" is misleading in this context, since the effect threshold value is calculated from the mean LC50 value given by the toxicity prediction model and a "typical" risk curve (dose/lethality –curve) for a theoretical species at the 5% level of the species sensitivity distribution curve (SSD5%).

Figure 2-1 illustrates the proposed method for establishing threshold values and damage functions for dissolved oil components in the EIF calculations:



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**Figure 2-1** Sketch showing the proposed method of establishment of threshold limit ("effect limit") and damage function for oil components, in this case toluene.

- The "sensitive species dose-response curve" or *damage function* (thick red line on Figure 2-1) is constructed by establishing an LC50 value for a potentially sensitive organism as the 5% percentile from distribution of LC50, zooplankton and fish (LC50-value corresponding to 5 % probability on the black line on Figure 2-1), and using a slope on the dose-response curve corresponding to the standard deviation from tests of single oil components (SD = 0.2).
- The dose-response curve for this selected species is steeper than the species sensitivity distribution of LC50 values; i.e. it is assumed that the intra species variation (the variation among individuals in a species) is smaller than the inter species variation (the variation between different species). To account for the uncertainty in the slope of the intra-species dose-response curves, we may assume that the slope is the same as found in the inter-species LC50 distribution (SD = 0.32). On this basis, the dose response curve will correspond to the thin red line on Figure 2-1.



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• The 5% percentile on the selected dose-response curve is used as threshold value (effect limit) for the dissolved oil component.



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LC50 values and threshold values (5 % lethal risk) to be used for dissolved oil components in

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Table 2-1

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FORMULA	Average LC50, Zooplankton	5% percentile LC50	Reduction factor <sup>a</sup>	Threshold value corresponding to 5 % lethal risk	"Assessment" factor <sup>b</sup>
C1-C4	35000.0	10416.3	3.4	3100.0	11.3
C5-sat	6206.1	1847.0	3.4	549.7	11.3
C6-sat	3521.7	1048.1	3.4	311.9	11.3
C7-sat	736.5	219.2	3.4	65.2	11.3
C8-sat	605.0	180.1	3.4	53.6	11.3
C9-sat	165.3	49.2	3.4	14.6	11.3
Benzene	28484.1	8477.1	3.4	2522.9	11.3
C1-Ben	7940.4	2363.1	3.4	703.3	11.3
C2-Ben	3422.6	1018.6	3.4	303.1	11.3
C3-Ben	1197.2	356.3	3.4	106.0	11.3
C4-Ben	347.2	103.3	3.4	30.7	11.3
C10-sat	90.9	27.1	3.4	8.1	11.3
C11-C12	50.0	14.9	3.4	4.4	11.3
C13-C14	50.0	14.9	3.4	4.4	11.3
C15-C16	50.0	14.9	3.4	4.4	11.3
C17-C18	50.0	14.9	3.4	4.4	11.3
C19-C20	50.0	14.9	3.4	4.4	11.3
C21-C22	50.0	14.9	3.4	4.4	11.3
C25+	50.0	14.9	3.4	4.4	11.3
Napth.1	1118.7	332.9	3.4	99.1	11.3
Napth.2	228.6	68.0	3.4	20.2	11.3
PAH-1	160.5	47.8	3.4	14.2	11.3
PAH-2	28.1	8.4	3.4	2.5	11.3
Phenols	4334.9	1290.1	3.4	383.9	11.3

a) This reduction factor corresponds to the ratio between the median LC50 and the 5 % percentile value. The ratio depends on the standard deviation (SD) in the logarithmic distribution of the LC50 values. In this example SD is chosen as 0.32, based on the variance in the reported data.

b) The safety factor corresponds to the ratio between the median LC50 and the 5% lethal risk value for the same component. That ratio depends on the standard deviation in the distribution of LC50 values, as well as the SD of the dose-response curve. In this example, the SD values are presumed to be 0.32 for both curves. Note that with SD = 0.2 for the chosen dose-response curve – corresponding more to experimental dose-response curves for single species, the safety factor will be 7.2.

#### 2.2 Establishment of *threshold values for effects* and *damage functions* for dispersed oil

In the EIF method used for produced water, a PNEC value of  $40.4 \mu g/L$  (ppb) is applied for the aliphatic hydrocarbons (dispersed oil). This PNEC value was determined by TNO (4),

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based on toxicity studies carried out with various petroleum oils, including the contribution from the water-soluble fraction of both aromatic and aliphatic hydrocarbons.

The toxicity of oil is examined in different ways in the laboratory and in most cases the wateraccommodated fraction (WAF) is used. A WAF test medium is almost completely based on the water-soluble compounds. However, stable micro-emulsions of dispersed droplets can be present as well. A WAF from crude oil generally contains a significant proportion of aromatics, and a minor proportion (about 1%) is capable of forming dispersions (9). In other cases an oilin-water dispersion (OWD) is used, also containing hydrocarbons with low solubility, which can form oil-in water dispersion. An OWD, therefore, gives a better representation of the situation that occurs in the field. However, there are large technical problems in maintaining a stable dispersion of small droplets on a laboratory scale. In small test systems small droplets will aggregate rapidly, and a floating film will reform. This implies that most of the available toxicity data on oil concerns the hardly representative WAF fraction.

Still, a limited amount of data from experiments with dispersed oil exists in the literature, and Figure 2-2 shows a collection of LC50-values for dispersed oil reported from studies on various aqueous species (6). The median LC50 value in this data set is 650 ppb, and the 5 % percentile is about 100 ppb. This implies a standard distribution which is about 0.45, which is significantly larger than the SD value of 0.32 mentioned earlier for dissolved oil components.

If we presume that 650 ppb is a representative LC50 for dispersed oil, but assume that the SD value will be the same as found from toxicity data for dissolved oil components (SD = 0.32), the 5 % percentile LC50 will of about 190 ppb (thin black line on Figure 2-2). If we as before assume that the 5 % percentile LC50 is representative for sensitive species, we get a dose-response curve corresponding to the red line on Figure 2-2. Based on this curve, the 5 % lethal risk (i.e. the threshold value) is found to be 58 ppb, and the 40.4 ppb value applied for dispersed oil in EIF for produced water will correspond to a lethal risk of 1.7 %.

Obviously, more reliable data on the toxicity of dispersed oil – excluding the contribution from the aromatic hydrocarbons is needed. Meanwhile, we recommend that the 5 % lethal risk value





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of 58 ppb derived above should be used as a threshold value for acute toxicity of dispersed oil, and that a dose-response curve should be established from this value and the "standard" SD = 0.32 (red line on Figure 2-2). It should be noted that on the basis of this dose-response curve, the threshold value of 40.4 ppb ( $\mu$ g/L) recommended by TNO (4) for EIF produced water will correspond to a lethal risk of 1.7 %.



**Figure 2-2** LC50 values from toxicity studies on dispersed oil on various aquatic species (6). The thin black curve is a log-normal distribution with a median of 650 ppb, corresponding to the median LC50 in the data set, and a standard deviation of 0.32, equal to the SD recommended for dissolved oil components. The red line is a sensitive species dose-response curve, based on the 5 % percentile LC50 value and SD = 0.32. From this dose-response curve, the threshold value (5 % lethal risk) is found to be 58 ppb.



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#### 3 Discussion

The concepts proposed above for establishing threshold values and dose-response curves for oil components in the water column has a lot in common with methods proposed earlier by Deborah French McCay and others. However, some minor, but important differences may be noted, as discussed in the following review. The review is based on two major documents of McCay's concepts; the NRDAM report (7), and the Oil Aromatic Toxicity Guide developed from NOAA Damage Assessment centre, with a final report issued in 2001 (8). The Toxicity Guide includes a description of the Oil Toxicity and Exposure Model (OilToxEx), which is applied exclusively for dissolved oil components.

The Oil Toxicity and Exposure Model is based on estimates of LC50 values for specific oil components derived from empirical relations between experimentally observed LC50 values and log (KOW) values for the different oil components. The variance in the observed logarithmic LC50 values relative to the predicted mean logarithmic LC50 values can be expressed in terms of a standard deviation (SD). Sensitive species is defined as species with log LC50 values on the 2.5% percentile of this distribution, corresponding to 2 SD values below the mean log LC50 value. In comparison, the EIF Acute project has proposed to represent sensitive species by the 5% percentile. In addition, the correlation between log LC50 and log KOW, as well as the corresponding SD values will differ between the two methodologies, mainly due to the efforts STATOIL and SINTEF has made in terms of quality assessments of the experimental data (1).

The LC50 values established in EIF Acute Project so far are values valid for long exposure times (hours). A correction is applied for shorter exposure times, with a reduction factor, depending on the Kow value for the respective oil components. The same corrections are used in the OSCAR risk calculations for dissolved oil components. The Oil Toxicity and Exposure Model also have a correction for temperature, which is not used in the OSCAR model for EIF Acute so far. However, the OSCAR model applied in EIF Acute uses the same "mixing rule"

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for LC50 values as are used in the The Oil Toxicity and Exposure Model, i.e. based on the equation:

 $LC50_{mix} = 1/\sum F_i / LC50_i$ .

In OSCAR, this implies that LC50-values are established for each dissolved component in subsequent 96 hour time windows, with corrections made for the actual exposure time in that period (this exposure time may be shorter than 96 hours). The lethal risk in that period is computed from the time-averaged concentration of dissolved components and the computed LC50 value from the mixture, assuming a certain slope s = 1/SD of the dose-response function. No actual numbers are given for the chosen slope in the Toxicity Guide, but a graph is given in conjunction with the following statement: "The percent mortality is then calculated using the log-normal function centred on LC50 that is standard in aquatic toxicity". The curve shown in the figure is consistent with a slope of 1.2, corresponding to SD = 0.83 given in the NRDAM report. The choice of this value is based on a very limited set of data, all based on studies in the 1980's. Recent studies made by STATOIL and SINTEF indicate considerably larger values of the slope, in the range 3 to 5, with SD in the range from 0.2 - 0.3. It should be noted that such differences in slope of the dose-response curves will imply significant differences in the resulting lethal risk values.

We should also note that the exposure model described in the Toxicity Guide is limited to dissolved oil components, which in practical oil spill situations will account for only a minor fraction of the total oil concentrations. However, the oil industry is now working to provide more reliable data on dispersed oil both from literature and experimental studies. When this work is advancing we will have a better decision basis for evaluating if the suggested SSD methodology is the best methodology to use for establishing threshold values and dose-response curves for dispersed oil. It is of great importance to harmonize this work with the EIF Produced Water Project, which also is seeking the same information.

In the meanwhile, as long as the theoretical foundation of toxicity of dispersed oil droplet is missing, the EIF Acute Model will base lethal risk assessment on estimates of threshold values



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and corresponding dose-response curves for the total oil mixture, rather that for distinct components in the mixture. However this is under constant evaluation and will probably be changed in the years to come when more reliable data on dispersed oil are in place.

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