EXPOSURE ASSOCIATED WITH MANUFACTURE

This document was endorsed at the 22nd meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (7-8 September 2006).

One of the issues discussed since the first Competent Authorities (CA) meeting is the degree to which the manufacturing process is relevant when carrying out the risk assessment provided for in Directive 98/8/EC; without however arriving at common point of view between all Member States.

With the assessment of the first dossiers submitted for the inclusion of existing active substances in annex I or IA of the Directive, it has become clear that Member States have indeed different requirements regarding the need for information relating to manufacture.

The purpose of this document is to outline the problem and to suggest a practical approach to this issue.

Background

When referring to the manufacturing process, it can either be the manufacture of the active substance, or the manufacture of the biocidal product.

At previous meetings the Member States have expressed very different points of view with regard to the level of risk assessment seen as appropriate for the manufacturing process and thereby also data requirements regarding human exposure associated with the manufacturing process, especially for the manufacture of the active substance.

One reason for the lack of agreement on this issue is that Directive 98/8/EC is vague in this regard (see annex, which provides the relevant text from Directive 98/8/EC, where reference is made, directly or indirectly, to exposure associated with manufacture).

At the first CA meeting, when these discussions started, it was clear that one problem related to the language versions and the slight differences in those leading to different perceptions of the degree to which the manufacturing process is covered, and thus human and environmental exposure associated with the manufacturing process.

At the 16th CA meeting (28-29 June 2004), it was clarified that information on exposure associated with manufacture/production of an active substance or a biocidal product is only required when manufacture/production takes place in the European Economic Area (EEA). Member States can therefore not reject dossiers as incomplete if such information was missing and manufacture/production taking place outside the EEA, nor can the substance not be included in Annex I or IA based on this. However that CA meeting did not clarify how far manufacturing processes within the EEA would be covered under the BPD.

The issue was raised again during the 20th CA meeting in December 2005, when CEFIC inquired about the right of Competent Authorities to require information on exposure at the manufacturing site. CEFIC was particularly concerned that one Member State had developed a form requesting very detailed information, which was used now by several other Member States.

At this meeting, the Commission recalled that this question had already been discussed extensively in the past. Where production of an active substance takes place outside the EEA, no such information is required. Otherwise, Directive 98/8/EC does establish that information on exposure during production should be submitted (in line with what is required for new substances notification). However, a non-inclusion of an active substance into Annex I could not be justified based on this data. The Commission therefore invited the Member States to request such information only to the extent that it was proportionate to the purposes for which it could be used.

Conclusions

Based on the above, it can be concluded that:

(1) Directive 98/8/EC is unclear with regard to how far the production process is covered, both for active substances and biocidal products.

(2) Member States Competent Authorities do not have a harmonised point of view on this question.

(3) Information on the production process can in any case only be required when manufacturing takes place within the European Economic Area.

In addition, Directive 98/8/EC only addresses **the placing on the market of biocidal products**, whilst, for example, the protection of workers, or, the manufacture and placing on the market of chemical substances, are already addressed by other pieces of legislation.

Therefore, before requiring very detailed information on exposure associated with the manufacturing process, when it takes place within the EEA, Member States should take into account that this is already addressed through other pieces of legislation. Only in the case when the substance is exclusively manufactured for biocidal purposes within the EEA should this information be required in great detail. Otherwise, Member States should request such information only to the extent that it is proportionate to the purposes for which it can be used.

ANNEX

Relevant text from Directive 98/8/EC

Directive 98/8/EC does not contain clear specifications on what information is required relating to the human and environmental exposure associated with the manufacture of active substances and biocidal products. The relevant text parts are presented in text boxes below.

Text from the Whereas clauses in Directive 98/8/EC

(14) Whereas when an active substance is evaluated for its entry or otherwise in the relevant annexes of the Directive, it is necessary for such an evaluation to cover, where appropriate, the same aspects as those covered by the evaluation made under Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (1) and Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (2) as far as the risk assessment is concerned; whereas, therefore, the risks associated with the production, use and disposal of the active substance and materials treated with it are to be considered in a similar way as they are in the aforementioned legislation;

Art 1(3) (d) Scope

[…] 3. This Directive shall apply, without prejudice to relevant Community provisions or measures taken in accordance with them, in particular, to: […] (d) Council Directive 80/1107/EEC of 27 November 1980, on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work (12), Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (13) and individual Directives based on these Directives […]

Annex IIA on the Common core data set for active substances

2.10. Exposure data in conformity with Annex VIIA to Directive 92/32/EEC.[1]

Annex VI on the Common principles for the evaluation of dossiers for biocidal products

30. Where toxicity data derived from observations of human exposure, e.g. information gained from manufacture, from poison centres or epidemiology surveys, are available special consideration shall be given to those data when carrying out the risk assessment. 31. An exposure assessment shall be carried out for each of the human populations (professional users, non-professional users and humans exposed indirectly via the environment) for which exposure to a biocidal product occurs or can reasonably be foreseen. The objective of the assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of each active substance or substance of concern to which a population is, or may be exposed during use of the biocidal product.

[1] This requirement is further specified in the Technical Notes for Guidance (TNsG) on Data Requirements, which states that *Information should be sufficient to allow an approximate but realistic estimation of human (occupational and consumer) and environmental exposure associated with the production process, the proposed/expected uses and disposal of an active substance. Precise details of the production process, particularly those of a commercially sensitive nature, are not required. Substances manufactured outside the EU do not need a description of the manufacturing process for exposure estimation purposes. The prediction of the exposure levels should also describe a reasonable worst case situation, excluding accidental exposure and abuse. Exposure levels or concentrations need to be derived based on available measured data and/or modeling.*