

AISE/CESIO opinion on Annex IV of the Detergents Regulation

Industry welcomes the opportunity provided in the Draft Detergents Regulation to allow marketing of small-volume detergent products for specialised industrial and/or institutional cleaning which contain surfactants not meeting the standard "ultimate biodegradability" requirements as stipulated in Annex III of the Regulation. Application for the necessary derogation, however, requires fulfilment of "primary biodegradability" requirements and the provision of test results as stipulated in Annex IV of the Regulation. The intention of Annex IV is to facilitate a complementary risk assessment of such surfactants, primarily to judge the environmental impact of the surfactant itself and of any persistent degradation products. For this purpose, a technical file is to be provided containing at least the information described in the Annex IV, i.e. information about the identity, the function of and the environmental exposure to the surfactant. Furthermore, information on the identity, aquatic toxicity and biotic/abiotic degradability of any potentially recalcitrant metabolite(s) is demanded.

The Annex IV requirements (for every surfactant applying for derogation) imply the generation of data based on a long list of tests covering virtually all existing EU biodegradability test methods. Several of the required biodegradation test methods will lead to almost synonymous data. They are not arranged in a scientifically sensible sequence and it must be questioned whether the high cost of this proposed standard biodegradability test programme (ca. 30 TEUR per substance) is justified and proportionate. In addition, the required toxicity testing of biodegradation test liquors, which is supported in principle by industry, lacks as yet any generally agreed or standardised test procedure, so that a consistent evaluation of such data seems almost impossible. Some of the further information requirements, particularly relating to characterisation and testing of metabolites, call into question their experimental feasibility within a viable economic cost frame.

In summary, the data requirements in Annex IV are not appropriate guidance for generating a scientifically sound, technically feasible and economically defensible data package. This lack of clarity and precision is, perhaps, not surprising since the technical prerequisites of a derogation, which is an important aspect of the detergents legislation, have never been discussed at any of the Member States expert meetings.

AISE/CESIO strongly suggests a revision of Annex IV, aiming at a structure which clearly indicates a "stepwise approach". The amount of evidence needed to support safety should be proportional to the risk and, for a given toxicity potential, to the volumes used. A flexible approach should impose lower test requirements for low-volume materials and, when volumes justify it, should focus on the potential toxic impact of the metabolite(s) but not necessarily on full characterisation. Otherwise, Annex IV will become a non-surmountable obstacle to a number of small-volume speciality surfactants, particularly in specialist applications important to SME's niche players.

Industry is prepared to co-operate in a revision of Annex IV to structure it more adequately as a tiered approach and has developed an alternative proposal; which is offered as a basis for such a change. As a minimum, however, the wording in Annex IV, last paragraph of Introduction should be modified into: "The technical file referred to in Articles 5 and 9 should consider for example the information described here below".

ANNEX IV

Complementary risk assessment for surfactants in detergents

For those surfactants for which environmental risk assessment is available in the context of Directive 93/67/EEC, or Regulation (EEC) No 793/93 and Regulation (EC) No 1488/94, and Technical Guidance Documents, this risk assessment shall be considered together with the complementary risk assessment run in the scope of this Regulation.

The complementary risk assessment run in the scope of this Regulation, in case it is likely that recalcitrant metabolites are produced, shall be considered in the context of assessments made on the basis of Directive 93/67/EEC and Regulation (EEC) No 793/93. This is to be assessed case by case and in particular on the basis of the results of the tests referred to in part 3 of this Annex.

The study shall cover the aquatic environmental compartment. Additional information relating to specific risk assessment concerns might be required by the Committee on a case by case basis. Additional information might include other environmental compartments such as sewage sludge and soil.

As noted in Articles 12(2) and 13 the guidelines included in this Annex for the Decisions on derogation may be adapted as appropriate on the basis of the accumulated experience.

The technical file referred to in Articles 5 and 9 shall contain at least the information described here below.

1. **Identity of the surfactant** (in accordance with the provisions laid down by Annex VII.A of Directive 67/548/EEC.)
 - 1.1. *Name*
 - 1.1.1. Names in the IUPAC nomenclature
 - 1.1.2. Other names
 - 1.1.3. CAS number and CAS name (if available)
 - 1.1.4. EINECS¹ or ELINCS² numbers (if available)
 - 1.2. *Molecular and structural formula*
 - 1.3. *Composition of the surfactant*

³⁰ European Inventory of Existing Chemical Substances.

³¹ European List of Notified Chemical Substances.

2. Information on the surfactant use profile

2.1. Quantities of the surfactant used in detergents

2.2. The information on use patterns given in this section shall be sufficient to allow an approximate but realistic estimate of function and environmental exposure to the surfactant as associated with its use in detergents. It shall include the following:

- importance of the application (societal value);
- use conditions (release scenario);
- use volume;
- availability and suitability of alternatives (performance and economic considerations);

3. Assessment of relevant environmental information

Depending on the surfactant use profile and volume; the release scenario and the existing biodegradability data; relevant additional information shall be provided and/or appropriate additional studies conducted.

4. Additional studies

4.1. Biodegradability tests

4.1.1. Pre-adapted inoculum

Any of the preferred tests described in Annex III, may be run with pre-adapted inoculum. Depending on the environmental release profile, no further environmental information may be needed if the mineralisation level in one of these tests is $\geq 60\%$.

4.1.2. Inherent Biodegradability Tests

Data from one of the tests referred to below may be taken into account.

- method Directive 67/548/EEC Annex V.C.12 (Modified SCAS test);
- method Directive 67/548/EEC Annex V.C.9 (Zahn-Wellens).

Depending upon the environmental release profile, no further environmental information may be needed if the DOC-removal in one of these tests is ≥ 70 .

4.1.3. Activated Sludge Simulation Biodegradability Tests

Data from the test referred to below may be taken into account:

- method Directive 67/548/EEC Annex V.C.10;

(including possible changes in operating conditions as proposed in EN ISO 11733).

Depending upon the environmental release profile, no further environmental information may be needed if the DOC-removal in the test is $\geq 70\%$.

4.2 *Toxicity testing of biodegradation test liquors:*

The formation of possibly toxic recalcitrant metabolites is assessed by determination of the acute daphnia or algae toxicity of the degradation products present in the test liquor of an 'ultimate biodegradability test' (see Annex III) after a sufficient test period.

It is the objective of the test to find out if the degradation products (quantified on the basis of organic carbon) are more or less toxic than the parent compound. The test strategy aims at assessing if the ecotoxicity data of the parent surfactant provides a sufficiently conservative basis for the estimation of the aquatic toxicity of the possibly recalcitrant metabolites.

If the toxicity testing of the test liquor shows that the degradation metabolites are not more toxic than the parent surfactant, a complementary risk assessment can be done on the basis of the ecotoxicity data of the parent surfactant (see 4.3).

If the metabolites prove to be more toxic than the parent surfactant, metabolites characterisation is needed (see 4.4).

4.3 *Risk evaluation*

The main objective of a simplified risk evaluation procedure (based on a PEC/PNEC comparison) is to provide perspective on the amount and the distribution of metabolites and their possible environmental impact.

Exposure information may be obtained from the surfactant tonnage and the release scenario (see 2.) by taking account of key physical chemical properties (e.g. log Pow etc.) and data on the removal of the surfactant in sewage treatment plants (e.g. CAS test data). The PEC_{acqua} values resulting from this exposure assessment are compared with the PNEC data derived from the ecotoxicological data of the parent surfactant according to the TGD.

4.4 *Metabolite characterisation*

Specific information is to be provided about the chemical nature of the main degradation products of the surfactant, their relevant physical-chemical properties, their biodegradation/elimination and ecotoxicological behaviour. This information may be used for a risk evaluation; taking account of the use profile of the parent surfactant. The data set may include elements of the following:

4.4.1. Chemical and physical information, such as:

- identity of the metabolite (and analytical means by which it was obtained)
- key physical chemical properties (water solubility, Octanol: Water partition coefficient (Log Po/w, etc.).

4.4.2. Effects on organisms

Fish: The test recommended is that in Annex V.C.1 of Directive 67/548/EEC

Daphnia: The test recommended is that in Annex V.C.2 of Directive 67/548/EEC

Algae: The test recommended is that in Annex V.C.3 of Directive 67/548/EEC

Bacteria: The test recommended is that in Annex V.C.11 of Directive 67/548/EEC

4.4.3. Degradation

Biotic: The test recommended is that in Annex V.C.5 of Directive 67/548/EEC

Abiotic: The test recommended is that in Annex V.C.7 of Directive 67/548/EEC. The information to be provided will consider as well the potential of metabolites for bio-concentration and their partitioning to the sediment phase.

Moreover, if some metabolites are suspected for endocrine disrupting activity, it is recommended to determine if these have potential to result in adverse effects as soon as validated testing schemes to assess such adverse effects are available.

N.B. – All the above mentioned methods from Directive 67/548/EEC can also be consulted in the publication *Classification, Packaging and Labelling of Dangerous Substances in the European Union*; Part 2: “Testing Methods”. European Commission 1997. ISBN 92-828-0076-8.