European Commission finally proposes MMVF classification system

The European negotiations on the classification and labelling of man-made vitreous fibres which have been going on in the Commission's CMR Working Group since the start of the nineties[1] may be approaching completion. A pre-Technical Progress Committee meeting on 6 May this year brought majority agreement at European level on the proposed classification and labelling system a significant step closer.

Three new entries

Three separate generic entries in Annex I to Directive 67/548/EEC were considered:

1. Man made vitreous (silicate) fibres (MMV(S)F) with an alkaline oxide and alkali earth oxide content $\leq$ 18% with the exception of those specified elsewhere in Annex I;
2. MMV(S)F consisting of borosilicate glasses with an alumina content of $\geq$ 10% and
3. MMV(S)F with an alkaline oxide and alkali earth oxide content > 18% with the exception of those specified elsewhere in Annex I

Group 1 (refractory ceramic fibres and special glass fibres) and 2 (one particular type of insulation wool) fibres are classified as follows:

- Category 2 carcinogens (substance which should be regarded as if they are carcinogenic to man), Risk phrase R49 (may cause cancer by inhalation);
- and Xi, Risk phrases R36/37/38 (irritating to eyes, respiratory system and skin).

Group 3 fibres (insulation wool) are classified as:

- Category 3 carcinogens (substance which cause concern to man owing to possible carcinogenic effects), Risk phrase R40 (possible risk of irreversible effects);
- and Xi, Risk phrases R36/37/38.

Two notes

Two draft "Notes" to be included in the Foreword to Annex I were also considered:

Note X is a general note applicable to all Annex I entries for MMVF and includes the relevant diameter considerations. It refers to both parallel and random oriented fibres:

" Classification as a carcinogen need not apply to:

- *fibres with a random orientation with a length weighted geometric mean diameter > 6 µm; or*
- *fibres with parallel orientation with a geometric mean diameter > 4 µm."*

Note Y refers only to group 3. It lays down the conditions in which a producer or importer can justify not classifying as a carcinogen an individual fibre included in the generic entry:

" Classification as a carcinogen need not apply if

- *the $T_{1/2}$ (half-life time) for the biopersistence of fibres > 20 µm is less than 10 days in an inhalation study;*
  or
- *the $T_{1/2}$ for the biopersistence of fibres is less than 40 days following intratracheal instillation;*

or

- *the $K_I > 40$ where K_I = å (Na, K, Ca, Mg, Ba, B oxides) - 2 (Al oxides) expressed as a mass percentage*[2].

  or
- *there is adequate long term inhalation study with no evidence of excess pathogenicity or carcinogenicity"*

Note Y will apply only for a period of three years, so that its conditions for derogation can be reviewed at a later date in the light of new scientific evidence and technical progress.

In principle, the CMR Working Group is free to deviate from this scheme for the classification of individual fibres if deemed necessary on the basis of scientific evidence.

This proposed classification is based essentially on the unanimous agreement among the scientific community that the carcinogenic potential of fibres is directly related to:

- the size of fibres, which effects their respirability (only fibres above a certain length, below a certain diameter and above a certain length/diameter ratio are considered as respirable), and
- the biosolubility (measured as the rate at which a fibre dissolves in a biological environment) and/or biopersistence (measured as the rate at which a fibre persists in a biological environment) of fibres. Biosolubility is referred to in three of the four derogation conditions listed in Note Y.

However, the debate on how to determine these characteristics and the criteria to use is far from over.

Controversial derogations

The German trade union IG BAU and the International Federation of Building and Wood Workers (IFBWW) organised an expert meeting on man-made vitreous fibres in Dresden to discuss the Commission's activities and proposal (see inset on the Dresden recommendations).

Most criticism was levelled at the conditions for derogation in Note Y. Briefly, they were:

- The $T_{1/2}$ values used in the biopersistency studies (inhalation = 10 days; intra-tracheal instillation = 40 days)[3] have not yet been scientifically validated, as the Commission's consultant who was commissioned to carry out the relevant study has not yet completed his research assignment.
- Although scientists are at odds about whether long-term inhalation studies with man-made vitreous fibres on rats are suitable for determining the carcinogenic potential for man, negative results in experiments of this kind are given equal value with the other derogation conditions.

  This is not a criticism of the principle of animal inhalation experiments and their relevance to humans. However, inhalation studies on rats have proved to be too insensitive. For instance, such inhalation studies with asbestos only cause significant tumour rates when the fibre concentration used is an order of magnitude higher than that which (according to epidemiological evidence) causes an increase in the carcinogenic risks to humans.
- Intraperitoneal tests, on the other hand, clearly prove asbestos to have a carcinogenic effect. This is why such tests are also used in Germany to determine the carcinogenic

potential of man-made vitreous fibres. Even so, controversy also surrounds these tests. There are claims that the resultant tumour rate is unspecific and caused only by the abnormally high doses administered. From the viewpoint of worker protection particularly, it is hard to see why one disputed carcinogenicity test (i.e. inhalation test) should take precedence over another (i.e. intraperitoneal test) for setting the conditions for derogation, when from the prevention viewpoint, the very opposite should be the case[4].

- Even though doubt has been cast on the K_I value, it remains a decisive factor for the German Committee for Dangerous Substances[5] in considering man-made vitreous fibres for classification as carcinogenic. This process was also recently endorsed by a German court.

  The main criticism of this value is that the formula is too simple to be able to derive such complex toxic effects as carcinogenicity. Also certain fibres do not fulfil a criterion which is taken for granted in this formula, namely that the biosolubility of fibres increases with a rising K_I value, and vice versa.

Conclusions of the IG BAU/IFBWW Experts' Meeting on Synthetic Mineral Fibres

The IG BAU/IFBWW Experts' Meeting held on 8 and 9 April 1997 in Dresden was attended by 40 participants from trade unions, companies, scientists, employers' associations, mineral fibre manufacturers and professional associations from Denmark, the Netherlands, Sweden and Germany, representatives of the Nordic Federation of Building and Wood Workers (NBTF), the International Federation of Chemical, Energy and Mine Workers' Union (ICEM), the ILO and the TUTB.

The participants discussed the problems of the scientific documentation of synthetic mineral fibres, and occupational and health protection requirements. The planned ILO Code of Practice in the use of insulation wools was also discussed. A follow-up meeting should be held in two years' time at the latest.

The trade union participants formulated the following recommendations for further work in this field:

1. The development and use of new fibres such as $K_I > 40$ fibres and biosoluble fibres in Germany should be welcomed.
2. Further scientific studies are needed to feature the effects of these new $K_I > 40$ fibres and biosoluble fibres on human beings and on the environment, and should be conducted by national entities and the European Labour Protection Agency of the European Union.
3. A scientific evaluation of these new $K_I > 40$ fibres and biosoluble fibres by the International Agency for Research on Cancer (IARC) would be desirable.
4. A concerted effort is needed to make an input into the elaboration of the ILO Code of Practice in the use of insulation wools.
5. Encouragement should be given to studies on mineral fibre substitutes ensuring at least the same safety and health standards.
6. Trade union representation in European Union bodies concerned with mineral fibres must be ensured and better coordinated.
7. Intra-industry dialogue should be conducted within individual countries on the topics outlined above.
8. Dialogue should be held at the European level with EURIMA, FIEC and with the European Commission on the subject of best practices, inter alia, in regard to dust control, $K_I > 40$ fibres and biosoluble fibres.

Conclusions

The conditions for derogation are not rated in any way, but are indiscriminately grouped together. As a result, most fibres on the European market will not be classified as carcinogenic, simply because they fulfil either the first or second derogation condition in Note

Y. This 'equivalence' of the derogation conditions in Note Y is a problem for worker protection because they do not all represent the same level of reduction in the carcinogenicity of fibres. For instance, a higher biosolubility criterion - which can be expressed by a $K_I > 40$ - represents a reduced carcinogenic potential of fibres, whereas a negative inhalation test does not.

This does not mean that we favour only the use of fibres with a $K_I > 40$ because it is not yet clear whether these fibres may also be carcinogenic. Their potential health effects need evaluating by the IARC or other scientific institutions (see inset).

Despite the limited influence that trade unions can have on the European decision process (a final decision is likely in the autumn), pressure can be exerted elsewhere, like the sectors and firms in which MMVFs are used. Works councils and/or worker's representatives must use every means at their disposal to ensure that only fibres with a higher biosolubility are used.

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[1] See the proposal for a classification of man-made mineral fibres made at a TUTB seminar held in 1995: *The carcinogenicity of man-made mineral fibres*, K. Van Damme, L. Casteleyn, E. Heseltine, TUTB, March 1995.

[2] Fibres with a K_I value >40 are generally considered as highly biosoluble and therefore non-carcinogenic

[3] The latest information is that these values have been left open in the Commission's proposed directive which was presented and discussed at the pre-TPC.

[4] The information is that the intraperitoneal test is now the fifth derogation criterion in the proposal for a directive.

[5] A quadripartite consultative body of the Federal Ministry for Labour and Social Affairs.