

Unclassified

ENV/JM/MONO(2006)10

Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

20-Apr-2006

English - Or. English

**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

Series on the Safety of Novel Foods and Feeds, No 14

**AN INTRODUCTION TO THE FOOD/FEED SAFETY CONSENSUS DOCUMENTS OF THE TASK
FORCE**

JT03207766

Document complet disponible sur OLIS dans son format d'origine
Complete document available on OLIS in its original format



**ENV/JM/MONO(2006)10
Unclassified**

English - Or. English

Also published in the Series on the Safety of Novel Foods and Feeds:

- No. 1, Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) (2001)
- No. 2, Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients (2001)
- No. 3, Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-Nutrients (2002)
- No. 4, Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants (2002)
- No. 5, Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, February 2001 (2002)
- No. 6, Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites (2002)
- No. 7, Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (*Triticum aestivum*): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2003)
- No. 8, Report on the Questionnaire on Biomarkers, Research on the Safety of Novel Foods and Feasibility of Post-Market Monitoring (2003)
- No. 9, Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants (2003)
- No. 10 Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients and Anti-nutrients (2004)
- No. 11 Consensus Document on Compositional Considerations for New Varieties of Cotton (*Gossypium hirsutum* and *Gossypium barbadense*): Key Food and Feed Nutrients and Anti-nutrients (2004)
- No. 12 Consensus Document on Compositional Considerations for New Varieties of Barley (*Hordeum vulgare* L.): Key Food and Feed Nutrients and Anti-Nutrients (2004)
- No. 13 Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites (2005)

© OECD 2006

Applications for permission to reproduce or translate all or part of this material should be made to: Head of Publications Service, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16, France.

OECD Environment, Health and Safety Publications

Series on the Safety of Novel Foods and Feeds

No. 14

**AN INTRODUCTION TO THE FOOD/FEED SAFETY
CONSENSUS DOCUMENTS OF THE TASK FORCE FOR
THE SAFETY OF NOVEL FOODS AND FEEDS**

Environment Directorate

Organisation for Economic Co-operation and Development

Paris 2006

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in nine different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides and Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; and Emission Scenario Documents.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (<http://www.oecd.org/ehs/>).

This publication is available electronically, at no charge.

**For this and many other Biosafety publications, consult the OECD's
World Wide Web site (www.oecd.org/biotrack/)**

or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division**

**2 rue André-Pascal
75775 Paris Cedex 16
France**

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

FOREWORD

The OECD's Task Force for the Safety of Novel Foods and Feeds decided at its first session, in 1999, to focus its work on the development of science-based *consensus documents*, which are mutually acceptable among member countries. These consensus documents contain information for use during the regulatory assessment of a particular food/feed product. In the area of food and feed safety, consensus documents are being published on the nutrients, anti-nutrients or toxicants, information of its use as a food/feed and other relevant information.

This text was prepared by the Task Force for the Safety of Novel Foods and Feeds to provide an introduction to the consensus documents of the OECD's Task Force. It explains, amongst other things, why the Task Force decided to prepare consensus documents as part of its programme of work. It describes their purpose and their use as a practical contribution to the risk/safety assessment of foods and feeds derived from transgenic organisms. It also explains the process by which consensus documents are drafted and brought to final publication.

This document is published on the responsibility of the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals of the OECD.

TABLE OF CONTENTS

About OECD's Task Force	7
The Emergence of the Concept of Consensus Documents.....	7
The Purpose of Consensus Documents	8
Current and Future Trends in the Task Force.....	10
ANNEX I LIST OF TASK FORCE CONSENSUS DOCUMENTS	10
ANNEX I LIST OF TASK FORCE CONSENSUS DOCUMENTS	11
ANNEX II BIOSAFETY CONSENSUS DOCUMENTS PUBLISHED BY THE WORKING GROUP...	12
ANNEX III REFERENCES/ADDITIONAL READING.....	14
ANNEX IV	14
ANNEX IV	15

This text describes the origin of OECD's Task Force for the Safety of Novel Food and Feeds and explains why Consensus Documents were included as the main part of its work. It also addresses the purpose of these documents and their intended use as a practical contribution to the risk/safety assessment of foods and feeds derived from transgenic organisms.

About OECD's Task Force

The Task Force for the Safety of Novel Foods and Feeds was established in 1999. One of the primary goals of the Task Force is to promote international harmonisation in biotechnology among member countries. Regulatory harmonisation is the attempt to ensure that the information used in risk/safety assessments, as well as the methods used to collect such information, are as similar as possible. It could lead to countries recognising or even accepting information from one another's assessments. The benefits of harmonisation are clear. It increases mutual understanding among member countries, which avoids duplication, saves on scarce resources and increases the efficiency of the risk/safety assessment process. This in turn improves safety, while reducing unnecessary barriers to trade (OECD 2000).

OECD's Task Force comprises delegates from the 30 Member countries of OECD and the European Commission. A number of observer delegations and invited experts also participate in its work. They include: Argentina; the Russian Federation; Slovenia; the Food and Agriculture Organization of the United Nations (FAO); the World Health Organization (WHO); and the Business and Industry Advisory Committee to OECD (BIAC). Since 2002, a number of other non-member countries have participated in activities of the Task Force under the auspices of OECD's Centre for Co-operation with Non-member countries (CCNM) and its Global Forum on the Knowledge-based Economy.

Typically, delegates are from those government ministries and agencies, which have responsibility for the food or feed safety assessment of products of modern biotechnology, including foods and feeds derived from transgenic organisms. In some OECD countries this is the Ministry of Health; in others it is the Ministry of Agriculture. Other countries have specialised agencies with this responsibility. Often, it is a shared responsibility among more than one ministry or agency. The expertise that these delegates have in common is related to their experience with food and or feed safety assessment.

The Emergence of the Concept of Consensus Documents

By 1997, several OECD countries had gained experience with safety assessment of foods derived through modern biotechnology. An OECD Workshop at Aussois, France, examined the effectiveness of the application of substantial equivalence in safety assessment. It was concluded that the determination of substantial equivalence provides equal or increased assurance of the safety of foods derived from genetically modified plants, as compared with foods derived through conventional methods (OECD, 1998).

At Aussois, it was also recognised that a consistent approach to the establishment of substantial equivalence might be improved through consensus on the appropriate components (*e.g.* key nutrients, key toxicants and anti-nutritional compounds) on a crop-by-crop basis, which should be considered in the comparison. It is recognised that the components may differ from crop to crop.

Following the Aussois Workshop, there was a detailed analysis of whether there was a need to undertake work on food/feed safety at OECD, and if so, what that work would entail. This analysis was undertaken by an Ad Hoc Group on Food safety (established by the Joint Meeting¹). It took into account

1. The Joint Meeting was the supervisory body of the Ad Hoc Group and, as a result of its findings, established the Task Force as a subsidiary body. Today, its full title is the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

the results of national activities, the results of previous OECD work, as well as the activities of FAO and WHO.

As a result of the work of the Ad Hoc Group, the Joint Meeting established the Task Force with the development of consensus documents on compositional data as a major part of its programme of work. These data are used to identify similarities and differences following the **comparative approach** as part of a food and feed safety assessment. They should be useful to the development of guidelines, both national and international and to encourage information sharing among OECD member countries as well as with non OECD member economies.

Participation from non OECD member economies is strongly encouraged by the Task Force. This exchange has increased and now involves more actively the expertise, for example two consensus documents, papaya (Thailand) and cassava (South Africa), are being drafted in co-operation with member countries. This broadens the expertise that is available to the Task Force, while addressing a wider range of food and feed products that are of global interest.

The Purpose of Consensus Documents

These documents are a compilation of current information that is important in food and feed safety assessment. They provide a technical tool for regulatory officials, and also for industry and other interested parties, as a general guide and reference source, while complementing those of the Working Group on Harmonisation of Regulatory Oversight in Biotechnology (Annex II). They are mutually acceptable to, but not legally binding on, member countries. They are not intended to be a comprehensive description of all issues considered to be necessary for a safety assessment, but a base set for an individual product that supports the comparative approach. In assessing an individual product, consideration of additional components may be required depending on the specific case in question.

Key background concepts and principles

The work of the Task Force builds on previous OECD's experience in biotechnology safety-related activities, dating back to the mid-1980s. Initially, much of the work concentrated on the environmental and agricultural implications of the use of transgenic crops. By the end of 1990, however, work had been established to develop scientific principles for food safety assessment of products of modern biotechnology. This work was often undertaken in parallel to complementary activities of FAO and WHO.

In 1990, a joint consultation of FAO and WHO established that the comparison of a final product with one having an acceptable standard of safety provides an important element of safety assessment (WHO, 1991).

In 1993 the OECD further elaborated this concept and advocated the approach to safety assessment based on substantial equivalence as being the most practical approach to addressing the safety of foods and food components derived through modern biotechnology (as well as other methods of modifying a host genome, including tissue culture methods and chemical or radiation induced mutation).

A Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety (1996) elaborated on compositional comparison as an important element in the determination of substantial equivalence. A comparison of critical components can be carried out at the level of the food source (*i.e.* species) or the specific food product. Critical components are determined by identifying key nutrients and key toxicants and anti-nutrients for the food source in question. The comparison of critical components should be between the modified variety and non-modified comparators with an appropriate history of safe use. The data for the non-modified comparator can be the natural ranges published in the literature for commercial varieties or those measured levels in parental or other edible varieties of the species (FAO/WHO, 1996).

The comparator used to detect unintended effects for all critical components should ideally be the near isogenic parental line grown under identical conditions. While the comparative approach is useful as part of the safety assessment of foods derived from plants developed using recombinant DNA technology, the approach could, in general, be applied to foods derived from new plant varieties that have been bred by other techniques.

The Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology in 2000 (FAO, 2000) concluded that the safety assessment of genetically modified foods requires an integrated and stepwise, case-by-case approach, which can be aided by a structured series of questions. A comparative approach focusing on the determination of similarities and differences between the genetically modified food and its conventional counterpart aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy for the safety and nutritional assessment of genetically modified foods. The concept of substantial equivalence was developed as a practical approach to the safety assessment of genetically modified foods. It should be seen as a key step in the safety assessment process, although it is not a safety assessment in itself; it does not characterise hazard, rather it is used to structure the safety assessment of a genetically modified food relative to a conventional counterpart. The Consultation concluded that the application of the concept of substantial equivalence contributes to a robust safety assessment framework.

Between 2000 and 2003, the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology undertook work to develop principles and guidelines for foods derived from biotechnology. The full report of the Codex Task Force to the Codex Alimentarius Commission in 2003 included:

- Principles for the risk analysis of foods derived from modern biotechnology.
- A Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants.
- A Guideline for the conduct of food safety assessment of foods produced using recombinant-DNA micro-organisms.

One notable feature of the Principles is that they make reference to a safety assessment involving the comparative approach between the food derived from modern biotechnology and its conventional counterpart.

In addition, the OECD Task Force is working closely with the Codex Task Force in order to strengthen their complementary activities.

The Process through which Consensus Documents are Initiated and Brought to Publication

There are a number of steps in the drafting of a specific consensus documents. The first step occurs when a delegation, in a formal meeting of the Task Force, makes a proposal to draft a document on a new topic, typically a major food crop. This is made in writing, at least six weeks before a Task Force meeting. If the Task Force agrees to the proposal, a first draft is prepared by either a single country or two or more countries working together. This is often called the "lead country approach". Typically, the lead country(ies) has had experience with the crop in question and is able to draw on experts to prepare a provisional draft.

The first draft is then considered by the full Task Force. This is the opportunity for each delegation to review the text, tables and figures, and provide comments based on data and information provided by its scientific experts. The incorporation of the data and information into the draft document leads to a second

draft, which is again circulated for review and comment to the Task Force. At this point, the Task Force may be asked to recommend that the document be declassified. Such a recommendation is only forthcoming when all delegations have come to a consensus that the document is complete and ready for publication. Sometimes, however, the text may need a third or even a fourth discussion in the Task Force before a recommendation for declassification is possible.

When the Task Force has agreed that a document can be recommended for declassification, it is forwarded to the supervisory Committee, *the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology* (Chemicals Committee), which is invited to declassify the document. Following the agreement of the Joint Meeting, the document is then published.

It is important to note that the review of Consensus Documents is not limited to formal meetings of the Task Force. Much discussion also occurs through electronic means, especially via the Task Force's Electronic Discussion Group (EDG). This enables a range of experts to have input into drafts.

Current and Future Trends in the Task Force

The Task Force is currently continuing its work on a range of issues designed to promote international harmonisation in the field of food/feed safety assessment. However, the main area of work remains the development of consensus documents.

In order to ensure that scientific and technical developments are taken into account, member countries have agreed that consensus documents will be reviewed periodically and updated as necessary. Users of these documents have been invited to provide the OECD with new scientific and technical information, and to make proposals for additional areas to be considered.

A current issue is to consider whether the consensus documents are also useful within the context of the work of the Codex Alimentarius Commission (Codex) and how to continue strengthening complementary work between Codex work and OECD work.

ANNEX I
LIST OF TASK FORCE CONSENSUS DOCUMENTS

- No. 1 Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (*Canola*), 2001
- No. 2 Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-Nutrients, 2001
- No. 3 Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Antinutrients, 2002
- No. 4 Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants, 2002
- No. 6 Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea Mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites, 2002
- No. 7 Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (*Triticum aestivum*): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants, 2003
- No. 9 Considerations for the Safety Assessment of Animal Feedstuffs derived from Genetically Modified Plants, 2003. Also available in Japanese
- No. 10 Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients and Anti-Nutrients, 2004
- No. 11 Consensus Document on Compositional Considerations for New Varieties of Cotton (*Gossypium hirsutum* and *Gossypium barbadense*): Key Food and Feed Nutrients and Anti-Nutrients, 2004
- No. 12 Consensus Document on Compositional Considerations for New Varieties of Barley (*Hordeum vulgare* L.): Key Food and Feed Nutrients and Anti-nutrients
- No. 13 Consensus Document on Compositional Considerations for New Varieties of Alfalfa and other Temperate Forage Legumes: Key Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites

ANNEX II BIOSAFETY CONSENSUS DOCUMENTS PUBLISHED BY THE WORKING GROUP

To date, 24 consensus documents have been published by OECD's Working Group for Harmonisation of Regulatory Oversight in Biotechnology. They are complementary to those of the Task Force as they deal with environmental safety issues. These consensus documents comprise technical information for use during environmental regulatory assessment of products of biotechnology and are intended to be mutually recognised among OECD Member countries. They focus on the biology of organisms (such as plants, trees or micro-organisms) or introduced novel traits. A description of the Working Group and its consensus documents are given in the published text, *An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology* [ENV/JM/MONO(2005)5].

The full list of published documents is as follows:

- Information concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection (1996)
- Information Used in the Assessment of Environmental Applications Involving *Pseudomonas* (1997)
- The Biology of *Brassica napus* L. (Oilseed Rape) (1997)
- The Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato) (1997)
- The Biology of *Triticum aestivum* (Bread Wheat) (1999)
- Information Concerning the Genes and their Enzymes that Confer Tolerance to Glyphosate Herbicide (1999)
- Information Concerning the Genes and their Enzymes that Confer Tolerance to Phosphinothricin Herbicide (1999)
- The Biology of *Picea abies* (L.) Karst (Norway Spruce) (1999)
- The Biology of *Picea glauca* (Moench) Voss (White Spruce) (1999)
- The Biology of *Oryza sativa* (Rice) (1999)
- The Biology of *Glycine max* (L.) Merr. (Soybean) (2000)
- The Biology of *Populus* L. (Poplars) (2000)
- The Biology of *Beta vulgaris* L. (Sugar Beet) (2001)

- Information used in the Assessment of Environmental Applications Involving Baculovirus (2002)
- The Biology of *Picea sitchensis* (Bong.) Carr. (Sitka Spruce) (2002)
- The Biology of *Pinus strobus* L. (Eastern White Pine) (2002)
- The Biology of *Prunus sp.* (Stone Fruits) (2002)
- Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants (2002)
- The Biology of *Zea maize subsp.mays* (Maize) (2003)
- The Biology of European White Birch (*Betula pendula Roth*) (2003)
- The Biology of *Helianthus Annuus* L. (Sunflower) (2004)
- An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology (2005).
- The Biology of Papaya (*Carica Papaya*) (2005)
- The Biology of *Pleurotus spp.* (Oyster Mushroom) (2005)
- Points to Consider for Consensus Documents on the Biology of Cultivated Plants (2006)

**ANNEX III
REFERENCES/ADDITIONAL READING**

- FAO/WHO Joint Consultation Report, Biotechnology and Food Safety. FAO Food and Nutrition Paper 61. Food and Agriculture Organization of the United Nations (FAO), Rome, 1996.
- Organisation for Economic Co-operation and Development (OECD), Safety Considerations for Biotechnology: Scale-up of Crop Plants, OECD, Paris, 1993, a.
- Organisation for Economic Co-operation and Development (OECD), Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles, OECD, Paris, 1993.
- Organisation for Economic Co-operation and Development (OECD), Food Safety Evaluation (Oxford Workshop Report), OECD, Paris, 1996.
- Organisation for Economic Co-operation and Development (OECD), Report of the OECD Workshop on the Toxicological and Nutritional Testing of Novel Foods (Aussois, France, 5-8 March 1997), OECD, Paris, 1998.
- Organisation for Economic Co-operation and Development (OECD) The web site of Task Force for the Safety of Novel Foods and Feeds can be accessed via: <http://www.oecd.org/biotrack/>
- Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology;
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
- Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Micro-organisms.

ANNEX IV

This text is provided as the first page of all published consensus documents. It is shown here to address an issue raised during the special session on consensus documents at the 9th meeting of the Task Force. That is, that the secretariat contact points should be clearly identified so that copies of consensus documents can easily be requested by users.

ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Pacific, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised Committees and subsidiary groups composed of Member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's Workshops and other meetings. Committees and subsidiary groups are served by the OECD Secretariat, located in Paris, France, which is organised into Directorates and Divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in nine different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides and Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; and Emission Scenario Documents.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (<http://www.oecd.org/ehs/>).

This publication is available electronically, at no charge.

**For the complete text of this and many other Biosafety publications, consult the OECD's
World Wide Web site (<http://www.oecd.org/biotrack>)**

or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division**

**2 rue André-Pascal
75775 Paris Cedex 16
France**

Fax: (33-1) 45 24 16 75

E-mail: ehscont@oecd.org