

R+D Project FKZ 204 67 456/02

## **Branch- and product-related emission estimation tool for manufacturers, importers and downstream users within the REACH-system**

### **Project B1 and B2**

#### **Contact Persons of the Consortium (ARGE)**

Dirk Bunke

Öko-Institut e.V., Geschäftsstelle Freiburg

*Tel: 0781 – 45 295 46, E-Mail: d. bunke@oeko.de*

Andreas Ahrens

Ökopol, Hamburg

*Tel: 040 - 3910020, E-Mail: ahrens@oekopol.de*

#### **Contact Persons of UBA**

Silke Müller

German Federal Environment Agency (UBA), Section IV 2.2

*Tel: 030-8903 . Email: silke.mueller@uba.de*

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## 1. Background

The REACH system as proposed by the EU Commission in a draft regulation issued in October 2003 includes a requirement to carry out a Chemicals Safety Assessment (CSA) for substances to be registered. Any company manufacturing or importing new substances or existing substances in amounts > 10 t/a is obliged to carry out such CSA (including documentation in a chemicals safety report [CSR]). If such substances are dangerous according to the criteria laid down in the current Directive 67/548, a CSA must include an exposure assessment and a risk characterisation. According to annex 1 of the draft REACH regulation the exposure assessment consists of

- exposure scenarios for all life cycle stages, reflecting the type, duration, frequency and condition of use (including risk management measures) as far as they are relevant for the emission rate; determining the pathways into the environment and the dilution in the receiving environment;
- calculation of compartment specific exposure concentration at local, regional or continental level (PEC = predicted environmental concentration) based on relevant environmental fate models (or measured data, if exist).

Up to now such assessments have been carried out in the framework of the *EU Existing Substance Program* under Regulation 793/93. A harmonised methodology to carry out exposure assessment of substances is laid down in the EU Technical Guidance Document (TGD) and specified for various sectors of industry or types of chemicals in the Emission Scenario Documents (ESDs). Calculation of PECs is usually carried out with the EUSES model.

Under the REACH system, responsibilities for assessment of *existing* substances will be shifted from authorities to industry. In addition, manufacturers and industrial/professional users of preparations will be included into a system of shared responsibility for product safety related to chemicals. Thus, exposure information needs to be transported and communicated over at least three stages in the supply chain and need to be evaluated at each of these stages. No tools are available yet to implement such mechanism. Hence the methodology of the TGD and the ESDs (possibly complemented by other existing methodology) need to be translated into tools ready for use by companies in the supply chains.

At the current stage of the legislative process, Council and Parliament have not yet come up with an opinion and are not expected to do so before spring/summer 2005. Nevertheless the Commission is going to start various Reach Implementation Projects (RIPS) in order develop guidance and instruments needed for companies and authorities to successfully implement the new system. The current project is expected to contribute to a technical guidance document for industry how to carry out a chemicals safety assessment (RIP 3.2).

## 2. Objectives

The overall objective of the project is to develop a set of technical guidance documents ( manual and software-tools) for emission and subsequent exposure estimation as outlined in annex 1 of the draft REACH Regulation. Such guidance shall be robust and easy to use by manufacturers, importers and downstream users of substances. The conceptual approach shall be based on the methodology laid down in EU TGD on Risk Assessment of New and

Existing Substances and the OECD Emission Scenario Documents (ESD). In addition the tool is expected to fit into the EUSES methodology.

The sub-projects A<sup>1</sup> and B<sup>2</sup> and the three phases of project B form a develop process which is expected to deliver a set of software-tools (computerised modules) useful for various supply chains (as determined by industry categories and substance use categories). Such tools would help to practically implement the REACH system with respect to calculation of local (and potentially regional) emission rates from the relevant lifecycle stages to the relevant environmental compartments (including the waste pathway). In combination with standard environmental fate-models, an environmental concentration will be predicted (PEC). The tools will consist of generic components and supply chain specific components.

In order to ensure a common conceptual basis for all tools and workability across a large number of supply chains, the development process will take place in 4 steps:

- The sub-projects A and B1 aim to structure the uses of substances, the sectors involved in the life cycle of the substance and the related patterns of emission/exposure in such way that it supports the REACH mechanisms. The desired outcome is a classification or matrix system based on which any stakeholder in the supply chain across Europe will be able to identify the appropriate emission estimation module, applicable for himself, his suppliers and his customers (*target funnel*). In this work, it is important to use as much as possible existing systems of use classification in order to facilitate a harmonised implementation across Europe and global trade.
- At the same time the matrix to be developed in phase B 2 will be the basis to create a well structured tool box, and fill it during phase B3 in a step-wise process based on existing information. The matrix will also indicate where tool development need to wait until more information on emission scenarios has become available. In this respect the project B1 will contribute to a working plan for the whole process.
- The sub-project B2 aims to carry out a development process in two supply chains, serving as a blueprint for the same process and output in other relevant supply chains. Thus, the tool will be developed and tested in co-operation with companies acting in the selected supply chains.
- Project B3 aims to copy the blueprint (B2) to other supply chains and provide a toolbox for a larger number of relevant supply chains.

The outlined working process can be seen as a contribution to the REACH Implementation Project 3.2 (RIP) as outlined by the European Chemicals Bureau in February 2003 and adopted by the CA meeting in summer 2004, as part of the so called *Interim Strategy*<sup>3</sup>. The RIP 3.2 aims to develop a technical guidance document for industry on how to carry out a chemicals safety assessment under REACH.

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<sup>1</sup> carried out by RIVM (Netherlands)

<sup>2</sup> carried out by Öko-Institut, Ökopol and Chemie Daten (Germany)

<sup>3</sup> Strategy to maintain the work under the current regulatory system and by this preparing for REACH.

### **3. Approach to exposure assessment under the REACH System**

The approach to exposure assessment under REACH necessarily differs from the exposure assessment as it has been carried out up to now by the authorities. The ESDs and the TGD have been developed for in-depth-assessment of existing substances carried out under the responsibility of authorities. The ESDs play an important role for setting default scenarios in order to trigger generation of more realistic data by industry. Under REACH, this changes:

- The exposure assessment becomes part of the safety assessment for a whole life cycle and industry will be liable if risks are not sufficiently addressed. On the other hand, each company will seek to maintain and increase market shares for their products. Hence the definition of defaults will become a crucial point for business.
- Exposure related data will need to be communication up and down the chain. Hence confidentiality issues will increase.
- The emission and exposure scenarios will be communicated over at least three steps in the supply chain, involving SMEs at each level. Shared responsibility demands understandability of any tool for all actors in the chain, not only for the big manufacturers. This applies at least for the assessment level aiming to identify the needs for deeper assessment. The current understanding related to tiered assessment may need modification here. Hence it would be worthwhile to evaluate whether the number and structure of factors triggering emissions can be reduced for the lower tier assessments.
- It may turn out that the current IC/UC structure does not sufficiently support the definition of scope related to tools to be used in supply chains. Hence project Phase A is crucial for phase B2 and phase B3.
- Depending on the case, the level of involvement of supply chain actors in the development of the ESDs has been very different. Thus, it needs some considerations to which extent the ESD may be accepted in the supply chain as a basis for tool development. Thus during the development of each tool, stake-holder dialogue is crucial.
- The abatement-factor-approach is still based on end of the pipe emission control measures. Hence it would be necessary to evaluate whether risk management and in particular the process-integrated measures are sufficiently reflected in the existing ESDs.

Based on these considerations, the project phase B2 includes room for dialogue and cooperation with companies and other stakeholders in the chain. In addition, phase B1 will include an effort to i) to explain the common structure of ESDs in simple words and ii) to develop a consistent approach to transform the ESD into a tiered system of emission estimates.

## 4.1 Project phase B1

### Definition of the matrix presenting industrial and use categories versus life cycle stages and emission pathways

The main task of this project phase is to allocate the components existing emission scenarios to a matrix of 55 use categories and 15 industry categories. New categories of use, eventually identified in project A, and other sources of information should be taken into account.

**Deliverables:** As main result of B1 a ES (emission scenario data) - matrix becomes available. The matrix itself structures the huge amount of existing information on branch specific emission situations. The matrix indicates for all industrial and use categories, life cycles stages and emission pathways the existence or the absence of emission scenarios or related data. In this respect the matrix is the basis to set up a work plan for the further development of emission estimation tools. Depending on the outcome of project A, the matrix may be also used as a basis to create a “pathfinder” (target funnel) for companies to identify a suitable emission estimation tool for their type of business. Each ESD included in the matrix will be characterised in a uniform ESD profile.

Based on the outcome of A (target funnel) and B1, recommendations for priority setting and structural work within Phase B2 and B3 will be developed.

## 4.2 Project Phase B.2

### Filling the matrix with stand alone emission scenarios

In project phase B.2 the relevant guidance manuals and emission estimation tools will be developed for two selected supply chains. The chains should be selected in a way that they are as representative as possible for the tools to be developed in B3. A stepwise process, involvement of companies acting in the chains and a series of 5 workshops will help to develop the tool as close as possible to the needs of the companies and the expectations of the steering group.

**Deliverables:** Two supply-chain specific guidance manuals on emission (and exposure) estimation under REACH and a software-tool (likely consisting of various modules) to calculate the emission (and subsequent exposure). The guidance will translate the requirements in annex 1 of the draft REACH regulation into a working procedure for

- setting up an appropriate exposure scenario based on existing information
- estimating the level of emission and
- first refinement of the exposure assessment if there is a concern
- processing of the exposure scenario at the level of formulators and users of preparations.

The tool will be useful for the first steps in the iterative process of safety assessment, rather than supporting in depth assessment. Thus the tool will help to screen out those types and conditions of use that are of no immediate concern and to identify cases for which a deeper assessment is needed.