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English - Or. English

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

ENV/JM/FOOD/M(2009)1
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Task Force for the Safety of Novel Foods and Feeds

DRAFT SUMMARY RECORD OF THE 15th MEETING OF THE TASK FORCE

held in Paris, France, on 10-12 February 2009

JT03261450

English - Or. English

General points

The 15th Meeting of the Task Force for the Safety of Novel Foods and Feeds took place at the OECD Headquarters, Paris, France from 10 February (10 a.m.) to 12 February 2009 (1: p.m.). The list of participants is shown in Annex II.

A joint session with the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology (WG-HROB) was organised on 10 February afternoon, mainly to discuss items 12, 13 and 14 reported below.

Item 1 Adoption of the Draft Revised Agenda

The Agenda for the meeting [ENV/JM/FOOD/A(2009)1/REV1] was adopted without changes.

Item 2 Adoption of the Draft Summary Record of the 14th Meeting

The Summary Record of the last meeting of the Task Force held in Paris on 8-10 April 2008 [ENV/JM/FOOD/M(2008)1] was adopted with the following editorial change: page 6, paragraph 36, the deadline for comments should read May ***2007*** (instead of May 2008).

Item 3 Developments since the 14th Meeting – Report from the Secretariat

Delegates took note of the report made by the Secretariat, including agreements reached at the last Joint Meeting and updates on WG-HROB developments, as summarised in ENV/JM/FOOD(2009)1.

Item 4 Developments on Safety Assessment of Novel Foods/Feeds in Delegations – a Tour de Table

Summaries of statements presented by delegations (texts provided to the Secretariat in advance to the meeting or within the 27 Feb. 09 deadline) are reproduced in Annex I. The PowerPoint presentation from ILSI is available at the Task Force password-protected Website.

Item 5 Consensus Document on Cassava

Document ENV/JM/FOOD(2006)6/REV3 with Addendum 1, presented by South Africa, was found to be good but needing improvements before declassification. It was agreed for an ad hoc group of experts from South Africa (leader), Canada, Brazil, Sweden and the United States to finalise it as follows:

- Brazil, Canada, Sweden and the US will transmit major revised sections to South Africa, with copy to the Secretariat. South Africa will prepare a comprehensive draft revision, taking also into account other changes suggested during the 15th Meeting, by 30th April 2009.
- The ad hoc group will examine the draft and provide comments to the OECD Secretariat by 30th June 2009. A new version (draft REV4) will be prepared accordingly and placed on the password-protected Website by 15th July 2009.
- All delegates will be invited to examine the draft REV4 and to provide remarks with last minor changes to the OECD Secretariat by 15th September 2009.
- Pending no significant adverse comment, the Secretariat will finalise the text and submit REV4 to the Joint Meeting for ***declassification***. The new Consensus Document is aimed to be issued before the 16th Meeting of the Task Force (mid-November).

Item 6 Consensus Document on Sweet Potato

The Task Force agreed to recommend declassification of document ENV/JM/FOOD(2007)2/REV2, presented by Japan, pending some amendments and according to the following schedule:

- The United States (regarding Tables) and Canada (regarding biofuel and allergens sections) will provide their amended texts to the Secretariat by 15th April 2009.
- South Africa and Japan will prepare a revision accordingly, taking also into account other changes suggested during the 15th Meeting, to be sent to the Secretariat by 1st July 2009. The new version (draft REV3) will be prepared and placed on the password-protected Website by 15th July 2009.
- All delegates will be invited to examine the draft REV3 and to provide remarks with last minor changes to the OECD Secretariat by 15th September 2009.
- Pending no significant adverse comment, the Secretariat will finalise the text and submit REV3 to the Joint Meeting for ***declassification***. The new Consensus Document is aimed to be issued before the 16th Meeting of the Task Force (mid-November).

Item 7 Draft Consensus Document on Grain Sorghum

- Delegates are invited to provide written comments and inputs on the first draft ENV/JM/FOOD(2009)2 to the United States, with copy to the Secretariat, by 10th April 2009.
- The United States will prepare a new version accordingly (REV1), to be sent to the Secretariat by 12th September 2009 latest deadline, for submission at the 16th Meeting.

Item 8 Draft Consensus Document on Papaya

- Thailand and the United States will prepare a new version (REV3) of April 2007 paper [ENV/JM/FOOD(2006)2/REV2], to be sent to the Secretariat by 12th September 2009 latest deadline, for submission at the 16th Meeting.

Item 9 Draft Consensus Document on Sugarcane

- Australia, lead country in the preparation of a new document, called for assistance from other experts. Brazil, South Africa and BIAC expressed their wish to participate and should identify suitable specialists in the coming weeks. Other delegations interested to be part of the ad hoc experts group are invited to inform the Secretariat as soon as possible.
- Australia and assisting experts will prepare a first draft document, to be sent to the Secretariat by 12th September 2009 latest deadline, for submission at the 16th Meeting.

Item 10 Draft Revised Consensus Document on Low Erucic Acid Rapeseed

- Delegates are invited to provide: a) written comments on the first draft ENV/JM/FOOD(2009)6; and b) additional compositional data for food and for feed to Canada with copy to the Secretariat, by 10th April 2009.
- Canada will prepare a new version accordingly (REV1), to be sent to the Secretariat by 12th September 2009 latest deadline, for submission at the 16th Meeting.

Item 11 Draft Revised Consensus Document on Soybean

- Delegates are invited to provide: a) written comments on the first draft ENV/JM/FOOD(2009)5; and b) additional compositional data for food and for feed to the United States with copy to the Secretariat, by 10th April 2009.

- The United States will prepare a new version accordingly (REV1), to be sent to the Secretariat by12th September 2009 latest deadline, for submission at the 16th Meeting.

Item 12 Molecular Characterisation Project

The revised draft Consensus Document ENV/JM/FOOD(2007)3/REV1, prepared by the Steering Group, was discussed during the Joint Session with the WG-HROB. Significant progress was acknowledged, and the following process was agreed for further developments:

- Delegates of the Task Force and the Working Group are invited to submit written comments on the draft document to the Secretariat by 1st May 2009.

- The Steering Group will prepare a new draft (REV2) accordingly, to be submitted to the Secretariat by 1st September 2009, for examination by the next meetings of the WG-HROB and the Task Force.

Item 13 Update on FAO-OECD Database Interoperability

- As presented during the Joint Session with the WG-HROB, a final report will be presented by the Secretariat at the 16th TF meeting.

Item 14 Progress Report on Consensus Document on the Biology of Atlantic Salmon

During the Joint Session, an update was given on the Biology document on Atlantic Salmon (*Salmo salar*) developed by the WG-HROB. The draft text, recently completed for discussion at the 22nd meeting of the Working Group [ENV/JM/BIO(2008)4/REV2], is currently open for comments. A finalised version might be submitted for agreement at the next WG-HROB meeting.

Item 15 EC Proposal for inclusion of whole-food testing in the OECD Test Guideline No.408; Repeated Dos 90-day toxicity study in rodents

The proposal [ENV/JM/FOOD(2009)3], prepared by the European Food Safety Authority (EFSA), was submitted by the European Commission. If agreed, the project would have to be implemented in collaboration with the OECD Test Guidelines Programme (WNT). The Task Force did not reach a consensus on the proposal, but agreed on this follow-up:

- The Secretariat will prepare a paper for presenting the situation to -and seeking for advice from- the *Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology* (parental body of both the Task Force and the Test Guidelines Programme), at its next meeting to be held on 8-12 June 2009.

- The Task Force will be invited to comment on the draft document, to be made available as soon as possible.

Item 16 Quality of the data for the Consensus Documents

- The Task Force is invited to send written comments on document ENV/JM/FOOD(2009)4, as well as additional suggestions for moving forward this issue, to the OECD Secretariat by 10th May 2009.
- The Secretariat will report on inputs received and ways identified to move forward at the 16th Meeting.

Item 17 Resources

The Secretariat reminded the status of the budget needed by the Task Force to implement its work programme [see ENV/JM/BIO(2009)1], supported primarily through extra-budgetary resources. It is important that member countries continue to provide the necessary contributions.

Item 18 Date of Next Meeting

- The 16th TF Meeting will be held on **17-19 November 2009** in Paris, France.

Item 19 Other Business

ILSI-IFBiC offered to possibly hold a Workshop back-to-back with the 16th TF Meeting, in order to exchange information and favour synergies on toxicology studies and other resources developed by this Organisation of common interest. This could take place on 16 or 20 November 2009 in Paris, allowing for interested delegates to participate. A decision will be taken by ILSI later this year.

The Task Force members and the OECD Secretariat wish to express to the delegation of Australia their deepest sympathy at the recent death of Dr. Carol Andersson, Senior Food Scientist at the Risk Assessment Branch of Food Standards Australia New Zealand (FSANZ), after a long battle with illness.

Dr. Andersson will be greatly missed by all Task Force delegates for her high level of competence and friendship. A moment of silence was observed during the meeting in her memory. We also wish to express our condolences to Dr. Andersson's family and her colleagues in the FSANZ biotechnology team.

ANNEX I

RECENT DEVELOPMENTS ON SAFETY ASSESSMENT OF NOVEL FOODS & FEEDS IN DELEGATIONS (SUMMARIES OF "TOUR DE TABLE" STATEMENTS)

AUSTRALIA

New Approvals

Since the last Task Force meeting in April 2008, Food Standards Australia New Zealand (FSANZ) has approved food from the following genetically modified (GM) crops:

- Insect-protected corn line MON89034 (Application A595) [1]
- Insect-protected cotton line COT67B (Application A615) [2]
- Glyphosate tolerant cotton line GHB614 (Application A614) [3]
- Insect-protected CORN line MIR162 (Application A1001) [4]

A total of 37 GM food crops are now approved in Australia. The final assessment reports, which include the safety assessments, are available from the FSANZ website (links provided in the footnotes below). The approval given to insect-protected cotton COT67B and glyphosate tolerant cotton GHB614 is currently being considered by the Ministerial Council. The approval given to insect-protected corn line MIR162 is currently under Ministerial review.

Ongoing Assessments

FSANZ is currently in the process of assessing foods from the following GM crops:

- Herbicide tolerant soybean event DP-356043-5 (Application A1006)
- High Oleic Acid Soybean Line DP-305423-1 (Application A1018)

FSANZ is also assessing the following as a novel food:

- Conjugated Linoleic Acid (CLA) (Applications A1005 and A1012; different applicants) [*Note*: both CLA applications are currently on hold while the Applicants address a number of technical questions.]

Impact of Austrian reproduction study on the safety of GM corn lines MON810 and NK603

A report titled, *Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice*, was posted on the website of the Austrian Ministry of Health, Family and Youth in November 2008. FSANZ reviewed the data and statistical analyses presented in the report to ascertain

[1] http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa595foodd3492.cfm

[2] http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa615foodd3783.cfm

[3] http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa614foodd3782.cfm

[4] http://www.foodstandards.gov.au/standardsdevelopment/applications/applicationa1001food3769.cfm

whether the findings could have an impact on the previous safety assessment of corn lines MON810 and NK603. The complete FSANZ review of the Austrian report is available on the FSANZ web site[5].

Despite the comprehensive nature of the studies, the results showed no differences of biological significance in reproductive performance or longevity of mice fed a diet containing GM corn, compared with mice fed a conventional corn diet - any differences between dietary groups detected in this study merely reflected normal biological variability. Based on the available evidence, FSANZ has reaffirmed the conclusions of the previous safety assessments of corn lines NK603 and MON810.

Nanomaterials and Food Safety

Within Australia and New Zealand, several government agencies, including FSANZ, are monitoring the emergence of commercial applications of nanotechnology. FSANZ's focus is to consider the potential applications of nanotechnology in terms of food safety and regulation.

FSANZ has yet to receive any applications to amend the *Australia New Zealand Food Standards Code* (the Code) to permit any foods developed using nanotechnology. In preparation for the likely use of nanotechnology in food, or food packaging, FSANZ has undertaken a number of initiatives including:

- Amending its *Application Handbook* to clarify the circumstances in which additional information about particle characteristics might be required. In cases where particle size is important to achieving technological function, nutritive purpose, functionality of a novel food, or may relate to a difference in toxicity, applicants must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties.
- Refining its risk analysis framework to assess the toxicity of nanomaterials added to food or present as contaminants.

AUSTRIA

This update lists legislative measures and point to recently completed biosafety projects relevant to the Agenda of the Task Force.

Legislative measures

Two new Ordinances on bans of the placing on the market of genetically plants were issued in 2008, three already existing bans were renewed or prolonged resp.

- Ordinance to ban the placing on the market of genetically modified rape Ms8, Rf3 und Ms8xRf3 in Austria (http://www.bmgfj.gv.at/cms/site/attachments/3/0/9/CH0817/CMS1215778250501/rapsverbotsvo.pdf, German language). The scientific reasons are summarised in http://www.bmgfj.gv.at/cms/site/attachments/3/0/9/CH0817/CMS1215778250501/importverbot_osr_ms8xrf3_-_internetfassung.pdf, English). The same Ordinance is also lifting the ban on genetically modified maize Bt176.
- Ordinance to ban the placing on the market of genetically modified maize MON863 in Austria (http://www.bmgfj.gv.at/cms/site/attachments/8/3/3/CH0817/CMS1216370866299/verbotsvo_mon_863bgbl_ii_257_2008.pdf, German language). The scientific reasons are summarised in http://www.bmgfj.gv.at/cms/site/attachments/8/3/3/CH0817/CMS1216370866299/austrian_scientific_arguments_-_import_ban_maize_mon_863.pdf, English).

5 http://www.foodstandards.gov.au/_srcfiles/FSANZ%20Review%20of%20Austrian%20Report%20AB%20cleared%20Jan09.pdf

- The Ordinance to ban the placing on the market of genetically modified rape GT73 in Austria has been prolonged up to the end of 2010 (http://www.bmgfj.gv.at/cms/site/attachments/6/0/0/CH0817/CMS1200574298070/findbgbl_aspx.pdf, German language).

- The Ordinance to ban the placing on the market of genetically modified maize MON810 was renewed for the cultivation aspect in May 2008 (http://www.bmgfj.gv.at/cms/site/attachments/2/2/5/CH0817/CMS1212741055132/findbgbl[1].pdf,and http://www.bmgfj.gv.at/cms/site/attachments/2/2/5/CH0817/CMS1212741055132/findbgbl%5b1%5d.pdf; German language).

- The Ordinance to ban the placing on the market of genetically modified maize T25 was renewed for the cultivation aspect in May 2008 (http://www.bmgfj.gv.at/cms/site/attachments/6/8/1/CH0817/CMS1212741178772/findbgbl[1].pdf, and http://www.bmgfj.gv.at/cms/site/attachments/6/8/1/CH0817/CMS1212741178772/findbgbl%5b1%5d.pdf, German language).

An English overview of Austrian legislation on GMOs including coexistence measures is provided at http://www.bmgfj.gv.at/cms/site/standard.html?channel=CH0808&doc=CMS1217417300079.

Biosafety research

Several studies on GM plant biosafety commissioned by the Austrian Competent Authority, the Federal Ministry of Health, Family and Youth (BMGFJ) been completed at the end of 2008.

The preliminary results and conclusions of a long-term animal feeding study in mice of genetically modified maize NK603xMON810 are summarised at http://www.bmgfj.gv.at/cms/site/attachments/3/2/9/CH0810/CMS1226492832306/forschungsbericht_3-2008_letztfassung.pdf. The study design includes a multi-generation study, a reproductive assessment by continuous breeding, and a life-term feeding study. The study is currently under re-evaluation with regard to the statistical models used by the authors.

A study investigating the allergenicity of genetically modified maize NK603xMON810 is available at http://www.bmgfj.gv.at/cms/site/attachments/3/8/1/CH0810/CMS1227514126227/forschungsbericht_4-2008.pdf, German language; a summary is available in English). The study was focussing on a comparative analysis of whole-plant allergenicity employing a mouse model.

An overview of biosafety relevant studies on genetically modified plants an animals commissioned by the BMGFJ is available at http://www.bmgfj.gv.at/cms/site/thema.html?channel=CH0810 (partly in German language).

BELGIUM

Notifications for commercialisation

There are no new dossiers as lead CA under the Directive 2001/18/EC. Relevant documents can be consulted on the following address: http://www.bio-council.be

Belgium is actively involved in the evaluation of applications of GM crops to be placed on the market according to Regulation 1829/2003 on GM Food and Feed. The Belgian Biosafety Advisory Council (BAC) is involved provides input in the ***risk assessment*** systematically for all applications submitted. This input relates to food and feed aspects as well as environmental impacts of GM crops.

The Biosafety Council is also engaged since several months in bilateral discussions with EFSA aiming at resolving outstanding scientific issues regarding specific aspects of the risk assessment. Broadly speaking, the BAC and the Division of Biosafety and Biotechnology (SBB) of the Scientific Institute of Public Health bring their contributions to the improvement of EFSA guidances related to the above-mentioned matters.

Belgium is carrying out the ***environmental risk assessment*** of two GM Maize dossiers submitted under the GM Food and Feed Regulation:

- 59122x1507xNK603, expressing Cry34Ab1, Cry35Ab1, Cry1F, CP4 EPSPS and PAT
- MON88017, expressing Cry3Bb1 and CP4 EPSPS

GMO detection in Belgium

There is no significant information since the '***National Reference Laboratory***' for Genetically Modified Organisms was officialised on 15 June 2006. The NRL-GMO is fully operational and has been involved in all the enforcement actions implemented by the Belgian Federal Agency for the Safety of the Food Chain.

A Rapid Alert System for Food and Feed (RASFF) by Belgium (week 12/2008) was launched in 2008 on the availability of unapproved genetically modified *Arabidopsis thaliana* on the market.

Announcement: 4th Meeting of the European Advisory Committees on Biosafety

Belgium will organize the next Meeting of the European Advisory Committees on Biosafety (MEACB). The Division of Biosafety and Biotechnology (Scientific Institute of Public Health) and the Belgian Biosafety Advisory Council are pleased to announce that the next Annual MEACB will take place on ***29 - 30 October 2009***, in Brussels, Belgium.

For the first time, this meeting will gather together representatives of European Advisory Committees on Biosafety dealing with contained use of GMOs and/or deliberate release of GMOs into the environment and placing on the market. This will give a good opportunity for all the European Biosafety Advisory Committees to establish and to strengthen contacts and to provide a forum for discussion of cross-related topics dealing with contained use and deliberate release of GMOs into the environment.

Detailed information regarding the scientific program, registration, accommodation and travel will soon be available at the following URL: http://meacb09.biosafety.be.

The topics for this meeting will include: Plant molecular farming, Gene therapy, Transgenic trees and New techniques for genetic engineering.

Nanotechnology and safety with respect to novel foods and feeds

As requested at the last meeting of the Task Force, some information are provided regarding activities in Belgium related to nanotechnology.

Research project: "Optimization and adaptation of an in vitro strategy for the assessment of human toxicity of nanoparticles ». ***Division of Toxicology*****,** Scientific Institute of Public Health**:** involved in the OECD Working Party on manufactured nanomaterials (WPNM).

The aim of this project is to contribute to the evaluation of the potential harmful effects of the nanoparticules on human health and, with information from the *in vitro* mechanism, to optimize, adapt

and/or replace the animal studies by alternative methods in order to respond to regulatory, politic, financial and ethical demands.

Several *in vitro* techniques involving diverse cell lines as an alternative to *in vivo* assays (kidney toxicity, LD50, general toxicity, ocular irritation, dermal irritation) were adapted and developed.

The interest of the study is to refine the experimental conditions of these assays in order to use them for the assessment of the acute or delayed toxicity of nanoparticules.

For this project the *in vitro* techniques developed as alternatives to *in vivo* testing will be assessed. The data on cytotoxicity and cellular responses after a short and/or a long exposure time to various nanoparticules and nanomaterials available on the market and susceptible to interact with living organisms in a form where their nanostructure is biologically accessible will be collected.

> *Tested Nanoparticles*: This project will evaluate nanoparticles manufactured at the industrial level and susceptible to come in contact with the human organism (for detailed list of assessed nanomaterials see the following webpage: http://www.iph.fgov.be/toxico/toxenglish/r&dframeset.htm).
>
> *Cell types used*: Two different cell lines will be used to evaluate the in vitro nanoparticles cytotoxicity
>
> *Assays*: Hepatocytes (HepG2) and Kidney cells (HK2)
>
> *In vitro assays – cell mechanisms tested:* Cell viability, cytotoxicity (CBQCA total protein cytotoxicity test and NRU delayed cytotoxicity test), the oxidative stress and the Pro-inflammatory response.

Note: This project is not directly related to nanotechnology and safety with respect to novel foods and feeds but may contribute to the evaluation/adaptation of existing *in vitro* techniques developed to assess the acute or delete toxicity of nanomaterials.

Contact: http://www.iph.fgov.be/toxico/toxenglish/task.htm

CANADA

Safety Assessment of Foods and Feeds Derived from Biotechnology

Food Activities:

To date, Health Canada has permitted 112 novel foods to be sold in the Canadian marketplace. Since April, 2008, six novel foods have been approved. These include:

- Enhanced Stearate Soybeans
- Insect Protected Corn line MON 89034
- Clearfield Canola quality *Brassica juncea* S006
- Papaya Drink with Lutein
- Omega Pro Shell Eggs with Lutein
- Omega Pro Liquid Eggs with Lutein

A list of approved products, each summarized by a decision document, can be found at www.novelfoods.gc.ca.

Feed Activities:

The Canadian Food Inspection Agency (CFIA) is responsible for the pre-market assessment of novel feeds, in accordance with the Feeds Act and Regulations. To date, the CFIA has approved over 70 novel feeds derived from plants sources and over 15 novel feeds from microbial sources. Since the last Task Force meeting in April 2008, 3 novel feeds from plant sources have been authorized. These include:

- Enhanced Stearate Soybeans
- Insect Protected Corn line MON 89034
- Clearfield Canola quality *Brassica juncea* S006

A complete list of approved novel feeds from plants sources is available at: http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml

The CFIA has completed revisions to Directive 95-03 (Dir95-03), entitled "Guidelines for the Assessment of Novel Feeds: Plant Sources". No substantial changes have been made to the content of the Regulatory Guidance. There were minor edits to correct errors, reduce duplication and add internal links. Directive 95-03, now referred to as "Section 2.6 of the Regulatory Guidance: Feed Registration Procedures and Labelling Standards", was revised and reorganized to provide greater clarity for preparing submissions and to make it more user-friendly; however the basic requirements have not changed. The Regulatory Guidance is available at: http://www.inspection.gc.ca/english/anima/feebet/regdir/regdire.shtml.

The Animal Feed Division of the Canadian Food Inspection Agency (CFIA), which administers the Feeds Act, has developed a regulatory guidance document on the use of DG from fuel ethanol as feed. Following extensive consultation with the ethanol industry, feed industry, federal departments and other affected stakeholders (notably livestock producer organizations), the guidance document, entitled "Ethanol Distillers' Grains for Livestock Feed", was posted on the CFIA web site and distributed to stakeholders last July. This document sets out the policy of the Canadian Food Inspection Agency (CFIA) on the use of Distillers' Grains (DGs), produced as by-products of ethanol manufacturing, that are sold or manufactured in, or imported into Canada as livestock feed. It is important to note that this policy document only serves to clarify how the existing Feeds Regulations apply to DGs, and does not introduce new regulations. It does not set out regulatory requirements for the manufacture of fuel ethanol or potable alcohol, as this is outside of the CFIA's mandate. The document can be found at: http://www.inspection.gc.ca/english/anima/feebet/pol/distillerse.shtml.

Capacity Building

Health Canada and CFIA officials have presented workshops on the safety assessment of genetically modified foods and feeds (GM) to over 20 countries since 1999. Many of these have been conducted in collaboration with regulatory authorities in Australia and the United States (US) and international organizations such as the Association of Southeast Asian Nations (ASEAN), the Asia-Pacific Economic Cooperation (APEC), and the International Life Sciences Institute (ILSI). These training workshops highlight Canada's comprehensive regulatory approach to the safety assessment of genetically modified foods which is based on internationally established scientific principles and guidance, including the recently adopted Codex Guidelines for the Conduct of Safety Assessment of Foods Derived from rDNA-Recombinant Plants.

As part of Health Canada's and CFIA's on-going efforts to increase international capacity in the risk assessment of GM crops, the Departments have participated as a member of the drafting team for the OECD's consensus document on molecular characterization. In January, 2009 representatives of Health Canada and the CFIA attended a meeting in Washington, DC to prepare a revised document on molecular characterization to be presented at this (15th) Task Force meeting.

Agriculture and Agrifood Canada, in consultation with Health Canada and CFIA, will present Canada's approach on the issue of Low Level Presence (LLP) of unauthorized GM crops, as part of a preliminary roundtable meeting on the use of the LLP Annex, preceding the next APEC High Level Policy Dialogue on Agricultural Biotechnology, in Singapore, in early February 2009.

Recent Consultations - Guidance on Novelty

The CFIA and Health Canada are continuing to work on development of guidance that would help to clarify the determination of "novelty" within the plant breeding community. This guidance would help plant breeders to determine whether a particular plant-based food or feed is "new enough" or sufficiently different from foods or feeds already in the Canadian marketplace to trigger the requirement for pre-market assessment by the relevant government authorities. The CFIA and Food Directorate, Health Canada have working to develop greater clarity regarding the use of "novelty" as a regulatory oversight trigger, via multi-stakeholder consultations as well as ongoing internal meetings.

Food Directorate and Animal Feed Division officials are working to enhance the efficiency of the pre-market review process associated with genetically modified and other novel foods/novel feeds. Communication and education tools are being developed to improve industry's understanding and knowledge of the policies, guidelines and regulatory requirements for novel foods. The Directorate, in conjunction with the CFIA, organized a training workshop series to educate industry on the preparation of submissions for novel foods, novel feeds and plants with novel traits. To date two workshops have been held reaching a large number to industry stakeholders. As a result of these workshops Health Canada and the CFIA have organized a formal working group on increasing efficiency and transparency in the regulation of novel foods, feeds and PNTs. This group is currently developing a number of communication and guidance documents to aid petitioners through the regulatory process.

Another area of focus is to strengthen the risk based approach to the safety assessment of foods derived from biotechnology and other novel foods. Work is underway to explore the use of a tiered approach to the regulation and assessment of novel foods. The concept of tiered assessments could be used as a process to streamline the novel food regulatory process based on past experience and familiarity with certain food products. The goal is to ensure that products receive an efficient review that is proportionate to the potential risks posed by a particular submission.

Animal Biotechnology

As the final CODEX Guidelines for the conduct of food safety assessment of foods derived from recombinant DNA (rDNA) animals are complete, Health Canada will continue the drafting its own Guidelines for the Safety Assessment of Novel Foods derived from rDNA Animals.

The Government of Canada has completed a draft Scientific Opinion on SCNT cloning, which covers potential safety considerations for use of these animals and products derived from them as foods and feeds, and the impact of the technology on animal health. The Document was sent for review by 12 external peer reviewers, and is presently being further refined based on the peer review. The document is proposed for electronic consultation on HC's website, pending proper approval. The finalized document will serve as the scientific underpinning for further policy analysis of the issue.

Until a final policy is decided, as an interim policy, HC will consider foods produced from livestock developed using SCNT and the progeny of such livestock to be captured under the definition of "novel food" in the Food and Drug Regulations in that they have been obtained by a reproductive technology which has not previously been applied to generate animals that would be used to manufacture foods (meat, eggs, milk, etc.) and which may result in a major change in these foods. Developers producing cloned animals through SCNT must, therefore, not sell the products or by-products of any cloned animals or their progeny in the human food supply in Canada unless they have been subjected to the pre-market safety assessment required of novel foods. However, as there is currently insufficient data to guide the pre-market safety assessment of the products, developers who wish to use this technology for producing food livestock are requested to withhold novel food notifications until requirements are determined and guidance is available. The interim policy is available at: http://www.novelfoods.gc.ca.

Similar to HC, CFIA is considering feeds derived from livestock developed using SCNT and the progeny of such livestock to be captured under the definition of "novel feeds" under the *Feeds Act and Regulations*.

Nanotechnology

Health Canada has participated in several activities to promote the responsible stewardship of nanotechnology. Last year, the Health Minister sought advice on the subject of nanotechnology first by sponsoring two workshops held by the Canadian Institute for Environmental Law and Policy (CIELAP) (March 2007 - http://www.cielap.org/pub/pub_NanoFramework.php, March 2008) to raise awareness and to seek discussion, from a broad range of interested parties, on the challenges of the technology and secondly by commissioning advice in a form of a report from the Canadian Council of Academies on the topics of definition of nanomaterials, current issues in the science of nanomaterials, and issues for the appropriate approach to regulation. As a result of these consultations, Health Canada has developed an overall draft framework approach to the products and substances generated by the application of nanotechnology, including foods, but the framework has yet to be officially adopted by the Department. This document is intended to assist Health Canada in the development and application of the appropriate choice of instruments for regulatory and non-regulatory approaches regarding the responsible management of Health Canada regulated products derived from the use of nanotechnology, including foods.

The Health Department has also held several discussions and meetings to shed light on definitional issues for nanomaterials and has recently adopted a proposed approach which is modelled after the core definition of the International Standards Organization (ISO 27687). This definition has been supplemented by additional information which provides for flexibility within specific legislative and regulatory contexts and will be of assistance in clarifying distinctions between particular categories of nanomaterials.

It is the intention of the Department to develop an integrated research agenda where key areas where research is needed to ensure Health Canada has the appropriate knowledge and skills to fulfil its mandate will be outlined.

In Canada, food products are regulated under the *Food and Drug Act and Regulations*. The use of nanomaterials as a component of food or used to produce food products are currently subject to the same rigorous health and safety regulations that apply to conventional materials. Health Canada considers the Food Additive Regulations (Division 16), Novel Food Regulations (Division 28, Part B), and Food Packaging Materials Regulations (Division 23), to be relevant for food products derived or using nano-objects. Consistent with approaches adopted by other major regulatory bodies, Health Canada is taking a case-by-case approach to the safety assessment of products containing or using nanomaterials.

The Directorate has been actively engaged in bilateral discussions with the Food and Drug Administration in the United States, the European Commission, the Food Standards Australia New Zealand and with the Japanese regulatory authorities as well as participates in international harmonization efforts (e.g., OECD, ISO, WHO/FAO, etc.) on safety and regulation of nanotechnology in food.

Health Canada's Food Directorate has established a Working Group in July 2008 to 1) facilitate information exchange between the Directorate and the Departmental governance structure as well as other federal and international organizations on various nano-related initiatives, 2) enhance the Directorate's capacity to provide coordinated input into these initiatives as needed in a timely and efficient manner and 3) coordinate the establishment of a Directorate-wide approach to policy development on nanotechnology. The Working Group is committed to adopting a proactive approach to the management of nanotechnology within the Directorate by establishing and implementing concrete actions in the areas of research, risk assessment and management, regulations, policies and food safety while enhancing transparency and efficiency in the way the Directorate is addressing nanofood-related issues.

The Food Directorate has not yet approved any food products containing nanomaterials but has received its first submissions in the area of food packaging materials.

CZECH REPUBLIC

GM Food/Feed

(Responsibility of the Ministry of Agriculture, contact persons for this update: Mr. J.Kucera, j.kucera@vupp.cz and Mr. P. Hanak p.hanak@vupp.cz).

The Ministry of Agriculture of the Czech Republic holds an opinion concerning the GMO that the strong limitation of the application of GMO is not efficient, but the reasonable use of GMO would be profitable. The immediate goal of the Ministry of Agriculture of the Czech Republic is to provide availability of safe food and feed, including GMO. The ministry favors to facilitate the consumers as well as farmers to select freely between the products available, including GMO.

The area seeded with maize Bt was grown up to more than 8.000 hectares during the year 2008. While in 2005 (the first year of growth) the total area was as low as 270 ha, in 2006 it was 1290 ha and 2008 it was as much as 8380 ha. No other GMO plants are grown at present.

The Czech Ministry of Agriculture determines to stem off two genetically modified plants (rice Bt63 and rice LLRICE 601) illegally distributed in the Czech Republic.

The Scientific Committee for Genetically Modified Food and Feed of the Czech Ministry of Agriculture continue to evaluate GMO introduced to use. This Scientific Committee organized a workshop entitled, "The news in GMO food". The same committee negotiates the "Update guidance document of the scientific panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed."

Novel Food/Feed (non GM)

(Responsibility of the Ministry of Health, contact person for this update: Mr. J.Ruprich, jruprich@chpr.szu.cz)

Responsible authorities and legislation

The Czech Republic, as a member state of EU, uses common legislation of EU, namely regulation of European Parliament and Council No. 258/1997. On 15 January 2008, the Commission submitted a proposal for a regulation aimed at replacing Regulation (EC) No 258/97 on the authorisation of novel foods and novel food ingredients. The proposal aims to ensure food safety, protection of human health and consumer interests and the effective functioning of the internal market. The Commission proposed to keep 15 May 1997 as the threshold date for determination of the novelty of the food. There are two large categories of novel foods: foods resulting from new technologies and foods imported from third countries. There is ongoing discussion in European Parliament and Council directed mainly on the following issues:

- How to address the food derived from cloned animals? It is recalled in one amendment that the EP had proposed the ban of the cloning of animals for food supply purposes; it is suggested in another amendment to exclude cloned animal and their offspring from this Regulation and to submit them to a specific legislation.
- The application of the precautionary principle;
- The authorisation of food produced by new processes, such as nanotechnology or nanoscience; the EP introduced definitions of "nanomaterial" and of "nanotechnology";
- The possibility for a Member State to restrict the placing on the market of a product that falls within the definition of "medicinal product";
- Provisions for labelling requirements;
- The elements to be taken into account when assessing a novel food;
- The importance of ethical and environmental considerations.

Czech Working Group for Novel Foods

Daily work on the field of authorization of novel foods in the country is done by the expert group at the National Institute of Public Health in Brno. This group participates in the EU network for NF (CAFAB). Following table refer to work output for 2008. Cases represent mainly “history of use for food supplement ingredients”.

Type of opinion	Number of cases
Opinions on NF applications from other EU MSs	**30**
Opinions on NF notifications from other EU MSs	**33**
Answers prepared by CZ for other EU MSs and CAFAB	**140**
Questions risen by CZ for other EU MSs and CAFAB	**7**
Other cases	**4**

GERMANY

Besides other dossier EFSA is reviewing the renewal dossier for placing on the market, including cultivation, of RR Soybean GTS 40-3-2 in the EU. The RR soybean was cultivated e.g. in Romania before it joins the EU. According to the existing legislation in the EU, EFSA has to request a national Competent Authority (CA) under Dir.2001/18/EEC of the EU Member States to carry out an environmental risk assessment (ERA) regarding the cultivation of the GMO. In the case of RR soybean the CA of Germany,

Federal Office of Consumer Protection and Food Safety (BVL), has offered to carry out the ERA. At the meeting of EFSA´s GMO Panel on 10th September 2008 in Berlin, BVL has presented its report on the ERA of RR soybean to EFSA and the GMO Panel.

In December 2008, the German CA (BVL) has received a dossier under Dir.2001/18/EEC regarding the cultivation genetically modified sugar beet H7-1. BVL has forwarded this dossier to EFSA and has expressed its interest to carry out the ERA. EFSA has requested the BVL to provide the ERA report.

The German recombinant DNA advisory committee (Central Commission on Biological Safety, ZKBS) has renewed its opinion of 1999 on the use of antibiotic resistance marker genes in genetically modified genes at its meeting in December 2008. The new opinion has been published in the official federal journal (Bundesanzeiger 13, 353-359). A translation into English language is annexed as follows:

ANNEX TO STATEMENT FROM GERMANY:

OPINION OF THE CENTRAL COMMITTEE ON BIOSAFETY (ZKBS) ON THE SAFETY ASSESSMENT OF ANTIBIOTIC RESISTANCE GENES IN THE GENOME OF GENETICALLY MODIFIED PLANTS (December 2008)

1. Introduction

In March 2008, the Danish government kindly asked the EU Commission for clarification of a discrepancy in opinions by the European Food Safety Authority (EFSA) on the assessment of antibiotic resistance genes (ARGs) in genetically modified (GM) plants (EFSA, 2004 and 2007). From the EFSA opinion of 2007 on the ARG *npt*II, Denmark concluded that the medical relevance of correspondent antibiotics was not a significant criterion for the safety assessment of ARGs. According to the Danish authorities, this finding is inconsistent with a previous opinion issued by the EFSA in 2004.

The enquiry prompted the EU Commission to request the EFSA to produce a consolidated opinion on the safety assessment of ARGs in GM plants, taking previous opinions into account. In drafting the statement, the EFSA was asked to cooperate with the European Medicines Agency (EMEA) and other institutions with recognised expertise in the field of antibiotic resistance. The statement was to present the arguments supporting its conclusions in such a way as to qualify it as a basis for future individual safety assessments of GM plants containing ARGs.

In view of discussions conducted during the period 2004-2007 between the EFSA, the EMEA and the EU Commission (EMEA, 2007; WHO, 2005; EFSA, 2004) on ARGs as markers in the genome of GM plants, the ZKBS also reviewed its statement of 1999 on the issue in 2007. This resulted in the confirmation of the statement of 1999 that classified ARGs into 3 groups (ZKBS, 1999 and 2007), which correspond largely to the EFSA classification of 2004. The ZKBS opinion of 1999 took the following factors into account:

- Probability of horizontal gene transfer of ARGs from GM plants to bacteria (eubacteria and archeabacteria),
- natural distribution of ARGs in the environment,
- relevance of antibiotics in human and veterinary medicine.

Contingent upon the spread of ARGs and the therapeutic relevance of corresponding antibiotics, the opinion of 1999 categorized the ARGs *npt*II, *hph*, *cm*R, *aad*A, bla_{TEM-1}, *npt*III and *tet*A into three groups. The corresponding antibiotics were classified as follows:

- "little or no therapeutic relevance in human and veterinary medicine" (Group 1),
- "relevant in certain areas of human and veterinary medicine" (Group 2),
- "therapeutic relevance in human medicine" (Group 3).

The mandate for a consolidated opinion to the EFSA by the EU Commission also affects the evaluation criteria and facts drawn on by the Central Commission for Biosafety (ZKBS) to assess ARGs in GM plants. As the national advisory committee on safety in genetic engineering, the ZKBS also deals with the risk assessment of GM plants. Taking the international discussion about the relevance of antibiotics and the latest research findings into account, the ZKBS has therefore drafted a new opinion on the safety assessment of ARGs in the genome of GM plants. This opinion replaces the previous opinion of 1999 and the revised version of June 2007 (ZKBS, 1999 and 2007). Due to inconsistencies in assessing the relevance of certain antibiotics for human and veterinary medicine in various regions of the world, this factor is considered less relevant than factors such as

- the probability of horizontal gene transfer of ARGs from GM plants to bacteria and
- the natural distribution of ARGs in the environment.

The present opinion relates to ARGs which, in recent years, have featured in applications for placing on the market of GM plants within the EU. It comprises the assessment of the ARGs *npt*II, *aad*A, bla_{TEM-1} and *tet*A, because they are inserted in GM plants as intact genes or as functionless fragments.

2. Scientific assessment of the possibility of horizontal gene transfer of ARGs from GM plants to bacteria and the spread of these resistance genes in the environment

The assessment of the safety of bacterial ARGs in the genome of GM plants requires an evaluation of the probability of a horizontal gene transfer of the ARGs from these plants to bacteria. Furthermore, the impact of a potential transfer on the existing distribution of bacterial ARGs in the environment has to be considered.

To assess the risk of horizontal gene transfer from plants to bacteria, the first part of this section examines the various mechanisms underlying the lateral transfer of genes and evaluates the probability of horizontal gene transfer from GM plants to bacteria. This probability is compared to the natural frequency of horizontal gene transfer among bacteria. The impact of a potential transfer of bacterial ARGs from the genome of GM plants to bacteria will be examined in the second part of this section, taking into account the emergence of new resistant organisms created by horizontal gene transfer between bacteria of identical and different species and by mutations. The existing distribution of ARGs in bacteria is contrasted to the putative horizontal gene transfer from GM plants to bacteria.

2.1 Probability of a horizontal gene transfer from GM plants to bacteria

Horizontal gene transfer in bacteria can be triggered by a variety of mechanisms (including transduction, conjugation and transformation) and is seen as one of the driving forces for the genetic adaptation of these organisms to an altered environment. Throughout evolution, horizontal gene transfer has helped to shape the structure of bacterial genomes. The archaeology of *Escherichia coli* shows that at least 234 horizontal gene transfer events have occurred in the last 100 million years that can still be traced in the genome today (Lawrence and Ochman, 1998). This proves that long-term traceable HGT events are rare.

The mechanism of transduction can be discounted for the safety assessment of bacterial ARGs in the genome of GM plants and the potential risk of horizontal gene transfer from plants to bacteria. No known viruses exist that simultaneously use plants and bacteria as hosts and are capable of transferring genetic material. The same applies to the mechanism of conjugative transfer of DNA from plants to bacteria. Plants are not known to contain any autonomous or passive mobile genetic elements that can be transferred to bacteria by conjugation.

The most likely possibility for the transfer of DNA from plants to bacteria is the process of natural transformation of bacteria. Transformation is the uptake of free DNA and its stable integration into bacterial cells. This process would require the following steps:

1) Release of DNA from the cells of GM plants into the environment (e.g. soil, water, digestive tract);
2) Presence of bacteria capable of DNA uptake (competence);
3) Contact between intact plant DNA and the cells, followed by uptake in the cells;
4) Integration of the plant DNA into the genome of the cells through recombination or establishment of the DNA as an autonomously replicating plasmid;
5) Persistence of cells, proliferation and expression of integrated DNA.

The transformation of bacteria containing DNA from GM plants or other DNA with bacterial ARGs has been the subject of numerous experimental studies. It is consistently reported that horizontal gene transfer of bacterial ARGs from DNA sequences - as found in GM plants – to bacteria is possible, if homologous DNA regions to the antibiotic resistance gene were already present in the bacteria (de Vries and Wackernagel, 1998; de Vries *et al.*, 2001; de Vries *et al.*, 2003; Gebhard and Smalla, 1998; Iwaki and Arakawa, 2006; Kay *et al.*, 2002; Meier and Wackernagel, 2003; Nielsen *et al.*, 2000; Tepfer *et al.*, 2003). The homologous region facilitates the integration of the transferred bacterial ARG by means of homologous recombination. In all of the studies, no transfer could be detected in the absence of the homologous region in the genome of the bacteria. The detection limit in these experiments was 10^{-11} (transformation events per bacterial cell).

Recently, horizontal gene transfer of a bacterial ARG in the absence of a homologous sequence in the bacteria with a frequency of 7×10^{-13} was observed for the first time. It was 10^{10} times lower than in the presence of a homologous sequence (Hülter and Wackernagel, 2008). This frequency was obtained in an optimised laboratory experiment, in which a maximally competent pure culture of bacteria was treated with a concentrated solution of DNA fragments, all of which contained the resistance gene. The very low frequency in the optimised laboratory experiment would be further reduced for the transfer of bacterial ARGs from GM plants under natural conditions, because

a) the concentration of the resistance gene is already greatly reduced (ca. 10^6 times) by the residual plant DNA (genome and plastome),
b) only about 1% of all bacteria identified to date is known to be transformable in specific growth phases (de Vries *et al.*, 2004) and
c) transformation under natural circumstances (e.g. in soil) is far less efficient than in artificial *in vitro* experiments.

It is very feasible that many other factors combine to further reduce the chances of transformation. These include the relatively brief half-life values of free DNA in soils (ca. 9 to 28 h; Blum *et al.*, 1997; Recorbet *et al.*, 1993; Romanowski *et al.*, 1992; Romanowski *et al.*, 1993; Wackernagel, 2006; Widmer *et al.*, 1997), in waters (ca. 1 min. to a few hours; Fibi *et al.*, 1991; Lorenz and Wackernagel, 1994; Paul *et al.*, 1989; Phillips *et al.*, 1989) and in the digestive tract (a few seconds to a few hours; (Einspanier *et al.*, 2001; Hohlweg *et al.*, 2001; Klotz *et al.*, 2002; Mercer *et al.*, 2001; Schubbert *et al.*, 1994; Sharma *et al.*, 2006; van den Eede *et al.*, 2004) due to the presence of DNA-degrading enzymes in the respective habitats (DNases). Even the processing of foodstuffs from plants causes the degradation of DNA (van den Eede *et al.*, 2004). Moreover, ARGs in GM plants are generally equipped with plant regulation sequences (promoters), which often inhibit or greatly diminish the expression of the genes in bacteria (Lewin *et al.*, 1998; Jacob *et al.*, 2002). If all of these facts are taken into account, the result is a reduction of the transformation frequency under laboratory conditions from 7×10^{-13} to extremely low values (ca. 10^{-20} or lower) for the putative transfer of a bacterial ARG from GM plants to bacteria. It follows that this theoretical transfer of bacteria by transformation is roughly one thousand billion times lower (10^{12}) compared to the natural transfer of bacterial ARG between bacteria in the environment, e.g. by conjugation, with frequencies of 10^{-1} to 10^{-8} (Dröge *et al.*, 1998).

No indications of horizontal gene transfer from plants to bacteria were found in studies of soil bacteria from areas cultivated with GM plants (Badosa *et al.*, 2004; Demanèche *et al.*, 2008; Gebhard and Smalla, 1999). Likewise, no other horizontal gene transfer – apart from conjugation – was detected in the digestive tracts of animals (van den Eede *et al.*, 2004; Licht *et al.*, 2002; Alper *et al.*, 2003). Only the experimental transformation of *Streptococcus gordonii* with plasmid DNA in the human oral cavity was reported (Mercer *et al.*, 2001).

2.2 Spread of antibiotic resistance in the environment

Despite the extremely low probability of horizontal gene transfer from GM plants to bacteria, the possibility is not ruled out completely in the safety assessment. It is weighed against the current distribution of resistance to the relevant antibiotic.

Many antibiotics are natural products of the secondary metabolism of microorganisms. In the event of sensitivity to their own antibiotic, the microorganisms have to protect themselves from potential suicide by their own antibiotics, e.g. with the help of resistance genes or chromosomal mutations. Independent of the antibiotic producers, antibiotic resistances have also formed in other microorganisms as an evolutionary response to the natural occurrence of antibiotics. Consequently, nature generates resistances to every natural antibiotic, generally based on chromosomal mutations or resistance genes transferred by mobile genetic elements (Aminov and Mackie, 2007; Courvalin, 2008). Since the discovery of the transfer of resistance determinants by conjugative plasmids and transposons, conjugation among bacteria has been seen as the crucial mechanism for the spread of bacterial ARGs (Watanabe, 1963; Courvalin, 2008).

Studies confirm that environmental habitats such as soil or water show that ARGs in bacteria occur with relatively high frequency, even if the respective antibiotics have not been inserted by humans (Seveno *et al.*, 2002; Leff *et al.*, 1993). The following list is a sample compilation of such studies:

- Ampicillin-resistance genes (e.g. bla_{TEM}) were found in 87,7% of 576 ampicillin-resistant isolates from cultivated soils; the frequency of ampicillin-resistant bacteria in tested agricultural soils from France amounted to 0.4% - 8%. In the non-cultivated soils tested, the ampicillin-resistance was even higher (Demanèche et al., 2008).
- The kanamycin-resistance gene *npt*II was present in 12.6% of 355 isolates from water, soil, manure or waste water in Germany (Smalla *et al*., 1993).
- Tetracycline-resistance genes (e.g. *tet*L, *tet*T and *tet*W) were detected in bacteria from cultivated soils from Switzerland, Germany and the USA as well as in non-cultivated soils in the USA (Ghosh and LaPara, 2007; Schmitt *et al*., 2006).
- Streptomycin-resistance genes (e.g. *aph* (3″), *aph* (6)-1d, *aph* (6)-1c, *ant* (3″) and *ant* (6)] were found in organisms of numerous samples from soils and water of varying European origin; four of the observed genes occurred in 58% of the habitats investigated (van Overbeek *et al*., 2002).
- Streptomycin/spectinomycin-resistance genes (*aad*A) were found in bacterial isolates from the Siberian permafrost regions (Mindlin *et al*., 2008; Petrova *et al*., 2008).

Laboratory experiments show that slurry and manure increase horizontal gene transfer among soil bacteria (Götz and Smalla, 1997; Smalla *et al.*, 2000). In the agricultural sector, not only antibiotics seeped into the soil during the fertilization of fields with slurry and manure from livestock farming, but also bacteria with ARGs and correspondent mobile genetic elements (Witte, 2000; Boxall *et al.*, 2004; Binh *et al.*, 2008; Ghosh and LaPara, 2007; Heuer and Smalla, 2007; Smalla *et al.*, 2000).

Pathogenic bacteria have also frequently shown resistance to antibiotics even prior to the use of antibiotics in medicine. As an exemple, 2% of 433 Enterobacteriaceae isolated between 1917 and 1954 were resistant to tetracycline (Hughes and Datta, 1983).

The global proliferation of bacterial antibiotic resistance genes in pathogenic and commensal bacteria, probably due to the use of antibiotics in medicine, is very well-documented:

- Of 49 multi-resistant *Acinetobacter baumannii* isolates from various European hospitals, 75% contained *tet*A or *tet*B (Huys *et al*., 2005).
- In 105 multi-resistant clinical isolates of *Escherichia coli* O111 from Germany, USA, Australia and other countries, the identified integrons contained *tet*A (86%), bla_{TEM} (94%) and *aad*A1-like (66%) genes as well as other bacterial ARGs (Guerra *et al*., 2006).
- Of 135 antibiotic-resistant *Salmonella enterica* isolates from clinical and other samples in Brazil, 56 contained integrons with various bacterial ARGs; 18.5% of the isolates contained *tet*A, 59.3% bla_{TEM} and 32.6% aadA (Peirano *et al*., 2005).

This list can be complemented by a series of further studies (e.g. Bartoloni *et al.*, 2006; Pallecchi *et al.*, 2008; Brenciani *et al.*, 2004; Cabrera *et al.*, 2004; Zolezzi *et al.*, 2007). In Germany and other European countries, antibiotic resistances in a range of pathogenic bacteria are mapped by antibiotic and resistance-monitoring programmes which also suggest widespread distribution and large concentrations of antibiotic resistances (GERMAP, 2008; Ferech *et al.*, 2006; Danish Zoonosis Institute and Danish Veterinary Institute, 2001; EARSS, 2006).

The global proliferation of ARGs in bacteria isolated from livestock animals or meat is also well-documented:

- Of 30 *Salmonella* isolates from pigs in China (2001-2003), 93% carried at least one ARG (Ma *et al*., 2007).
- Of 123 *Salmonella* isolates from chickens, pigs and turkeys in the Czech Republic, 83% were resistant to streptomycin, 83% to ampicillin, 55% to chloramphenicol, 74% to tetracycline and 4% to kanamycin (Havlickova *et al*., 2008).

- Of 317 *Escherichia coli* isolates obtained from cattle, pigs and fowl in Germany from 1999-2001, 40% were resistant to antibiotics, the most common resistances being to sulfmethoxazole, tetracycline or streptomycin (28%-30%) and ampicillin or spectinomycin (15%-19%) (Guerra *et al*., 2003).
- Of 133 Salmonella isolated in meat from the retail chain in the USA and China, 55% were resistant to one antibiotic and 23% were multi-resistant (Chen *et al*., 2004).

In the here exemplarily cited studies, ARGs such as *sat*1, *tet*A, *tet*B, *npt*I, *npt*II, bla_{PSE-1}, bla_{TEM-1} or *aad*A were detected. Some of these ARGs were organised in integrons, which is why the strains with integrons showed multiple resistances to antibiotics.

The analysis of samples of probiotic bacteria of the genera *Lactobacillus*, *Weissella* and *Bifidobacterium* of African and European origin used as starter cultures in the food industry show the widespread presence of ARGs such as *npt*II, *npt*III, *aad*A, *aad*E, *tet*S or *gyr*A in these bacteria (Ouoba *et al.*, 2008).

The ubiquitous spread of antibiotic resistances in the two main reservoirs, man and animal, and the consequent global spread due to mass tourism, industrial livestock farming and international trade is documented in a series of further studies (Miko *et al.*, 2005; Guerra *et al.*, 2006; Peirano *et al.*, 2005; Travis *et al.*, 2006; Heuer *et al.*, 2002; Levy and Marshall, 2004; Molla *et al.*, 2007). In these studies, the selection pressure built up by the use of antibiotics is viewed as one of the prime forces behind the spread of ARGs by mobile genetic elements.

The horizontal gene transfer of one of the bacterial ARGs *npt*II, *aadA*, bla_{TEM-1} and *tet*A from GM plants to bacteria in a habitat no longer constitutes a selection advantage, if resistance already exists in the habitat, e.g. in the form of ARGs or chromosomal mutations.

In this case, the gene merely returns to its natural, global gene pool (Bennett, 2008). The very unlikely event of a horizontal gene transfer from plants to bacteria in the environment or in the intestinal tract of humans and animals cannot alter the frequency of bacteria resistance to the relevant antibiotics in a way that poses a potential risk to humans, animals, plants or the environment.

3. Conclusions of the scientific assessment

The scientific safety assessment of the bacterial ARGs *npt*II, *aad*A, bla_{TEM-1} and *tet*A in GM plants shows that the use of these genes is unlikely to have any damaging effects on the health of humans, animals, plants or the environment. Besides the data contained in this paper, supplementary data on the above ARGs and their correspondent antibiotics are contained in the appendix for further reference.

In laboratory experiments under artificial conditions, a horizontal gene transfer of bacterial sequences as they occur in GM plants was induced by transformation, albeit only with a very low frequency of approx. 10^{-13}. This transformation, accelerated by optimised laboratory conditions, was 10^{5} - 10^{12} times lower than the natural and relatively frequent horizontal gene transfer by conjugation between bacteria in the environment (10^{-1}-10^{-8}). No horizontal gene transfer of bacterial ARGs from GM plants to bacteria was detected in a natural setting. The probability analysis for the type of horizontal gene transfer conducted here presupposes a frequency of less than 10^{-20}. Such an extremely low frequency cannot be verified by the available technology and is simply an estimate for the potential occurrence of such an event. In this scenario, the low chance of transfer ($<10^{-20}$) must also be compared to the far higher chance of horizontal gene transfer by conjugation in the environment (10^{-1}-10^{-8}), since it is at least 10^{12} - 10^{19} lower. Nonetheless, the safety assessment of bacterial ARGs in GM plants still assumes the potential occurrence of a horizontal gene transfer of resistance genes from plants to bacteria and evaluates the resulting consequences against the background of the existing global prevalence of antibiotic resistance and the spread of specific bacterial ARGs such as bla_{TEM-1}, *npt*II, *aad*A and *tet*A.

The research literature shows that antibiotic resistances coincide with the occurrence of antibiotics in nature. Antibiotics and ARGs play a major role in the competition between microorganisms for habitats and nutrients. The emergence of resistant microorganisms is mainly caused by random mutations and the more frequent transfer of mobile genetic elements (e.g. conjugative plasmids or transposons) with ARGs. Selection pressure caused by antibiotics can reinforce the accumulation of mobile genetic elements with ARGs in communities of microorganisms. Over the past 60 years, the intensive use of antibiotics in human and veterinary medicine and agriculture has promoted the global spread of resistance to all antibiotics in use and even to some not in use. A vast number of studies document the existence of a global gene pool of bacterial ARGs, including the genes bla_{TEM-1}, *npt*II, *aad*A and *tet*A which we considered in more detail here. Given its rareness and the global spread and high frequency of antibiotic resistance determinants, a potential horizontal gene transfer of these ARGs from GM plants to bacteria would not causes any measurable increase in the overall frequency. Likewise, it has no negative impact on the medical combat against pathogenic bacteria by antibiotics or the equilibrium between sensitive and resistant microorganisms in their habitats.

In 1999, the classification of ARGs into groups by the Central Committee on Biosafety (ZKBS) was based solely on the therapeutic relevance of specific antibiotics and did not give consideration to the potential horizontal gene transfer of resistance genes. However, due to the lack of consistent international standards on the use of antibiotics to treat infections, a universal classification of antibiotics and their resistance genes into groups appears no longer expedient. In future, the ZKBS will refer to ARGs in GM plants in the safety assessment of these plants unitarily, disregarding the groups classified in 1999. At the same time the new safety assessment of the horizontal gene transfer of ARGs from GM plants to bacteria draws upon the latest research findings in the field. This leads us to conclude that the impact of such potential horizontal gene transfer events is negligible when compared to the natural processes of their transfer and re-emergence and the natural presence of these resistance genes in the global community of microorganisms.

Literature: *[Not reproduced here, please consult the original article]*

Appendix: Information on individual ARGs and their correspondent antibiotics

A1. Aminoglycosides

In human medicine, aminoglycosides are of limited value for antimicrobial therapy.

The GERMAP Study 2008 confirms that few aminoglycosides are used in hospitals. They are not even listed among the antibiotics prescribed to outpatients within the German public health care system (GERMAP 2008). In the European Surveillance of Antimicrobial Consumption Report, aminoglycosides are listed along with other antibiotics in the small category "Others" (Ferech *et al.*, 2006).

The marginal use of this groups of antibiotics in human medicine is in part due to the method of application: apart from the parenteral route, it is only effective if administered topically (especially on the skin, eye, the gut lumen) or inhaled in the form of a nebulised spray (Stille *et al.*, 2006). Furthermore, it can only effectively be applied parenterally in combination with other antibiotics, never as a mono-therapeutic agent (Vogel *et al.*, 2004; Scholz *et al.*, 2004). Today, equally effective combination therapies can be conducted in virtually all cases using alternative groups of agents (Ho and Barza, 1987; Dupont *et al.*, 2000; Yildirim *et al.*, 2008; Bliziotis *et al.*, 2005).

The development or existence of resistance is irrelevant for topical monotherapies with aminoglycosides, because very high concentrations of antibiotics can be applied locally that by far exceed tolerable tissue levels for patients.

In addition, aminoglycosides can, depending on the dosage, be oto- and nephrotoxic or paralyse the neuromuscular end-plate (e.g. amicacyn) (Stille *et al.*, 2006). These side effects alone render them inferior to many more modern antibiotics.

Kanamycin is viewed as a potential standby antibiotic for infections with multiresistant *M. tuberculosis*. Like amicacin and capreomycin, however, it is just one of several potential standby antibiotics. It is also a fact that kanamycin resistance in *M. tuberculosis* is generally of chromosomal origin, triggered by point mutations in the 16S rRNA gene. These bacteria are not naturally competent, making the availability of the *npt*II gene in the environment irrelevant for the development of resistance.

Other intracellular pathogens (e.g. *Mycobacterium*, *Chlamydia*, *Rickettsia*, *Coxiella* and *Ehrlichia*) are also not known to exchange DNA under natural conditions (Courvalin, 2008). Streptomycin and spectinomycin are only used to a limited degree in human medicine for the treatment of tuberculosis (streptomycin), gonorrhoea (spectinomycin), for tularaemia or brucellosis or in combination with β-lactam antibiotics to treat endocarditis caused by entercocci.

A1.1. The nptII gene

The *npt*II gene stems from the transposon Tn5 found in *Escherichia coli* K12 (Berg *et al.*, 1975) and codes for a neomycin phosphotransferase. Neomycin phosphotransferase is a type II aminoglycoside-3'-phosphortransferase (APH(3')II), which catalyzes the ATP-dependent phosphorylation of the 3'-hydroxyl group of the aminohexose ring of specific aminoglycoside antibiotics, ultimately inactivating them. The enzyme is characterised by high substrate specificity (Nap *et al.*, 1992). Among the substrates of APH(3')II enzymes are the antibiotics kanamycin, neomycin, geneticin, butirosin, gentamicin A and B, and paromomycin.

The antibiotics amicacin, gentamicin (mainly C1, C1α and C2) and other aminoglycosides and aminocyclitoles do not belong to the substrate spectrum of the APH(3')-II enzymes (Davies, 1991; Stille *et al.*, 2006; Trieu-Cuot *et al.*, 1987).

A1.2. The aadA [strepR/specR] gene

The *aad*A gene [*ant*(3´´)-Ia; strepR/specR] originates from the plasmid R538-1 from *Escherichia coli* and encodes a streptomycin adenyltransferase (Davies and Smith, 1978; Sanders and Sanders, 1992). Tomalsky and Crosa (1987) also demonstrated the presence of the *aad*A gene on the multi-resistant transposon Tn1331 in *Klebsiella pneumoniae*. The streptomycin adenyltransferase modifies the 3''-OH position of the streptomycin-N-methyl-L-glucosamine ring and a 9-OH position of spectinomycin.

A2. ß-Lactams

The β-lactam antibiotics all exhibit a lactam ring in their core structure. They derive from penicillin, which was isolated from the culture of the fungus *Penicillium notatum*. They are bactericidal as they inhibit the synthesis of peptidoglycan during cell division.

Varying levels of efficacy of β-lactam antibiotics are mainly due to varying affinity and penetrative competence. B-lactam antibiotics are now predominantly semi-synthetic products.

In both human and veterinary medicine, β-lactam antibiotics and tetracyclines are the most frequently used group of antibiotics. In humans, ampicillin is widely used for the treatment of respiratory diseases. It also remains the agent of choice for infections caused by bacteria such as enterococci or *Listeria monocytogenes*. In veterinary medicine ampicillin is used to treat mastitis in cattle, and amoxycillin to treat bacterial respiratory infections as well as infections of the urogenital tract in cattle, pigs, and sheep. Amoxycillin is also used to treat bacterial infections in dogs and cats.

Over time, many pathogenic bacteria have developed a resistance to β-lactam antibiotics. The medical use of ampicillin today is only indicated if ampicillin sensitivity of bacteria have been shown in prior tests.

A2.1. The bla_{TEM-1} gene

The bla_{TEM-1} gene codes for the widespread TEM-1-ß-lactamase (Sanders and Sanders, 1992). This gene was isolated with the transposon Tn3 (from the plasmid R7268) from a bacterial isolate of the patient Thomas Edison Murphy (TEM). In molecular biology terms it is designated as *amp*^{r} *or* bla_{TEM-1} and is present on a range of cloning vectors (pBR322-derivatives, pUC series, etc.). The substrat spectrum of the TEM-1 enzyme primarily comprises ampicillin, penicillin G and amoxycillin. More recent cephalosporins show very low sensitivity to bla_{TEM-1}-ß-lactamase. The enzyme can also be inhibited by ß-lactamase inhibitors such as clavulanic acid or tazobactam.

However, in *E. coli* a high expression rate of bla_{TEM-1} can induced resistance against amoxicillin/tazobactam and against other combinations of ß-lactam antibiotics with ß-lactamase inhibitors (Sanders and Sanders, 1992). Mutations of the *bla* gene (e.g. TEM-30 to TEM-41) can also lead to an altered enzyme only being poorly inhibited by clavulanic acid. In the classification scheme by Bush et al. (1995) such variants were added as their own sub-class 2br.

At the beginning of this century, 35% of clinical *E. coli* isolates were ampicillin resistant (Kresken *et al.*, 1999). This was mainly, i.e. up to 90%, caused by the ß-lactamase TEM-1 (Livermore, 1995), which is also detected in other species of enterobacteria as well as in *Haemophilus* and *Neisseria gonorrhoeae.*

It can be assumed that almost all humans harbour *E. coli* cells in their intestinal tracts, which contain the bla_{TEM-1} gene, even without having been exposed to ß-lactam antibiotics.

A3. Tetracyclines

Tetracylines are among the cheapest antibiotics on the market today. This makes them particularly attractive for developing countries with limited healthcare budgets.

In Germany they rank next to ß-lactam antibiotics, as the most frequently used antibiotics in human and veterinary medicine (GERMAP, 2008; Ferech *et al.*, 2006).

Streptomycetes naturally synthesise tetracyclines as biogenic secondary metabolites via a polyketide pathway. Tetracyclines block both the binding of aminoacyl-tRNA to the acceptor site of the 30S ribosomal subunit and the extension of the peptide chain (Chopra *et al.*, 1992). Their comparably low toxicity for humans can be explained by its selective interaction with bacterial ribosomes, but not with eukaryotic ribosomes.

Since the early 1950s, tetracyclines have frequently been prescribed in human medicine for the prevention and treatment of general infections, particularly for respiratory diseases. It was the preferred antibiotic for treating pneumonia caused by *Mycoplasma pneumoniae*, *Chlamydia pneumoniae* and *Chlamydia psittaci* (Chopra and Roberts, 2001). Nowadays, macrolides and newer quinolones are often preferred to combat infections caused by *Mycoplasma* and *Chlamydia*. The discovery that tetracyclines can be used in the prevention and treatment of malaria has broadened its spectrum of use in recent decades. Doxycyclin is the agent of choice particularly in the treatment of mefloquine-resistant *Plasmodium falciparum* (Bunnag *et al.*, 1996; Pradines *et al.*, 2000; Schwarz and Regev-Yochay, 1999). Tetracyclines are also used to treat infections caused by *Entamoeba histolytica*, *Giardia lamblia*, *Leishmania major*, *Trichomonas vaginalis a*nd *Toxoplasma gondii*. It has recently emerged that using tetracycline to treat animals infected with nematodes reduces the number of adult worms and microfilaria, suggesting that this group of antibiotics could also be useful in the treatment of humans infected with nematodes (Smith and Rajan, 2000). Since we can assume that more and more protozoa will become resistant to conventional antiparasitic drugs, tetracyclines could become more prevalent in the treatment of these diseases in coming years.

Tetracyclines have a series of further effects which affect their range of use. They are, for instance, anti-inflammatory and immunosuppressive, inhibit lipase and collagenase activities and promote wound repair. These properties make tetracyclines attractive for the treatment of non-infectious conditions such as acne and rosacea. (Chaidemenos, 2001; Ramaswamy and Musser, 1998).

Mainly in the USA, tetracyclines are used in subtherapeutic doses as growth promoters in livestock farming (Georgetown University Center for Food and Nutrition Policy, 1999). In Europe, the use of tetracyclines as growth promoters is illegal. It is also used to prevent infections in fish-farmed salmon, lobster and catfish (DePaola *et al.*, 1988; Institute of Medicine, 1998).

In addition to usage in human and veterinary medicine, tetracycline is also used in agriculture to combat bacterial infections (e.g. *Erwinia amylovara* or *Xanthomonas campestris*) of commercially-grown trees, including fruit and palm trees from plantations (Levy, 1992).

A3.1. The* tetA *gene

The *tetA* gene originates from the transposon Tn10, which was discovered from *Escherichia coli* and various enterobacteria and codes for a membrane protein that transport tetracyclines out of the cells (antiporter; Bryan, 1984; Postle *et al.*, 1984). The active efflux of tetracycline occurs in the form of a tetracycline-cation complex in exchange for a proton.

Together with the proteins *Tet*B, *Tet*C, *Tet*D, *Tet*E, *Tet*G, *Tet*H, *Tet*I, *Tet*J, *TetZ* and *Tet*30, *Tet*A forms the first of six groups of tetracycline transport proteins. The group classification is based on the level of amino acid sequence identity and the protein structure. The tetracycline-resistant genes of group 1 have 41-78% amino acid identity and possess 12 membrane-spanning α-helices and a long, nonconserved central loop between the 6th and 7th helix.

All proteins of this group occur only in gram-negative bacteria, except for *TetZ*, which has also been found in gram-positive bacteria (Tauch *et al.*, 2000). The tetracycline resistance determinants in gram-negative bacteria always consist of groups of two genes. One gene codes for the antiporter, and the other for a repressor protein. Both genes are regulated by tetracycline. In the absence of the antibiotic, the expression of both genes is blocked by the binding of the repressor to the overlapping promoter/operator region of the opposing genes. The expression of both genes is only activated by interaction of a tetracycline $Mg2^{+}$ complex with the repressor protein (Hillen and Berens, 1994; Levy, 1984).

GREECE

Greece, as a member state of the EU, applies the EU legislation and more specifically:

a) the Council Directive 2001/18 on the deliberate release into the environment of genetically modified organisms (GMOs) at all stages of their placing on the market
b) the Regulation 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, and
c) the Regulation 1830/2003 of the European Parliament and of the Council concerning the traceability of food and feed products produced from GMOs.

In Greece there are four different authorities that are involved in the assessment of novel foods and feeds, each one in their field of authority. These are the Hellenic Ministry of Rural Development and Food, the Hellenic Ministry for the Environment, Physical Planning and Public Works, the Hellenic Food Authority and the General Chemical State Laboratory. Moreover, Greece participates in the European Network of GMO Laboratories.

As far as Novel Foods are concerned, Greece applies the Regulation 258/97 of the European parliament and of the Council concerning novel foods and novel food ingredients. The authorization procedure for novel foods and novel food ingredients has been incorporated in the Greek Codex for Foodstuffs and Beverages (Article 5), according to the decision 366/1997 of the Supreme Chemical Council, countersigned by the Ministers of National Economy and Finance (Governmental Gazette issue 597/B'/17-7-1997). The competent authority for the application of Reg 258/97 is the General Chemical State Laboratory and the competent Assessment Body is the Supreme Chemical Council, according to the above mentioned Ministerial Decision. Hellenic Food Authority also is participating in the EC working group. The General Chemical State Laboratory as the competent authority participates in the authorization procedure of novel foods and novel food ingredients evaluating the application files and the initial assessment reports of the national assessment bodies. After the evaluation GCSL submits comments or reasoned objections, as the Reg 258/97 provides for. The General Chemical State Laboratory also participates at the Standing Committee on the Food Chain and Animal Health when the Decision for approval is taken on community level.

Since last year Greece has not received any application for the use or placing on the market neither for novel foods, novel food ingredients or novel feed, nor has Greece received any application for GMO foods, GMO food ingredients or GMO feed for the time period 1997 to 2004.

HUNGARY

Legislative measures

Hungary participates in GM product decisions according to the common EU legislature. The competent authority in Hungary is the Ministry of Agriculture and Regional Development (MARD).
A new, harmonized Governmental Food Decree (2008/XLVI) has been issued on food chain and authority surveillance comprising all aspects of the animal welfare and plant health, and the food and feed safety including the GMO related issues as well.

Biosafety research

The Presidency of the Hungarian Academy of Sciences has established a new Scientific Sub-Committee on Food Safety which is developing the National Food Safety Strategy including the GM and novel food safety strategy.
A new research activity has started at the Central Food Research Institute, Budapest concerning the GM-Post Market Monitoring (http://www.gmsafood.com). The newly established consortium GMSAFOOD has been established by scientists in Austria (co-ordinator), Ireland, Norway, Hungary, Turkey and Australia. The objective of the 3-year European Commission funded project is to identify a panel of biomarkers, which could be used to predict harmful GM food effects after product authorization.
A new food safety publication has been issued on GM plant:
Genetically Modified Plants in the Food Chain. Food Safety Booklets V. Eds.: D. Bánáti., É. Gelencsér. Central Food Research Institute. Hieroglif Reklam Kft., Budapest, Hungary. ISBN 978-963-7358-10-4. p.1-158.

IRELAND

GM Food and Feed

The coalition Government in place in Ireland since 2007 has not defined a specific policy on GMOs, GM food or GM feed. However, due to the Green influence in this coalition, Ireland has consistently voted against the EU authorisation of live GMOs under EU Directive 2001/18/EC while abstaining from votes to authorise GM food and feed through EU Regulation 1829/2003.

Routine surveys show that Ireland continues to be a consumer of modest amounts of GM food and relatively high proportion of GM animal feed, all of which are imported as Ireland does not cultivate any GM crops.

Non-GM Novel Foods

The Food Safety Authority of Ireland (FSAI) carried out safety assessments on the following novel foods in 2008/2009 as the initial step in the novel food authorisation process:

- Psyllium Seed Husk
- Conjugated Linoleic Acid
- Synthetic Lycopene
- Ferrous Ammonium Phosphate

Research & Development of functional foods and ingredients is a significant focus of domestic research funding in the dairy and aquaculture sectors.

Nanotechnology in Food Production

The FSAI published a report of its Scientific Committee in 2008 entitled “The Relevance for Food Safety of Applications of Nanotechnology in the Food and Feed Industries”. The report examines the unique characteristics of nanoparticles while identifying current and potential uses in the food, feed and other sectors. The report concludes that while nanotechnology is an emerging science with many potential benefits, a considerable information deficit exists with respect to the effects of inorganic nanoparticles on the health of humans, animals and the environment. The report can be accessed at the following FSAI web site: http://www.fsai.ie/publications/reports/Nanotechnology_report.pdf

ITALY

Italy, as member of the EU, is aligned with the European legislation, decision and regulation, including the recent EU Regulation 834/2007 related to the threshold for the organic product that has been very relevant and effective for all the involved stakeholders and for the official control Authorities, since it contributes to eliminate legal disputes and economic consequences.

The activities at national level that are relevant for the task force context, include: the publication of the results of Official Control activities for the year 2007 (1) and the new plan 2009-2011 of control for GMO food products and feed products (2, 3).

The Ministry of Environment, as National Competent Authority for Directive 2001/18/CE, chairs the Interministerial Assessment Committee (CIV) that is responsible for the authorization process (according to CIV positions). This technical Committee during the last year performed the safety assessment of 33 applications including the placing on the market of GM maize, soybean, cotton and rapeseed; Advexin EMEA, and biomass from Escherichia coli.

The National Institute for Health (ISS), that is the Italian governmental body committed by EFSA, has established an ad hoc working group for GMOs. The main issues of this group include all the matters related to the GMOs risk assessment and communication, in addition, publications and dissemination of GMO risk assessment procedures, addressed to different audiences, are in preparation and will be published within 2009.

The ISS, throughout the GMO and mycotoxin Unit, participates in several national and international projects, among the research activities at international level, the most relevant is the participation in the EU sixth framework programme Integrated project Co-Extra (4) (GM and non-GM supply chains: their CO-Existence and TRAceability. The relevance of CoEXtra is of significant interest for the implementation of official control and traceability. The Co-Extra project will held a two-day open session in Buenos Aires (Argentina) on 19th – 20th March 2009 to inform stakeholders about the results of the project and to exchange views and experiences with systems of coexistence and traceability currently in place in South America and in the European Union. In addition the results of the project will be presented at the Final Conference that will be held in Paris on June 2009.

For more details on GMO and Mycotoxin Unit activities, contact: marina.miraglia@iss.it; roberta.onori@iss.it; carlo.brera@iss.it

1. http://www.ministerosalute.it/imgs/C_17_pubblicazioni_935_allegato.pdf
2. http://www.ministerosalute.it/imgs/C_17_pubblicazioni_936_allegato.pdf
3. http://www.ministerosalute.it/imgs/C_17_pubblicazioni_831_allegato.pdf
4. http://www.coextra.eu/

JAPAN

In Japan, the Food Safety Commission (FSC), the Ministry of Health, Labour and Welfare (MHLW), and the Ministry of Agriculture, Forestry and Fisheries (MAFF) are currently involved in safety assessment and management of genetically modified (GM) foods, feeds, and their additives. The FSC is primarily responsible for the assessment of safety relevant to human health.

Safety assessment of GM foods and food additives (MHLW and FSC)

Since the last OECD Task Force meeting in April 2008, FSC has assessed safety of foods derived from 5 GM crops and 3 food additives;

- based on the "Standards for the Safety Assessment of Genetically Modified Foods (Seed Plants)":
    - Maize resistant to Coleoptera (MIR604) (reassessment)
- based on the "Guideline Regarding the Risk Assessment of Combined-Trait Products (Stacked Varieties) of Genetically Modified Plants":
    - Maize resistant to Lepidoptera and Coleoptera, and tolerant to glufosinate herbicide (Bt11×MIR604) (reassessment)
    - Maize resistant to Coleoptera and tolerant to glyphosate herbicide (MIR604×GA21) (reassessment)
    - Maize resistant to Lepidoptera and Coleoptera, and tolerant to glufosinate and glyphosate herbicide (Bt11×MIR604×GA21) (reassessment)
    - Maize resistant to Lepidoptera and Coleoptera, and tolerant to glufosinate and glyphosate herbicide (MON89034×1507×MON88017×B.t. Cry34/35Ab1 Event DAS-59122-7
- based on the "Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms":
    - L-serine
    - Chitinase
    - L-histidine hydrochlorid

Related information is available on the FSC web site:
http://www.fsc.go.jp/english/evaluationreports/newfoods_gm.html

Since the last TF meeting, the MHLW has approved 9 varieties (including stacked events) of GM crops. As of December 2008, 97 varieties of crops and 14 items of food additives have been approved, and currently, safety assessments of 4 varieties of crops and 1 item of food additive are ongoing.

Related information including the list of approved GM foods and additives:
http://www.mhlw.go.jp/english/topics/food/index.html

Safety assessment of GM feeds and feed additives (MAFF and FSC)

Since the last TF meeting, FSC has assessed safety of feeds derived from 1 GM crop;

- based on the "Guideline Regarding the Risk Assessment of Genetically Modified Feeds and Feed Additives":
    - Maize resistant to Coleoptera (MIR604) (reassessment)

Related information is available on the FSC web site:
http://www.fsc.go.jp/english/evaluationreports/newfoods_gm.html

As of January 2009, MAFF has approved 52 GM feeds and 4 GM feed additives.

Related information including the list of approval GM feeds and feed additives:
http://www.maff.go.jp/j/shouan/tikusui/siryo/pdf/dna_itiran.pdf (in Japanese)

NETHERLANDS

The Dutch delegate mentioned four issues of possible interest in the area of food and feed safety of GMOs and novel foods/feeds:

1. A Dutch coordinator, i.e. Prof Frewer at Wageningen University, will lead the PEGASUS project funded by the European Commission's Seventh Framework Program for Research And technology Development (PEGASUS = "Public PErception of Genetically modified Animals – Science, Utility, and Society; Pegasus = winged horse in old Greek mythology). This three-year project will consider public perceptions, advantages, and disadvantages of genetically modified (GM) animals that may enter the food chain. Both social and technical scientists will be involved in this three-year project, which is expected to start by mid 2009. One of the main goals is to develop recommendations for policy makers.

2. The Dutch delegate has been approached by a sociological researcher, Dr D. Demortain, who conducts a survey with regard to the role of key players and stakeholders in the evolution of regulatory toxicology applied to GMOs. This survey is part of project of the French National Institute for Agricultural Research (INRA). As the researcher is currently in Paris, other Task Force members may contact him (ddemortain@gmail.com) if they are interested in this research, for example if they wish to be interviewed.

3. "Cisgenesis" comprises the use recombinant DNA technology for genetic modification of a host organism with DNA sequences from a source that is the same as the host. This contrasts with "transgenesis," in which "transgenes," i.e. genes from unrelated organisms, are used. Various Dutch institutions are currently developing cisgenic crops, such as disease-resistant potato. In the past years, "cisgenesis" has been the subject of debate within The Netherlands, focusing on issues such as regulatory requirements for safety testing and public acceptance. This debate is still ongoing, as exemplified by a recently held meeting between scientists, plant breeders, government, and interest groups on the issue. Currently, cisgenic crops are considered genetically modified organisms (GMOs) according to the definition of EU legislation and thus will have to undergo a regulatory approval procedure, including a safety assessment. With regard to these regulatory requirements, in January 2009 the Dutch Senate adopted a resolution that requests the Dutch Government:

a) to explore in the European context a further study on new breeding techniques (among which cisgenesis) to examine for which techniques a simplified authorization procedure might be possible; and

b) in addition to guard that the organic food chain will be preserved, so that the freedom of choice for the consumer to buy GMO-free food is maintained (a Dutch summary of Senate's debate can be found at the following website: http://www.eerstekamer.nl/nieuws/20090128/eerste_kamer_opent_debat_over).

4. A genetically modified tomato that is rich in anthocyanins, which impart a purple colour and which has been developed by British and Dutch scientists, received media attention when a scientific article describing the potential protective effects of this tomato against cancer in a rat feeding experiment was published in October 2008. It was noted, though, that the tomato could not be used for consumption yet as it still had to go through regulatory safety assessment.

SLOVAK REPUBLIC

National Legislation

Important for farmers decided to cultivate authorized GM crops is the act No. 184/2006 Coll. on cultivation of genetically modified plants in agricultural production (so called Co-existence Low) amended by act No. 78/2008 Coll., which is in accordance with the act No. 151/2002 Coll. as amended on use of genetic technologies and genetically modified organisms. The original act on cultivation of GMP is in accordance with Commission recommendation of 23 July 2003 No. 2003/556/EC on guidelines for the development of national strategies and best practices to ensure genetically modified crops coexistence with conventional or organic farming. The act on cultivation of GMP is executed by decree No. 69/2007 Coll. (adopted by the EC under No. 2006/0455/SK).

GM Crop Cultivation

First time GM maize line MON 810 was cultivated in Slovakia in 2006 covering totally 30 hectares on three small farms. In 2007 the sowing area of GM maize was 950 ha (16 farmers). During the season 2008 in the Slovak Republic were already grown 1.940 ha of the same Maize variety (13 farmers). Forecast for this season predicted by CCTIA is 2.000 - 2.500 ha.

Monitoring

The monitoring principle is given by above mentioned Co-existence Low (184/2006). Competent authority for monitoring under the regulation is Central Control and Testing Institute for Agriculture in Bratislava (hereinafter referred as to CCTIA). The regional inspectors control the compliance of GM plants cultivation with "Professional plan of cultivation of genetically modified plants" (a set of technical, professional and organizational rules for cultivation of GMP) throughout the growing season to further treatment of the production. After harvesting, CCTIA carry out monitoring of adventitious release of genetic characteristics of GMP into the standard convention plant production of the surrounding lands with non-GM cultivation management. In the case, the surrounding crop production contamination with authorized GM material is higher than that given in the Directive No. 18/2001/ES of EP and the Council as amended (0,9%), the harmed farmer has right to the compensation for the damage suffered under article 12 of act No. 184/2006 Coll. as amended.

Area Food and Feed Safety

Ministry of Agriculture of the SR is Contact Point to EFSA (National Food Act No. 152/1995 Coll. as amended). On the EU level the Contact Point cooperates with Scientific Panels of EFSA, Scientific Committee of EFSA and is member of advisory forum of EFSA. Within the international level Office for GM Food and Scientific Co-operation as part of Department for Food Safety and Nutrition of Foodstuff, Nutrition and Trade Section of the Ministry of Agriculture of the Slovak Republic is Focal Point to Codex Alimentarius to FAO/WHO according Food Safety Assessment of r-DNA Plants.

From this point of view, this office is acting in following fields:

a) Developed special national advisory expert groups dealing with specific fields of Food/Feed Safety Assessment (25 groups). To this groups belongs as well the GMO group (round 41 experts from whole Slovakia) – level of scientists from Slovak Academy of Sciences, Research Institutes, Authorities from official control and supervise (CCTIA, State Veterinary and Food Administration), Institute for Public Health, NGOs and both Slovak Chambers (Agricultural and Foodstuff Industry). To this group were included the experts for Nanotechnology and Cloning.

b) Cooperate within SCFCAH and EFSA on the legal framework of draft document *"Updated guidance document of the scientific panel on GMOs for the risk assessment of genetically modified plants and derived food and feed.*" Final approved above mentioned document will be the base for working out the national instruction/decree for applicants applied for authorisation of GM food and feed on the market.

c) The intergovernmental cooperation between MoA (responsible for Regulation 1829/2003 -Food Safety) and MoEnv. of the Slovak Republic (responsible for Directive 2001/18/EC - Biosafety) and their subordinated bodies has been basically improved as follows:
   - establishing channels facilitating the reciprocate communication on this field. Especially web sites of both ministries are interoperable and ready for access to FAO/WHO network.
   - developing of the draft proposal of the National Biosafety Strategy of the Slovak Republic within the cooperation and assistance of Horizons, s.p.r.l. Belgium (Piet van der Meer).

Official Control and National Reference Laboratory

Official Food and Feed Control Bodies carry out the regular inspection on the market on Food, Feed and Seeds. Results are published on the web-page of the State Veterinary and Food Administration of the SR. Beginning of the year 2008 was in Slovakia detected, as well as in the year 2007, one case of non-authorized GM long grain Rice LL601. This occurrence has been notified through RASFF System to EC and the product has been withdrawn from market and destroyed.

Nanotechnology

The use of nanotechnology and nanomaterials in food in Slovak Republic is on the same level as in all EU countries. Labs dealing with this issue in Slovakia are - Institute of Experimental Oncology SAS participating in the EU FP7 project entitled "The risk assessment of engineered nanoparticles on human and ecosystem health: Understanding the problem." The member of Consortium Project EP7 NanoImpactNet, within it is collected the database of knowledge on nanomaterials harmfulness, is the Slovak Sanitary University. The next one is at the Faculty of Chemical and Food Technology, Institute of Physical Chemistry and Chemical Physics, where they deal with the physicochemical properties of nanoparticles and their interaction with biomatrices. The laboratory is a member of EFSA working group on nanotechnology. Several laboratories in Slovakia are dealing with the application of nanodots in medicine, encapsulation of pharmaceutics, encapsulation of vitamins and flavours for application in foods, etc.

Cloning

Slovakia has no institute directly dealing with this topic.

Elaborated by *Milan Peško, February 06th 2009* **-** *Bratislava, Slovak Republic*

SWEDEN

Sweden is a member of the European Union, having harmonized laws on genetically modified food and feed. At the national level, GMO issues related to foods are dealt with by The National Food Administration, whereas the Swedish Board of Agriculture is responsible for issues related to feed and issues related to the environment. Last week, an official governmental report announced that the term for the present four authorities giving advice to the Ministry of Agriculture are proposed to come to an end at the end of this year, and instead three new authorities, building on the principles from stable to table and separation of risk assessment and risk management, are proposed to be established from the 1 January 2010. The new authority dealing with food and feed issues will employ a staff of more than 900 persons, be situated in Uppsala, 70 km North of the capital Stockholm, and will be called the Swedish Food Safety Authority. At present it is unclear whether this Authority giving advice on GMOs will be established and whether it also will give advice on the environmental issues.

The control whether industry and Swedish merchants fulfil the European legislation on food labelling, the National Food Administration during 2008 studied the appropriateness of the labelling of foods in relation to their content of GMO. Only approved GMO are allowed in foods and feeds, and products containing GMO ingredients needs to be labelled. Despite advice from the Authority not to label foods "Free from GMO", several producers are using this phrase on the label. In many cases such products contains small quantities of GMO.

The National Food Administration has launched an in-house developed tool for bioinformatics assessment of IgE-mediated allergenicity. The bioinformatics tool is available on the net: http://www.slv.se/templates/SLV_Page.aspx?id=19259&epslanguage=EN-GB.

There is no cultivation of approved GMO in Sweden. However, a substantial number of field trials with non-approved GMOs were performed in Sweden 2008; four different notifications were related to pre-market cultivation of oilseed rape, one was related to maize and one concerned cultivation of the small weed *Arabidopsis thaliana*.

The only notification to market an originally Swedish food-related GMO product that has been notified in the European Union is a technical potato for production of the starch component amylopectin for technical use; mainly for paper production. This notification dates back to the spring 1996. In February 2006 the European Food Safety Authority gave a positive opinion on the notification. Thereafter, neither the Standing Committee, nor the European Council, was been able to reach a majority vote on allowing or not allowing this product on the market. Therefore, the responsibility to take a decision has for some time now been on the European Commission.

Uppsala 2009-02-08

SWITZERLAND

Ordinance on Feedstuffs

The Ordinance on Feedstuffs has been changed concerning traces (low level presence) of unauthorized genetically modified organisms in feedstuffs.

According to this new legislation, feedstuffs containing adventitious traces of non-authorized GMOs may be put on the market if the level of non-authorized material does not exceed 0.5%, if measures to prevent co-mingling have been taken; and if the GMO-derived material may be put on the market according to the regulation (EC) No. 1829/2003 or is tolerated in the countries of the European Community or if it is tolerated as a foodstuff in Switzerland.

In addition, if a lot of feedstuffs does not fulfil the above mentioned conditions, the authority may tolerate the lot under specific conditions. These conditions are: the adventitious trace of non-authorized GMO does not exceed 0.5%, the GMO is authorized in the USA or Canada for feed use, reference material and analysis method are available, the co-mingling with foodstuff can be excluded, and all the necessary data are delivered to the authorities from the owner of the specific lot of the feedstuffs.

Ordinance on Deliberate Release of Organisms into the Environment

The Ordinance on the Deliberate Release of Organisms into the Environment (Release Ordinance) has been revised according to the Gene Technology Law that entered into force 2004, and the Environmental Protection Law. The revision brings new and more stringent requirements to the deliberate release of GMOs into the environment for experimental and commercial purposes. In addition, regulations concerning the handling of pathogenic organisms have been revised, and alien plants or animals are now regulated; in particular, a number of recognised invasive species is now banned from marketing. The ordinance also regulates the environmental aspects of the use of GMOs as food or feed; however, these regulations remain essentially unchanged. The revision entered into force on 1 October, 2008.

Link:http://www.bafu.admin.ch/dokumentation/medieninformation/00962/index.html?lang=en&msg-id=21266.

National Research Programme 59 on "*Benefits and Risks of the deliberate Release of Genetically Modified Plants*"

The National Research Programme 59 (NRP 59) on "Benefits and risks of the deliberate release of genetically modified plants", launched 2007, aims at studying biosafety and risk management issues and the potential effects of GM plant use in Swiss agriculture. The NRP should also look at the problems involved in risk management on the legal, political and administrative levels. Information is available under http://www.nfp59.ch/e_index.cfm.

Field experiments with transgenic wheat with fungal disease resistance have taken place in 2008. However, the trial site was vandalized, and the field plots were substantially damaged. The analysis of the data that could be collected is in progress, and it remains to be seen which conclusions can be taken. The experiments will be repeated this year.

Moratorium on GMO use in agriculture

Presently, GMOs cannot be commercially used in Swiss agriculture due to the five-year moratorium on the use of genetically modified organisms (GMOs) in agriculture imposed by a public vote on 27 November, 2005. Swiss agriculture until the end of 2010.

In May 2008, the Federal Council (i.e. the Swiss government) proposed a change to the Gene Technology Act in order to extend the moratorium by another 3 years to the end of 2013. The Council argues that the results of the National Research Programme will not be published by 2010, leaving questions on co-existence to be answered. It is now up to the Federal Assembly (i.e. the Swiss parliament) to decide on the issue.

The import of food and feed is not covered by the moratorium now and would not be covered if the moratorium were extended.

Nanotechnology

TA Swiss, the Swiss Centre for Technology Assessment affiliated to the Swiss Academies of Arts and Sciences has published the results of a study on "Nanotechnology in the Food Sector". The report can be ordered, while a short version can be downloaded from the TA Swiss website: http://www.ta-swiss.ch/e/them_nano_nafo.html.

The report deliberates on regulation, transparency, labelling, traceability, the application of the precautionary principle and risk research to be undertaken.

National authorities, notably the FOPH, will analyse the report and continue the dialogue with stakeholders.

UNITED STATES

FDA has completed its evaluation of 6 bioengineered varieties: a plum pox resistant variety of **plum** (ARS-PLMC506) developed by the U.S. Department of Agriculture; a variety of **soybean** expressing increased amounts of oleic acid and decreased amounts of linoleic and linolenic acids (305423 soybean) developed by Pioneer Hi-Bred International (Pioneer); a **papaya** ringspot virus resistant variety of papaya (X17-2) developed by the University of Florida; an insect resistant variety of **corn** (MIR162), developed by Syngenta Seeds; an herbicide tolerance variety of **cotton** (GHB614) developed by Bayer CropScience ; and an herbicide tolerant variety of corn (event 98140) developed by Pioneer. More information on completed consultations is available at: http://www.cfsan.fda.gov/~lrd/biocon.html.

EPA has registered three new products, all of which are **stacked events** and are conditionally registered in June, 2009. The three products are: (1) Bt corn Event MON89034 containing two cry proteins, Cry1A.105 and Cry2Ab2; (2) Bt corn Events MON89034 + MON88017 containing three cry proteins, Cry1A.105, Cry2Ab2 and Cry3Bb1; and (3) Syngenta cotton containing VIP3Aa19 plus modified Cry1Ab. More information on EPA registered products is available at: http://www.epa.gov/oppbppd1/biopesticides/pips/pip_list.htm.

On April 25, 2008, EPA published a notice in the Federal Register announcing the availability of a **final White Paper** that reviews the data on the level in the human food supply of Cry9C protein from StarLink® corn grain (73 FR 22715). It concludes that the protein has been sufficiently removed from the human food supply to render the level of risk low enough that continued testing for the protein in yellow corn at dry mills and masa production facilities provides no added health protection. The White Paper therefore recommends that FDA withdraw its guidance recommending testing yellow corn grain for Cry9C at dry mills and masa production facilities. Concurrent with this notice, FDA published a notice in the Federal Register that FDA is withdrawing its guidance for industry "FDA Recommends for Sampling and Testing Yellow Corn and Dry-Milled Yellow Corn Shipments Intended for Human Food Use for Cry9C Protein Residues" (73 FR 22716). The final White Paper, which includes EPA's responses to comments received during the open comment period, can be found in the electronic docket at http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPP-2007-0832.

On February 25 - 27, 2009, an EPA Federal Insecticide, Rodenticide and Fungicide Act Scientific Advisory Panel (SAP) will meet to consider and review a set of scientific issue being considered by the EPA that are associated with the data required to support registration of pesticides classified as **plant incorporated protectants** (PIPs). The scientific issues for consideration by the SAP include gene/protein nomenclature, bioinformatics assessment of novel proteins, synergistic effects of multiple PIPs in a plant, soil microbial community effects, and the environmental assessment of gene flow. This SAP review, along with other past PIP-related SAPs, will aid the EPA in preparing a proposed rule to establish data requirements for PIPs.

EUROPEAN COMMISSION

Legislation on GM food and feed

The Regulation on GM food and feed is regulating the placing on the market of GM food and feed in the EU. All the products that may be placed on the market are in the register of GM food and feed (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm). The authorisations adopted in 2008 are related to 1 GM maize (GA21 with Unique Identifier (UI) MON-ØØØ21-9), 2 GM soybean (A8704-2 with UI ACS-GMØØ5-3 and MON98788 with UI MON-89788-1), and 1 GM cotton (LL25 with UI ACS-GHØØ1-3). The opinions of the European Food Safety Authorities on GMO applications as well as information on the applications currently undergoing safety assessment is available on the website of EFSA (http://registerofquestions.efsa.europa.eu/roqFrontend/questionsList.jsf?nocache=1235729565513).

With respect to guidelines for the safety assessment of GM plants and their derived food and feed, the GMO Panel published an updated draft version of its guidance for safety assessment of GM plants and derived food and feed. This update take into account the most recent published reports from the GMO Panel, including the draft report on Statistical considerations for the safety evaluation of GMOs that was adopted on 2 July 2008 for public consultation. On the basis of this update, the Commission is currently preparing a Regulation providing rules for applications submitted under the Regulation on GM Food and Feed.

Legislation on Novel Foods

Seven authorisations were adopted during the last year under the legislation on Novel Foods:

- leaves of Morinda citrifolia,
- arachidonic acid-rich oil from Mortierella alpine,
- Baobab dried fruit pulp,
- allanblackia seed oil,
- refined echium oil ,
- alpha-cyclodextrin, and
- rice drinks with added phytosterols/phytostanols.

The list of authorisations is available at:
http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm

In January 2008, the Commission adopted a proposal for the revision of the legislation on Novel foods. This proposal is now subject to the co-decision procedure involving the European Parliament and the European Council. As part of the revision, discussions are ongoing on the appropriate way to regulate the use of nanotechnologies as well as the use of Somatic Nuclear Cell transfer ("cloning") in food production.

BRAZIL

The National Technical Committee on Biosafety (CTNBio) has approved five requests for commercial release of GM plants in Brazil in 2008, three for GM maize and two for GM cotton. Therefore, a total of 10 requests for commercial release of GM plants were approved so far in the country (see Table 1). Regarding field trials (research), a total of 122 requests were approved in 2008 (83 in 2007, 127 in 2006). The first 2009 meeting of the CTNBio will be held on 11-12 February; where six new requests for commercial release will be evaluated.

Table 1. GM plants approved for commercial release in Brazil by the National Technical Committee on Biosafety (until December 2008)

Description of Permit	Date of approval by CTNBio
10) GM corn resistant to insects of the *Lepidoptera* order (Bt Cry1F 1507), as well as all the progenies coming from the transformation **event TC1507**, and its derivatives of lineages crossings, and non-transgenic populations of corn with lineages bearing event TC1507.	December 11, 2008
9) GM Cotton tolerant to glyphosate (Roundup Ready), as well as all the progenies coming from the transformation **event MON1445**, and its derivatives of lineages crossings, and non-transgenic populations of corn with lineages bearing event MON1445.	September 18, 2008
8) GM corn tolerant to glyphosate (GA21), as well, as of all the progenies coming from the transformation **event GA21**, and its derivatives of the crossing of lines of non-transgenic populations of corn with lines bearing the event GA21.	September 18, 2008
7) GM corn tolerant to glyphosate - Roundup Ready 2, as well, as of all the progenies coming from the transformation **event NK603**, and its derivatives of the crossing of lines of non-transgenic populations of corn with lines bearing the event NK603.	September 18, 2008
6) GM Cotton tolerant to glufosinate (phosphinotricin) of ammonium herbicide (LibertyLink), as well as all the progenies coming from the transformation **event LLCotton25**, and its derivatives of lineages crossings, and non-transgenic populations of corn with lineages bearing event LLCotton25.	August 21, 2008
5) GM corn resistant to insects of the *Lepidoptera* order (Bt11 corn), as well as all the progenies coming from the transformation **event Bt11**, and its derivatives of lineages crossings, and non-transgenic populations of corn with lineages bearing event Bt11.	September 20, 2007
4) GM corn resistant to insects of the *Lepidoptera* order (Guardian Corn), as well as all the progenies coming from the transformation **event MON180**, and its derivatives of crossing of lineages, and non-transgenic populations of corn with lineages bearing event MON810.	August 16, 2007
3) GM corn tolerant to glufosinate (phosphinotricin) of ammonium herbicide, as well as of all the progenies coming from the transformation **event T25** and its derivatives of the crossing of lines of non-transgenic populations of corn with lines bearing the event T25.	May 16, 2007
2) GM cotton resistant to insects of the *Lepidoptera* order (Bollgard), as well, as of all the progenies coming from the transformation **event 531** and its derivatives of the crossing of lines of non-transgenic populations of corn with lines bearing the event 531.	March 17, 2005
1) GM soybean tolerant to glyphosate (GTS 40-3-2), as well, as of all the progenies coming from the transformation **event GTS 40-3-2**, and its derivatives of the crossing of lines of non-transgenic populations of corn with lines bearing the event GTS 40-3-2.	September 29, 1998.

CHILE

LIST OF EVENTS FOR HUMAN CONSUMPTION

The Ministry of Health, in accordance to its Sanitary Regulation of Foods, has published the Resolution N° 83 of 2007 which establish a Technical Administrative Norm on the incorporation to a list of biotechnological events of human consumption.

Principal aspects to be considered:

a) All GM events that appear in the list could be commercialized in the country.
b) The responsibility of the evaluation will be at the expense of the Institute of Public Health.
c) A committee will have to evaluate the differences and similarities between a genetically modified food and his conventional counterpart, considering toxicity, acute effects, allergy and long-term effects
d) At this moment, there are no events in this list.

Events under public consultation for human consumption

Four events are now under public consultation by the **Institute of Public Health**, in the process for the **use for human consumption,** under the technical Standard N° 83, of 2007:

Soybean: ROUNDUP READY MON 04032
Maize: MON 00810
MON 00603
GA21

LATVIA

Institutional changes

Because of reorganization since 10th of March, 2008, the Veterinary and Food department responsible for national biosafety policy has divided in two: Food department, and Veterinary department. The Food department is currently responsible for development of national biosafety policy and legislation in the field of GMOs and novel food.

Regulatory framework

Four new regulations of Cabinet of Ministers were adopted since last OECD meeting:

1) Procedures for the contained use of genetically modified organisms and issuance of a permit;
2) By-law of the Monitoring Council of Genetically Modified Organisms;
3) Risk assessment methodology of Genetically Modified Organisms;
4) Regulations on the State duty for preparation of GMO risk assessment report.

Regulations regarding the Requirements for Co-existence of Genetically Modified Crops, as well as the Procedures for Supervision and Control (adopted last year) are in force started from 1st of January, 2009.

There is no GM plant cultivation in Latvia currently.

We have new draft regulations relating GMO deliberate release into environment and placing on the market as well as monitoring requirements and public participation at decision making process. We suppose the draft will be adopted at the first half of this year.

GMO risk assessment

No one application with respect to deliberate release or placing on the market of GMO as well as import of LMOs has been submitted to the Competent Authority, the expert's activities are still limited in this area.

Last year we have finalized scientific projects supported by Ministry of Agriculture "Potential Economical impact of cultivation of GM plants in Latvia".

Capacity building

Since the last Task Force meeting the following activities have been conducted with the aim to strengthen the biosafety framework:

1) National Biosafety clearing house http://lv.biosafetyclearinghouse.net/;
2) Leaflets on GMOs and their use in food production;
3) Workshops on capacity building for participation in the BCH.

All activities were done within framework of UNEP-GEF funded project "*Building Capacity for Effective Participation in the Biosafety Clearing House*".

SLOVENIA

Traceability of GMO foods and feeds on the market and laboratory capacity

Traceability of GMOs in foods and feeds

The results of official control of food and feed samples on the presence of GMOs in year 2008 are as follows:

- The Inspectorate of the Republic of Slovenia for Agriculture, Forestry and Food, within the Ministry of Agriculture, Forestry and Food, controlled the presence of GMOs in 20 food samples and agricultural products, labelled as *organically produced*: 11 of soya, 9 of maize. The examined samples of soya did not contain RR Soya and samples from maize did not contain 35 S promoter or NOS terminator.
- The Ministry of Agriculture, Forestry and Food took 53 feed samples from the Slovenian market (maize, soy, rapeseed and compound feed). Four samples contained RRS (more than 0.9%) and were labelled in accordance with requirements. Additionally, the Inspectorate of the Republic of Slovenia for Agriculture, Forestry and Food tested 29 feed samples (13 of feed material and 16 of compound feed). No GM maize was found. Three samples were positive (more than 0.9%) to RRS and were not labelled in accordance with requirements.

The results of the Health Inspectorate of the Republic of Slovenia, which took food products from the Slovenian market and border control in year 2008, will be known in the near future.

Laboratory's Capacity

Four laboratories are accredited for detection of GMOs in plant materials in Slovenia. These are the laboratory of the National Institute of Biology, Plant Physiology and Biotechnology Department, the laboratory of the Institute of Public Health of the Republic of Slovenia, the laboratory of the Institute of Public Health Maribor and the laboratory of the Agricultural Institute of Slovenia, Crop and Seed Science Department.

The National Institute of Biology is working as the National Reference Laboratory for detection of genetically modified organisms in food and feed. At the moment, the Department of Biotechnology and Systems Biology, National Institute of Biology has 35 accredited methods for qualitative and quantitative testing of genetically modified organisms in foodstuffs and agricultural products of plant origin. It cooperates intensively with the European network of GMO laboratories (ENGL) as well as with the Community Reference Laboratory (CRL), and participates also in international research projects developing new methods for GMO detection. The Institute is providing scientific and technical support to authorities, among other –also in 2008- for MOP COP Meeting during Slovenian Presidency.

The Seed testing laboratory of the Agricultural Institute of Slovenia is accredited according to the ISTA standard for detection/quantification of genetically modified organisms. It performs analysis of GMOs in seeds for customers. The laboratory is a member of the ENGL. It also collaborates with the CRL with participation in collaborative validation studies.

Slovenian cooperation by preparing new EU Regulation concerning novel foods

Slovenia, as the other 26 EU member States, takes part in harmonized procedure for authorisation of novel food by giving opinions or objections to initial assessment reports in accordance with Regulation 258/97 concerning novel food and novel food ingredients. Since April 2008, seven initial assessment reports were closely studied by the Institute of Public Health of the Republic of Slovenia. In 3 cases significant objections were made and sent to European Commission.

Slovenia cooperates in the procedure for the adoption of proposed new Regulation concerning novel foods. Slovenia supports a quick adoption of the proposed Regulation in view to achieve greater clarity as to the definition of novel food and the procedure for establishing if a food is considered to be novel.

The survey for possible occurrence of GM rape seed in the Slovene environment

In 2008, a survey was performed for the Ministry of Agriculture, Forestry and Food regarding possible occurrence of genetically modified rapeseed in the Slovene environment. Plant samples were taken on 100 locations along major transport routes in Slovenia, around production fields and rape seed processing facilities. None of the samples analysed was found positive for the four screening elements applied (bar, EPSPS, p35S, tNos).

Slovenian act on co-existence: *"Act on the Co-existence of Genetically Modified Plants with other Agricultural plants"*

In 2006, the Republic of Slovenia prepared the first proposal of the Act and sent it for notification in accordance with Directive 98/34. In May 2008, after intensive dialogue, we finally get the positive answer from the European Commission for further procedure of adopting the Act. The proposal of the Act was brought into line with NGO's and other stakeholders. Because of the election in Slovenia in the autumn of 2008, the Act was not adopted yet.

SOUTH AFRICA

Legislation and governance:

- The Genetically Modification Organisms Act, 15 of 1997 (GMO) has been amended to incorporate the requirements of the Cartagena Protocol. It will come into force when the amended regulations are approved by the Minister of Agriculture.
- Regarding oversight of the Biodiversity Act, the Department of Environmental and Tourism has delegated some functions to the South African Biodiversity Institute. One of their responsibilities is to monitor impact of GMOs on biodiversity.
- Access to the South African website that links the Biosafety Clearing House has been redesigned and will be in operation soon.
- Most GMO activities require a permit under the GMO Act. During 2007 calendar year some 379 permit approvals were granted, 91% involving maize and 223 of these were grain imports
- New labelling regulations for genetically modified food have been published for comments under the draft consumer protection Bill that will be administered by the Department of Trade and Industry.

Commercial Production of biotech crop:

In 2008, South Africa maintained its number eight position in the world ranking with a total biotech crop acreage of 1.8 million hectares. The commercialized biotech crops are HT/Bt/HT-Bt cotton; HT/Bt/HT-Bt maize and HT soybean.

THAILAND

Biotechnology policy

Thailand allows importation of genetically modified (GM) corn and soybean for: 1) food processing and industrial use; and 2) food and feed.

A ban on all GM crop field trials was introduced in April 2001 but was subsequently revoked by the Thai Cabinet in December 25, 2007. Currently field trails are dealt with on a case-by-case basis and are subject to public hearings. All field trials must be conducted on government property subject to a number of restrictions.

National Biosafety Framework

There are a number biosafety related regulatory frameworks across different agencies including the "Plant Quarantine Act (1964)", "Plant Variety Protection Act (1999)" and "Food Act (1979)". These regulations support the "National Biosafety Act" (currently in draft format) and the "Biosafety Guidelines". "The National Biosafety Act" was prepared by the office of "Natural Resources and Environmental Policy and Planning (Ministry of Natural Resources and Environment)". After several public hearings and reviews, the Act was approved in principle by the cabinet on January 22, 2008. The contents of this Act include appointment and responsibilities of the "National Biosafety Committee", appointment and responsibilities of the "Biodiversity Office", the control of "living modified organisms" (LMO's), public participation and information access, biosafety fund organization, responsible officers, the right of law petition, violation and compensation and penalties. Currently the Act is under review by the "Office of the Council of State".

Research and Development

Research and development into GM crops is conducted mainly in public universities and research institutes. The research is generally confined to disease resistance and quality (added value) traits. Each research institute is required to have an "Institutional Biosafety Committee" (IBC) whose responsibility is to oversee any GM research within the institute. Recently, research into the safety of GM crops and their possible effects on the environment was established to assist in the evaluation of GM crops.

Public awareness and education

Public awareness of biotechnology and GM crops plays a crucial role in the regulatory process. Stakeholders are identified and activities such as seminars, displays, newsletters, site visits, radio and television programs as well as various web sites are used to communicate with the individuals and groups. Booklets containing accurate information regarding GM crops are distributed.

CODEX ALIMENTARIUS COMMISSION

1. The Codex *ad hoc* Intergovernmental Task Force on Foods derived from Biotechnology

This Task Force had been re-established by the decision of the 27th Session of the Codex Alimentarius Commission in 2004 and was to accomplish its work within the five-year period.

The 31st Session of the Commission (July 2008) adopted the following three texts finalized by the Seventh Session of the Task Force (Chiba, Japan, 24-28 September 2007) and agreed to dissolve the Task Force as its work had been completed. The texts have been published on the Codex website (http://www.codexalimentarius.net/web/standard_list.do) in English, French and Spanish.

a. Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals:

- A guideline for conducting safety assessments specifically for foods derived from recombinant-DNA animals

b. Proposed Draft Annex: Food Safety Assessment of Foods Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits

- General guidance for the safety assessment of foods derived from recombinant-DNA plants is provided in the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) (Codex Plant Guideline). This Annex to the Codex Plant Guideline provides additional considerations that are specific to foods derived from recombinant-DNA plants modified for nutritional or health benefits.

c. Proposed Draft Annex: Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food (See ALINORM 08/31/34 par.106 and Appendix IV).

- An increasing number of recombinant–DNA plants are being authorized for commercialization in many countries. However, they are not necessarily authorized for use in trade partner countries at the same time. As a consequence of asymmetric authorizations, low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Plant Guideline in one or more countries may, on occasion, be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined. This Annex describes the recommended approach to the food safety assessment in such situations of low-level presence of recombinant-DNA plant material or in advance preparation for such potential circumstances.

In order to support the provisions on information exchange contained in the Proposed Draft Annex on Low-level Presence [(c) above], FAO has developed an international database in cooperation with the OECD, with a view to facilitating the exchange of information on official food safety assessments of recombinant-DNA plants conducted by governments. Please refer to the submission from FAO for details.

2. Handling, Transport, Packaging and Identification

Apart from the above work by the Codex Task Force, the Codex Alimentarius Commission has been working on: 1) appropriate labelling provisions to genetically modified food through the Codex Committee on Food Labelling (CCFL); 2) methods of analysis and sampling for the detection of genetically modified foods through the Codex Committee on Methods of Analysis and Sampling (CCMAS); and 3) more general work on traceability/product tracing through the Codex Committee on Import and Export Inspection and Certification Systems (CCFICS).

Committee on Food Labelling (CCFL)

The Codex Committee on Food Labelling (CCFL) has been considering, since 1996, appropriate food labelling provisions for foods derived from biotechnology. This work aims at establishing "Definitions and Guidelines for the Labelling of Foods obtained through Certain Techniques of Genetic Modification/Genetic Engineering".

However, these draft texts are still under discussion due to lack of consensus. The most controversial point is whether or not mandatory labelling provisions should be established for the case where the difference between original products and genetically modified products is solely the production method.

The 36th Session of CCFL (28 April - 2 May 2008 in Ottawa, Canada), following up on its previous discussions, had an exchange of views on labelling requirements as related to "Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering". The Committee recognised that there was large support for proceeding with the work and agreed to circulate the Proposed Draft Recommendations for the Labelling of Foods and Food Ingredients Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering at Step 3 for comments and consideration at the 37th Session of the CCFL in May 2009.

Committee on Methods of Analysis and Sampling (CCMAS)

The Codex Committee on Methods of Analysis and Sampling (CCMAS) has been discussing appropriate methods of detection and analysis for the GM foods since 2002. In view of the absence of specific labelling provisions for GMOs in Codex and of difficulties with the practical application of methodology in this area, the CCMAS proposed to develop recommendations with respect to criteria for methods of analysis and for quality control measures that should be introduced in laboratories offering GM analysis (Guidelines for the Validations and Quality Control Requirements for the Analysis of Foods derived from Biotechnology).

The 28th Session of the CCMAS held in March 2007 considered a new revised document on the criteria for the detection and identification of foods derived from biotechnology, including: i) the information required for the validation of quantitative and qualitative methods, ii) the characteristics that could be used to consider existing validated methods; iii) issues related to measurement uncertainty and interpretation of the results; and iv) proficiency testing. The 29th Session of CCMAS in March 2008 further discussed the matter and agreed to start new work for developing a proposed draft Guidelines for the Validation and Quality Control Requirements for the Analysis of Foods Derived from Biotechnology. The proposed draft Guidelines, to be discussed by the 30th Session of the CCMAS in March 2009, is available from the Codex website (http://www.codexalimentarius.net).

Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)

Following the adoption by the Codex Alimentarius Commission of the definition of "traceability/product tracing", the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS), at its 13th Session in December 2004, started new work to develop the principles on traceability/product tracing in the context of food import and export inspection and certificate systems. The Principles for Traceability/Product Tracing as a Tool within a Food Inspection and Certification System were subsequently adopted by the 29th Session of the Commission in July 2006 and have been published in the Codex Alimentarius (CAC/GL 60-2006).

The CCFICS at its 17th Session in November 2008 discussed the need for further guidance on traceability/product tracing by Codex and agreed to recommended to the Commission to request the Codex Regional Coordinating Committees to discuss whether there was a need for further guidance on

traceability/product tracing, because there was not sufficient information from members for the Committee to clearly identify gaps and specific needs in relation to the implementation of traceability/product tracing

3. The Collaboration with other relevant International Organizations

The Codex Alimentarius Commission has maintained its collaboration with other multilateral regulatory instruments and conventions. Since the international standards and related texts produced by Codex are recognized as international benchmarks by the WTO Agreements, the Commission is closely cooperating with the SPS and TBT Committees of WTO and their secretariats. On the matter of food and biotechnology, the Commission is maintaining cooperation and coordination with other standard setting bodies such as the World Organization for Animal Health (OIE), the Convention on Biological Diversity (CBD) and the OECD.

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO)

Background

Member countries look to FAO to provide sound and unbiased advice on the safety of novel foods and feeds. As delegates will be aware, the Food Quality and Standards Service (AGNS) of FAO has been closely involved in a wide range of biotechnology related issues in recent years.

In close collaboration with the Codex *Ad hoc* Intergovernmental Task Force on Food Derived from Biotechnology (established in 1999), FAO, together with WHO, has been contributing to the scientific foundation for the relevant work on risk analysis principles.

GM food safety assessment tool

FAO's new publication entitled "*GM food safety assessment: tools for trainers*" is currently available in English and has been translated into Spanish and French. All language versions together with a multi-language CD-ROM will be available early spring 2009.

The objective of the publication is to assist developing countries to carry out food safety risk assessment of foods derived from r-DNA plants.

The package is composed of three parts with a CD-ROM containing the visual aids and other relevant reference materials. The first part, "Principles of Safety Assessment of Foods Derived from Recombinant-DNA plants", provides guidance text for the implementation of an effective framework for safety assessment of foods derived from recombinant-DNA plants. The second part, "Tools and Techniques for Trainers", offers a practical guide for preparing and delivering a workshop on the topic of safety assessment of foods derived from recombinant-DNA plants. This section includes various checklists and forms, a sample workshop agenda, sample workshop evaluation sheet, and five useful presentation modules for trainers. All forms, presentations and copies of the relevant Codex Alimentarius documents are included in the CD-ROM in electronic format. The third part, "Case studies", presents three safety assessment dossiers, summarized for training purposes, to serve as practical and concrete examples on how risk assessment can be conducted.

FAO-OECD LLP food safety assessment database

Following up on the decision at the final meeting of the Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology, FAO and OECD BioTrack are closely working together to develop a publicity accessible central database containing relevant information to food safety assessment of recombinant-DNA plants, authorized in accordance with the Codex Plant Guideline.

This database has been maintained by FAO as part of the existing International Portal on Food Safety, Animal and Plant Health (www.ipfsaph.org). FAO is pleased to report good progress in developing the database further – the database will facilitate rapid access by importing Member Countries to additional information relevant to assessment of food safety in low level presence (LLP) situations of r-DNA plant materials in foods.

Currently FAO/IPFSAPH database obtains the data on the risk assessment information from four major sources including EUROPA, BCH, FSANZ and OECD. FAO has full xml (RSS feed, automated data import system) web services arrangement between IPFSAPH and OECD, which generates two OECD related data pools. The IPFSAH currently contains any food safety assessments held by OECD, including the information sources from USA and Canada.

Currently 11 countries (Argentina, Sweden, Spain, Australia/New Zealand, Zimbabwe, Norway, Slovak Republic, Japan, Canada and Denmark) have submitted details of contact points on food safety assessments of r-DNA plants to IPFSAH. FAO/IPFSAPH continues to accept submissions from other countries at IPFSAPH-Safety-Assessment@fao.org.

Nanotechnology

FAO and WHO are planning the Joint Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, to be held from 1 to 5 June 2009 at FAO Headquarters in Rome, Italy.

The scope of the Expert Meeting should cover actual and anticipated nanotechnologies applied in the food and agriculture sectors, with particular attention to:

- The application of nanotechnologies in all aspects of the primary production of foods of plant and animal origin;
- The application of nanotechnologies in food processing, packaging and distribution; and
- The use of nano-diagnostic tools1 for detection and monitoring in food and agriculture production.

And the objectives of the meeting are:

- to take stock of actual and anticipated applications of nanotechnologies in the food and agriculture sectors;
- to identify potential food safety implications associated with actual and anticipated applications of nanotechnologies in the food and agriculture sectors;
- to determine the need for additional tools or metrics and to identify any data requirements and research gaps;
- to consider the application of current risk assessment methodologies to evaluate the safety
- to identify priority areas for which scientific advice should be requested from FAO/WHO in accordance with their Joint framework for the provision of scientific advice; and
- to advise on ways and means of fostering transparent and trustful dialogue among all stakeholders.

INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI)

I. ILSI International Food Biotechnology Committee (IFBiC) – "*THE resource for science on agricultural biotechnology*"

IFBiC Objectives

- Collaborate with international scientific leaders to identify and address key issues with sound science
- Publish scientific underpinnings for the safety assessment of foods and feeds derived from biotech crops
- Ensure scientific information on the safety of biotech food and feed crops is available to regulatory communities
- Build global scientific capacity

2008 IFBiC Highlights

- Publications: 2 published; 4 in progress
- Reach: Programs and CDs to >800 research professionals in 25 countries
- Building capacity: 9 workshops/training courses, travel support for experts (9)

Core Activities (supported by all members to build capacity, increase knowledge)

- Informing NAFTA: Joint meeting among IFBiC, HESI, ILSI RF and NAFTA scientists on research priorities and future challenges—April 2008
- Sampling and Detection Methods
  - Symposium and Laboratory Training Workshop—Singapore, March 2008, with ILSI SEAR)
  - South Andean Regional Symposium—Santiago, Chile, August 5-6, 2008 (with ILSI South Andean)
  - Symposium and Laboratory Training for Caribbean/North Andean Region, Bogota, Colombia, Nov 4-7, 2008, with ILSI SEAR
  - Survey of International Testing Labs: Approaches to Qualitative and Quantitative Methods for GMOs
- Knowledge and Capacity Building Outreach Activities
  - Support expert travel/presentations to international workshops and symposia
  - Co-organize workshops on safety assessment and applications of plant biotechnology (with ILSI Argentina, ILSI Brazil, ILSI Korea ,ILSI South Africa, and ILSI Southeast Asia Region
  - Partner with IFIC to submit proposal for educational session at 2009 Am. Dietetic Assn. Meeting.

Task Force Activities (supported by at least 5 members to advance a specific objective)

- Task Force Paper: Nutrition and Safety Assessments of Foods and Feeds Nutritionally Improved through Biotechnology: Case Studies, 2008 CRFSFS, open access
- Expert Paper: Evaluation of Protein Safety in the Context of Agricultural Biotechnology, 2008 *Food & Chem Tox*
- ILSI Crop Composition Database—www.cropcomposition.org (v.4.0 mid-2009, publication under review, JFCA)
- Safety Assessment Principles for Evaluating New Technologies: Transcription Factors, RNAi—international review
- Best Practices for Conducting Safety Assessments on Stacked (Combined) Events Products
- Application of Mammalian Toxicology Studies for Safety Assessment of GM Crops

2008 IFBiC Members:	BASF	Bayer CropScience, LP	Cargill
	Conagra Foods	Dow AgroSciences, LLC	Masterfoods
	Monsanto Company	Procter & Gamble Company	Pioneer, A DuPont Company
	Syngenta Biotechnology, Inc		
IFBiC Science Advisor	Wayne Parrott, University of Georgia	**IFBiC Staff**	Marci Levine

II. Task Force: Use of Mammalian Toxicology Studies in the Safety Assessment of GM Foods

Background

The safety assessment for human consumption of foods/feeds derived from GM crops typically considers the potential health effects from any introduced protein(s), the safety of the intended changes (e.g., improved nutrition), and the possible unintended effects attributable to the process of genetic modification within the context of expected consumption. Safety assessment includes an evaluation of whether there is a history of safe consumption of the protein or structurally/functionally related proteins, bioinformatics searches to determine if the protein has homology to known toxins or allergens; characterization of the biochemical mode of action and specificity; and digestibility by enzymes, pH and, sometimes, heat or other processing.[1] Assessing the safety of whole foods derived from GM crops is generally conducted by comparing the agronomic properties, composition, and nutritional value of the GM crops and food/feed to that of conventional crops and food/feed.

Acute and/or repeated dose mammalian toxicity studies with the transgenic proteins and subchronic feeding studies with the whole GM food or processed fraction(s) are sometimes conducted to provide additional confirmatory information.[1] However, there is no international consensus on when these studies are needed; which studies are most appropriate; their design; and how their results studies should be used. In fact, the need for additional guidance and a more uniform approach to the design and analysis of these studies has recently been acknowledged by EFSA.[2]

Task Force Plan of Action

The Task Force assembled an international panel of scientific experts to develop consensus recommendations on when it is scientifically appropriate to conduct mammalian toxicity studies with genetically modified (GM) proteins and/or foods and how to best design and use such studies in the safety evaluation. A first draft of the monograph will be shared with OECD Novel Food Task Force delegates in Fall 2009.

Impact

The Task Force's work will facilitate international harmonization on the appropriate use of mammalian toxicity studies in the safety assessment of GM foods.

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ANNEX II

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