

Proposal of a new Annex XVa to the REACH-Regulation “Monitoring of substances of very high concern”

(developed with reference to Annex VII of the Directive 2001/18/EC)

Paper within the context of the project: Development of minimum criteria and institutional conditions for an „effective control“ of substances within the authorisation

comissioned by the German Federal Environmental Agency¹ and

carried out by
Sonderforschungsgruppe Institutionenanalyse – sofia, Darmstadt in co-operation with
Öko-Institut e.V., Freiburg-Darmstadt-Berlin and Ökopol GmbH, Hamburg

MONITORING PLAN

This annex describes the objective to be achieved, the general principles and the most basic guidance elements to be followed by the applicant for an authorisation (manufacturer, importer and downstream user) in the process of setting up a monitoring plan in accordance with the procedure laid down in Art. 60 (9) lit. f REACH and in respect of the release of the substances of very high concern by virtue of Article 55 et seq. REACH.

1. Objective

The monitoring aims to secure a high level of protection for the environment and human health concerning substances of very high concern - including affected population groups and eventually sensitive population with higher need of protection (e.g. children or older people). To ensure this objective the monitoring is supposed to guarantee that the substances of very high concern will be handled with high caution according to the precautionary principle.

The monitoring encompasses the realisation of case-by-case specific and general observations of the environment and human health aiming to:

- *verify* the effectiveness of risk management measures taken in accordance with Art. 60 (5) lit. a REACH,
- *confirm* that for substances of very high concern the conditions of Annex I Nr. 6.4 REACH and of Annex I Nr. 6.5 REACH are observed,

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- *ascertain* the occurrence of so far unknown adverse effects on the human health or on the environment caused by a substance of very high concern or its application as well as degradation product(s).

2. General principles

The monitoring measures set out in the monitoring plan shall be started at the latest after the *European chemical agency* has decided about the authorisation of the substance compliant with the Art. 60 (2) and (4) REACH.

The monitoring measures for substances of very high concern shall enable the holder of an authorisation to bring objective evidence that the exposures of the substances are in accordance with article 60 (10) REACH reduced to a level as low as technically and practically possible (principle of minimization).

The evaluation of the data gathered in the process of monitoring shall also take into account other environmental conditions not addressed in the chemical safety report (CSR) as well as the observation of all relevant emission pathways.

If changes in environment or effects on human health are observed, further evaluation should follow in order to ascertain whether these changes or effects are caused by a substance of very high concern, its degradation products or respectively by its use in products.

Voluntary monitoring schemes can support and go beyond those risk measurements determined in the monitoring plan, but cannot replace the setting up of a monitoring plan according to Art. 60 (9) lit. f REACH.

In the establishment of monitoring measurements the precautionary principle, especially the principle of proportionality, must be obeyed.

3. Generation of a monitoring plan (monitoring of emission sources / local and/or regional environmental and health monitoring)

The **monitoring plan** shall:

- 3.1 *be cater to* every single substance of very high concern as well as its authorized application. Furthermore it shall take into account the measurements given in the CSR.
- 3.2 *take into account* the characteristics of the substances listed in Art. 57 REACH, the scope of the application of the substance as well as the range of environmental sphere, in which the substance shall be released according to the exposure scenario;
- 3.3 *regard* the features and effects of the measurements foreseen in the authorisation to limit emissions from point sources and diffuse sources and consider the opinion of the Risk Assessment Committee according to Art. 64 (4) lit. a REACH;

3.4 *provide for* a local and/or regional environmental and health monitoring of unexpected adverse effects and also for a monitoring of emissions from point sources and diffuse sources.

3.4.1 The objective of the **monitoring of emissions** is to check the efficacy of the planned risk management measures and the estimated risk both laid down in the authorisation. Thereto the applicant shall carry out the monitoring of emissions during the period of the authorisation.

The monitoring of emissions shall comprise:

- the identification and description of each individual point source and diffuse source (life-cycle stage, operational conditions, etc.)
- the environmental compartments to which the release occurs
- the exposure route and population (workers, consumers etc.) for direct human exposure
- the physical state of the released substance
- In case the substance is released associated to a matrix: the nature of the matrix and the nature of the interaction between the matrix and the substance (e.g. chemically bound) should be included
- for point sources the continuous or intermittent release and the description and efficiency of abatement technique(s)
- for diffuse sources the length of service life for articles or materials

3.4.2 The **local and/or regional environmental and health monitoring** shall be carried at least during the period of the authorisation. The competent authority can define an even longer period if necessary. The monitoring shall:

- establish the trends in levels of contamination for both the substance and its more toxic and bioaccumulative degradation products over a suitable period of time;
- ascertain the occurrence of unexpected direct/indirect or accumulative effects, which were neither designated in the authorisation nor in the associated dossiers (including the CSR);
- take into account further existing general routine monitoring measurements, e.g. cancer register, blood and breast milk monitoring or bio-monitoring programs

The general monitoring measurements shall take into account all substances on the candidate list of REACH virtue by Annex XIV.

3.5 *facilitate* the systematic observation of effects caused by the production and application of authorized substances or the placing on the market of products containing substances of very high concern with respect to the analysis of the protection of human health and of the environmental spheres.

3.6 *determine* that the applicant shall be responsible for the monitoring of emissions and has the overall responsibility for the different tasks determined in the

monitoring plan and is as well responsible for the working-out and duly realisation of the monitoring plan if the implementation is delegated to other parities;

- 3.7 *make* the applicant responsible to inform the competent authority about the monitoring results (setting up a time frame and schedules for reports on the conclusions of the monitoring).
- 3.8 *consider* the mechanism for determination and affirmation of all observed adverse effects on the human health and the environment and to put the applicants or if necessary the competent authorities in the position to take appropriate measures in order to protect the human health and the environment.

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