

EXPERT GROUP ON VITAMINS AND MINERALS

PAPER FOR DISCUSSION

21 January 1999

Agenda Item 5

TERMS OF REFERENCE

Purpose

1. This paper is provided as a basis for the discussion of the terms of reference of the Expert Group on Vitamins and Minerals (EVM).

Introduction

2. The EVM's published terms of reference are to:
- *establish principles on which controls for ensuring the safety of vitamin and mineral supplements sold under food law can be based;*
 - *review the levels of individual vitamins and minerals associated with adverse effects;*
 - *recommend maximum levels of intakes of vitamins and minerals from supplements if appropriate;*
 - *report to the Food Advisory Committee (FAC).*

The Group will also be able to advise on the levels of vitamins and minerals in fortified foods, if it considers this is appropriate.

3. These have been endorsed by Ministers and cannot be changed without their agreement. However, the Group will need to discuss how the terms of reference should be interpreted. In doing so it will need to take account of the broader context within which the terms of reference were established, in particular the current regulatory regime and wider Government policy. It will also need to consider the respective roles of the EVM and the Food Advisory Committee (FAC).

The Broader Context

4. A description of the current regulatory regime is given in EVM/99/2. As will be seen from this, most dietary supplements are regulated as foods and are subject to the general requirements of the Food Safety Act 1990 which effectively requires that products should not be injurious to health.

5. Although the Government is concerned about the potential adverse effects of high dose vitamin and mineral supplements it believes that they should continue to be available under food law except where they may pose a risk to health. It is also of the view that in cases where limits on the levels of vitamins and minerals are considered to be necessary these should be based on safety considerations.

6. As is clear from the terms of reference, the EVM's remit is concerned with the safety of vitamin and mineral supplements sold under food law. It does not extend to the consideration of the possible benefits of vitamins and minerals at doses in excess of the Dietary Reference Values (DRV) established by the Committee on Medical Aspects of Food and Nutrition Policy. Nor is it part of the EVMs remit to review the adequacy of the current DRVs.

7. More generally, the Government is also committed to ensuring that regulations are only imposed where necessary, are effective in securing the desired benefits and that the costs that they impose are justified. It believes that regulations should be consistent, targeted and proportionate. In particular, they should focus on the problem and be appropriate to the particular risk or risks being considered.

8. The Group will need to work within the confines of these broader policy considerations when formulating its advice. This means, for example, that it would not be appropriate for the EVM to recommend upper limits based on nutritional need, such as arbitrary multiples of the Recommended Daily Amount.

The Role of the FAC

9. The FAC is an independent non-statutory advisory body appointed by Ministers and has the following terms of reference:

“To assess the risk to humans of chemicals which are used in or on food and to advise Ministers on the exercise of power in the Food Safety Act 1990 relating to the labelling, composition and chemical safety of food. The Committee will also advise Ministers on general matters relating to food safety. In exercising its functions the Food Advisory Committee will take the advice and work of the

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), the Advisory Committee on Novel Foods and Processes (ACNFP), the Advisory Committee on the Microbiological Safety of Food (ACMSF) and other relevant advisory committees into account.”

10. The FAC has a membership drawn from a diverse range of backgrounds, which enables it to take a wide view of the issues which come before it. However, it tends not to deal with complex technical matters in relation to toxicology but instead relies on advice from the committees such as the COT, ACNFP and European Union Scientific Committee for Food. The FAC's primary role is therefore to advise on the management of risks which have been assessed elsewhere. It does this by (i) considering the output of the risk assessment process, which ideally should cover the *nature* and *extent* of the assessed risk, and any *uncertainties* in the risk assessment; (ii) assessing the available options for managing the risk; and (iii) advising on the pros and cons of the different options.

11. The overall risk analysis scheme, and the relationship among its three components - risk assessment, risk management and risk communication - is summarised in Annex 1. The scheme represented here is as recommended by FAO and WHO for use in food safety policy-making and follows a number of Joint FAO/WHO Expert Consultations in which UK experts were involved. The scheme has now been recommended by Codex for use in standard setting in its various committees and has also been adopted by the European Union (EU). It has also been discussed with Ministers and is gaining acceptance as a suitable model for use in food safety risk analysis in the UK.

12. The need to distinguish between the risk assessment and risk management functions is one which has been recognised for many years in the area of food chemical safety and there is also the recognition that the two activities require different kinds of expertise. Part of the intention behind the separation of the assessment and management is to protect the scientific assessment of risk from being confused with other non-scientific factors, such as considerations of costs, benefits, stakeholder views and their perceptions of the risk, etc. which, in this instance will be considered by the FAC in the risk management phase.

13. To date the FAC's role in risk management has been mainly concerned with food additives and contaminants. However the approaches needed for vitamins and minerals will not always be the same as those used in considering additives and contaminants. In particular there is an issue over the use of 'safety factors' (more correctly called 'uncertainty factors'). The EVM will have to decide whether to apply uncertainty factors in the consideration of minerals and vitamins and if so, what factors should be used.

EVM's Role in relation to the FAC

14. The EVM's principal role is to carry out risk assessment function. However, in order to ensure that the process is transparent and to enable the FAC to carry out its role effectively, it is important that the EVM's report, which will be published, sets out clearly the background to its advice, together with what the risk analysis approach refers to as the *risk characterisation*. This is the output of the risk assessment process and according to the risk analysis should include an account of (i) the *nature* of the risk; (ii) its *magnitude*; and (iii) *the uncertainties* surrounding the assessment of the risk. The EVM is also likely to be responsible for the exposure assessment part of the risk assessment process in which the potential exposures in different population subgroups will need to be assessed.

15. When it comes to establishing principles on which controls for ensuring the safety of vitamin and mineral supplements sold under food law can be based, the EVM will wish to consider whether to recommend a single model to the FAC or present a range of options, explaining the pros and cons of each.

Other Considerations

16. The potential differences in exposures in different population subgroups has already been mentioned. There is also the fact different exposures may be considered toxicologically unacceptable in different groups. The Group will wish to consider whether it is appropriate to have a single set of principles to cover the differing risks posed by individual vitamins and minerals. However, it may also wish to consider whether there is a need for different principles to apply to different population groups, for example, pregnant women, infants, children, adults and adults aged over 65 years or whether these groups can be accounted for in a single model by, for example, varying uncertainty or safety factors.

Fortified Foods

17. The terms of reference allow the EVM to advise on the levels of vitamins and minerals in fortified foods, if it considers this is appropriate. Some existing compositional standards, e.g. those for infant formulae, set limits on the amounts of vitamins and minerals that may be added, but for most foods there are no specific limits. In practice the amounts currently added to foods do not, in themselves, give rise to any concerns. But in developing general principles for dietary supplements the Group may wish to take account of the contribution of fortified foods to dietary exposures to vitamins and minerals and

the potential implications of possible future increases in either the levels of fortification and/or the range of fortified foods.

Turning the EVM's/FAC's advice into policy

18. The final responsibility for government policy on food safety lies with Ministers, and whilst advice from the advisory committees is always crucial, it is not necessarily the only consideration. However, in practice Ministers will usually follow their recommendations unless there are good reasons not to do so.

Conclusion

19. Members are invited to:

- i) consider the terms of reference of the EVM;
- ii) note that the terms of reference have already been agreed by Ministers and that Ministers are committed to a safety based approach to limits on vitamins and minerals;
- iii) agree on their interpretation of the terms of reference.

Prepared by:

The Expert Group on Vitamins and Minerals Secretariat
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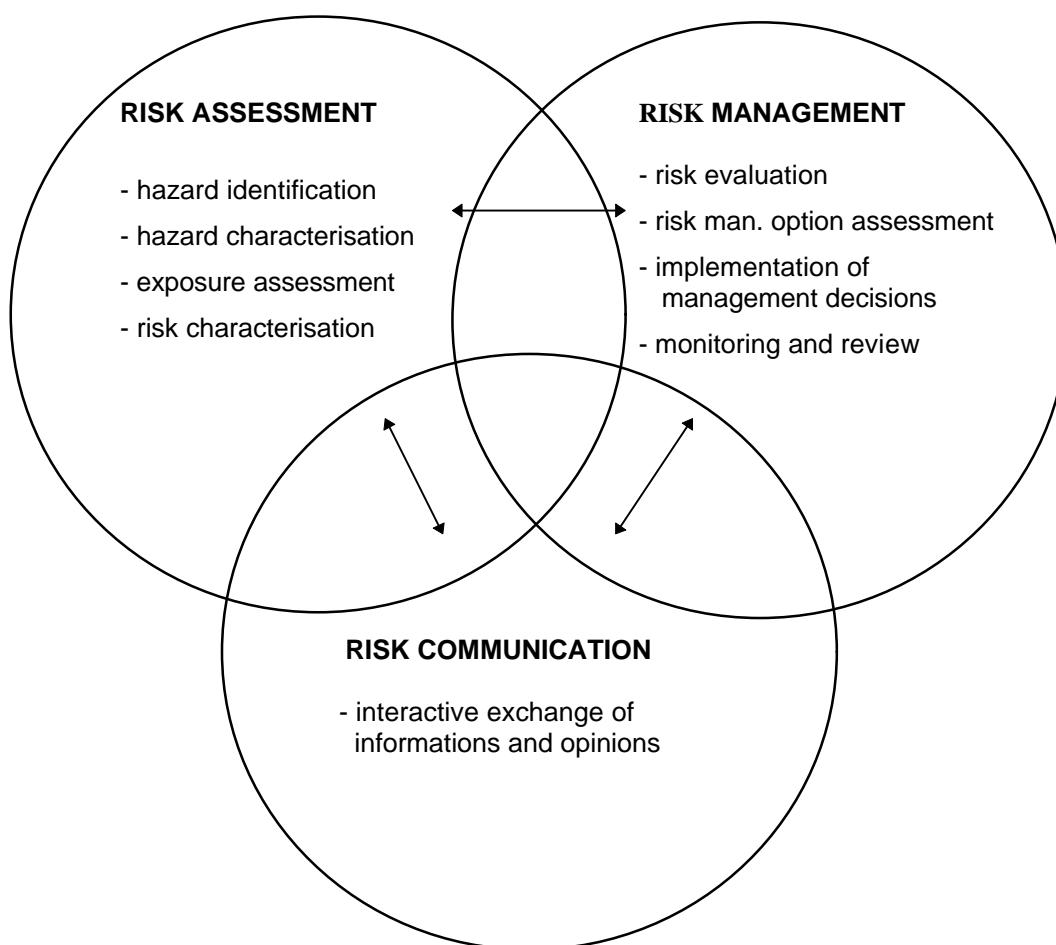
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The Expert Group on Vitamins and Minerals Secretariat
MAFF, Room 306B Ergon House
17 Smith Square
London, SW1P 3JR

THE RISK ANALYSIS SYSTEM

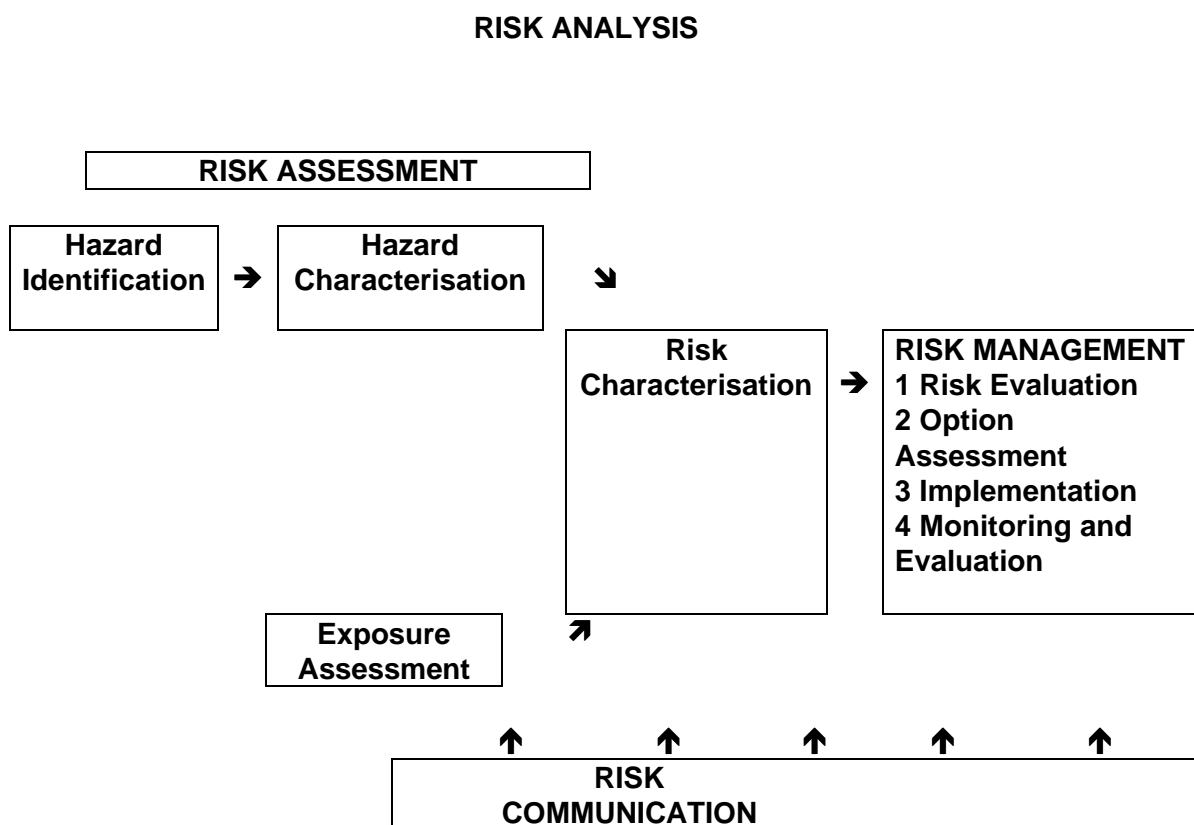
1. At the 1997 FAO/WHO Consultation on Risk Management the Risk Analysis Framework was represented as a 'three-balloon' diagram as shown below:

Figure 1. Risk analysis framework as set out at the 1997 FAO/WHO Consultation on Risk Management



2. An alternative representation, which emphasises the different stages of the risk assessment and risk management processes, is shown below:

Figure 2. Risk Analysis Scheme as Developed by FAO and WHO at the Risk Analysis Consultation (1995)



3. The linear representation loses something of the feeling of interaction and feedback but shows more clearly the interaction between the various parts of the risk assessment process.

4. The major steps in the overall scheme were defined at the FAO/WHO Consultation on Risk Analysis, held in Geneva in 1995, as follows:

Risk Analysis includes **Risk Assessment**, **Risk Management** and **Risk Communication**;

Risk Assessment consists of (i) *hazard identification* (ii) *hazard characterisation* (iii) *exposure assessment* and (iv) *risk characterisation*;

Risk Management is the process of managing the output of the Risk Assessment step (the Risk Characterisation);

Risk Communication is a two-way exchange of views covering the whole process.

5. A subsequent Consultation on Risk Management then defined four main subdivisions of risk management as follows:

Risk Evaluation - a series of elements:

- Identification of a food safety problem
- Establishment of a risk profile which is a description of the problem and its context
- Ranking of the hazard for risk assessment and risk management priority
- Establishment of risk assessment policy for the conduct of risk assessment
- Commissioning of risk assessment
- Consideration of risk assessment result

Option Assessment - the identification of available management options, the selection of the preferred management option, including the consideration of an appropriated safety standard and the final management decision.

Implementation of Management Decision

Monitoring and Evaluation - which involves assessment of the measures taken and review of risk management and/or assessment

6. Thus in summary:

Risk Analysis includes **Risk Assessment, Risk Management** and **Risk Communication**;

Risk Assessment consists of (i) *hazard identification* (ii) *hazard characterisation* (iii) *exposure assessment* and (iv) *risk characterisation*.

Risk Management consists of (i) *risk evaluation* (ii) *option assessment* (iii) *implementation of management decision* and (iv) *monitoring and evaluation*.

7. Normally the *option assessment* would be the point at which the process leaves the hands of officials and goes instead to Ministers: but thereafter the *implementation of the management decision* and the *monitoring and evaluation* steps are once again for officials.