Scientific Colloquium Series

EFSA Scientific Colloquium n° 13

What's new on Novel Foods

Amsterdam, the Netherlands, 19 – 20 November 2009

BRIEFING NOTES FOR DISCUSSION GROUPS

These briefing notes are prepared to provide participants with the relevant background information so as to be prepared for an interactive exchange of views and expertise during the Colloquium.

Background

Novel foods are foods and food ingredients that were not used for human consumption to a significant degree within the European Community before 15 May 1997. Regulation (EC) No 258/97 of January 1997 lays out detailed rules for the authorisation of novel foods and novel food ingredients. These rules were applicable also to foods containing or consisting of a genetically modified organism (GMO) until 2003 when the Regulation on genetically modified food and feed came into force. The scientific aspects of information necessary to support applications for placing on the European market novel foods and novel food ingredients were addressed by recommendations of the Scientific Committee on Food (SCF).

In 2003 EFSA took over the tasks of the SCF in providing a safety assessment on novel food applications requested by the European Commission. In the light of the upcoming revision of the Novel Food Regulation and considering the significant development of emerging sciences such as nanotechnology and the proposed introduction of the assessment of traditional foods from non-EU countries on the basis of a history of safe use, EFSA expects to be asked by the European Commission to provide scientific and technical guidance for applicants in their preparation and presentation of the application for novel food and novel food ingredients.

Objectives

- To bring together international experts and interested parties from different sectors for an open scientific debate on key issues related to the foreseen revision of the Novel Foods Regulation that will serve as input for the preparation of an EFSA Guidance for applicants.
- Discussions will focus on various aspects in the safety assessment of Novel Foods including traditional foods from countries outside the EU, history of (safe) use, toxicological data requirements, the derivation of acceptable/tolerable intake levels, allergenicity, intake assessment, and emerging sciences such as nanotechnology.

Organizing Committee

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General background documents

- Commission Recommendation 97/618/EC concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council. OJ L 253 , 16/09/1997 P. 1 – 36. Available at: http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997H0618&model=guichett
- Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX. COM(2007) 872 final. Available at: http://ec.europa.eu/food/food/biotechnology/novelfood/COM872_novel_food_proposal_en.pdf
- Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Available at: http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997R0258&model=guichett
- Summary report on the impact assessment for a Regulation replacing Regulation (EC) no 258/97 on novel foods and novel food ingredients. Available at: http://ec.europa.eu/food/food/biotechnology/novelfood/nf_summary_ia_en.pdf

DISCUSSION GROUP 1 - *History of (safe) use and traditional foods from non-EU-countries*

INTRODUCTION

The revision proposed by the European Commission (EC) for the Novel Food Regulation aims a safety assessment based on history of safe food use for traditional foods from third countries. If the history of safe food use in the country of origin has been demonstrated, and the Member States and EFSA do not present reasoned safety objections, based on scientific evidence, the food could be placed on the market on the basis of a notification of the food business operator intending to market the food.

"Traditional food from a third country" are defined by this proposal as novel food with a "history of food use" in a third country, meaning that the food in question has been and continues to be part of the normal diet for at least one generation in a large part of the population of the country. According to the EC's proposal, "History of safe food use" means that the safety of the food in question should be confirmed with compositional data and from experience of use and continued use in the normal diet of a large part of the population of a country. Instead, Constable et al., have argued that the term "history of safe use" should be regarded as a working concept used to assist the safety assessment of a food product. The description of a 'history of safe use' is not a safety assessment in itself, but can help with data to support the safety of a new product and highlight knowledge gaps or concerns.

The discussion should take into account that EFSA's task will not be to classify whether a food is a "traditional food", but EFSA might be tasked to issue guidance for applicants on how to prepare and present data on the "history of safe food use" subject to such a notification procedure for traditional foods.

DISCUSSION POINTS

1. Can general requirements for the food characteristics and compositional data be specified applicable to all traditional foods, to foods with novel breeding methods, to foods that are marketed to another target group and to foods that are consumed at another stage of their development?
2. How detailed should data on the macronutrients and micronutrients be documented (amount and type of fat, protein, carbohydrates, or also the lipid acid profile, amino acids, vitamins, minerals, ...).
3. What are the data requirements to establish the "specifications" of such as batch testing, methods, validations, certification and documentation?
4. Which data should be requested for the history of safe use (including possible adverse effects)?
5. Discuss the data requirements and the relevance with respect to 'significant changes' related to the production process, considering composition, residuals and critical toxicants.
6. Which considerations should be addressed by an applicant with regards to non-nutritive dietary constituents such as secondary plant metabolites, anti-nutritional factors and contaminants.
7. What is the relevant information on the "experience of use and continued use in the normal diet of a large part of the population of a country", which should be provided by an applicant?

BACKGROUND DOCUMENTS

- Constable A, Jonas D, Cockburn A, Davi A, Edwards G, Hepburn P, Herouet-Guicheney C, Knowles M, Moseley B, Oberdörfer R, Samuels F. History of safe use as applied to the safety assessment of novel foods and foods derived from genetically modified organisms. Food Chem Toxicol. 2007 Dec;45(12):2513-25. Epub 2007 Jun 21. http://www.ilsi.org/Europe/Publications/2007Hist_Safe.pdf
- Jones, A. and Craddock, N., 2009, Definitions, Concepts and History of Safe Use Assessment. Issue Paper Prepared for UNCTAD BioTrade Initiative concerning the proposed amendment to the European Novel Foods Regulation with particular reference to Traditional Foods from Third Countries, UNCTAD and GTZ. Available at: http://www.biotrade.org/BTFP/BTFP-docs/novelfoods-issue.pdf
- Verhagen H., te Boekhorst J., Kamps L., van Lieshout M.J., Ploeger H., Verreth D., Salminen S., and van Loveren H. (2009). Novel Foods: an explorative study into their grey area. British Journal of Nutrition 101: 1270-1277. doi:10.1017/S0007114508184690. http://www.ncbi.nlm.nih.gov/pubmed/19175945

DISCUSSION GROUP 2 - *Data requirements and approach for anticipated intake*

INTRODUCTION

A proper estimate for anticipated intake (exposure assessment) for average and high consumers is a key element in risk assessment. The exposure assessment allows estimation whether the anticipated intake would be higher/lower than a specific toxicological reference value (e.g. tolerable upper intake level, acceptable daily intake). Where no such value has been derived it allows estimating the margin of safety (MOS), i.e. the anticipated intake in relation to a no-observed adverse effect level (NOAEL) from an appropriate toxicological study.

DISCUSSION POINTS

1. What are the requirements for a food consumption database for the purpose of intake assessment for the population in the EU?
2. Discuss different approaches to derive intake estimates, their advantages and disadvantages. How can "reasonable worst case" intake estimates be derived for high consumers? How to derive a reasonable intake estimate for the average consumer?
3. Discuss uncertainties when estimating intakes, and how to address them.
4. Which approach should be followed by the applicant for his proposal of an intake estimate? What kind of data is required from the applicant?

BACKGROUND DOCUMENTS

- Project to update the principles and methods for the assessment of chemicals in food Request for comments on draft document, Posted 30 June 2008. Chapter 6: Dietary exposure assessment.
  http://www.who.int/ipcs/food/dietary_exposure.pdf
- The Acceptable Daily Intake: A Tool for Ensuring Food Safety
  http://www.ilsi.org/Europe/Publications/C2000Acc_Dai.pdf

DISCUSSION GROUP 3 - *Key issues in absorption, distribution, metabolism, and excretion (ADME) studies, toxicology and allergenicity*

INTRODUCTION

Novel foods and novel food ingredients comprise a wide variety of different types of products, i.e. single chemical substances, simple or complex mixtures as well as complex foods. Therefore the specific requirements for the safety assessment need to be considered on a case-by-case basis. In the risk assessment process toxicological testing may be required for hazard identification and hazard characterisation. The results of studies on toxicokinetics (absorption, distribution, metabolism and excretion – ADME) should be taken into account when considering the toxicological testing programme. Whereas this approach functions well for single substances and defined mixtures, the testing of complex foods poses specific problems, and more than for single substances and well defined mixtures, data from human studies may be required for the safety evaluation.

There are currently no validated approaches for the prediction of allergenicity of food. This may become more of an issue with foods coming to the market, that have hitherto not been used in the EU, but that have a history of use outside of the EU.

The discussion in this group will not deal with nanotechnology issues as this is dealt with separately by discussion group 4: Data requirements to demonstrate safety of foods derived by nanotechnologies.

DISCUSSION POINTS

1. How should the different types of novel foods and food ingredients be tested? Is it possible/appropriate to recommend standard toxicological testing programmes for specific types of products in order to derive safe intake levels for consumers?
2. What are the key issues for ADME studies in the safety testing of food ingredients (i.e. single substances and chemical mixtures) and complex novel foods?
3. What are the criteria to be applied in the safety assessment of complex foods? Are specific toxicological studies required and how can applicants be advised in making the respective decisions?
4. Should a subchronic (90-day) feeding study in rodents be generally recommended? In which cases should additional studies be conducted, e.g. on chronic toxicity, reproductive and developmental toxicity, neurotoxicity, immunotoxicity, endocrine activity? Should genotoxicity studies be carried out and which ones are appropriate? When are animal studies sufficient, and when are human safety studies required?
5. Can concerns on the allergenic risk of traditional foods be addressed based on "compositional data" and on "experience of continued use in the normal diet of a large part of the population of a country"? If not, how should applicants demonstrate that a food is not of concern with regards to its allergenic potential, and what kind of testing scheme can be followed? Is there a hierarchy for certain tests?

BACKGROUND DOCUMENTS

- EFSA Scientific Committee. Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. EFSA Journal 2009; 7(9):1249. [19 pp.]. doi:10.2093/j.efsa.2009.1249. Available online: www.efsa.europa.eu
- Report of the EFSA GMO Panel Working Group on Animal Feeding Trials. Safety and nutritional assessment of GM plants and derived food and feed: The role of animal feeding trials. Food and Chemical Toxicology 46 (2008) S2–S70 http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902590265.htm
- Scientific Committee on Food. SCF/CS/ADD/GEN/26 Final. 12 July 2001. Guidance on submission for food additive. Evaluations by the Scientific Committee on food. Available at: http://ec.europa.eu/food/fs/sc/scf/out98_en.pdf

DISCUSSION GROUP 4 - *Data requirements to demonstrate safety of foods derived by nanotechnologies*

INTRODUCTION

The special characteristics and properties of engineered nanomaterials (ENMs), such as the small size, surface reactivity and translocation across biological membranes as well as interactions of ENMs with the surrounding matrix and unexpected effects resulting from this may require generation of specific data for risk assessment purposes. There is a need for proper identification (including physico-chemical characterization) of ENMs used in the food and feed sector. There are at present difficulties detecting ENMs in food and feed matrices and consequently exposure assessment is difficult. Generic data requirements and guidance for risk assessment of ENMs have been presented in various reports over the last five years, including OECD documents and the recent EFSA Opinion. However, today there is still a lack of detailed description of data requirements to demonstrate the safety of foods derived from nanotechnologies.

DISCUSSION POINTS

1. In addition to the OECD endpoints, are there other appropriate endpoints for food risk assessment?
2. Can food groups be grouped for ENM risk assessment, and if so, what criteria could be applied?
3. Assess current knowledge and identify data gaps on ENM stability in various food matrices and in the gastro-intestinal tract.
4. Try to define crucial elements for a tiered risk assessment for soluble and endogenous ENMs (e.g. vitamins, nutrients).
5. Please list possible methods (advantages and disadvantages) to assess changes in bioavailability.
6. Specify data requirements and discuss suitable methods to generate data for exposure assessment.

BACKGROUND DOCUMENTS

- EFSA Scientific Opinion: The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety, especially section 3, 4 and 6, and conclusions and recommendations. The EFSA Journal (2009) 958, 1-39. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm
- OECD, Preliminary review of OECD test guidelines for their applicability to manufactured nanomaterials. ENV/JM/MONO(2009)21. http://www.olis.oecd.org/olis/2009doc.nsf/linkto/env-jm-mono(2009)21
- OECD, List of Manufactured Nanomaterials and List of Endpoints for Phase One of the OECD Testing Programme. No. 6 - ENV/JM/MONO(2008)13/REV. http://appli1.oecd.org/olis/2008doc.nsf/linkto/env-jm-mono(2008)13-rev
- SCENIHR 2009 (Scientific Committee on Emerging and Newly Identified Health Risks), 19 January 2009, Risk assessment of products of nanotechnologies http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf
- Zolnik BS, Sadrieh N (2009). Regulatory perspective on the importance of ADME assessment of nanoscale material containing drugs. Adv Drug Deliv Rev. 2009 Jun 21;61(6):422-7. Epub 2009 Apr 20. http://www.ncbi.nlm.nih.gov/pubmed/19389437