



3rd November 2005

EXPLANATORY NOTE

of the Opinion on a Harmonised Approach for the Risk Assessment of Substances which are both Genotoxic and Carcinogenic

One of the most difficult issues in food safety is to advise on the potential risks to human health for substances found in food which are both genotoxic (damaging DNA, the genetic material of cells) and carcinogenic (leading to cancer). For these substances, it is generally assumed that even a small dose can have an effect. Nowadays, with the development of scientific research, improved analytical techniques and increased surveillance, scientists are able to detect genotoxic and carcinogenic substances, even at very low levels (less than 1 trillionth of a gramme). All of the information available has to be evaluated to determine the possible impact on human health. Only then can a decision be made by risk managers on possible actions needed, for instance, to reduce or eliminate the presence of such substances in food.

Until now the risk assessors have advised to keep the exposure to such substances at the lowest possible level. This approach is known as the ALARA principle (“as low as reasonably achievable”). A disadvantage of this approach is that it cannot be used to compare risks posed by different substances. Furthermore, the application of the ALARA principle does not take into account the effectiveness of a substance and the actual (sometimes extremely low) level of occurrence in food.

To address these disadvantages of the ALARA principle, different methods are currently used world-wide. In its opinion, the Scientific Committee (SC) of the European Food Safety Authority recommends a harmonised concept using the “margin of exposure” (MOE) approach, a methodology that does enable the comparison of the risks posed by different genotoxic and carcinogenic substances. Differences in potency of the substances concerned and consumption patterns in the population are taken into account when applying the MOE approach.

The Scientific Committee recommends the application of the MOE approach as a harmonised methodology for assessing the risk of genotoxic and carcinogenic substances which may be found in food and feed, irrespective of their origin. Independent of this

recommendation, the Scientific Committee emphasizes its overall aim to keep the exposure to those substances at the lowest level possible.

It is for the risk manager to decide if the magnitude of the MOE is acceptable, and if further action is needed taking into consideration additional aspects, such as the feasibility of removing the substance from the food supply. The MOE approach could be applied for instance to environmental contaminants, substances occurring naturally in foods and those resulting from food preparation or manufacturing processes – acrylamide would be a case in point.

The Scientific Committee is of the opinion that, in principle, substances which are both genotoxic and carcinogenic should not be deliberately added to food and feed at any point in the food chain. The same also applies for substances which may leave residues that could have both genotoxic and carcinogenic properties (e.g. pesticides).