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POSITION PAPER OF DG ENTR / G2
ON THE
CLASSIFICATION AND LABELLING OF PREPARATIONS WITH EXTREME pH VALUES
(11.5 < pH < 2)

1. BACKGROUND

According to Article 3 of Directive 1999/45/EC (the Dangerous Preparations Directive or DPD), the health hazards of preparations shall be determined in accordance with the provisions laid down in Article 6;

According to Article 6 (1) of the DPD, the health hazard(s) of a preparation shall be assessed by either

a) the conventional method described in Annex II or

b) by tests performed according to the methods outlined in Annex V to Directive 67/548/EEC (the DSD) and according to the criteria established in Annex VI to the DSD.

Article 6 (2) offers the person responsible for placing a preparation on the market the possibility to use test results on animals to demonstrate that the classification achieved by applying the conventional method is not justified.

Article 6 (2) also stipulates that, if test results for the preparation on animals achieved in line with the methods outlined in Annex V to the DSD are available, they have to be used for the classification of the preparation (except in the case of carcinogenic, mutagenic or toxic effects for reproduction).

Article 6 (3) finally stipulates that, if human evidence is available, this human evidence prevails over the results obtained by the conventional method and the validated animal test data.

Annex II to Directive 1999/45/EC describes in detail the conventional method to be used in accordance with Article 6 to determine the health hazards of a preparation.

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Table IV and IV A in Annex II, Part B to Directive 1999/45/EC provide for the general concentration limits (GCLs) to be used for the classification of a dangerous preparation containing substances classified for either their corrosive or irritant effects.

Both tables contain a *Nota Bene* (N.B.) as a footnote, which makes reference to a paragraph of Annex VI to the Dangerous Substances Directive (DSD), which itself provides for a third criterion for the classification and labelling of corrosive substances or preparations. According to this provision in Annex VI to the DSD,

> *"A substance or a preparation should also be considered corrosive if the result can be predicted, for example from strongly acid or alkaline reactions indicated by a pH of 2 or less, or of 11,5 or greater. However, where extreme pH is the basis for classification, acid/alkali reserve may also be taken into consideration. If consideration of alkali/acid reserve suggests the substance or preparation may not be corrosive then further testing should be carried out to confirm this, preferably by use of an appropriate validated in vitro test. Consideration of acid/alkali reserve should not be used alone to exonerate substances or preparations from classification as corrosive."*

As a consequence, a preparation with a pH value of either equal to or below 2 or equal to or above 11.5 should be classified as corrosive unless additional evidence to demonstrate otherwise is provided..

This quasi-automatic procedure has been challenged by Industry for those preparations for which the application of the conventional method would result in a less severe classification. It has been challenged in particular for preparations containing corrosive substances which are assigned Specific Concentration Limits (SCLs) in Annex I to Directive 67/548/EEC and where use of the specific concentration limit would lead to a less severe classification, even if the pH is <2 or >11.5. Member States do not have a harmonized approach to this question.

DG Enterprise and Industry has been approached several times by both Industry and the Competent Authorities of the Member States, in order to provide its opinion on the following questions:

- Does the Nota Bene only apply to preparations containing corrosive substances when the general concentration limits mentioned in Table IV and Table IV A of Annex II are used or is it also applicable to preparations containing corrosive substances which are assigned SCLs in Annex I to Directive 67/548/EEC?

- Does the classification resulting from the application of the conventional methods for corrosive substances assigned SCLs in Annex I to Directive 67/548/EEC prevail over the Nota Bene in Annex II to Directive 1999/45/EC or even over results achieved in validated in vivo or in vitro tests?

2. POSITION OF DG ENTR

2.1. Application of the Nota Bene

The reference in the Nota Bene to paragraph 3.2.5. of Annex VI to Directive 67/548/EEC is only mentioned explicitly in Part B of Annex II to the DPD.

However Article 6 (1) of Directive 1999/45/EC makes reference to the test methods of Annex V and the criteria in Annex VI to Directive 67/548/EEC of which this particular paragraph is a part. Therefore, paragraph 3.2.5 which itself refers to substances and preparations is applicable in all cases, meaning that preparations with extreme pH values should in general be classified as corrosive unless there is evidence to the contrary.

2.2. Prevalence of a classification achieved by applying the conventional method for preparations containing corrosive substances assigned SCLs

Article 6, Directive 1999/45/EC establishes a clear prevalence amongst the three possibilities foreseen under the Directive according to which dangerous preparations shall be classified: where available, human evidence prevails over animal test results which prevail over results achieved by applying the conventional method. However, this should not be interpreted in such a way that the Commission would encourage tests on animals or even on human beings in order to override a classification resulting from the conventional method or the application of the Nota Bene as part of Table IV and IVA of Annex II to the Directive. In fact, the Directive clearly stipulates in Article 6 (2) 1 the following:

> *" …..only **where it can be scientifically demonstrated** by the person responsible for placing the preparation on the market that the toxicological properties of the preparation cannot correctly be determined by the method outlined in paragraph 1(a), or **on the basis of existing test results on animals**, the methods outlined in paragraph 1(b) may be used, provided they are justified or specifically authorised under Article 12 of Directive 86/609/EEC.*

As a more specialised law, Directive 1999/45/EC prevails over Directive 67/548/EEC as a general law ("lex specialis derogat legi generali") with regard to matters specifically addressed in Directive 1999/45/EC. The established prevalence amongst the three possibilities to classify a preparation clearly falls under this principle. The Directive does not discriminate between a classification achieved by applying the conventional method using general concentration limits or by applying the conventional method using SCLs. Therefore the prevalence as outlined above is also valid for preparations with extreme pH values containing corrosive substances assigned SCLs. This conclusion is also based on the following consideration:

In general, the classification based on an extreme pH value of a preparation should not be different from the classification of a given preparation using the SCL assigned to a substance contained in the preparation and the conventional method, because this SCL should have taken the pH value and / or in vitro/in vivo test results into account. However, due to the fact that the establishment of a SCL is based on test results of a limited number of preparations with different concentrations of a substance (and not a continuous spectrum), it can lead to a situation, where the classification based on the application of the conventional method and SCLs deviates from the classification of the same preparation based on its measured pH value and the application of the Nota Bene.

The Nota Bene in conjunction with Articles 6 and 8 of Directive 1999/45/EC and section 3.2.5 of Annex VI to Directive 67/548/EEC provides the basis for industry to make use of the acid/alkali reserve method in deciding whether a preparation with extreme pH should or should not be classified as corrosive. However, where industry decides to use this method it has to carry out further confirmatory testing, preferably by means of an appropriate validated in vitro test. If industry does not want to perform such additional tests, classification should be done on the basis of extreme pH.

3. JUSTIFICATION

3.1. Lex specialis prevails over a lex generalis

It is a well established and recognised legal principle in Community Law that lex specialis (in this case Directive 1999/45/EC) derogates legi generali (in this case Directive 67/548/EEC) on the matters specifically addressed in the special law. This means that the more specific provisions foreseen under the DPD have precedence over general provisions under the DSD. This is also confirmed in Article 4 (2) of the DSD, which stipulates that

> 'The general principles of the classification and labelling of substances and preparations shall be applied according to the criteria in Annex VI, *save where contrary requirements for dangerous preparations are specified in separate Directives*.

3.2. The decision logic under the DPD for the assessment of health hazards of dangerous preparations

According to Article 3 of the DPD, the health hazards of preparations shall be determined in accordance with the provisions laid down in Article 6;

Article 6 (1) offers two possibilities for the human health hazard evaluation

(a) the conventional method (CM) described in Annex II or

(b) tests performed according to the methods outlined in Annex V to the DSD and according to the criteria established in Annex VI to the DSD;

When it can be scientifically demonstrated, for example on the basis of already existing test results on animals, that the CM does not lead to a correct classification of the preparation, Article 6(2) 1st para offers the possibility to the person responsible for placing the preparation on the market to perform animal tests in line with the methods outlined in Annex V to the DSD (i.e. those referred to in Article 6 (1) b of the DPD) can be used.

However, Article 6 (2) 3rd para stipulates that, if test results on animals achieved in line with the methods outlined in Annex V to the DSD are available, they have to be used for the classification of the preparation (except in the case of carcinogenic, mutagenic or toxic effects for reproduction).

Article 6 (3) 1st para stipulates that human evidence overrides results achieved via the CCM and tests on animals.

In conclusion, the lex specialis (the DPD) says that the conventional method can be used as long as no validated animal test data or human evidence is available. In the case of the availability of validated animal test data, those prevail over the conventional method classification. If human evidence is available, this human evidence prevails over the results obtained by the conventional method and the validated animal test data.

3.3. The conventional method

Article 6 (1) (a) refers to the whole Annex II and does not discriminate between Part A and Part B, therefore when using the conventional method, both parts of Annex II are applicable. This is repeated in the introduction to Annex II to the DPD, where it is stated that

> "the conventional method described in Part A and B …. is applicable to all preparations".

It is true that Annex II distinguishes for the assessment of the health effects of a preparation in the introduction between preparations containing

(a) dangerous substances listed in Annex I to Directive 67/548/EEC and assigned SCLs

and

(b) dangerous substances not listed in Annex I to Directive 67/548/EEC or listed there without SCLs,

It is also true that for these two categories of substances a different reference is made to either Part A (substances mentioned under (a)) or to Part A and B (substances mentioned under (b)) of Annex II.

However, this distinction is only made with respect to the type of concentration limit which has to be used for the hazard assessment of a preparation when using the conventional method: If no SCLs are assigned, the GCLs provided for in Annex II Part B have to be used in the formula given in Part A of Annex II. If SCLs are assigned, they have to be used instead.

No other discrimination with respect to the use of Part A or B is made in the Annex.

The assumption, that Part A of Annex II is only applicable for preparations containing substances assigned SCLs is also disproved by the fact that the formulas contained in Part A of this Annex must be used when deriving the classification of a preparation containing more then one dangerous substance classified for the same endpoint and where GCLs are to be used.

Therefore - and as stated clearly in the introduction to Annex II and in Article 6 (1) - all other provisions foreseen in Part A and B (besides the different

concentration limits) are applicable for the classification and labelling of dangerous preparations.

3.4. The Nota Bene

The Nota Bene contained as a footnote in Table VI and VIA of Annex II to Directive 1999/45/EC stipulates the following:

> *Simple application of the conventional method to preparations containing substances classified as corrosive or irritant may result in under-classification or over-classification of the hazard, if other relevant factors (e.g. pH of the preparation) are not taken into account. Therefore, in classifying for corrosivity, consider the advice given in paragraph 3.2.5 of Annex VI to Directive 67/548/EEC and in the second and third indents of Article 6(3), of this Directive.*

The advice given in paragraph 3.2.5. of Annex VI to Directive 67/548/EEC with respect to the pH stipulates that

> *"A substance or a preparation should also be considered corrosive if the result can be predicted, for example from strongly acid or alkaline reactions indicated by a pH of 2 or less, or of 11,5 or greater. However, where extreme pH is the basis for classification, acid/alkali reserve may also be taken into consideration. If consideration of alkali/acid reserve suggests the substance or preparation may not be corrosive then further testing should be carried out to confirm this, preferably by use of an appropriate validated in vitro test. Consideration of acid/alkali reserve should not be used alone to exonerate substances or preparations from classification as corrosive."*

This is mentioned as a third criterion in accordance to which substances or preparations shall be classified as corrosive and assigned the symbol 'C' and the indication of danger 'corrosive'. The other two criteria are validated in-vivo or in-vitro test results.

Article 6 (1) of the DPD refers back to the tests performed according to the methods outlined in Annex V to the DSD and according to the criteria established in Annex VI to the DSD.

Therefore the provisions expressed in the Nota Bene are implicitly also contained in Article 6 (1) which applies to all preparations.

3.5. Test results versus conventional method

Article 6 (2) of the DPD stipulates that[1] if test results are available which were made according to Article 6 (1) (b), these test results prevail over the health hazard assessment achieved by the conventional method.

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[1] Subject to the provisions of paragraph 3 [*of Article 6*] where a toxicological property has been established on the basis of both the methods outlined in paragraphs 1(a) and (b), the results from the methods outlined in paragraph 1(b) shall be used for classifying the preparation

Article 6 of the DPD does not discriminate between a classification achieved by applying the conventional method using GCLs or by applying the conventional method using SCLs. Therefore the prevalence as outlined above is valid also for substances assigned SCLs.

3.6. The rights and the obligation of a Member State

Article 8 of the DPD obliges the Member States not to allow the placing on the market of preparations which do not fulfil the requirements of the Directive. In order to ensure compliance with the Directive, paragraph 2 of Article 8 offers the Member States the possibility to request "information on the composition of the preparation and any other pertinent information from any person responsible for placing the preparation on the market". Taken the nature of a preparation and a certain use pattern into account, the pH of a preparation is certainly 'pertinent information' which can be requested by Member States from Industry in order to justify its classification for a given preparation.

Such a measurement does not require animal testing nor is it expensive to carry out. If as a result of such pH measurement, the calculated pH is below 2 or higher than 11.5, the Member State Competent Authority is certainly entitled to ask for additional data which would support the classification derived by Industry based on the conventional method. This supportive information should already be available taken the provisions of paragraph 3.2.5. of Annex VI to Directive 67/548/EEC into account. If the competent authority of a Member State is not satisfied with the supportive data delivered by Industry, additional animal tests should, however, also only be requested from Industry, as long as other supporting data has not been examined.