

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

NORDIC COUNCIL REPORT ON NOVEL PLANT FOODS

Issue

This paper invites the Committee to consider certain proposals related to the risk assessment and risk management of novel plant foods, suggested by a Working Group set up under the Nordic Council. The Committee is also asked to identify any other aspects covered by this report that it wishes to examine in more detail.

Background

1. The attached report *Risk Assessment and Risk Management of Novel Plant Foods* (Annex A) was published in September 2005 under the auspices of the Nordic Council of Ministers, the body that represents mutual interests of a grouping of five Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) and their dependent territories including Greenland. The key findings from the report are set out in the following sections.
2. The report focuses on the situation where food plants with a traditional history of food use outside the EU are proposed for introduction to the EU market. The report estimates that there are about 300 established species of food plants in the EU, compared with around 7000 world-wide.
3. Plant foods from other parts of the world will almost always fall within the scope of the current EU novel foods regulation (Regulation (EC) No 258/97) and a small number of examples have been evaluated for possible authorisation under that regulation:
 - Stevia leaves (*Stevia rebaudiana*), rejected in February 2000
 - Nangai nuts (*Canarium indicum*), rejected in December 2000
 - Juice from noni fruit (*Morinda citrifolia*) authorised in 2003
 - Chia seed (*Salvia hispanica*) currently under evaluation (see paper ACNFP/75/3)
4. The first three, along with certain other "new" plant foods that were introduced to Europe before the novel foods regulation came into force, are described in Chapter 3 of the report (pages 33-37). Based on this experience, the report recommends a number of changes to the current regulatory scheme, based on a 2-step evaluation:
 - a formal assessment of the novelty and "risk profile" of the food, followed by
 - a risk assessment, whose scope is determined by the outcome of the first step.

5. The report considers that the establishment of criteria for "novelty" and the definition of risk assessment policies for different types of novel food are risk management decisions, which define the questions to be addressed in the risk assessment.

Step 1 Definition of novelty (Chapter 6.1, page 56)

6. The report proposes a series of definitions (page 56) and concludes that pre-market assessment is necessary for plants that have no significant history of consumption in the EU, and for which there is insufficient knowledge in the general population for their safe consumption. The second part of this mirrors the equivalent definition that is currently in force in Australia and New Zealand. (Note: the ANZ authorities have recently (October 2005) proposed a revised definition that does not include this criterion, evidently on the grounds that it is too ambiguous).
7. The report suggests that, for some foods that are new to the EU, an initial judgement based on a history of safe use might reasonably conclude that they are not sufficiently "novel" to require a formal risk assessment.

Step 2 Risk assessment (Chapter 6.2, page 60)

8. The report notes that few novel plant foods will have closely-related counterparts already on the EU market. In such cases the novel food is, in principle, completely new in all traits and risk assessment cannot logically be focussed on specific points of difference with existing counterparts. The Nordic Working Group proposes a strategy for the risk assessment of this type of novel food (Figure 2, page 62). This results in a case-by-case approach which may require information on some or all of the items described in the diagram depending upon the nature of the food, its history of (safe) consumption, and the outcome of the earlier parts of the evaluation. This may, in some cases, result in an iterative risk assessment where further data requirements are identified as the evaluation progresses. The report suggests however that the 90-day rat feeding study has a role as a "biological filter" adding safety assurance to the earlier stages in the assessment scheme.
9. On quantitative terms, the report concludes that it is not appropriate to apply safety factors to the available safety data to derive a "safe" level of intake, as would be done for example to derive an Acceptable Daily Intake for a food additive. Instead, it recommends that the quantitative outcome of the risk assessment should be the Margin of Exposure (MoE) – the ratio between the likely level of human exposure and the estimated "safe" level of exposure that is identified in the hazard characterisation. Whether or not the MoE for a given product is sufficiently high for the novel food to be accepted would be a risk management decision.
10. The report also concludes that (page 63):

"the degree of safety assurance required or expected by the society is a societal and moral issue and therefore the implementation of mandatory animal safety studies and/or formal human epidemiological data in a fixed premarket data package is a management decision to be taken in the political system"

This appears to be a significant departure from current practice, where the minimum data requirements have been defined in guidance issued by the expert risk assessors, with little or no influence from risk managers.

11. Chapter 7 of the report provides more details of the data that might be used at various stages of the hazard characterisation and risk assessment. Chapter 8 is a more general discussion emphasising the need for closer dialogue between those involved in the risk assessment and risk management of novel foods.

Committee Action Required

12. This is a wide-ranging report that covers a number of complex issues related to the regulation of novel plant foods. The Committee is asked:

- Does it find this report useful, specifically in the context of the assessment and authorisation of “exotic”, minimally-processed plant products that have a significant history of “safe” use in other regions of the world?
- Does it support the proposal for a two-stage evaluation, in which an initial assessment defines whether or not a formal risk assessment is necessary? (para 4 above)
- Is it valid for risk managers to define the mandatory safety data requirements for novel foods? (para 10)
- Would it like to consider these or any other parts of the report in more detail at future meetings?

**Secretariat
January 2006**

Annex attached

Annex A: Knudsen, Søborg, Eriksen, Pilegaard and Pedersen (2005) “Risk assessment and risk management of novel plant foods: Concepts and principles”. Published by the Nordic Council of Ministers.

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Knudsen, Søborg, Eriksen, Pilegaard and Pedersen (2005) "Risk assessment and risk management of novel plant foods: Concepts and principles." Published by the Nordic Council of Ministers.

This report can be obtained via the Nordic Council website at:

www.norden.org