COMMITTEE ON CARCINOGENICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

FURTHER CONSIDERATION OF THE MOE APPROACH FOR COMMUNICATING THE RISKS OF EXPOSURE TO GENOTOXIC CARCINOGENS

Introduction

1. The Margin of Exposure (MOE) approach for prioritisation of risks has been developed by the European Food Safety Authority (EFSA), WHO and the International Life Sciences Institute (ILSI) for providing risk assessment advice on unavoidable exposure to genotoxic carcinogens in food that is more informative than recommending that exposure should be as low as reasonably practicable (ALARP) . It has also been incorporated in the guidance document for risk assessment of carcinogens under the EU Risk Evaluation, Assessment and Authorisation of Chemicals (REACH) initiative. At the November 2006 meeting, Members agreed that the MOE approach might be used to aid risk managers to prioritise the risks of genotoxic carcinogens and to communicate those risks to the public. Members agreed that this could be done using a system of banding of MOE values (CC/06/20; CC/MIN/2006/3). However, the committee was unsure about where the bands should fall and what terminology should be used to describe the bands to a lay audience. They requested a further discussion on this after advice had been received from Professor Frewer and, possibly, other risk communication experts.

2. Members considered advice from a colleague of Professor Frewer at the last meeting but found it did not help in discussing a banding approach. The secretariat has some further suggestions for descriptions for the bands of MOE values for members to consider and these are given below.

Banding

3. The original banding ranges suggested by the FSA are given in the table below:

MOE Band for long term exposure	**MOE Band for relatively short term exposure, e.g. if action is being taken to minimise future exposure**	**Interpretation**
<10,000		Possible concern
10,000-1,000,000		Low concern
>1,000,000	>100,000	Negligible concern

These would apply when the MOE is derived by dividing the estimated human exposure by the lower confidence limit of the bench mark dose for a 10% increased

incidence in cancer (BMDL10). Larger MOEs would be required if, for example, a TD25 was used rather than a BMDL10.

It was suggested that, if COC identified an appropriate reference point on the dose-response relationship from an appropriate carcinogenicity study, the FSA could use this to calculate an MOE when exposure data became available in order to provide information to consumers underpinned by COC advice. This would be for communication purposes, and a large MOE would not be used as a basis for condoning illegal use of genotoxic carcinogens in food.

4. In general, Members considered that the additional band of >100,000 was confusing. Some also considered that it was not the COC's responsibility to advise where the bands should lie. Therefore, a simplistic approach is proposed with the following bands: <10,000; 10,000 -100,000; and 1,000,000.

Descriptions

5. Some suggestions are given below:

A.

MOE Band	**Interpretation**
<10,000	May be a risk to health
10,000-1,000,000	Very little risk to health
>1,000,000	Negligible risk to health

B.

MOE Band	**Interpretation**
<10,000	The margin of protection is lower than we would like.
10,000-1,000,000	There is a large margin of protection and there is very little cause for concern.
>1,000,000	There is a very large margin of protection and there is no cause for concern.

C.

MOE Band	**Interpretation**
<10,000	May pose a risk
10,000-1,000,000	Unlikely to pose a risk
>1,000,000	Highly unlikely to pose a risk

Question for the committee

Members are asked whether any of these suggestions would appear suitable for communicating the risk of genotoxic carcinogens in food and other media. Do Members have any alternative suggestions?

Secretariat

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