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ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Chemicals and construction  
**Chemicals**

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**DRAFT POSITION PAPER OF DG ENTR / G2  
ON THE  
CLASSIFICATION AND LABELLING OF PREPARATIONS USED TO PRODUCE OTHER  
PREPARATIONS**

**1. BACKGROUND**

The Dangerous Preparations Directive 1999/45/EC (DPD) foresees three possibilities to classify dangerous preparations:

- a) classification based on the classification of the individual components by using the so-called 'conventional method';
- b) classification based on in vivo or in vitro test results;
- c) classification based on human evidence.

Except for section 1.7.3.1<sup>1</sup> of Annex I to the Dangerous Substances Directive 67/548/EEC (DSD), neither the DPD nor the DSD contain any provision or guidance on how to deal with preparations which contain dangerous substances and are then subsequently used as components in other preparations.

Depending on the methodology used, the resulting classification can be different, at least for those preparations which contain dangerous substances classified for human health and environmental effects which are considered to be additive. These are:

- acute lethal effects (T<sup>+</sup> R26, R27, R28 / T R23, R24, R25 / X<sub>n</sub> R20, R21, R22),
- corrosive / irritating effects ((C R34, R35, X<sub>i</sub> R36, R41, X<sub>i</sub> R38, X<sub>i</sub> R37)
- effects to the aquatic environment (N, R50 to R53).

In principle, two different approaches can be distinguished when using the conventional method:

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<sup>1</sup> Preparations or substances described in section 1.7.2.1 used as constituents of another preparation

- (1) Whenever information is available for the individual components of a preparation (P1) used as a component in another preparation (P2), this information should be used to classify P2.
- (2) When P1 has been tested or human evidence is available, the classification of P1 based on these test results / human evidence should be used for the classification of P2. The classification of the individual components of P1 is not taken any longer into account. P1 is then treated with regard to classification as a “substance”.

## 2. WHAT IS THE POSITION OF DG ENTR?

Article 6(2) of the DPD provides for the following:

*Subject to the provisions of paragraph 3, where a toxicological property has been established on the basis of both the methods outlined in paragraphs 1(a) [the conventional method] and (b)[by means of the methods laid down in Part B of Annex V to Directive 67/548/EEC = validated in vivo or in vitro tests], the results from the methods outlined in paragraph 1(b) shall be used for classifying the preparation, except in the case of carcinogenic, mutagenic or toxic effects for reproduction for which only the method outlined in 1(a) shall be used.*

Therefore, preparations for which the classification has been established by validated in vivo or in vitro test methods, the classification resulting from these test methods is considered to be more reliable than the classification resulting from the conventional method.

In addition, Article 6(3) provides for the following:

### 3. *Furthermore, where it can be demonstrated:*

*by epidemiological studies, by scientifically valid case studies as specified by Annex VI to Directive 67/548/EEC or by statistically backed experience, such as the assessment of data from poison information units or concerning occupational diseases, that toxicological effects on man differ from those suggested by the application of the methods outlined in paragraph 1, then the preparation shall be classified according to its effects on man,*

According to this paragraph, human evidence prevails over in vivo and in vitro test data and a classification based on the conventional method.

With respect to preparations which contain dangerous substances and are used as components in other preparations, this would then lead to the following possibilities:

- a) A preparation (P1) has been tested by means of the methods laid down in Part B of Annex V to Directive 67/548/EEC. In that case, P1 has to be classified according to the test results and this would overrule the results of the conventional method if these were indeed different.

When P1 is used as a component in another preparation (P2) which is to be classified by applying the conventional method, it then has to be treated as a 'substance' with respect to its classification and its contribution to the classification of P2.

This applies only to those endpoints for which P1 as it is placed on the market has been tested. If P1 contains a substance / substances which is / are classified for additional endpoints than those for which P1 has been tested, then the conventional method should be used to determine for those endpoints the resulting classification of P2.

b) If P1 has not been tested, the classification of P2 should be based on the concentration of all individual ingredients (P1 and P2) by using the conventional method or by using test results or human evidence for P2 as it is placed on the market.

c) If P1 has not been tested and / or the information provided on the label or in the Safety data Sheet of P1 is insufficient to enable other manufacturers who wish to use it as a constituent of their own preparation(s) to carry out the classification and labelling of their preparation(s) correctly<sup>2</sup>, those manufacturers should contact the person responsible for placing the original preparation on the market in order to request the missing information concerning the dangerous substances present to enable correct classification and labelling of the new preparation.

### 3. JUSTIFICATION

In case (a), more reliable information about the properties of P1 has been received by means of validated test methods. The test results refer to the preparation as it is placed on the market, meaning to the preparation as a whole and not to individual ingredients of the preparation. Therefore it would not be logic to treat a tested preparation that is used as a component in another preparation in a different way than a tested substance. The conventional method is used to avoid animal testing and should be used as long as other information is not available. However, it is only a mathematical model which tries to estimate – based on a conservative approach – the potential hazards of a preparation.

In case (b) the more conservative approach is justified because no reliable test data on the combined effects of all substances contained in P1 is available. Therefore the conventional methods should be used by breaking down the individual components of P1 and P2 to each of its ingredients.

If this is not possible (case c) the missing information should be requested from the manufacturer of the individual components.

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<sup>2</sup> for example in cases where the concentration of the individual components is not completely revealed but necessary for the classification of another preparation