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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Scientific Steering Committee

OPINION OF THE SCIENTIFIC STEERING COMMITTEE ACCOMPANYING THE GUIDANCE DOCUMENT FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND FEED

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BACKGROUND

In its opinion of 26-27 October 2000 on risk assessment in rapidly evolving fields, the SSC illustrated the difficulties encountered and its approach to make a scientific assessment [Ref. 1]. The example selected was one that is considered by a significant part of the European public as an issue of concern, namely genetically modified (GM) plants.

The SSC highlighted that the question of genetic modification includes multiple societal, ethical, economical and other aspects, but its analysis was focussed on the scientific assessment of food and feed safety and on the environmental impact of GM plants.

The principal issues considered in the risk assessment of GM plants and derived food and feed were identified as: (1) the potential for transfer of the introduced gene(s) to other species and the consequences thereof, (2) the safety of the introduced gene product(s) and (3) the potential for the introduction of unintended secondary changes.

The SSC signalled the wider difficulty of testing the safety of any food, whether traditional, novel or genetically modified. Whilst addressing the potential safety issues of GM plants it also recognised that breeding techniques in general produce genetic changes in plants and that an evaluation of the long-term impact of these often unpredictable changes on health and the environment is poorly documented. This applies to traditional breeding as well as to cell fusion and mutagenesis approaches used to induce genetic variation.

Various international initiatives continue to improve data collection on the above through the establishment of accessible databases containing information obtained by validated and harmonised methods. This is necessary for an adequate interpretation of observed differences between GM and non-GM materials with respect to any possible impact on human and animal health. Both the Scientific Committee on Plants (SCP) and the Scientific Committee on Food (SCF) have, in the past, expressed opinions on the information necessary to support applications for the placing on the market of GM plants [Ref. 2] or derived foods [Ref. 3]. The SCP and SCF have concluded in their published risk assessments of GM crops to be marketed in the European Union that the GM crops and derived products do not present new safety issues to human or animal health or to the environment [Ref. 4]. Also published review of data do not indicate that the GM crops presently in cultivation pose any more risks for humans, animals and the environment than do their conventional counterparts [Ref. 5 & 6].

Currently applied analysis methods used to detect potential effects which may arise from the genetic modification involve primarily targeted analyses which may not detect all potential unintended effects. New and developing scientific approaches might widen the scope. Profiling technologies such as metabolomics, proteomics and transcriptomics are considered as emerging technologies which could be used in risk assessment, when appropriate, to detect unintended effects [Ref. 7]. These were discussed extensively in the annex to the SSC opinion of 2000 [Ref. 1].

Opinion

As a follow-up to that exercise and on the basis of experience of risk assessment of the dossiers, the Joint Working Group on Novel Foods and GMOs, composed of members of the Scientific Committee on Plants, the Scientific Committee on Food and the Scientific Committee on Animal Nutrition, launched a broad interdisciplinary exercise which involved the general public through internet consultation. The aim was to develop a guidance document for the risk assessment of GM plants and derived food and feed. The result of this exercise and the public consultation is the attached Guidance Note[1].

The specific information for the risk assessment of GM plants and derived food and feed included in the attached Guidance has been structured around the following key areas:

- Molecular characteristics of the genetically modified plant
- Comparative analysis
- Environmental risk assessment
- Food/feed safety assessment
- Nutritional assessment of GM food and feed.

Risk assessment that is required may be less complex if transgenes or sequences extraneous to the successful deployment of the target transformation event are not present in the GM plant. Notifiers are encouraged to develop, for commercial release, those transgenic lines in which only DNA essential to the modification of the trait is transferred to the plant and in which superfluous expression and potential dispersal of transgenes in the environment is minimised [Ref. 8].

Post-market monitoring as such is not addressed in the attached Guidance document. The specific need for post-market monitoring will be dictated case-by-case by issues highlighted in the risk assessment. There is, however, a clear need for guidance and harmonisation for post-market monitoring, which should be addressed.

The basis of the risk assessment strategy is the *comparative* safety assessment. The concept of substantial equivalence, as developed by OECD and WHO/FAO for the assessment of genetically modified foods/feeds, is based on the idea that an existing crop used as food/feed and with a history of safe use, can serve as a comparator when assessing the safety of the genetically modified food/feed. This comparison includes the comparative analysis of the chemical composition and the molecular, agronomic and morphological characteristics. It may result in identification of potential differences between the GM food/feed and their unmodified counterpart. The outcome will structure the safety assessment procedure, which may then include

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[1] Guidance document for the risk assessment of genetically modified plants and derived food and feed. Prepared for the Scientific Steering Committee by *The Joint Working Group on Novel Foods and GMOs* composed of members of the Scientific Committees on Plants, Food and Animal Nutrition. 6-7 March 2003.

further toxicological and nutritional testing. The SSC stresses that the application of the substantial equivalence concept is a *starting* point for the safety assessment, rather than a safety assessment *per se*. The concept has been misinterpreted as being an *endpoint* of the safety assessment.

The impact of new GM crops grown for non-food/feed purposes is likely to become increasingly important. GM plants are now being developed to produce pharmaceuticals, therapeutics or chemicals for industrial processes. Such crops might require strict segregation from the human, livestock and wildlife food chains. It is clear that, although many issues considered in the present Guidance document are applicable to the risk assessment of non-food crops, these will raise other safety and risk management issues that will require additional guidance.

The SSC stresses that the Guidance document will need to be updated regularly both in the light of the experience gained from its application and of new data and evidence that will gradually become available.

References

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