

Opinion on the relationship between scientific data and the labelling of genetically modified foods and their derived products (expressed on 19th September 1997)

Terms of reference

The Committee is asked to advise on:

- the factors to be taken into consideration to demonstrate that the composition of a novel food or a novel food ingredient is different in comparison with a conventional food or food ingredient based upon an appropriate analysis of existing data and having regard to the control methods currently available and the current variations within the family of foods or food ingredients when they are obtained by conventional means.
- the qualitative and/or quantitative conditions that such factors would have to fulfill.

Background

Authorisations for placing on the market have been given in conformity with the provisions of Directive 90/220/EEC (EEC 1990) concerning the deliberate release into the environment of genetically modified organisms for Monsanto's soybeans (1) and for Ciba-Geigy's maize (2). These authorisations were given before the entry into force of Regulation (EC) No 258/97 (European Commission 1997) without requiring any specific labelling provisions because Directive 90/220/EEC did not provide for such provisions except if justified by safety reasons.

(1) Commission decision of 3 April 1996

(2) Commission decision of 23 January 1997.

The Commission has deemed it necessary to lay down additional labelling provisions for foods and food ingredients derived from the genetically modified soybeans or maize according to Article 8 in Regulation (EC) No 258/97.

In view of the above and having regard to the fact that the Scientific Committee for Food has already given its opinion concerning the guidelines for the scientific evaluation of novel foods and novel food ingredients and, conscious of the major role that the Committee will have during the implementation of this Community Regulation, the Commission has considered it desirable to consult the Committee on the scientific evaluation of the term "equivalence" as used in Article 8, § 1a), in Regulation No 258/97.

Approach

In considering this question the Committee felt that it might be best answered by addressing some generic issues relating to "substantial equivalence" and "equivalence", rather than issues specific for genetically modified maize and soya beans.

The notion of safety

It should be emphasised that all novel foods accepted as being in accordance with requirements of the SCF's opinions on the assessment of novel foods (SCF 1996a, 1996b, 1996c) are, on the basis of current knowledge, safe for human consumption. This statement applies regardless of whether the particular novel food must be labelled according to the pertinent section of the regulation. The objective of the SCF's opinions mentioned above is primarily to provide guidelines for safety and nutritional evaluation of novel foods and ingredients in order to avoid ambiguity and to achieve coherence of the regulatory process within the entire EU.

The principle of substantial equivalence

The concept of "substantial equivalence" in the context of the SCF Opinions on the Assessment of Novel Foods (SCF 1996a,1996b,1996c) embodies the idea that existing organisms or products used as foods or food sources, can serve as a basis for comparison when assessing the safety and nutritional value of a food or food ingredient that has been modified or is new. If a new food or food ingredient is found to be substantially equivalent to an existing food or food ingredient, it can be treated in the same manner with respect to safety and nutritional value, keeping in mind that establishment of substantial equivalence is not a safety or nutritional assessment in itself, but an approach to compare a potential new food with its conventional counterpart.

The application of the principle of substantial equivalence can be extended to the evaluation of foods from novel sources and processes. Substantially equivalent novel foods and novel food ingredients are thus comparable, in terms of safety and nutritional value, to their conventional counterparts. Substantial equivalence may be established either for the whole food or food component including the introduced "new" change, or it might be established for the food or food component except for the specific "new" change introduced. If a novel food or novel food ingredient has not been found to be substantially equivalent to an existing food or food component, this does not imply that it is unsafe. It simply indicates that such a novel food or novel food ingredient should be evaluated on the basis of its unique composition and properties.

The demonstration of substantial equivalence contains a dynamic element, as the continuing modification of a food requires that the basis of comparison will evolve in a way that the most recent novel food or novel food ingredient is compared with an appropriate predecessor and not necessarily with the most traditional counterpart.

The technical approach to substantial equivalence is addressed in detail in the SCF opinions but essentially leads to one of three scenarios:

i. Substantial equivalence to a traditional counterpart:

If substantial equivalence to a traditional counterpart is established, the novel food or novel food ingredient can be regarded as wholesome and to be toxicologically and nutritionally acceptable for use in the overall diet in a manner comparable to its counterpart or as replacement of its counterpart. When judging the comparability of the novel food or novel food ingredient to its counterpart, the limits of known and measurable natural diversity of any conventional counterpart are taken into account.

ii. Substantial equivalence except for one or more defined traits:

If substantial equivalence except for one or more defined traits is demonstrated, the assessment focuses on these traits. These are evaluated on a case-by-case basis and may in certain cases require information, matching that needed for the safety evaluation of food additives (European Commission 1989).

iii. No substantial equivalence:

If substantial equivalence to a traditional food or food ingredient is not established, the novel food requires an extensive data-base as outlined in the SCF opinions

Comparison of the legal term "equivalence" with the concept of "substantial equivalence"

The term "equivalence" is not explicitly defined in Regulation No 258/97 concerning novel foods and novel food

ingredients, but article 8 sets out the conditions under which a novel food or novel food ingredient can no longer be considered to be equivalent to an existing food or ingredient:

"A novel food or food ingredient shall be deemed to be no longer equivalent for the purpose of this Article if scientific assessment, based upon an appropriate analysis of existing data, can demonstrate that the characteristics assessed are different in comparison with a conventional food or food ingredient, having regard to the accepted limits of natural variations for such characteristics."

Essentially the legal term "equivalence" relates to inherent and analytical variance in composition and supports the consumer's entitlement to know about the origin and composition of the novel food, whereas the scientific concept of "substantial equivalence" embraces an assessment of safety and nutritional adequacy. The SCF emphasises the importance of differentiating between labelling issues and those relating to safety and nutritional value.

Use of data submitted for safety and nutritional evaluation for the specific labelling of novel foods

The SCF advises that safety and nutritional data used for the evaluation of substantial equivalence may also contribute to the identification of measures to monitor the correct implementation of labelling and the spread of novel foods in the market place. The application of the data for this purpose will have to be established on a case-by-case basis paying particular attention to key-macro and micro nutrients and to potential toxic and anti-nutritional factors which might be either inherently present or process derived.

Foods which have been shown to be substantially equivalent and to be as safe as their traditional counterparts, may contain modified DNA. In such cases, this DNA, although it does not change the composition and safety of the final food product, may facilitate monitoring and control. It may be relevant to use the presence of residues of the marker genes and of their expression products along with the primarily targeted modification as a logical handle for labelling. Account should be taken of the nature and possible persistence of the primary modification.

For foods where substantial equivalence is established except for certain defined traits, the defined changes provide a logical starting point for the selection of parameters for monitoring and control of labelling and trade as wished. These indicators of novelty may embody introduced changes of the genetic material, derived novel proteins and new secondary metabolites to be chosen on a case-by case basis.

For foods where no substantial equivalence to existing foods can be established, but the wholesomeness has been confirmed on the basis of submitted data, there will be a variety of analytical possibilities, again to be determined on a case-by-case basis.

The control of labelling: possibilities and limitations

The correct labelling of a novel food or novel food ingredient cannot be verified if no differences to the conventional counterpart can be detected.

The following situations are examples for the limitations of labelling:

- - advances in the sampling and analytical procedures used during the control procedures might in the future reveal previously unrecognised structural and compositional differences; these might allow identification of new markers of the novel product.
- - as new techniques will probably lead to higher sensitivities, it is recommended that validated methods with defined limits of determination be used.
- - in the case of methods based on the detection of recombinant DNA it is recommended that regulating authorities be informed of the introduced sequences including unique border sequences suitable for PCR-techniques.
- - during the harvesting, transportation and processing of food, cross-contamination may occur between a substantially equivalent novel food and its traditional counterpart. Such technological carry-overs would be

acceptable from a safety point of view but for management purposes defined tolerable limits are recommended. For example, in accordance with Directive EC 2731/75 amended by EC 2094/87, contamination of common wheat, durum wheat, rye, barley or maize by grains of other cereals is accepted at levels ranging from 1.5 to 4 %.

At the present time, methods for quantitative determination of functional/transcriptional DNA-sequences are still developing. It is recommended that validated standards containing defined concentrations of GM-markers only, should be supplied to facilitate sensitive and validated methods for sampling and monitoring.

It should also be appreciated that the final product might not contain any detectable markers of an earlier modification or process, because such markers have been removed during processing. This would render the regulation of such products difficult. Nonetheless it might be desirable for the product to be monitored for the absence of such markers as an aspect of control.

Conclusions

This opinion delineates the presently known technical possibilities for monitoring and control as well as the associated limitations for labelling purposes.

The SCF emphasises that "equivalence" is a legal term which applies to the inherent analytical compositional characteristics of a food or food ingredient, whereas "substantial equivalence" represents a safety and nutritional evaluation of such products in comparison to appropriate predecessors.

The SCF advises that safety and nutritional data used for the evaluation of substantial equivalence may also contribute to the basis for the identification of measures to monitor the correct implementation of labelling and the spread of novel foods in the market place. The application of the data for this purpose will have to be established on a case-by-case basis paying particular attention to key macro- and micro-nutrients and to potential toxic and anti-nutritional factors which might be either inherently present or process derived.

The Committee suggests based on its considerations, that if obligatory labelling requirements for novel foods which from a legal point of view are no longer equivalent to traditional foods are introduced, they should for practical reasons be combined with a management decision to introduce an acceptable level for the accidental mixing of the safe novel food with its conventional counterpart.

Furthermore, analytical methods should be employed that are standardised and validated. For determination of recombinant DNA in a food or food ingredient, all available information concerning unique sequences should be revealed for use by control laboratories

The Committee also points out that foods which have been shown to be substantially equivalent and to be as safe as their traditional counterparts, may contain modified DNA but otherwise be identical to their traditional counterpart. In such cases, this DNA, although it does not change the composition and safety of the final food product, may facilitate monitoring and control.

References

- European Commission 1997, Regulation (EC) 258/97 concerning novel foods and novel food ingredients; OJ L 43/1 14.2.97
- EEC 1990, Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms; OJ No L 117, 8.5.90 as amended by Directive 94/15/EC OJ No L 103; 22.4.1994.
- European Commission 1989; Presentation of an application for assessment of a food additive prior to its authorisation, Luxembourg 1989
- SCF 1996a: SCF opinions on the assessment of novel foods Part I. Recommendations concerning scientific aspects of information necessary to support an application for placing on the market of novel foods and novel foods ingredients (expressed on 7 June 1996)

- SCF 1996b: SCF opinions on the assessment of novel foods Part II Recommendations concerning the scientific aspects of the presentation of information necessary to support applications for placing on the market of novel foods and novel food ingredients; (Expressed on 13 December 1996)
- SCF 1996c. SCF opinions on the assessment of novel foods Part III. Recommendations concerning the scientific aspects of the preparation of the initial assessment reports on applications for placing on the market of novel foods and novel food ingredients. (Expressed on 13 December 1996)