SAFEWARE QUASAR LTD

Delivering chemical regulatory compliance

Exposure Scenarios in a Nutshell

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What is an Exposure Scenario (ES)?

Introduction

Following the introduction of REACH, industry is now starting to experience some of its impact. In line with the legislation, chemical producers have an obligation to communicate safe use of chemicals to their customers.

The Exposure Scenario (ES) is the tool for this communication. The ES defines the conditions on how the dangerous substance can be handled without exposing workers, consumers or the environment to unacceptable risk. For customers these conditions of use are not legally binding, but failure to work within the conditions of the scenarios described by the supplier will need robust justification. (Remember – an ES is only relevant for dangerous substances.)

Information within the ES may result in companies revising their workplace risk assessments, and if necessary making adjustments to specific control and risk management measures, processes and training. Ultimately, there may be a need for substitution of chemicals for certain uses and it must be remembered that this was one of the objectives of REACH.

REACH Requirements for ES

The following definitions and Articles are of particular relevance when understanding the requirements of the ES.

> Means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

ES as defined in Article 3 (37)

- Manufacturer/Importer defines conditions of "Safe use" in chemical safety report (CSR) and communicates downstream in exposure scenarios *(Art. 14.4.)*.
- This information is received by Downstream Users as Annex of SDS *(Art. 31.7.).*
- The Downstream User is obliged to manage incoming information to implement it at their own production sites *(Art. 37.5)* and, if necessary, to pass it on in their own SDS's *(Art. 37.6.).*

Exposure Scenarios Simplified

A key element of the REACH registration of a substance is the demonstration and communication of safe use. The manufacturer of the substance is responsible for the evaluation of hazards and risks of their substances and for communication of safe use in the supply chain.

The demonstration of safe use for humans and the environment relies on two aspects: Hazard and Exposure.

The values under which no adverse effects are expected for humans for respective routes of exposure are the Derived No Effect level (DNEL) and for the environment, the Predicted No Effect Concentrations (PNEC). When exposures are below the DNEL and PNEC respectively, safe use is assumed.

The main focus of the ES surrounds the Identified Uses and the appropriate Operational Conditions (OC) and Risks Management Measures (RMM) necessary to keep exposure levels below the relevant threshold values. These OCs and RMMs in an ES should be followed by downstream users, unless justified.

A single substance can be applied and used in a variety of ways, for this reason there are normally many ES's for the same substance.

Prepared by - Manufacturers and Importers who have registered under REACH and passed on down the supply chain by Downstream Users.

Covers - Complete substance life cycle

Describes conditions under which each use of a hazardous substance is safe for:

- Worker exposure
- Consumer exposure
- Environmental emission

Exposure Scenarios Format

Unlike the Safety Data Sheet there is no mandated format for the ES, however there is wealth information available relating to these documents generated as ECHA and specific industry sector guidance. Based on this an ES comprising of four main sections has evolved.

Exposure scenarios form an integral part of the SDS and should be appended, where relevant, as an Annex to the SDS, the resulting document sometimes referred to as an (e-SDS). The Annex may contain a whole series of ES's covering the multiple uses for the chemical in the supply chain. The following page provides a concise overview of the 4 sections.

Section 1 Short title of the Exposure Scenario.

This section should include a “User Friendly” title for the ES which should be instantly recognisable.

The type of Exposure scenario should be indicated (Substance\Article – Consumer\Worker)

Using the R12 Use Descriptor system in the ECHA guidance include the Sector of use (SU’s) and Product categories (PC’s) A narrative description of the Process scope and typical activities may also be included.

Section 2 Operational Conditions and Risk Management Measures.

Using the R12 Use Descriptor system in the ECHA guidance include the following;

- Environmental Release Categories (ERC’s)
- Process Categories (PROC’s)
- Article Categories (AC’s)

The following information should also be considered for this section;

- Physical form of the product.
- Container size
- Duration and frequency of use.
- Amount used
- Concentration of substance.
- Other operating conditions.
- Further measures relating to protection, hygiene and health evaluation.
- Risk management measures for human health and environment
- Waste management

Section 3 Exposure estimation.

The following information should be considered for this section -

The Assessment methods and assumptions used in predicting the exposure. e.g ECETOC TRA.

Health (Risk Characterisation Ratio - RCR)

$$\text{In all scenarios the RCR} = \frac{\text{Predicted Exposure}}{\text{DNEL}} < 1$$

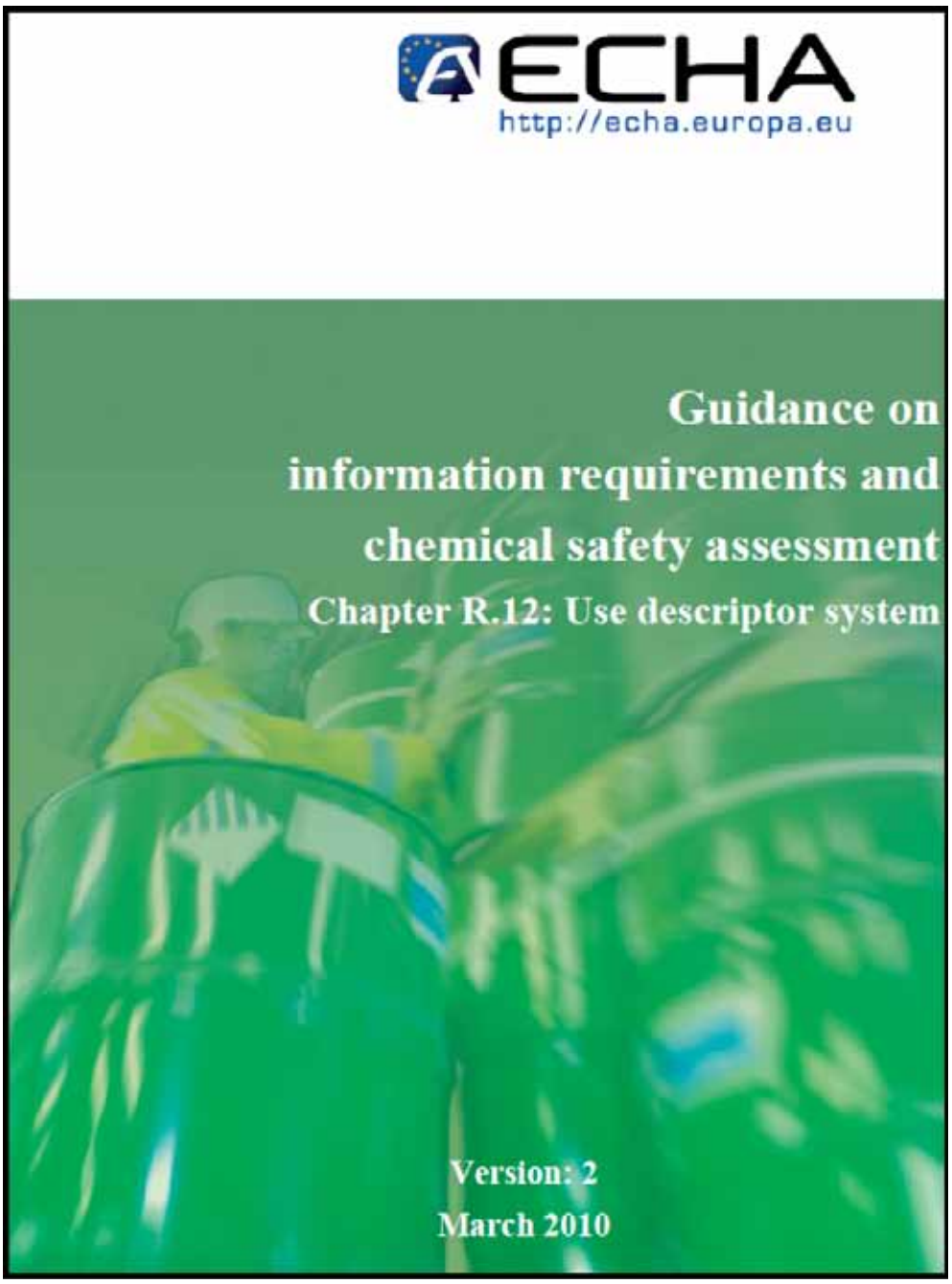
Environment (Risk Characterisation Ratio - RCR)

$$\text{In all scenarios the RCR} = \frac{\text{Predicted Exposure}}{\text{PNEC}} < 1$$

Section 4 Guidance to DU to evaluate whether boundaries set by the ES are being met.

This section should provide further guidance (if required) and statement of intent for example

Estimated exposures are not expected to exceed the DNEL/PNEC’s quoted when the identified risk management measures are adopted. Where other Risk Management Measures/Operational Conditions are adopted, then users should ensure that risks are managed to at least equivalent levels.



Use Descriptor System

Exposure Scenario Format

For more information visit **www.safeware.co.uk** ◆ **Tel: +44 (0)115 965 1888**

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