

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 3

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

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PROPOSED DRAFT WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY

The Proposed Draft Working Principles for Risk Analysis for Food Safety (Appendix III) are distributed for comments. Governments and international organizations wishing to comment are invited to do so in writing, preferably by Email, to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, Fax: +39 (06) 5705 4593, e-mail : codex@fao.org with a copy to the Codex Contact Point for France, SGAE, Secteur AGRAP, Carré Austerlitz, 2 Boulevard Diderot, 75572 Paris Cedex 12, Fax. 33 (0)1 4487 16 04, Email: sgae-codex-fr@sgae.gouv.fr, **before 28 February 2007.**

REPORT OF THE WORKING GROUP ON WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY

26th – 28th September 2006
Brussels, Belgium

1. The Working Group on the Working Principles for Risk Analysis for Food Safety established by the 23rd Session (April 2006) convened in Brussels, Belgium, September 26-28, 2006. The meeting was co-chaired by Mr. Paul Mayers (Canada) and Ms. Bodil Blaker (Norway) and was attended by 67 delegates representing 29 member governments and 5 observer organizations. The list of participants is attached in Appendix 1. The Working Group was mandated to:

- To discuss and articulate the rationale for guidance to governments related to the application of risk analysis by governments, based on the discussion of the present session and previous sessions of the CCGP;
- To describe the output that Codex may require to respond to this rationale; and
- To draft, for further discussion, some simple and horizontal principles on the implementation of risk analysis by governments.

2. The Working Group secretariat introduced the background paper prepared for the meeting (Appendix II) and the FAO representative gave an overview of the FAO/WHO Food Safety Risk Analysis: A Guide for National Authorities. The co-chairs reviewed the mandate of the Working Group, inviting open discussion by all members, encouraging them to avoid debating issues that had been tabled at previous Working Groups or CCGP meetings. The co-chairs also reminded the Working Group that its purpose was to provide recommendations to CCGP and not to make decisions which must be left to the Committee.

3. Members noted the importance of developing these principles given that national governments apply risk analysis. In their consideration of the rationale for guidance to governments, members provided their views and comments, summarized as follows:

- Governments apply risk analysis for food safety for the protection of consumers.

- Consistent risk analysis at the national level is most important. Thus, the importance of establishing principles for risk analysis at the international level was recognized.
- The absence of clear guidance can contribute to disputes and, therefore, a concise set of overarching principles to guide national governments would contribute to consistency, mutual recognition and predictability.
- The Working Group would not seek to develop a detailed guide or manual, but a practical, concise and outcome-driven set of principles that will provide for clarity of scope and will address the issue of dealing with scientific uncertainty in a directional though non-prescriptive manner.

4. In order to provide a starting point for discussions on proposed draft working principles for risk analysis for application by national governments, the co-chairs presented a suggested draft set of generic principles drawn from the Codex principles and from the FAO/WHO Food Safety Risk Analysis: A Guide for National Authorities. This approach was considered by the Working Group but it instead decided to use the text of the *Codex Working Principles for Application Within the Framework of Codex Alimentarius* as a starting point. The Working Group noted that this text had already been extensively debated, and it would be more expeditious to review the adopted text, retain those provisions which would apply to governments and revise or delete provisions that would not be applicable to governments.

5. During the development of the proposed draft Principles, the Working Group had comprehensive discussions on the various components of risk analysis principles for application by government. This report focuses on the significant conclusions of the Working Group and identifies those issues that the Working Group agreed should be brought up to the attention of the committee, as matters where further guidance would be useful and/or may need to be addressed in the future. It should be noted that these issues were not identified as gaps in the Proposed Draft Principles, but rather areas to be considered by the Committee.

General Aspects

6. The principles elaborated and agreed to by the Working Group do not address all health aspects but are focused on food safety. For example, it was recognized that CCNFSDU was undertaking new work with regards to risk analysis as it applies to nutrition. Therefore, at a future time, CCGP will need to consider the integration of these principles and the outcomes of the CCNFSDU work.

7. Noting the reference in the SPS Agreement to countries undertaking risk assessments according to techniques developed by the relevant international organizations, Working Group participants expressed the view that risk analysis activities should be based on the procedures established by the Codex Alimentarius Commission or other international organizations, especially in situations applicable to international trade.

8. It was recognized that a functional separation between risk assessment and risk management may not be feasible or practical. (See Appendix III, Principle 11) The Working Group agreed with this as a valid statement of principle while noting that greater guidance on how countries could achieve this functional separation between risk assessment and risk management would be useful. However, the Working Group did not undertake to develop this guidance as it was considered to be outside of its current mandate. The development of such guidance might be considered within the context of the FAO/WHO Food Safety Risk Analysis: A Guide for National Authorities.

9. The Working Group discussed the clarity of the following sentence at the end the principle addressing the use of precaution in risk analysis: "The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard." (See Appendix III, Principle 12) While the working group agreed to the text as a valid statement of principle, it noted that further clarification would be useful with respect to the practical application of that concept, specifically the linkage between the assumptions made and the characteristics of the hazard.

Risk Assessment Policy

10. Although it is recommended in the Principles that risk assessment policy should be established by risk managers in advance of risk assessment, it was recognized by participants that establishing such policy in advance of the risk assessment may not always be feasible at a national level. Members of the Working Group agreed that countries need to gain more experience in developing risk assessment policy, particularly

with regards to microbiological risk assessments. While agreeing with the Principle, the Working Group noted that some flexibility would therefore be needed in how this principle would be applied in practical terms until such experience has been gained. The Working Group noted that this was an important area where the development of appropriate guidance would be beneficial.

Risk Assessment

11. Although the scientific data to be used for risk assessment need to reflect the national context, the Working Group was of the view that a risk assessment should not be limited to the exclusive use of national data, as information or knowledge gathered or developed in other countries or by international organizations may also be applicable, depending on the risk being evaluated. The realities and conditions applicable to the national situation need be taken into consideration in the risk assessment steps, but should not exclude other valid data, including the outcomes of risk assessments in other countries, if applicable.

Risk Management

12. The Working Group noted the existing provision regarding the need for objectivity and avoiding conflict of interest for risk assessors and considered whether there was a need for a similar conflict of interest provision to be applied to risk managers. In this regard, the Working Group was of the view that the purpose of the conflict of interest provision with respect to risk assessors was to ensure the scientific integrity of the risk assessment. However, risk managers, in the process of decision-making, have to take into account a range of information, not just the scientific information. Furthermore, it was noted that provisions existed requiring transparency in, and review of, risk management decisions. Therefore the Working Group determined that there was no need for the inclusion of a conflict of interest provision to be applied to risk managers.

13. The Working Group recognized the dual context in which the principles would be applied; i.e., to products intended for the domestic market and products intended for international trade. In its deliberations on paragraph 36 (See Appendix III, Principle 36) while noting it was important not to create unjustified barriers to trade, the Working Group agreed the significant element of the principle was the recognition that the decision was based on measures that achieved equivalent protection of public health.

Risk Communication

14. One delegation suggested that an additional sub-principle to Paragraph 38 of Appendix III should be included on improving accessibility to and understanding of the risk analysis output by making it available in multiple languages. While recognizing the intent of the proposal, the Working Group noted the difficulty of addressing such a recommendation in the principles and agreed that it should be left to national governments to determine to what extent they would make information available in their respective indigenous language(s) or other languages. The Working Group was of the view that the various elements of Paragraph 38 (See Appendix III, Principle 38) in essence, incorporate the spirit of fostering greater understanding.

Implementation

15. The Working Group discussed the application of the draft Principles and agreed that a section on implementation should be included in these Principles since they are intended for application by national governments which have the responsibility of establishing and implementing food safety control systems.

16. It was further noted that the ability to apply these risk analysis principles varied amongst countries. It was also recognized that the costs and constraints of implementing *formal and structured* risk analysis activities may preclude their widespread and consistent application, even by developed countries, as emerging or urgent food safety concerns must be rapidly addressed to protect the health of consumers and/or resources may be limited. Developing countries may not have the food control infrastructure and/or the resources to fully apply the *Working Principles for Risk Analysis for Food Safety by Governments*. A footnote has been included with the “Implementation” section to reflect this. Nonetheless, it was felt that countries should aspire to apply these principles and should work towards this aim. Therefore, consideration would need to be given to the provision of technical assistance by FAO and WHO to developing countries

for the application of those principles. In this regard, Working Group participants noted the availability of funding from various sources, such as the Standards and Trade Development Facility (SDTF).

Conclusion

17. As a result of its deliberations, the Working Group reached consensus on the statements of principle contained in Appendix III. These principles are forwarded to the Codex Committee on General Principles for consideration by its 24th Session.

18. The co-chairs expressed their appreciation for the efforts and spirit of cooperation of all working group members towards a productive meeting, and in particular, the active participation by developing countries.

19. The Working Group Session concluded with the recognition of the European Community's contribution in hosting a successful meeting.

LIST OF APPENDICES

- Appendix I - List of Participants
- Appendix II - Background Paper prepared by the Canadian Secretariat
- Appendix III - Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments

LIST OF PARTICIPANTS
Working Group on Working Principles for Risk Analysis for Food Safety

26th-29th September 2006

Brussels, Belgium

Chairs:

Mr. Paul Mayers
 Executive Director, Programs
 Animal Products Directorate
 Canadian Food Inspection Agency
 59 Camelot Drive
 Ottawa, ON K1A 0Y9, CANADA
 Tel.: (613) 221-3773
 Fax: (613) 228-6631
 E-mail: mayersp@inspection.gc.ca

Mlle Bodil Blaker
 Senior Adviser
 Ministry of Health and Care Services
 P.O. Box 8011 Dep
 N-0030 Oslo, NORWAY
 Tel: +47 22 24 86 02
 Fax: +47 22 24 86 56
 Email: bob@hod.dep.no

ARGENTINA
ARGENTINE

Ing. Gabriela A. Catalani
 (Head of Delegation)
 Coordinadora del Punto Focal del Codex
 Secretaria de Agricultura, Ganadería
 Pesca y Alimentos
 Ministerio de Economía y Producción
 Av. Paseo Colón 922, Planta Baja, Oficina
 29
 C1063ACW Buenos Aires, ARGENTINA
 Tel.: +54 11 4349 2549
 Fax: +54 11 4349 2244
 E-mail: gcatal@mecon.gov.ar
 E-mail : codex@mecon.gov.ar

AUSTRALIA
AUSTRALIE

Ms. Jane Allen
 Deputy Section Manager
 Labelling and Information Standards
 Food Standard Australia New Zealand
 Food Standard Branch
 PO Box 7186, Canberra,
 BC ACT 2610, AUSTALIA

Tel.: +61 2 6271 2678

Fax: +61 2 6271 2278

E-mail:

jane.allen@foodstandards.gov.au

AUSTRIA
AUSTRIE
AUSTRIE

Michael Sulzner
 Fed. Ministry of Health and Women
 Rodetzkyst.2
 A-1031 Vienna, Austria
 Michael.sulzner@bngf.gv.at

BELGIUM
BELGIQUE
BÉLGICA

Monsieur Marc Cornelis
 Conseiller général
 Agence fédérale pour la sécurité de la
 chaîne alimentaire
 DG Politique de contrôle – Relations
 internationales
 Avenue Simon Bolivar, 30
 1000 Bruxelles, BELGIQUE
 Tel.: +32 2 2083834

Fax: +32 2 2083823
E-mail: marc.cornelis@favv.be

Monsieur Benoit Horion
Expert, Denrées alimentaires, Aliments
pour animaux et autres produits de
consommation
SPF Santé publique, Sécurité de la Chaîne
alimentaire et Environnement
EUROSTATION, Place Victor Horta 40
bte 10
Bloc II – 7^{ème} étage
1060 Bruxelles, BELGIQUE
Tel.: +32 2 5247360
Fax: +32 2 5247399
E-mail: benoit.horion@health.fgov.be

BRAZIL
BRÉSIL
BRASIL

Dr. Marcelo Bonnet Alvarenga
Head, Official Laboratory Network
Ministry of Agriculture, Livestock and
Food Supply
Official Laboratory
Secretariat of Animal and Plant Health
Canada Esplanada dos Ministerios –I
Bloco D
Anexo Sala 433 Sala B
70043-900, BRAZIL
Tel./Fax : +55-32255098
E-mail: apontes@agricultura.gov.br

Mr. Rafael Mafra
Technical Assistant
National Health Surveillance Agency
SEPN 515. Bloco B, Sala 3- 4th floor
CEP 70000 – 000
70000-000, BRAZIL
Tel.: +55-61-448-1091
Fax.: + 55-61-448-1089
E-mail: rafael.mafra@anvisa.gov.br

Mr. Alexandre Pontes
Codex Coordinator-MAPA
Secretariat of Agribusiness International
Relations
Department of Sanitary and Phytosanitary
Matters
Ministry of Agriculture, Livestock and
Food Supply
Esplanada dos Ministérios Bloco D Sede
Sala 347
70043-900 BRAZIL
Tel. : +55 61 32182308
Fax: +55 61 32254738
E-mail: apontes@agricultura.gov.br

Mrs. Reginalice Bueno
Food Inspector
National Health Surveillance Agency
Ministry of Health
SEPN 511, BRAZIL
Tel.: +55 61 34486280
Fax: +55 61 34481089
E-mail: gicra@anvisa.gov.br

CANADA

Mr. Ronald Burke
Director, Bureau of Food Regulatory,
International and Interagency Affairs
Food Directorate
Health Products and Food Branch
Health Canada
200 Tunney's Pasture Driveway (0702C1)
Ottawa, ON K1A 0L2, CANADA
Tel.: (613) 957-1748
Fax: (613) 941-3537
E-mail: ronald_burke@hc-sc.gc.ca

Dr. Thomas Edward Feltmate
Manager, Food Safety Risk Analysis Unit
Food Safety Directorate
Canadian Food Inspection Agency
3851 Fallowfield Road
Ottawa, ON K2H 8P9, CANADA
Tel.: (613) 228-6698, ext. 5982
Fax: (613) 228-6675
E-mail: tfeltmate@inspection.gc.ca

CHILE
LE CHILI

Sr. Pablo Urria Hering
Ministro Conjsejero conomica
Misión de Chile ante la UE
Rue des Advatiques 106,
1040, Belgia
Tel.: +32 2 743 3660
Fax: +32 2 788 1620
E-mail: pablo.urria@embachile.be

EUROPEAN COMMUNITY
(MEMBER ORGANIZATION)
COMMUNAUTÉ EUROPÉENNE
(ORGANISATION MEMBRE)
COMUNIDAD EUROPEA
(ORGANIZACIÓN MIEMBRO)

Mr. Michael Scannell
Head of Unit, Health and Consumer
Protection Directorate-General
European Commission
F101 2/54 – B-1049 Brussels, BELGIUM

Tel.: +32 2 2993364
Fax: +32 2 2998566
E-mail: michael.scannell@ec.europa.eu

Dr. Jérôme Lepeintre
Administrator
Health and Consumer Protection
Directorate-General (SANCO)
European Commission
F101 2/562– B-1049 Brussels, BELGIUM
Tel.: +32 2 2993701
Fax: +32 2 2998566
E-mail: jerome.lepeintre@ec.europa.eu

Ms. Jeannie Vergnettes
Administrator
Health and Consumer Protection
Directorate-General European Community
F101 3/171 – B-1049 Brussels,
BELGIUM
Tel.: +32 2 2951448
E-mail: jeannie.vergnettes@ec.europa.eu

Dr. Jean-Louis Jouve
Expert
9 rue du Pont au Choux
75003 Paris, FRANCE
Tel. : +33 6 07 87 96 53
E-mail: jeanlouis.jouve@wanadoo.fr

Dr. Marta Hugas
Scientific Coordinator Biohaz Panel
Biological Hazards Panel
European Food Safety Authority
Largo N. Palli 5/A
43100 Parma, ITALY
Tel.: +39 0521 036216
Fax: +39 0521 036316
E-mail: marta.hugas@efsa.europa.eu

Dr. David Demortain
Researcher
Institut des Sciences Sociales du Politique
Ecole Normale Supérieure de Cachan (F)
Rue Van Campenhout 22
B-1000 Brussels, BELGIUM
Tel.: +32 2 733 96 60
E-mail: ddemortain@gmail.com

**GENERAL SECRETARIAT OF THE
COUNCIL OF THE EUROPEAN
UNION**

Mr. Antonio Ataz
Administrator
General Secretariat of the Council of the
European Union
DGB II, Rue de la Loi 175,

B-1048 Brussels, BELGIUM
Tel.: +32 2 281 4964
Fax: +32 2 281 9425
E-mail:
antonio.ataz@consilium.europa.eu

**FINLAND
FINLANDE
FINLANDIA**

Ms. Anne Haikonen
Counsellor, Legal Affairs
Ministry of Trade and Industry
P.O. Box 32
FIN-00023 Government
Helsinki, FINLAND
Tel.: +358 9 1606 3654
Fax: +358 9 1606 2670
E-mail: anne.haikonen@ktm.fi

Dr. Sebastian Hielm
Senior Health Officer
Ministry of Social Affairs and Health
P.O. Box 33
FIN-00023 Government
Helsinki, FINLAND
Tel.: +358 9 1607 4121
Fax: +358 9 1607 4120
E-mail : sebastian.hielm@stm.fi

**FRANCE
FRANCIA**

Mme Catherine Chapoux
Direction générale de l'alimentation
Mission de coordination sanitaire
internationale
Ministère de l'Agriculture et de la Pêche
251, rue de Vaugirard
75 732 Paris Cedex 15, France
Tel.: +33 1 49 55 84 86
Fax: +33 1 49 55 44 62
E-mail:
catherine.chapoux@agriculture.gouv.fr

M. Pascal Audebert
Point de Contact du Codex Alimentarius
en France
Premier Ministre – Secrétariat général des
Affaires européennes
2, boulevard Diderot
75 572 Paris Cedex 12, France
Tel.: +33 1 44 87 16 03
Fax: +33 1 44 87 16 04
E-mail: sgae-codex-fr@sgae.gouv.fr
pascal.audebert@sgae.gouv.fr

Mme Roseline Lecourt
Chargée de Mission Codex Alimentarius
Direction Générale de la Concurrence, de
la Consommation et de la Répression des
Fraudes
Ministère de l'Économie, des Finances et
de l'Industrie – DGCCRF - Télédocus 051
59, boulevard Vincent Auriol
75 703 Paris, Cedex 13, FRANCE
Tel.: +33 1 44 97 34 70
Fax: +33 1 44 97 30 37
E-mail:
roseline.lecourt@dgccrf.finances.gouv.fr

GERMANY
ALLEMAGNE
ALEMANIA

Mr. Gerhard Bialonski
Referatsleiter
Bundesministerium für, Ernährung,
Landwirtschaft und Verbraucherschutz
(Federal Ministry of Food, Agriculture and
Consumer Protection)
Rochusstraße 1
53123 Bonn, GERMANY
Tel.: +49 228 529 4651
Fax: +49 228 529 4947
E-mail: 314@bmelv.bund.de

Mr. Michael Hauck
Referent
Bundesministerium für, Ernährung,
Landwirtschaft und Verbraucherschutz
(Federal Ministry of Food, Agriculture and
Consumer Protection)
Mauerstr. 29-32
10117 Berlin, GERMANY
Tel.: +49 30 2006 3263
Fax: +49 30 2006 3273
E-mail: codex.germany@bmelv.bund.de

GREECE
GRÈCE
GRECIA

Dr. Danai Papanastasiou
Officer, Department of Quality Standards
Greek Codex Contact Point
Directorate of Nutritional Policy and
Research
Ministry of Development – Hellenic Food
Authority
124 Kifisias Ave. & Iatridou Street
115 26 Athens, GREECE
Tel.: +30 210 6971660
Fax: +30 210 69716501
E-mail: dpapanastasiou@efet.gr

HUNGARY

Ms. T. Szerdahelyi
Senior Counsellor
Ministry of Agriculture and Regional
Development
Department of Food Industry
1055 Budapest,
Kossuth L. ter. 11
H-1860 Budapest, Pf. 1
Tel: +36 1 301 4110
Fax: +36 1 301 4808
E-mail: Tanya.szerdahelyi@fvm.hu

IRELAND
IRLANDE
IRLANDA

Mr. Richard James Howell
Agricultural Inspector
Research, Food and Codex Co-ordination
Division
Department of Agriculture and Food
7C Agriculture House, Kildare Street
Dublin 2, IRELAND
Tel.: +353 1 6072572
Fax: +353 1 6616263
E-mail :
richard.howell@agriculture.gov.ie

Ms. Siobhán McEvoy
A/Chief Environmental Health Officer,
Food Unit
Department of Health and Children
Hawkins House, Hawkins Street
Dublin 2, IRELAND
Tel.: +353 1 6354400
Fax : +353 1 6354552
E-mail :
siobhan_mcevoy@health.irlgov.ie

JAPAN
JAPON
JAPÓN

Dr. YODA Norihiko
Director, Office of International Food
Safety, Policy Planning and
Communication 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 2326
Fax: +81 3 3503 7965
E-mail: yoda-norihiko@mhlw.go.jp

Mr. FURUHATA Toru
Deputy Director
Food Safety and Consumer Policy
Division
Food Safety and Consumer Affairs Bureau
Ministry of Agriculture, Forestry and
Fisheries
1-2-1, Kasumigaseki, Chiyoda-ku
Tokyo 100-8950, JAPAN
Tel.: +81 3 3502 5722
Fax: +81 3 3597 0329
E-mail: toru_furuhata@nm.maff.go.jp

KOREA, REPUBLIC OF
CORÉE, RÉPUBLIQUE DE
COREA, REPÚBLICA DEL

Ms. Young Hui Shin
Deputy Director, Risk Management Team
Korea Food and Drug Administration
194 Tongil-ro, Eunpyung-gu
122-704 Seoul, REPUBLIC OF KOREA
Tel.: +82 02 352-4641
Fax: +82 02 352-0046
E-mail: yhshin@kfda.go.kr

Mr. Kyoung-Mo Kang
Research Chemist, Food Contaminants
Team
Food Safety Evaluation
Korea Food and Drug Administration
194 Tongil-ro, Eunpyung-gu
122-704 Seoul, REPUBLIC OF KOREA
Tel.: +82 02 380-1670-2
Fax: +82 02 380-1359
E-mail: kmokang@kfda.go.kr

Mr. Jae-Seok Park
Scientific Officer
Food and Risk Standardization Team
The Bureau of Risk Management
Korea Food and Drug Administration
194 Tongil-ro, Eunpyung-gu
122-704 Seoul, REPUBLIC OF KOREA
Tel.: +82 02 352-4797
Fax: +82 02 352-4606
E-mail: leo805@hanmail.net

MEXICO
MEXIQUE
MÉXICO

M. en C. Jose Alberto Castillo Rosales
Gerente Ejecutivo de Priorización de
Riesgos
Secretaría de Salud
Comisión de Evidencia y Manejo de
Riesgos

Comisión Federal para la Protección
Contra Riesgos Sanitarios (COFEPRIS)
Monterrey 33, Piso 9 Col Roma, Ciudad
de México
06700 MEXICO
Tel.: +52 55 50805457
Fax: +52 55 55148574
E-mail: arosales@salud.gob.mx

Carlos Almanza Rodriguez
Gerencia de Evaluación Epidemiológica de
Riesgos Comisión Federal para la
Protección Contra Riesgos
Sanitarios (COFEPRIS)
Monterrey 33 Col. Roma, Mexico. D.F.
02000 MEXICO
Tel : +52 55 55148583
E-mail : carlosalmanza@salud.gob.mx

Mariela Paz Vallejo
Gerente Ejecutiva de Asuntos
Internacionales en Inocuidad Alimentaria
Comisión Federal para la Protección
Contra Riesgos Sanitarios (COFEPRIS)
Coordinación General del Sistema Federal
Sanitario
Secretaría de Salud
Monterrey 33, Piso 1 Col Roma, Ciudad
de México
06700 MÉXICO
Tel.: +52 55 50805389
Fax: +52 55 55148574
E-mail: mvallejo@salud.gob.mx

NETHERLANDS
PAYS-BAS
PAISES BAJOS

Benno Ter Kuile
Deskundige Microbiologie
Office for Risk Assessment
Voedsel en Waren Autoriteit
Beatrixlaan 2
2595 AL The Hague
THE NETHERLANDS
Tel.: +31 70 448 4072
E-mail: benno.terkuile@vwa.nl

NEW ZEALAND
NOUVELLE-ZELANDE
NUEVA ZELANDIA

Dr. Steve Clive Hathaway
Director (Science Group)
New Zealand Food Safety Authority
P.O. Box 2835
Wellington, NEW ZEALAND
Tel.: +64 6 867 1144

Fax: +64 6 868 5207
E-mail: steve.hathaway@nzfsa.govt.nz

Mr. Sundararaman Rajasekar
Manager, Codex
New Zealand Food Safety Authority
P.O. Box 2835
Wellington, NEW ZEALAND
Tel.: +64 4 463 2576
Fax: +64 4 463 2583
E-mail: raj.rajasekar@nzfsa.govt.nz

NORWAY
LA NORVÈGE
NORUEGA

Mr. Lennart Johanson
Deputy Director General
Norwegian Ministry of Fisheries and
Coastal Affairs
P.P. Box 8118, Dep
N-0032 Oslo, NORWAY
Tel.: +47 22 24 26 65
Fax: +47 22 24 56 78
E-mail: Lennart.Johanson@fkd.dep.no

ROMANIA
ROUMANIE
RUMANIA

Ms. Adriana Berbec
Romanian Mission to the EU
Rue Montoyer 12
B-1000 Brussels
Tel: +32 2 700 06 40
Fax: +31 2 700 06 41
Email : bru@roumisue.org

SLOVAKIA
SLOVAQUIE
ESLOVAQUIA

Mr. Pavol Cery
First Secretary
Permanent Representation of Slovakia
Avenue de Cortenberg, 79
B-1000 Brussels
Tel: =32 2 743 68 11
Fax : +32 2 743 68 88
Email : slovakmission@pmsreu.be

SUDAN
SOUDAN
SUDÁN

Mr. Hamdi Abbas Ibrahim
Director, Standards and Quality Control
Unit

Ministry of Agriculture and Forestry
P.O. Box 285
Khartoum, SUDAN
Tel.: +249 9 18211470 / +249 183
774688
Fax: +249 183 782027
E-mail: hamdi20072000@yahoo.com

Dr. Awad Mohamed Ahmed Sokrab
Director, Technical Department
Sudanese Standards and Metrology
Organization
P.O. Box 13573
Khartoum, SUDAN
Tel.: +249912391190
Fax: +249183775247
E-mail: awadsokrab@hotmail.com

SWEDEN
SUEDE
SUECIA

Mrs. Kerstin Jansson
Deputy Director, Food and Animal
Division
Ministry of Agriculture, Food and
Consumer Affairs
SE-113 33 Stockholm, SWEDEN
Tel.: +46 8 405 11 68
Fax: +46 8 20 64 96
E-mail:
kerstin.jansson@agriculture.ministry.se

Dr. Lars Plym Forshell
Veterinarian, Food Control Department
Swedish National Food Administration
POB 622
SE-755 91 Uppsala, SWEDEN
Tel.: +46 18 175582
Fax: +46 18 175749
E-mail: lapl@slv.se

SWITZERLAND
SUISSE
SUIZA

Dr. Urs Klemm
Vice-Director, Swiss Federal Office of
Public Health
P.O. Box
CH-3003 Bern, SWITZERLAND
Tel.: +41 79 449 83 05
Fax: +41 62 822 74 21
E-mail: info@ursklemm.ch

THAILAND
THAILANDE
TAILANDIA

Mrs. Oratai Silapanaporn
Director, Office of Commodity and System
Standards, National Bureau of Agricultural
Commodity and Food Standards,
Ministry of Agriculture and Cooperatives
4th Floor, 3 Rajdamnern Nok Avenue
Bangkok 10200, Thailand
Tel.: + 66 2 280 3887
Fax: + 66 2 280 3899 or 283 1669
E-mail: codex@acfs.go.th /
oratai@acfs.go.th

Mr. Pisan Pongsapitch
Standards Officer, Office of Commodity
and System Standards,
National Bureau of Agricultural
Commodity and Food Standards,
Ministry of Agriculture and Cooperatives
4th Floor, 3 Rajdamnern Nok Avenue
Bangkok 10200, Thailand
Tel.: + 66 2 280 3887
Fax: + 66 2 280 3899 or 283 1669
E-mail : pisanp@yahoo.com

TUNISIA
TUNISIE
TÚNEZ

Mme Melika Hermassi
Chargée du secrétariat du Comité Tunisien
du Codex
Centre Technique de l'Agro-Alimentaire
Ministère de l'Industrie, de l'Energie et
des petites et moyennes entreprises
12, rue de l'usine
Charguia II - 2035 Tunis, TUNISIE
Tel.: +216 71 940 198
Fax: +216 71 941 080
E-mail: codextunisie@email.ati.tn

D^r Thouraya Annabi Attia
Chargée de la Direction Sanitaire des
produits
Agence Nationale de Contrôle Sanitaire et
Environnemental des Produits
Ministère de la santé Publique
37, Avenue Taieb Mhiri – Belevédère
1002 Tunis, TUNISIE
Tel.: +216 71 790 988
E-mail: thouraya.attia@rns.tn

UNITED KINGDOM
ROYAUME-UNI
REINO UNIDO

Mr. Steve Wearne
Head of Regulation, International and
Openess
Food Standards Agency

Aviation House, 125 Kingsway
London WC2B 6NH, UNITED
KINGDOM
Tel.: +44 20 7276 8338
Fax: +44 20 7276 8376
E-mail:
steve.wearne@foodstandards.gsi.gov.uk

UNITED STATES OF AMERICA
ETATS-UNIS D'AMÉRIQUE
ESTADOS UNIDOS DE AMÉRICA

Dr. Karen L. Hulebak
Chief Scientist
Office of Public Health Science
Food Safety Inspection Service
U.S. Department of Agriculture
1400 Independence Avenue – Room 3129-
S
Washington, DC 20250-3700, U.S.A.
Tel.: (202) 720-5735
Fax: (202) 690-2980
E-mail: karen.hulebak@fsis.usda.gov

Dr. Michael Wehr
Codex Program Coordinator
Centre for Food Safety and Applied
Nutrition (CFSAN)
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740, U.S.A.
Tel.: (301) 436-1724
Fax: (301) 436-2618
E-mail: michael.wehr@fda.hhs.gov

CONSUMERS INTERNATIONAL
ORGANISATION
INTERNATIONALE DES UNIONS DE
CONSOMMATEURS

Ms. Sue Davies
Chief Policy Adviser
Which? / For Consumers' International
2 Marylebone Road
London NW1 4DF, UNITED KINGDOM
Tel.: +44 20 7770 7274
Fax: +44 20 7770 7666
E-mail: sue.davies@which.co.uk

COUNCIL FOR RESPONSIBLE
NUTRITION (CRN) / CONSEJO
PARA UNA NUTRICIÓN
RESPONSABLE

Dr. John Hathcock
Vice President, Scientific & International
Affairs
Council for Responsible Nutrition (CRN)

1828 L Street, NW, Suite 900
Washington, DC 20036, U.S.A.
Tel.: (202) 776-7955
Fax: (202) 204-7980
E-mail: jhathcock@crnusa.org

Mr. Mark LeDoux
CEO & Chairman of the Board of
Directors
Natural Alternatives International, Inc.
1185 Linda Vista Drive
San Marcos, CA 92078, U.S.A.
Tel.: (800) 848-2646
Fax: (760) 744-9589
E-mail: mledoux@nai-online.com

**49th PARALLEL BIOTECHNOLOGY
CONSORTIUM (49P)**

Professor Philip L. Bereano
Professor Emeritus
49th Parallel Biotechnology Consortium
University of Washington
Box 352195
Seattle 98144, Washington, U.S.A.
Tel.: (206) 543-9037
Fax: (206) 543-8858
E-mail: pbereano@u.washington.edu

Professor Erik Paul Millstone
Professor of Science Policy
SPRU – Science and Technology Policy
Research
Freeman Centre, University of Sussex
Brighton BN1 9QE, UNITED KINGDOM
Tel.: +44 1273 877380
Fax: +44 1273 685865
E-mail: e.p.millstone@sussex.ac.uk

**INTERNATIONAL ALLIANCE OF
DIETARY/FOOD SUPPLEMENT
ASSOCIATIONS (IADSA)**

Mr. David Pineda Ereño
Manager, Regulatory Affairs
International Alliance of Dietary/Food
Supplement Associations (IADSA)
Rue de l'Association, 50
B-1000 Brussels, BELGIUM
Tel.: +32 22 09 11 55
Fax: +32 22 23 30 64
E-mail: secretariat@iadsa.be

**FOOD AND AGRICULTURE
ORGANIZATION OF THE UNITED
NATIONS (FAO)**

Dr. Sarah Marie Cahill
Nutrition Officer (Food Microbiology)
Food and Agriculture Organization of the
United Nations,
Agriculture, Biosecurity, Nutrition and
Consumer Protection,
Viale delle Terme di Caracalla
00100 Rome, ITALY
Tel.: +39 06 5705 3614
Fax: +39 06 5705 4593
E-mail: sarah.cahill@fao.org

WORKING GROUP SECRETARIAT

Mr. Allan McCarville
Senior Advisor, Codex
Bureau of Food Regulatory, International
and Interagency Affairs
Food Directorate
Health Products and Food Branch
Health Canada
200 Tunney's Pasture Driveway (0702C1)
Ottawa, ON K1A 0L2, CANADA
Tel.: (613) 957-0189
Fax: (613) 941-3537
E-mail: allan_mccarville@hc-sc.gc.ca

Dr. Reem Barakat
International Senior Policy Analyst,
Intergovernmental and International
Food Policy Coordination
Programs, Food Safety Directorate
Canadian Food Inspection Agency
159 Cleopatra Drive
Ottawa, ON K1A 0Y9, CANADA
Tel.: (613) 221-7182
Fax: (613) 221-7295
E-mail: barakatr@inspection.gc.ca

JOINT FAO/WHO FOOD STANDARDS PROGRAMME**CODEX COMMITTEE ON GENERAL PRINCIPLES**
Working Group on Working Principles for Risk Analysis for Food Safety
26 - 28 September 2006
Brussels, Belgium**BACKGROUND PAPER****(Prepared by the Canadian Secretariat)****INTRODUCTION**

1. This background paper is intended to facilitate constructive dialogue among the delegations to the Working Group on Working Principles for Risk Analysis for Food Safety. In order to establish a common basis for discussion, the paper seeks to provide a factual, impartial summary of the factors that led to the decision by the Codex Alimentarius Commission (CAC) to undertake new work on risk analysis, the considerations and decisions resulting thereof in succeeding meetings of the Codex Committee on General Principles (CCGP) and the CAC, and the key challenges currently faced by the CCGP in the conduct of this work. Finally, the paper proposes a direction forward for the Working Group to fulfil the terms of reference agreed by the CCGP during its 23rd session, without detracting from discussions and decisions at the 24th and subsequent sessions of the CCGP.

ORIGIN OF CODEX WORK ON RISK ANALYSIS

2. The FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, (March 1991) noted, with respect to the Uruguay Round of Multilateral Trade Negotiations under the General Agreement on Tariffs and Trade (GATT), that the negotiations in the area of sanitary and phytosanitary regulations and measures were important because the GATT agreement would accord a new international status to Codex standards, guidelines and other recommendations.¹ In view of this new international role, the conference recommended an early review programme to examine all Codex standards for their current relevance and sound scientific basis. The conference also recommended that the CAC and the relevant Codex Committees responsible for the development of standards, codes of practice or guidelines concerned with the protection of human health should make explicit the methods they have used to assess risk.

3. In response to the recommendations of the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, the CAC, at its 19th and 20th sessions (July 1991 and July 1993), agreed on the incorporation of risk assessment principles in its procedures. The 20th session considered the paper ALINORM 93/37: *Risk Assessment Procedures Used by the Codex Alimentarius Commission, and its Subsidiary and Advisory Bodies*. The paper provided recommendations with respect to actions required by the Expert Committees and Codex Committees and observed that there was wide opportunity for Codex to improve its performance by adopting risk analysis principles and methodology.

4. The CAC, noting the need for rapid progress in implementing risk analysis in Codex work, agreed to send ALINORM 93/37 to all relevant Codex Committees, including the CCGP, for review and discussion. In addition, it proposed that the CCGP should address the adoption of risk analysis, including the possibility of changes in the Rules of Procedure and in the Terms of Reference of Relevant Codex Committees.²

CONSIDERATION OF RISK ANALYSIS BY THE CODEX ALIMENTARIUS COMMISSION

¹ The Uruguay Round of Multilateral Trade Negotiations resulted in the establishment of the World Trade Organization and the elaboration of several trade instruments including the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade.

² ALINORM 93/40, Report of the 20th session CAC, paras. 57-71

5. Subsequent to the 20th session of the CAC, a Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues was held in Geneva from 13-17 March 1995. The Consultation defined risk analysis terms, reviewed current practices in the CAC and FAO/WHO committees and addressed the issues on risk assessment of chemical and biological agents in food and the problems related to uncertainty and variability in risk analysis.

6. The 21st session of the CAC (July 1995) endorsed the recommendations arising from the Consultation in principle. The Commission recommended further work to address risk management, risk communication and defining the roles and responsibilities of the different bodies involved in the risk analysis process as well as on uncertainty and variability in risk analysis in relation to standard setting and food regulation. The Commission also agreed that the Report and recommendations of the Consultation should be examined by relevant Codex Committees especially the CCGP so that the risk analysis concept would be incorporated into the Codex procedures and in the list of terms and definitions for Codex purposes.³

7. The 12th session of the CCGP (November 1996), in response to the Expert Consultation and the decisions of the 19th to 21st sessions of the CAC, noted the need for Codex to provide a clear, transparent and well-documented system for risk analysis in its own decision-making process so that governments would be able to determine their position when deciding on the use of Codex standards and related texts and in harmonizing their requirements on the basis of Codex standards. The Committee made a number of modifications to proposed statements incorporating risk analysis principles into the general procedures of the Commission, and proposed that definitions of risk analysis terms related to food safety be adopted by the CAC on an interim basis.⁴

8. At its 22nd session (July 1997), the CAC adopted the *Statements of Principle Relating to the Role of Food Safety Risk Assessment* and the *Definitions of Risk Analysis Terms Related to Food Safety*. The Commission also developed a strategy and action plan for the elaboration and application of risk analysis principles and guidelines in all Codex activities where appropriate. In particular, the action plan requested the CCGP to elaborate integrated principles for risk management and risk assessment policy setting, risk communication and documentation for inclusion in the Procedural Manual. The action plan also noted the need to prepare specific guidelines as required to aid in the uniform application of the principles, and that all relevant Codex Committees should be involved. The CCGP was requested to co-ordinate this exercise.⁵

9. On the basis of proposed “working principles” that had been developed as part of the *Action Plan for Codex-Wide Development and Application of Risk Analysis Principles and Guidelines* adopted by the 22nd session of the CAC, the CCGP, at its 13th session (September 1998) commenced work on the development of Working Principles for Risk Analysis. The inclusion of a reference to the “precautionary principle” was requested, and discussion on this point was initiated at this session.⁶

10. The 14th session of the CCGP (April 1999) examined the Working Principles for Risk Analysis section by section and had a general discussion on the application of the Principles, and especially whether they were directed to Codex Committees or to governments. The Committee recalled that the mandate of the Commission was to consider Working Principles for general application in Codex, following which guidelines should be developed to aid the uniform application of the principles. Considerable discussion took place on the inclusion of the precautionary principle in relation to the issue of how to address uncertainty in scientific evaluation while conducting the risk management process. The Committee recognized that it would be useful to consider further how to integrate the precautionary approach in the framework of risk management.⁷

11. At its 23rd session (July 1999), the CAC adopted the Medium-Term Plan (1998-2002) a component of which included work on risk analysis. The work on risk analysis specified that the elaboration of specific guidance on the application of risk analysis principles should be provided to Codex Committees on one hand and to Member Governments on the other: the former guidance to be included in the Procedural Manual, the

³ ALINORM 95/37, Report of the 21st session CAC, paras. 27- 30

⁴ ALINORM 97/33, Report of the 12th session CCGP, paras. 16-21

⁵ ALINORM 97/37, Report of the 22nd session CAC, paras. 26-31 and 160-164

⁶ ALINORM 99/33, Report of the 13th session CCGP, paras. 18-23

⁷ ALINORM 99/33A, Report of the 14th session CCGP, paras. 16-37

latter in the Codex Alimentarius itself.⁸

12. At the 15th session of the CCGP (April 2000), significant progress was made on most sections of the Working Principles; however, the application of precaution in risk management still needed additional discussion. The Committee also noted during its deliberations that, since the principles were intended for application in the Codex framework and also by governments where applicable, some confusion arose with the interpretation of specific articles. A drafting group was established to progress work between sessions on the issue of the application of precaution and a Working Group was convened immediately preceding the 16th session.⁹

13. Despite some progress being made in drawing together many of the diverse opinions with respect to the application of precaution, the 16th session of the CCGP (April 2001) noted that, without a clarification of the Scope of the Working Principles, the situation would remain confused as precautionary measures could take different forms according to whether they are taken within the Codex framework or by governments. As a result, the Committee requested clarification from the Commission whether it should develop principles for application within Codex only, or principles that would be applicable both within Codex and to governments. It also agreed to request the advice of the Commission on how Codex should react when scientific data were insufficient or incomplete and evidence of a risk to human health existed. A Working Group was convened to progress work between sessions.¹⁰

14. The 24th session of the CAC (July 2001) confirmed its initial mandate to the CCGP to complete the principles for risk analysis within Codex as a high priority, with a view to their adoption by 2003. It agreed that the Committee should develop guidance to governments subsequently or in parallel, as appropriate in view of its programme of work. The Commission also adopted the position that “When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.” Reservations on this text were expressed by several countries.¹¹

15. At its 17th session (April 2002), the CCGP considered text prepared in response to the decisions by the 24th session of the CAC and, at the conclusion of the discussion, agreed to advance the text of the Proposed Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius to Step 5 of the Procedure. The Committee also agreed to initiate new work on Proposed Draft Working Principles for Risk Analysis directed to governments.¹²

16. The 18th session of the CCGP (April 2003) agreed to advance the Draft Working Principles for Risk Analysis in the Framework of the Codex Alimentarius to Step 8 for adoption by the 26th Session of the CAC. The Committee also discussed the Proposed Draft Working Principles for Risk Analysis for Food Safety, in particular the overall structure and concept of the document, as well as whether there was a need for such additional guidance.¹³

17. The 26th session of the CAC (July 2003) adopted the Working Principles for Risk Analysis for Application in the Framework of the Codex.¹⁴

18. At its 20th session (May 2004), the CCGP held a general discussion on the Proposed Draft Working Principles for Risk Analysis for Food Safety and considered: 1) whether work should proceed on the development of risk analysis principles intended for governments; 2) whether the format of the document as basic principles should be retained; and 3) whether the principles applicable within Codex could be used as a basis for discussion. The Committee noted that the Proposed Draft Working Principles contained a number of provisions for which consensus was yet to be arrived at, including the issue of whether and how the concept of precaution could be applied in risk management by governments. A Working Group was

⁸ ALINORM 99/37, Report of the 23rd session CAC, para 34 and Appendix II, para. 3

⁹ ALINORM 01/33, Report of the 15th session CCGP, paras. 8-62

¹⁰ ALINORM 01/33A, Report of the 16th session CCGP, paras. 16-75

¹¹ ALINORM 01/41, Report of the 24th session CAC, paras. 71-85

¹² ALINORM 03/33, Report of the 17th session CCGP, paras. 15-72

¹³ ALINORM 03/33A, Report of the 18th session CCGP, paras. 10-42

¹⁴ ALINORM 03/41, Report of the 26th session CAC, para. 146

convened to progress work between sessions.¹⁵

19. At the 22nd session of the CCGP (April 2005), the key issues considered by the Committee were whether or not to continue work on the proposed draft principles, and the placement within these principles of the concept of caution/prudence/precaution. No consensus could be reached on whether to proceed with the Principles in their current form; however, the Committee was prepared to look at a fundamental restructuring of the Proposed Draft Principles in order to provide practical guidance to governments in the application of risk analysis. An electronic Working Group was established to progress work between sessions.¹⁶

20. At the 23rd session of the CCGP (April 2006), despite the preparation of the structure and outline of a possible new document, considerable diversity of opinion remained with respect to the need for the document, and the purpose and scope of future work. The Committee agreed to convene a physical working group, to be chaired by Canada with Chile and Norway as co-chairs. The Committee recalled the request of the Executive Committee to establish a timeline for the completion of work initiated prior to 2004 and agreed that its objective was adoption by the Commission by 2008.¹⁷

ISSUES IDENTIFIED BY MEMBERS

21. As evidenced in the previous section, despite best endeavours by all those who have participated in the discussions, the CCGP has been unable to reach consensus with respect to the development of principles or guidance on risk analysis for use by governments. Some of the issues that have been identified during sessions of the CCGP are:

- ! whether there is a need for Codex principles and/or guidance on the application of risk analysis by governments and, if so, the nature and extent of that guidance, taking into consideration the concurrent development by the FAO, working with the WHO, of a food safety risk analysis reference/training manual;
- ! the specific inclusion of references to the precautionary principle/precautionary approach in the Working Principles for Risk Analysis for Food Safety;
- ! the potential for the principles or guidance to alter the balance between the rights and obligations of WTO Members with respect to the establishment and maintenance of sanitary measures, as per the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement); and
- ! the extent to which other factors relevant for the health protection of consumers and for the promotion of fair practices in food trade should be incorporated into the Working Principles for Risk Analysis for Food Safety.

22. Recognition of these and other issues is necessary as part of the deliberations of the Working Group but not with the intention of repeating the discussions of past meetings of the CCGP. Rather, the Working Group must face these issues and seek out the underlying concerns, with the goal to identify a direction forward. Only then can progress be made, as was demonstrated with the Working Principles for Risk Analysis in the Framework of the Codex Alimentarius.

THE WORKING GROUP, ITS MANDATE AND A DIRECTION FORWARD

23. The 23rd session of the CCGP agreed that the terms of reference of the physical working group would be as follows:

- a) To discuss and articulate the rationale for guidance to governments related to the application of risk analysis by governments, based on the discussion of the present session and previous sessions of the CCGP;
- b) To describe the output that Codex may require to respond to this rationale; and
- c) To draft, for further discussion, some simple and horizontal principles on the implementation of risk analysis by governments.

The terms of reference indicate that the Working Group is expected to prepare a product for further

¹⁵ ALINORM 04/27/33A, Report of the 20th session CCGP, paras. 37-43

¹⁶ ALINORM 05/28/33A, Report of the 22nd session CCGP, paras. 31-54

¹⁷ ALINORM 06/29/33, Report of the 23rd session CCGP, paras. 58-76

discussion and decision at the CCGP.

24. Under part (a) of the terms of reference, the discussion on the rationale for guidance to governments could start with the premise that all national governments apply risk analysis for food safety. Consideration would be given to the benefits of a consistent approach, recognizing that risk management decisions are applicable to food that is imported as well as to that produced domestically. An integral part of this discussion should be to clearly identify the underlying concerns behind the reluctance of certain Member Governments to proceed with work on principles or guidance on risk analysis for use by governments, despite the numerous requests from many countries for technical assistance/capacity building with respect to the application of risk analysis.

25. In determining the output that Codex may require to respond to this rationale, as per part (b) of the terms of reference, the working group could consider the following questions:

- As the FAO, working with the WHO, is concurrently developing a food safety risk analysis reference/training manual, is it necessary for Codex to develop a document with a high level of detail? Could this result in duplication of effort and the potential for conflicting guidance? On the other hand, does the FAO manual include overarching principles that put the detailed guidance into the appropriate context in relation to the mandate of Codex, in particular with respect to its status under the WTO SPS Agreement? Is it practicable to have two documents that reference and complement each other?
- In relation to the international status accorded to Codex standards, guidelines and recommendations as a result of the GATT negotiations, the representative of the WTO has intervened at several sessions of the CCGP indicating the importance of risk assessment techniques developed by the relevant international organizations.¹⁸ As the OIE and IPPC have developed guidance on risk analysis for governments with respect to animal health and plant health respectively,¹⁹ to what extent should Codex provide similar guidance for risk analysis for food safety?
- If it is to successfully develop guidance on risk analysis for governments, regardless of the nature or extent of such guidance, Codex must have relevant and purposeful discussions in order to address and resolve the issues that the Committee has faced to this point. Can this be achieved by retaining a focus on the real challenges that risk assessors, risk managers and risk communicators confront in their day to day work? For example, the question of how to deal with uncertainty in science is common to the three components of risk analysis, and should probably be dealt with by the Working Group. Could the provision of guidance by Codex on how to deal with scientific uncertainty benefit from the approach employed in the OIE and IPPC guidelines for risk analysis?

26. In comments previously provided by Member Governments on the Principles for Risk Analysis for Food Safety there was, in general, qualified agreement on the development of broad, high level principles. This agreement finds expression in part (c) of the terms of reference. This can serve as important direction to focus the work in the Working Group on the development of such principles which can become the subject of discussion in the CCGP to determine whether they suffice or whether additional work is warranted.

¹⁸ ALINORM 03/33A, Report of the 18h Session of the CCGP, para. 36; ALINORM 04/27/33A, Report of the 20th Session of the CCGP, para. 42; ALINORM 06/29/33, Report of the 23rd Session of the CCGP, para. 67.

¹⁹ OIE: Guidelines for Import Risk Analysis, Terrestrial Animal Health Code - 2005, Chapter 1.3.2 IPPC: ISPM No. 2 (1995) Guidelines for pest risk analysis ISPM No. 21 (2004) Pest risk analysis for regulated non quarantine pests.

**Proposed Draft Working Principles for Risk Analysis for Food Safety for Application by Governments
(At Step 3 of the Procedure)**

Scope

1. The Working Principles for Risk Analysis for Food Safety for Application by Governments are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health.

General Aspects

2. The overall objective of risk analysis applied to food safety is to ensure health protection.
3. These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner.
4. To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.
5. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.
6. Risk analysis should be:
 - * applied consistently;
 - * open, transparent and documented; and
 - * evaluated and reviewed as appropriate in the light of newly generated scientific data.
7. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission²⁰, each component being integral to the overall risk analysis.
8. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties²¹.
9. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.
10. The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.
11. There should be a functional separation of risk assessment and risk management to the degree practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.
12. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis.

²⁰ FAO/WHO. 2005. Definitions of Risk Analysis Terms Related to Food Safety. In *Codex Alimentarius Commission Procedural Manual*. 15th Edition, pp. 44-46 (at: www.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf).

²¹ For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations” (see definition of “Risk Communication”).

The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

13. National governments should take into account relevant guidance, information and outputs obtained from risk analysis activities conducted by international organizations, with particular emphasis on the activities of Codex, FAO, WHO and their experts groups, OIE and IPPC.

Risk Assessment Policy

14. Determination of risk assessment policy should be included as a specific component of risk management.
15. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.
16. The mandate given by risk managers to risk assessors should be as clear as possible.
17. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

Risk Assessment

18. Each risk assessment should be fit for its intended purpose.
19. The scope and purpose of the particular risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.
20. Government officials involved in risk assessment should be objective in their scientific work and not be subject to any conflict of interest. Information on the identities of these government experts, their individual expertise and their professional experience should be publicly available, while taking into account the need to protect them from external influence during the risk assessment process. Experts from outside government involved in risk assessment should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved. Transparent procedures should be used to select these experts, including disclosure of conflicts of interest in connection with risk assessment.
21. Risk assessment should incorporate the four steps of risk assessment, i.e., hazard identification, hazard characterization, exposure assessment and risk characterization.
22. Risk assessment should be based on scientific data most relevant to the national context. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.
23. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.
24. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.
25. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.
26. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for

resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

27. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

Risk Management

28. National government decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers. Unjustified differences in the level of consumer health protection to address similar risks in different situations should be avoided.
29. Risk management should follow a structured approach including preliminary risk management activities²², evaluation of risk management options, implementation, monitoring and review of the decision taken.
30. The decisions should be based on risk assessment, and should be proportional to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles²³ as they relate to decisions at the national level. National governments may also base their decisions on Codex standards, recommendations and guidelines where available.
31. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.
32. Risk management should take into account the economic consequences and the feasibility of risk management options.
33. The risk management process should be transparent, consistent and fully documented. Decisions and recommendations on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties.
34. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.
35. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.
36. Risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, national governments should seek and take into consideration the potential impact of such measures on trade among and select measures that are no more trade-restrictive than necessary.
37. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. The relevance, effectiveness, and impacts of risk management decisions and their implementation should be regularly monitored and the decisions and/or their implementation reviewed as necessary.

²² For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

²³ FAO/WHO. 2005. Appendix: *General Decisions of the Commission*. In *Codex Alimentarius Commission Procedural Manual*. 15th Edition, pp. 159-160
(ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_15e.pdf).

Risk Communication

38. Risk communication should :

- i) promote awareness and understanding of the specific issues under consideration during the risk analysis;
- ii) promote consistency and transparency in formulating risk management options/recommendations;
- iii) provide a sound basis for understanding the risk management decisions proposed;
- iv) improve the overall effectiveness and efficiency of the risk analysis ;
- v) strengthen the working relationships among participants;
- vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
- vii) promote the appropriate involvement of all interested parties;
- viii) exchange information in relation to the concerns of interested parties about the risks associated with food; and
- ix) respect the legitimate concern to preserve confidentiality where applicable.

39. Risk analysis should include clear, interactive and documented communication, amongst risk assessors and risk managers and reciprocal communication with all interested parties in all aspects of the process.

40. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

41. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The decisions taken and the procedures followed to reach them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 26).

Implementation²⁴

42. With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective implementation of risk analysis principles and techniques in their food control systems.

43. National governments should share information and experiences on risk analysis with other national governments (e.g., at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate broader implementation of risk analysis.

²⁴ It is recognized that national governments will use different approaches and time frames in the application of these principles taking into account national capacities and resources.