- eliminate the responsibility of industries, exporters and, when applicable, national competent authorities to continue to meet countries' relevant import requirements, including in relation to unauthorized recombinant-DNA plant material.

SECTION 2 – SECTIONS OF THE CODEX PLANT GUIDELINE APPLICABLE TO THE LOW-LEVEL PRESENCE OF RECOMBINANT-DNA PLANT MATERIAL IN FOOD

7. The following sections of the Codex Plant Guideline apply to the assessment of the food safety considerations arising from low-level presence of recombinant-DNA plant material in food. Paragraphs that apply are specifically indicated. If paragraphs are not listed, they can be omitted from consideration.

GENERAL CONSIDERATIONS

DESCRIPTION OF THE RECOMBINANT-DNA PLANT

Paragraph 22 applies as written:

22. A description of the recombinant-DNA plant being presented for assessment of food safety considerations should be provided. This description should identify the crop, the transformation event(s) to be reviewed and the type and purpose of the modification. This description should be sufficient to aid in understanding the nature of the food being submitted for assessment of food safety considerations.

DESCRIPTION OF THE HOST PLANT AND ITS USE AS A FOOD

Paragraphs 23, 24 and 25 apply.

DESCRIPTION OF THE DONOR ORGANISM(S)

Paragraph 26 applies as written:

26. Information should be provided on the donor organism(s) and, when appropriate, on other related species. It is particularly important to determine if the donor organism(s) or other closely related members of the family naturally exhibit characteristics of pathogenicity or toxin production, or have other traits that affect human health. The description of the donor organism(s) should include:

A. its usual or common name;

B. scientific name;

C. taxonomic classification;

D. information about the natural history as concerns food safety;

E. information on naturally occurring toxins and allergens; for microorganisms, additional information on pathogenicity and the relationship to known pathogens; and,

F. information on past and present use, if any, in the food supply and exposure route(s) other than intended food use (e.g., possible presence as contaminants).

DESCRIPTION OF THE GENETIC MODIFICATION(S)

Paragraphs 27, 28 and 29 apply.

CHARACTERIZATION OF THE GENETIC MODIFICATION(S)

Paragraphs 30, 31, 32 and 33 apply, except that 32 (D) applies as written:

32 (D): the level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the edible portions of the plant; and

ASSESSMENT OF FOOD SAFETY CONSIDERATIONS

Expressed Substances (non-nucleic acid substances)

Assessment of possible toxicity

Paragraphs 35 and 36 apply as written:

35. The assessment of food safety considerations should take into account the chemical nature and function of the newly expressed substance and identify the concentration of the substance in the edible parts of the recombinant-DNA plant, including variations and mean values.

36. Information should be provided to ensure that genes coding for known toxins present in the donor organisms are not transferred to recombinant-DNA plants that do not normally express those toxic characteristics. This assurance is particularly important in cases where a recombinant-DNA plant is processed differently from a donor plant, since conventional food processing techniques associated with the donor organisms may deactivate, degrade or eliminate toxicants.

Paragraph 37 applies.

Paragraph 38 applies as written:

38. In the case of proteins, the assessment of potential toxicity should focus on amino acid sequence similarity between the protein and known protein toxins as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems. Appropriate oral toxicity studies[15] may need to be carried out in cases where the protein present in the food is not similar to proteins that have previously been consumed safely in food, and taking into account its biological function in the plant where known.

Paragraphs 39 and 40 apply.

Assessment of possible allergenicity (proteins)

Paragraph 41 applies as written:

41. When the protein(s) resulting from the inserted gene is present in the food, it should be assessed for potential allergenicity in all cases. An integrated, stepwise, case-by-case approach used in the assessment of the potential allergenicity of the newly-expressed protein(s) should rely upon various criteria used in combination (since no single criterion is sufficiently predictive on either allergenicity or non-allergenicity). As noted in paragraph 20, the data should be obtained using sound scientific methods. A detailed presentation of issues to be considered can be found in the annex to the Codex Plant Guideline entitled *Assessment of Possible Allergenicity.*[16]

Paragraphs 42 and 43 apply.

Analyses of Key Toxicants and Allergens

Paragraphs 44 and 45 apply as written:

44. Analyses of key toxicants[17] and allergens are important in certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted, such as potatoes, tomatoes, and papaya). Analyses of concentrations of key toxicants and allergens of the recombinant-DNA plant typical of the food should be compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The statistical significance of any observed differences should be assessed in the context of the range of natural variations for that parameter to determine its biological significance. The

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[15] Guidelines for oral toxicity studies have been developed in international fora, for example, the OECD Guidelines for the Testing of Chemicals.

[16] The FAO/WHO expert consultation 2001 report, which includes reference to several decision trees, was used in developing the allergenicity Annex.

[17] Key toxicants are those toxicologically significant compounds known to be inherently present in the plant, such as those compounds whose toxic potency and level may be significant to health (e.g. solanine in potatoes if the level is increased).

comparator(s) used in this assessment should ideally be the near isogenic parental line. In practice, this may not be feasible at all times, in which case a line as close as possible should be chosen. The purpose of this comparison is to establish that substances that can affect the safety of the food have not been altered in a manner that would have an adverse impact on human health.

45. The location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown. The number of trial sites should be sufficient to allow accurate assessment of key toxicants and allergens over this range. Similarly, trials should be conducted over a sufficient number of generations to allow adequate exposure to the variety of conditions met in nature. To minimize environmental effects, and to reduce any effect from naturally occurring genotypic variation within a crop variety, each trial site should be replicated. An adequate number of plants should be sampled and the methods of analysis should be sufficiently sensitive and specific to detect variations in key toxicants and allergens.

Evaluation of Metabolites

Paragraph 46 applies as written:

46. Some recombinant-DNA plants may have been modified in a manner that could result in new or altered levels of various metabolites in the food. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), consideration should be given to the potential for the accumulation of metabolites in the food that would adversely affect human health. Assessment of food safety considerations arising from low level presence of recombinant-DNA material in foods from such plants requires investigation of residue and metabolite levels in the food. Where altered residue or metabolite levels are identified in foods, consideration should be given to the potential impacts on human health using conventional procedures for establishing the safety of such metabolites (e.g. procedures for assessing the human safety of chemicals in foods).

Food Processing

Paragraph 47 applies as written:

47. The potential effects of food processing, including home preparation, on foods derived from recombinant-DNA plants should also be considered. For example, alterations could occur in the heat stability of an endogenous toxicant. Information should therefore be provided describing the processing conditions used in the production of a food ingredient from the plant. For example, in the case of vegetable oil, information should be provided on the extraction process and any subsequent refining steps.

OTHER CONSIDERATIONS

POTENTIAL ACCUMULATION OF SUBSTANCES SIGNIFICANT TO HUMAN HEALTH

Paragraph 54 applies as written:

54. Some recombinant-DNA plants may exhibit traits (e.g., herbicide tolerance) which may indirectly result in the potential for accumulation of pesticide residues, altered metabolites of such residues, toxic metabolites, contaminants, or other substances which may be relevant to human health. In certain cases of foods from recombinant-DNA plants (e.g., those that are commonly consumed whole and undiluted), the risk assessment should take this potential for accumulation into account. Conventional procedures for establishing the safety of such compounds (e.g., procedures for assessing the human safety of chemicals) should be applied.

USE OF ANTIBIOTIC RESISTANCE MARKER GENES

Paragraphs 55, 56, 57 and 58 apply.

SECTION 3 – GUIDANCE ON DATA AND INFORMATION SHARING

8. In order for Codex Members to use this Annex, it is essential that they have access to requisite data and information.

9. Codex Members shall make available to a central database (to be maintained by...) information on recombinant-DNA plants authorized in accordance with the Codex Plant Guideline This information shall be presented in accordance with the following format:

    a. name of product applicant

    b. summary of application

    c. country of authorization

    d. date of authorization

    e. scope of authorization

    f. unique identifier

    g. summary of safety assessment by competent authority(s), and

    h. contact details of the competent authority(s) responsible for the safety assessment and the product applicant.

10. This process shall facilitate rapid access by importing Codex Member countries to additional information relevant to the assessment of food safety considerations arising from low-level presence of recombinant-DNA plant material in foods in accordance with this Annex.

11. The authorizing Codex Member shall make available complementary information to other Codex Members on the outcome of its safety assessment in accordance with the Codex Plant Guideline, in conformity with its regulatory/legal framework.

12. The product applicant shall make all reasonable efforts to provide further information and clarification as necessary to allow the assessment according to this Annex to proceed, as well as a validated protocol for an event-specific or trait-specific detection method, as specified by the Codex Member, and non-viable reference materials.

13. As appropriate, new scientific information relevant to the conclusions of the food safety assessment conducted in accordance with the Codex Plant Guideline by the authorizing country should be made available

Attachment 3

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
LISTA DE PARTICIPANTES

Chairperson - President – Presidente

Dr. Eric Flamm
Senior Advisor
Office of the Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
United States of America
Tel: +1 301 827 0591
Email: Eric.Flamm@fda.hhs.gov

Dr. Thomas Meier
Federal Ministry of Agriculture, Food and Consumer Protection, Germany
Desk Officer, Biotechnology
Federal Ministry of Agriculture,
Food and Consumer Protection
Rochusstrasse 1
D 53123 Bonn
Germany
Tel: +49-228-529-55-4078
Email: Thomas.Meier@BMelv.Bund.de

Oratai Silapanapaporn
Director, Office of Commodity and System Standards
National Bureau of Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives
Rajadamnern Nok. Avenue
Bangkok 10200
Thailand
Tel: 66 2 280 3900
Fax: 66 2 280 3899, 283 1669
Email: oratai@acfs.go.th

ARGENTINA

Dr. Moises Burachik
General Coordinator of the Biotechnology Office
Secretary of Agriculture
Livestock, Fisheries and Food
Ministry of Economy and Production
Av. Paseo Colón 922, 2nd Floor, Of, N° 247
C1063ACW Buenos Aires
Argentina
Tel: 54-11 4349-2074 & 4349-2303
Fax: 54-11 4349-2178
Email: mburac@mecon.gov.ar &
burachik225@yahoo.com

Juan Carlos Batista
Agronomist Engineer
Senasa (National Agrifood Health and Quality Service)
Paseo Colon 367, (C1063ACW)
Buenos Aires, Argentina
Tel: 54 11 4121 5251
Fax: 54 11 4121 5258
Email: jbatista@senasa.gov.ar

Federico Alais
Biotechnology Negotiations Coordinator
Dirección de Relaciones Agroalimentarius
Internacionales – Secretaria de Agricultura, Ganadería,
Pesca y Alimentos
Av. Paseo Colon 922 – PB – Oficina 39 (1063)
Beunos Aires
Argentina
Tel: +54 (11) 4349-2019
Fax: +54 (11) 4349-2244
Email: falais@mecon.gov.ar

José Molina
Consejero Agricola
Sagpya-Embajada de la Republica
Argentina
1600 New Hampshire Ave., NW
Washington, D.C. 20009
EEUU
Tel: (202) 238-6443
Fax: (202) 332 1324
Email: Josed.Molina@verizon.net

AUSTRIA

Dr. Andreas Heissenberger
Deputy Unit Head
Umweltbundesamt-Federal Environment Agency
Austria
Spittelauer Laende 5
1090 Vienna
Austria
Tel: +43 1 31304 3032
Fax: +43 1 31304 3700
Email: andreas.heissenberger@umweltbundesamt.at

AUSTRALIA/AUSTRALIE\

Dr. Rob Williams
Agriculture, Fisheries & Forestry
Embassy of Australia
1601 Massachusetts Ave, NW
Washington, D.C. 20036
Tel: (202) 797-3319
Fax: (202) 797-3037
Email: Rob.Williams@dfat.gov.au

Dr. Carol Andersson
Senior Food Scientist
Food Standards Australia New Zealand
P.O. Box 7186
Canberra BC ACT 2610
Australia
Tel : +61-2-6271 2266
Fax : +61-2-6271 2278
Email : carol.andersson@foodstandards.gov.au

BELGIUM

Sarah De Munck
Expert GMO and Novel Food
Federal Public Service of Health
Food Chain Safety Environment
Eurostation II – 7th floor
Victor Hortaplein 40 bus 10
1060 Brussels
Belgium
Tel : +32 2 524 73 58
Fax : +32 2 524 73 99
Email : Sarah.demunck@health.fgov.be

BRAZIL/BRESIL/BRASIL

Emerson Kloss
Head of Delegation
Secretary
Embassy of Brazil
3006 Massachusetts Ave., NW
Washington, D.C. 20008
Tel : (202) 238-2758
Fax : (202) 238-2827
Email : ekloss@brasilemb.org

Paulo José Péret de Sant' Ana
General Coordinator for Biotechnology and Health
Ministry of Science and Technology
General Coordination of Biotechnology and Health
Esplanada dos Ministérios-
B1.E-2° andar-sala 256 – CEP : 70067-900
Brasília-DF-Brazil
Tel : +55 61 3317-8008
Fax : +55 61 3317-7766
Email: pperetsa@mct.gov.br

Marília Nutti
EMBRAPA
Av. das Américas
No. 29501
Guaratiba-RJ-CEP : 23020-470
Brazil
Tel : +55 21 2410-9555
Fax : +55 21 2410-9555
Email : marilia@ctaa.embrapa.br

Laila Sofia Mouawad
Health Expert
Brazilian National Health Surveillance Agency
SEPN 511, Bloco A, sala 215-A,
Brasília/DF
70750-541
Brazil
Tel : 55 61 3448 6330
Fax : 55 61 3448 6274
Email : Laila.mouawad@anvisa.gov.br

Elkiane Macedo Rama
Health Regulatory Expert
Brazilian National Health Surveillance Agency
General Office of Toxicology
SEPN 511, Blo co A, Sala 206B,
Brasília
DF, 70750-541
Brazil
Tel : +55 61 3448 6203
Fax : +55 61 3448 6287
Email : elkiane.rama@anvisa.gov.br

CANADA

Dr. William Yan
Chief
Evaluation Division,
Bureau of Microbial Hazards
Health Canada
251 Sir Frederick Banting Driveway
Ottawa, Ontario P.L. 2204A1
Tel: 01-613-941-5535
Fax: 01-613-952-6400
Email: William_Yan@hc-sc.gc.ca

Angela Behboodi
Senior Trade Policy Officer
Technical Barriers and Regulations Division
Foreign Affairs and International Trade Canada
125 Sussex Drive
Ottawa, Ontario
KIA0G2
Tel: 1-613-944-2100
Fax: 1-613-943-0346
Email: angela.behboodi@international.gc.ca

Brian Harrison
Scientific Evaluator
Health Canada
251 Sir Frederick G. Banting Driveway
Tunney's Pasture
PL 2204A1
Ottawa, Ontario KIA OK9
Canada
Tel: (613) 957-1405
Fax: (613) 941-8849
Email: brian_harrison@hc-sc.gc.ca

Émilie Bergeron
Trade Policy Analyst
Agriculture and Agri-Food Canada
Sir John Carling Building
930 Carling Av., room 10109
Ottawa, Ontario, Canada,
KIA OC5
Canada
Tel: 1-613-694-2324
Fax: 1-613-759-7503
Email: bergerone@agr.gc.ca

Angela Bilkhu
Program Officer
Canadian Food Inspection Agency
159 Cleopatra Drive
Ottawa, Ontario
K1A OY9
Canada
Tel: 1-613-221-7205
Fax: 1-613-221-7595
Email: bilkhua@inspection.gc.ca

CZECH REPUBLIC

Dr. Jaroslava Ovesna
Ministry of Agriculture/Crop Research Institue
Drnovska 507
161 06 Prague 6 – Ruzyne
Czech Republic
Tel : +420 233 022 424
Fax : +420 312 269 260
Email : Ovesna@vurv.cz

EUROPEAN COMMUNITY

Dr. Michael Scannell
Head of Unit
Directorate General for Health and Consumer Protection
Rue Froissart 101
B-1049
Brussels, Belgium
Tel: (+32-2)299.33.64
Fax: (+32-2) 299.85.66
Email: Michael.Scannell@ec.europa.eu

Dr. Sébastien Goux
Policy Officer
European Commission
Office B232 03/24
1049 Brussels
Belgium
Tel: +32 2 292 15 55
Fax: +32 2 295 60 43
Sebastien.goux@ec.europa.eu

Dr. Suzy Renckens
Head of Unit
European Food Safety Authority (EFSA)
DUSA 00/012
Largo Natale Palli, 5
43100 Parma
Italy
Tel: +39 0521 036 223
Fax: +39 0521 036 323
Email: Suzy.Renckens@efsa.europa.eu

FINLAND

Dr. Leena Mannonen
Commercial Counsellor
Ministry of Trade and Industry
P.O. Box 32
(Ratakatu 3, Helsinki)
FIN-00023 Government
Finland
Tel: +358 9 1606 3716
Fax: +353 9 1606 2670
Email: leena.mannonen@ktm.fi

FRANCE/FRANCIA

Emmanuelle Miralles
Chargèe des questions OGM
MINEFI – DGCCRF
59 Bd Vincent Auriol
Bureau C3 – Teledoc 051
75703 Paris CEDEX 13
France
Tel: +33 1 44 97 24 06
Fax: +33 1 44 97 30 37
Email: Emmanuelle.miralles@dgccrf.finances.gouv.fr

GERMANY

Dr. Maria Anna Schauzu
Scientific Director
Federal Institute of Risk Assessment
Thielallee 88-92
D-14195
Berlin, Germany
Tel: +49-30-8412-3758
Fax: +49-30-8412-3635
Email: maria-anna.schauzu@bfr.bund.de

Dr. Thomas Meier
Federal Ministry of Agriculture, Food and Consumer Protection, Germany
Desk Officer, Biotechnology
Federal Ministry of Agriculture,
Food and Consumer Protection
Rochusstrasse 1D-53123 Bonn
Germany
Tel: +49-228-529-4078
Email: Thomas.Meier@Bmelv.bund.de

GREECE

Kontolaimos Vasileios
Legal Advisor
Ministry of Rural Development and Food
Acharnon 29
10439 Athens
Greece
Tel : + 30210 8250307
Fax : +30210 8254621
Email : codex@efet.gr

IRELAND

Dr. Patrick O' Mahony
Chief Specialist, Biotechnology
Food Safety Authority of Ireland
Abbey Court
Lower Abbey Street
Dublin 1
Ireland
Tel : 353 1 8171300
Fax : 353 1 8171207
Email: pjomahony@fsai.ie

ITALY/ITALIE/ITALIA

Ciro Impagnatiello
Ministero delle Politiche Agricole
Alimentari e Forestali
Via XX Settembre, 20
I-00187 Roma
Italy
Tel : +39 06 46656046
Fax : +39 06 4880273
Email : c.impagnatiello@politicheagricole.it

JAPAN

Professor Yoshihiro Ozeki
Special Advisor
Food Safety Commission
184-8588
Tokyo University of Agriculture and Technology
2-24-16 Naka-machi, Koganei-shi,
Tokyo, Japan
Tel : +81 42 388 7239
Fax :
Email : ozeky@cc.tuat.ac.jp

Mari Yoshitomi
Deputy Director
Food Safety Commission Secretariat
100-8989
Prudential Tower 6F 2-13-10
Nagata-cho, Chiyoda-ku
Tokyo, Japan
Tel : +81 3 5251 9168
Fax : +81 3 3591 2236
Email : mari.yoshitomi@cao.go.jp

Dr. Hiroshi Yoshikura
Adviser
Department of Food Safety
Pharmaceutical and Food Safety Bureau
Ministry of Health,
Labour and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku
Tokyo, 100-8916
Japan,
Tel : +81-3-3595-2326
Fax : +81-3-3503-7965
Email : Codexj@mhlw.go.jp

Miyazako Mashahiro
Associate Director
International Affairs Division
Food Safety and Consumer Affairs Bureau
Ministry of Agriculture
Forestry & Fisheries
1-2-1, Kasumigaseki
Chiyoda-ku,
100-8950
Tokyo, Japan
Tel : +81-3-3502-8732
Fax :+81-3-3507-4232
Email : masahiro_miyazako@nm.maff.go.jp

Dr. Terumasa Matsuoka
Deputy Director
Standards and Evaluation Division
Department of Food Safety, Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare
1-2-2, Kasumigaseki, Chiyoda-ku,
Tokyo, 100-8916,
Japan,
Tel : +81 3 3595 2341
Fax : +81 3 3501 4868
Email : codexj@mhlw.go.jp

KENYA

Amos Alakonya
Plant Inspection Officer
Kenya Plant Health Services
P.O. Box 49592 00100
Nairobi Kenya
Tel : 254-20-884545
Fax : +254 20 882265
Email : director@kephis.org or aalakonya@kephis.org

Margaret Aleke
Head
Food Agriculture and Chemical Standards
Kenya Bureau of Standards
P.O. Box 54974 00200
Nairobi
Kenya
Tel : +254 20 605490 or 605506
Fax : +254 20 609660
Email : info@kebs.org or alekem@kebs.org

KOREA

Dr. Il Ung Oh
Senior Reviewer & Scientific Officer
Novel Food Team
Korea Food & Drug Administration
#194 Tongil-ro
Eunpyung-gu
Seoul, 122-704
Korea
Tel : 82-2 380-1332~4
Fax : 82-2 380-1656
Email : iuoh@kfda.go.kr

MEXICO

Dr. Carlos Lomelin
Executive Director
ILSI Mexico
FCO. Petrarca 133 – 403
Col. Chapultepec Morales
11570 Mexico, D.F.
Mexico
Tel : 52 55 5255- 2652
Fax : 52 55 5545-1074
Email : ilsimex@prodigy.net.mx

Sandra Piña-Salinas
Governmental Affairs
AgroBIO México, A.C.
Calderón de la Barca 78 PB
Col. Polanco, C.P. 11560
México, D.F.
Tel : 52 55 5282-1932
Fax : 52-55 5281 4400
Email : spina@agrobiomexico.org.mx;
sandrapina@prodigy.net.mx

Marcelo Signorini Porchieto
Jefe De La Delegación
Subdirector Ejecutivo De Efectos Poblacionales
Comisión De Evidencia Y Manejo De Riesgos
Comisión Federal para la Protección Contra Riesgos
Sanitarios (Salud-Cofepris)
Monterrey No.33 Piso 10 Col. Roma Delegación
Cuauhtémoc
C.P. 06700
Mexico
Tel : 52 55 5080 5147
Fax : 52 55 5208 3032
Email : msignorini@salud.gob.mx

NORWAY

Dr. Knut G. Berdal
National Veterinary Institute
Senior Scientist
National Veterinary Institute
Food and Feed Microbiology
P.O.B. 8156 Dep
N-0033 Oslo
Norway
Tel: +47 23 21 62 42
Fax: 47 23 21 62 02
Email: Knut.berdal@vetinst.no

Tove Elisabeth Løken
Norwegian Ministry of Health and Care Services
Senior Adviser
Department of Public Health
P.O. Box 8011 Dep
N-0030 OSLO
Norway
Tel: +47 22 24 87 72
Fax:
Email: tel@hod.dep.no

PHILIPPINES

Ampil Charo Amparo
Chief
Policy Advocacy and Legislative Support Division
Policy Research Division
Office for Policy & Planning
Department of Agriculture
Elliptical Road
Quezon City, Phillipines
1101
Tel: 622-9267439
Fax: 622-9280590
Email: amparo.ampile@lycos.com
acascolan@yahoo.com

Dr. Ernelea Cao
Director
Natural Sciences Research Institute (NSRI)
Office of the Director
University of the Phillipines, Diliman Quezon City
1101
Phillipines
Tel: 63-2 925 2963/ 63-2 925-2964
Fax: +63-2 928-6868
Email: ernelea.cao@up.edu.ph

SWEDEN

Anders Wannberg
Senior Administrative Officer
Ministry of Agriculture Food and Fisheries
103 33 STOCKHOLM
Sweden
Tel : +46-8-405 12 79 & +46-8-405 10 00
Fax : +46-8-20 64 96
Email : anders.wannberg@agriculture.ministry.se

Zofia Kurowska
Chief Government Inspector
National Food Administration
Box 622
SE-751 26 Uppsala
Sweden
Tel : +46 18 17 55 08
Fax : +46 18 10 58 48
Email : codex@slv.se

SWITZERLAND/SUISSE/SUIZA

Dr. Martin Schrott
Staff Scientist
Federal Office of Public Health
3003 Bern
Switzerland
Tel : +41 31 322 69 89
Fax : +41 31 322 95 74
Email : martin.schrott@bag.admin.ch

THAILAND/THAILANDE/TAILANDE

Oratai Silapanapaporn
Director, Office of Commodity and System Standards
National Bureau of Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives
Rajadamnern Nok. Avenue
Bangkok 10200
Thailand
Tel: 66 2 280 3900
Fax: 66 2 280 3899, 283 1669
Email: oratai@acfs.go.th

Darunee Edwards
Deputy Director
National Center for Genetic Engineering and Biotechnology (BIOTEC)
113 Thailand Science Park
Pathum Thani
12120
Thailand
Tel: 66 2 5646700 ext 3163
Fax: 66 2 5676701
Email: dedwards@biotec.or.th

Namaporn Attaviroj
Standards Officer
Office of Commodity and System Standards
National Bureau of Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives
Rajadamnern Nok. Avenue
Bangkok 10200
Thailand
Tel: 66 2 280 3887
Fax: 66 2 280 3899
Email: namaporn_jar@yahoo.com or namaporn@acfs.go.th

UNITED KINGDOM/ROYAUME-UNI/REINO UNIDO

Dr. Sandy Lawrie
Head of Novel Food Branch
Food Standard Agency
125 Kingsway
London WC2B 6NH
United Kingdom
Tel: +44 20 7276 8565
Fax: +44 20 7276 8564
Email: Sandy.Lawrie@foodstandards.gsi.gov.uk

UNITED STATES OF AMERICA/ETATS UNIS D'AMERIQUE/ESTADOS UNIDOS DE AMERICA

Dr. Eric Flamm
Senior Advisor
Office of the Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
United States of America
Tel: +301 827 0591
Email: Eric.Flamm@fda.hhs.gov

Dr. Kathleen Jones
Biotechnology Coordinator,
Office of Regulations and Policy, Center
For Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
United States of America
Tel: +301 436 1856
Email: Kathleen.Jones@fda.hhs.gov

Dr. Rebecca Edelstein
Chemist
Office of Pesticide Programs
U.S. E.P.A., OPP/BPPD (7511 P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460
United States of America
Tel: (703) 605-0513
Fax: (703) 305-0118
Email: Edelstein.Rebecca@epa.gov

Cindy Smith
Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Services
U.S. Department of Agriculture
4700 River Rd.,
Unit 98, Riverdale, MD 20737
United States of America
Tel: +1 301 734 7324
Email: cindy.j.smith@usda.gov

Beverly Simmons
Assistant Deputy Administrator
Office of Scientific and Technical Affairs
Foreign Agriculture Service
U.S. Department of Agriculture
1400 Independence Ave., S.W.
Washington, D.C., 20250
United States of America
Tel: +1 202 720-1286
Email: Beverly.simmons@usda.gov

Darci Vetter
Director for Agricultural Affairs
Office of the U.S. Trade Representative
600 17th St, NW
Washington, DC 20508
United States of America
Tel: (202) 395-9629
Fax: (202) 395-4579
Email: Darci_vetter@ustr.eop.gov

INTERNATIONAL GOVERNMENTAL ORGANIZATIONS

INTER-AMERICAN INSTITUTE FOR CORPORATION ON AGRICULTURE

John P. Passino
Advisor
1889 F. Street, NW
Suite 360
Washington, D.C. 20006
Tel: (202) 458-3767
Fax: (202) 458-6335

INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS

49th PARALLEL BIOTECHNOLOGY CONSORTIUM

Prof. Philip L. Bereano
Co-Director
49th Parallel
Box 352195
University of Washington
Seattle, Washington 98195
Tel: 1-206-543-9037
Fax: 1-206-543-8858
Email:pbereano@u.washington.edu

BIOTECHNOLOGY INDUSTRY ORGANIZATION

Dr. Michael Phillips
Vice President
Biotechnology Industry Organization
1225 Eye Street, NW
Suite 400
Washington, DC 20005
Tel: (202) 962-9200
Fax: (202) 962-9201
Email: mphillips@bio.org

Betsy Flores
Manager
Biotechnology Industry Organization
1225 Eye Street, NW
Suite 400
Washington, D.C. 20005
Tel: (202) 962-9200
Fax: (202) 962-9201
Email: bflores@bio.org

Dr. Roy Fuchs
Regulatory Affairs
Monsanto Company
800 North Lindbergh Blvd
Mail Zone E1NH-E1839N
St Louis, MO 63167
Tel: 314-694-3073
Fax:
Email: roy.l.fuchs@monsanto.com

Dr. Natalie Hubbard
Global Leader
Regulatory Affairs
DuPont-Pioneer Company
PO Box 80402
Wilmington, DE 19880
Tel: 302-695-1220
Fax: 302-695-3075
Email: Natalie.l.hubbard@cgr.dupont.com

Brad Shurdut
Global Leader
Government and Public Affairs
Dow AgroSciences
1776 Eye Street., NW
Washington, D.C. 20006
Tel: (202) 429-3434
Fax:
Email: bashurdut@dow.com

COMITÉ DU COMMERCE DES CÉRÉRALES, ALIMENTS DU BÉTAIL OLÉAGINUEX, HUILE D'OLIVE, HUILES ET GRAISSES ET AGROFOURNITURES (COCERAL)

Dr. Klaus Schumacher
Chair of Marrets Sections
Coceral
Rue Du Trône 98
1050 Bruxelles
Belgium
Tel : +32-2 502.08.08
Fax : +32 – 2 502.60.30
Email : secretariat@coceral.com

Kyd Brenner
Legal Counselor
Rue du Crône 98
1050 Brussels
Belgium
Tel: +32 2 502 08 08
Fax: +32 2 502 60 30
Email:

CONFEDERATION OF THE FOOD & DRINK INDUSTRIES OF THE EU

Beate Kettlitz
Director
Food Policy and R&D
Avenue des Arts 43
1040 Brussels
Belgium
Tel: +322 5008750
Fax: +322 5081021
Email: b.kettlitz@ciaa.eu

CONSUMERS INTERNATIONAL

Dr. Michael Hansen
Senior Scientist
Consumers Union
101 Truman Ave
Yonkers, NY 10703
Tel: 914-378-2452 or 914-378-2455
Fax: 914-378-2928
Email: hansmi@consumer.org

Toshiki Mashimo
Member of the Steering Committee
Consumers Union of Japan
Setagaya-ku, Sakura 2-21-23-301
Tokyo MZ 156-0053
Japan
Tel: +81-3-3427-8265
Fax: +81-20-4665-6950
Email: mashimo@kyodonomori.com

CROP LIFE INTERNATIONAL

Lucyna Kurtyka
Global Lead, International Organizations
Monsanto Company
1300 I Street, NW
Suite 450
Washington, D.C. 20005
Tel: (202) 383-2861
Fax: (202) 789-1748
Email: lucyna.k.kurtyka@monsanto.com

Dr. Susanne Maise
Senior Manager
Special Projects
143 Avenue Louise
1050 Brussels
Belgium
Tel: +32 (2) 5411669
Fax: +32 (2) 5420419
Email: susanne@croplife.org

Lisa Zannoni
Head
Global Biotechnology Regulatory Affairs
Syngenta Biotechnology, Inc.
P.O. Box 12257
3054 Cornwallis Road
Research Triangle Park
NC 27709-2257
Tel: +919-541-8535
Fax: 919-541-8535
Email: lisa.zannoni@sygenta.com

Ann Tuttle
Regulatory Affairs Manager
Syngenta Biotechnology, Inc.
P.O. Box 12257
3054 Cornwallis Road
Research Triangle Park, NC
27709-2257
Tel: 1-919-541-8667
Fax: 1-919-541-8535
Email: ann.tuttle@sygenta.com

EUROPABIO

Dr. Dirk Klonus
Manager Global Registration BioScience
Bayer Crop Science
Industriepark Höchst K607 65926 Frankfurt/Main
Germany
Tel: +49 69 30 51 47 58
Fax: +49 69 30 51 34 42
Email: Dirk.Klonus@bayercropscience.com

Raffaella Colombo
Europa GBE Project Manager
Av. De l'Armèe n°6
1040 Brussels
Belgium
Tel: +32 2 7391179
Fax: +32 2 735 49 60
Email: r.colombo@europabio.org

EUROPEAN FEED MANUFACTURER'S FEDERATION

Alexander Döring
Secretary General
223 Rue De La Loi
Box 3
1040 Brussels
Belgium
Tel: 32-2 285.00.50
Fax: 32-2 230.57.22
Email: fefac@fefac.org

Deirdre Webb
223 Rue De La Loi
Box 3
Noyo Brussels
Belgium
Tel: 32-2 285.00.50
Fax: 32-2 230.57.22
Email: fefac@fefac.org

GRAIN AND FEED TRADE ASSOCIATION

Randal Giroux
Gafta House
6 Chapel Place
Rivington Street
London EC2A 3SH
United Kingdom
Tel: +44 20 7814 9666
Fax: +44 20 7814 8383
Email: PaulCurtis@gafta.com

GROUPEMENT DES ASSOCIATIONS MEUNIÈRES DE L' UNION EUROPÉENNE

Chris Downes
EU Affairs Manager
GAM
Avenue des Gaulois 9
B-1040 Brussels
Belgium
Tel: +32.2.736.53.54
Fax: +32.2.732.34.27
Email: secretariat@gam.eu

INTERNATIONAL COUNCIL OF GROCERY MANUFACTURERS ASSOCIATION (ICGMA)

Dr. Jeffrey Barach
Vice President and Center Director
GMA/FPA
1350 I Street N.W. Suite 300
Washington, D.C. 20005
Tel: (202) 639-5955
Fax: (202) 639-5991
Email: jbarach@fpa-food.org

Peggy S. Rochette
Sr. Director of International Policy
GMA/FPA
1350 I Street, NW
Washington, D.C. 20005
Tel: (202) 639-5921
Fax: (202) 639-5991
Email: prochette@fpa-food.org

INTERNATIONAL GRAIN TRADE COALITION

Dennis Stephens
Secretary
International Grain Trade Coalition
Canada Grains Council
1215 Partage Avenue
Winnipeg, MB
Canada
R3C0A5
Tel: 1-204-925-2130
Cell: 1-204-955-2423
Fax: 1-204-925-2133
Email: dstephens@canadagrainscouncil.ca

INTERNATIONAL SEED FEDERATION

Dr. Roger Krueger
Chairman Sustainable Agriculture Committee
ISF
800 North Lindbergh Blvd
E2SN
Monsanto Company
St Louis, MO 63131
Tel: 314.694.3677
Fax: 314.694.2074
Email: roger.w.krueger@monsanto.com

Dr. Bernice Slutsky
Vice President, Science and International Affairs
American Seed Trade Association
225 Reinekers Lane
Suite 650
Alexandria, Virginia 22314-2875
Tel: (703) 837-8140
Fax: (703) 837-9365
Email: bslutsky@amseed.org

FAO/WHO SECRETARIAT

Mr. Masashi Kusukawa
Food Standards Officer
Viale delle Terme di Caracalla
00153
Rome, Italy
Tel: +39 06 570 54796
Fax: +39 06 5705 4593
Email: codex@fao.org

US SECRETARIAT/SECRETARIAT AMERICAIN/SECRETARIADO AMERICANO

Judy Garrison
USDA, APHIS
4700 River Road
Riverdale Md, 20737
Tel: 301-734-5769
Fax: 301-734-0767
Email: Judy.Garrison@aphis.usda.gov

Jaqueline Barnes
USDA, APHIS
4700 River Road
Riverdale Md, 20737
Tel: 301-734-0807
Fax: 301-734-0767
Email: Jacquelyn.D.Barnes@aphis.usda.gov

Dr. Donna Malloy
Veterinary Medical Officer
USDA, APHIS, BRS
4700 River Road #146
Riverdale, Md 20737
Tel: 301-734-0673
Fax: 301-734-3135
Email: Donna.L.Malloy@aphis.usda.gov

Paulo Almeida
Associate Manager
U.S. Codex Office
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 4861 South Bldg.
1400 Independence Ave. SW
Washington, DC 20250
Phone : 202-690-4042
Fax : 202-720-3157
Email: Paulo.Almeida@fsis.usda.gov

Jasmine Matthews
Program Analyst
U.S. Codex Office
U.S. Department of Agriculture
Food Safety and Inspection Service
Room 4861 South Bldg.
1400 Independence Ave. SW
Washington, DC 20250
Phone : 202-690-1124
Fax : 202-720-3157
Email : jasmine.matthews@fsis.usda.gov

Dr. Michael Watson
Branch Chief
Plants Pests and Protectancts Branch
USDA/APHIS/Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, MD 20737
Tel : (301) 734-0486
Fax : (301) 734-8669
Email : michael.t.watson@aphis.usda.gov

Dr. H. Michael Wehr
Codex Program Coordinator, International Activities Staff
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
Tel : +1 301 436-1724
Fax : +1 301 436-2318
Email : Michael.wehr@fda.hhs.gov

Dr. Robin Woo
Technical Assistance Specialist
International Affairs Staff
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740
Tel: +1 301 436-2776
Fax: +1 301 436-2328
Email : Robin.woo@fda.hhs.gov

SPECIALS/AUTRES PARTICIPANTS/OTROS PARTICIPANTES

Dr. Sally McCammon
Science Advisor
USDA APHIS
4700 River Road
Riverdale, MD 20737
Tel: (301) 734-5761
Fax: (301) 734-6352
Email: Sally.L.McCammon@usda.gov

Dr. Melissa Kramer
Biologist
U.S. Environment Protection Agency
1200 Pennsylvania Ave., N.W
(MC 7202M)
Washington, D.C. 20460
Tel: (201) 564-8497
Fax: (202) 564-8502
Email: Kramer.melissa@epa.gov

Corey Wright
International Trade Specialist
U.S. Department of Commerce
14th and Constitution Ave., N.W.
Washington, D.C. 20230
Tel: +1-202- 482 2844
Email: Corey_Wright@ita.doc.gov

Dr. In-Soon You
Biologist
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
Tel: (202) 564-8496
Fax: (202) 564-8502
Email: You.in-soon@epa.gov