CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

REP13/AF

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

Thirty sixth Session
Rome, Italy, 1-5 July 2013

REPORT OF THE SEVENTH SESSION OF THE *AD-HOC* INTERGOVERNMENTAL CODEX TASK FORCE ON ANIMAL FEEDING

Bern, Switzerland
4-8 February 2013

NOTE: This report contains Codex Circular Letter CL 2013/3-AF

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CL 2013/03-AF
February 2013

To: Codex Contact Points
Interested International Organizations

From: Secretariat,
Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome, Italy

Subject: **Distribution of the Report of the Seventh Session of the *Ad Hoc* Intergovernmental Codex Task Force on Animal Feeding (REP13/AF)**

The report of the Seventh Session of the *Ad Hoc* Intergovernmental Codex Task Force on Animal Feeding will be considered by the 36th Session of the Codex Alimentarius Commission (Rome, Italy, 1-5 July 2013)

MATTERS FOR ADOPTION BY THE 36TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Draft and Proposed Draft Standards and Related Texts at Step 8 and 5/8 of the Procedure

Draft Guidelines on Application of Risk Assessment for Feed at Step 8 (para. 27 and Appendix II).

Proposed draft Guidance on Prioritizing Hazards in Feed at Step 5/8 (para. 62 and Appendix III).

Governments and international organizations wishing to submit comment on the above texts should do so in writing to the Secretariat, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy (***e-mail***: codex@fao.org) **before 31 May 2013.**

Content

SUMMARY AND CONCLUSIONS

The Seventh Session of the *Ad Hoc* Intergovernmental Codex Task Force on Animal Feeding reached the following conclusions:

Matters for the 36th Session of the Codex Alimentarius Commission

Matters for adoption

Proposed draft Standards and Related Texts at Step 8 and 5/8 of the Procedure

The Task Force agreed to forward the draft Guidelines on Application of Risk Assessment for Feed and the renamed proposed draft Guidance on Prioritizing Hazards in Feed to the Commission for adoption at Step 8 and 5/8 respectively (*see* para 27 and 62 and Appendices II and III).

INTRODUCTION

1. The *ad hoc* Intergovernmental Codex Task Force on Animal Feeding (TFAF) held its Seventh Session in Bern, Switzerland, from 4 to 8 February 2013, at the kind invitation of the Government of Switzerland. Dr Eva Reinhard, Assistant Director-General of the Swiss Federal Office for Agriculture (FOAG), chaired the Session. The Session was attended by 101 delegates from 40 Member countries and one Member organization and seven international governmental and non-governmental organizations, including FAO and WHO. The list of participants, including the Secretariats, is given in Appendix I to this report.

OPENING OF THE SESSION

2. The Session was opened by Mr Jacques Chavaz, Deputy Director-General of the Swiss Federal Office for Agriculture. In his keynote address, Mr Chavaz emphasized the global need to ensure the safety of food of animal original along the food chain and hence the need to finalize the documents under discussion, which could contribute to this endeavour and that Switzerland was committed to achieving this. He noted that this was a shared responsibility and acknowledged the contribution of all in achieving progress to date. He informed the Task Force that livestock was one of the priority areas for the Switzerland support programme to FAO of which a key component was the development of the Global Agenda of Action in support of sustainable livestock sector development, a multi-stakeholder partnership, which would be launched at the FAO Conference in June 2013.

3. Mr Chavaz expressed his thanks to the three Ministries involved in the organization of the session and to the Codex Secretariat for their support, and wished the Task Force every success in finalisation of its work.

Division of Competence[1]

4. The Task Force noted the division of competence between the European Union and its Member States, according to paragraph 5, Rule II of the Rules of Procedure of the Codex Alimentarius Commission, as presented in CRD 1.

ADOPTION OF THE AGENDA (Agenda Item 1)[2]

5. The Task Force adopted the Provisional Agenda as its Agenda for the Session.

MATTERS REFERRED TO THE TASK FORCE BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES (Agenda Item 2)[3]

6. The Task Force noted relevant decisions of the 35th Session of the Codex Alimentarius Commission regarding the adoption at Step 5 and advancement to Step 6 of the draft Guidelines on Application of Risk Assessment for Feed and the status of the ongoing review of the existing Codex texts as to their applicability to animal feed. In particular, the Task Force noted the adoption of the revised definition for “contaminant” which now took into account feed.

REPORT ON ACTIVITIES OF FAO, WHO AND OTHER INTERNATIONAL INTERGOVERNMENTAL ORGANIZATIONS (Agenda Item 3)[4]

Report of Activities of FAO and WHO

7. The FAO Representative drew the attention of the Task Force to the information in CX/AF 13/7/3 and provided information on the FAO capacity development activities in the areas of animal nutrition, feeding and feed safety to support the sustainable development of the livestock sector. In this context FAO has linked animal feeding and feed safety not only to public health and food safety, but also to other important areas of work for FAO, such as animal health and welfare, the mitigation of possible negative impacts of livestock on the environment and climate change, food security and sustainable diets and the reduction of food losses and wastes.

8. The FAO Representative informed the Task Force of the recently produced Feedipedia[5], an on-line encyclopaedia of animal feed, developed in collaboration with the French National Institute for Agricultural Research (INRA), the Centre for Agricultural Research for Development (CIRAD) and the French Animal

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1 CRD 1 (Annotated Agenda – Division of competence between the European Union and its Member States)
2 CX/AF 13/7/1
3 CX/AF 13/7/2
4 CX/AF 13/7/3;CX/AF 13/7/3 Add.1
5 Available at http://www.feedipedia.org

Production Association (AFZ) and of the launch of an FAO Animal Feeding Twitter account[6] and a series of dedicated podcasts[7].

9. In addition the Representative referred to the FAO's strong collaboration with a wide range of stakeholders, in particular with the International Feed Industry Federation (IFIF), to develop the capacities of the sector players to ensure feed safety.

10. The Representative of WHO provided information on WHO activities on antimicrobial resistance, including the development and regular updating of a list of Critically Important Antimicrobials (CIA); the activities of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (WHO-AGISAR) and the recent FAO and WHO whole food chain studies to assess and quantify microbial contamination and antimicrobial resistance in some developing countries.

11. The Representative also provided information on a web-based tool developed by FAO and WHO to assess the performance of sampling plans for microbiological hazards in food and feed[8]. She further informed on the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Expert Meeting on Pesticide Residues (JMPR) activities related to the risk assessment of chemical substances and contaminants in food, which take into consideration the implication of contamination of animal feed or feed ingredients as appropriate.

12. The Representative informed the Task Force that the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) has enhanced its coordination with the animal production sector to strengthen its capacity to address issues such as feed safety and has also been addressing food safety events related to animal feed and pet food.

13. Given the Task Force's work on the development of Guidance for the Prioritization of Hazards in Feed (Agenda Item 5), the FAO Representative made a presentation on the ranking approach that had been applied by FAO and WHO in the ranking of foodborne parasites. The presentation focused on the approach taken, the steps therein and the challenges and lessons learned. A copy of the presentation is available on the Codex ftp site[9].

World Organisation for Animal Health (OIE)

14. The Codex Secretariat drew the attention of the Task Force to document CX/AF 13/7/3 Add.1 which provided a brief update on relevant OIE activities. In particular, the OIE had adopted standards in the *Terrestrial Animal Health Code* and the *Aquatic Animal Health Code* on the control of hazards of animal health and public health importance in animal feed and on the responsible and prudent use of antimicrobial agents.

Conclusion

15. The Task Force acknowledged and thanked FAO, WHO and OIE for their contribution.

PROPOSED DRAFT GUIDELINES ON APPLICATION OF RISK ASSESSMENT FOR FEED (Agenda Item 4)[10]

16. The Chairperson introduced the report of the physical Working Group (pWG), which met on 3 February 2013, to consider the draft Guidelines on Application of Risk Assessment for Feed (*see* CRD 2). The Task Force noted that the pWG had revised the document and, in particular: clarified the text and definitions; added the Codex definition for food; complemented Figure1; made some changes in the sections on risk assessment procedure, hazard characterization and exposure assessment; and revised Annex 1.

17. The Task Force agreed to consider the revised draft Guidelines, as in the Annex of CRD 2, and to consider a proposal of the Netherlands for the Sections on Exposure Assessment and Risk Characterization, as in CRD 5.

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6 https://twitter.com/FAOafeeding
7 http://vimeo.com/faocast
8 Available at www.mramodels.org/sampling
9 ftp://ftp.fao.org/codex/Meetings/TFAF/tfaf7/Risk%20ranking%20approach/
10 REP12/AF Appendix II; CL 2012/22-AF; CX/AF 13/7/4 (Comments of Argentina, Canada, Chile, European Union, India, Iran, New Zealand, Philippines, United States of America and IFIF); CX/AF 13/7/4 Add.1 (Comments of India and OIE); CRD 2 (Report of the physical Working Group); CRD 3 (Comments of Ghana, Indonesia, Kenya, Nigeria, Republic of Korea and Thailand); CRD 5 (Proposals of the Netherland for paras 39-43)

Specific comments

18. The Task Force accepted the majority of the changes proposed and, in addition to some editorial changes to improve clarity and consistency with other Codex documents, made the following changes and comments.

Definitions

19. The Task Force agreed that the definitions included in the document, the proposed draft Guidance for Governments on Prioritizing Hazards in Feed (Agenda Item 5) and the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004) should be consistent, and to delete the definitions of the terms which were not used in the two documents under development.

Risk Assessment in the Codex Risk Analysis Framework

20. The Task Force noted that preliminary risk management activities encompassed all those activities that would lead to a risk management decision and were, therefore, an integral part of the risk management process.

21. The Task Force added: (i) "definition of the output form of the risk assessment" to the list of preliminary risk management activities, consistent with the *Working Principle for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007); and (ii) a reference to the Guidance for Governments on Prioritizing Hazards in Feed (Agenda Item 5) to activity "ranking of the hazard for risk assessment and risk management priority" to establish a link between the risk assessment and the prioritization documents.

22. The Task Force complemented Figure 1 to ensure that the list of preliminary risk management activities was consistent with those listed in the text.

Exposure assessment

23. The Task Force agreed to merge the two paragraphs on sampling plans and analytical laboratory methods since both referred to data generation, and to introduce the word "testing" to the introductory sentence to give context to the paragraph.

Risk Characterization

24. The Task Force agreed with the proposal in CRD 5 to revise the Sections on Exposure Assessment and Risk Characterization to: better distinguish between the risk characterization and exposure assessment activities; clarify that the feed risk assessment derives a risk estimate for food safety and does not imply a full human risk assessment; and to illustrate the need for the risk characterization and subsequent risk management options to take into account exposure assessment of a hazard from sources other than feed (e.g. from the environment or food of non-animal origin).

25. The Task Force included a new paragraph which illustrated that an initial output of risk assessment might be a comparison of the estimated feed hazard in the edible products with an already existing limit in food, before taking a risk management decision related to the control of the hazard in the feed.

Conclusion

26. The Task Force agreed that the document was complete and that no further issues were outstanding.

Status of the proposed draft Guidelines on Application of Risk Assessment for Feed

27. The Task Force agreed to forward the draft Guidelines to the 36th Session of the Commission for adoption at Step 8 (*see* Appendix II).

PROPOSED DRAFT GUIDANCE FOR USE BY GOVERNMENTS IN PRIORITISING THEIR NATIONAL FEED HAZARDS (Agenda Item 5)[11]

28. The Delegation of Switzerland introduced the report of the electronic Working Group (eWG) and explained the relationship between prioritization and risk assessment. It was clarified that prioritization was a

[11] CX/AF 13/7/5; CX/AF 13/7/5 Add.1 (Comments of Argentina, Brazil, Canada, Chile, Colombia, Egypt, European Union, Iran, Japan, Norway, Philippines and United States of America); CX/AF 13/7/5 Add.2 (Comments of India, IFIF and OIE); CRD 2 (Report of the physical Working Group); CRD 4 (Comments of Ghana, Kenya, Nigeria, Republic of Korea, Thailand and IDF), CRD 6 (Proposed Draft Guidance for Governments on Prioritizing Hazards in Feed prepared by Switzerland); CRD 7 (Draft Guidelines for Governments on Prioritizing Hazards in Feed, proposal of 5 February 2013)

risk management step, the purpose of which in many or most cases was to establish which risk assessments needed to be done.

29. The Delegation highlighted the key tasks undertaken as given by the previous session of the Task Force. It was explained that the eWG had further revised the document to provide a globally applicable step-by-step guidance for prioritization, which would enable national risk managers to prioritize feed hazards in a multitude of situations. The document included two annexes on examples of hazards and a partially completed example of the prioritization process.

30. To facilitate discussion at the Session, the Delegation of Switzerland had prepared a revised document (CRD 6), which took into account the written comments received and the FAO/WHO report on ranking of foodborne parasites (*see* Agenda Item 3). The Delegation noted that this approach to prioritization was a first and innovative attempt in Codex.

31. The Delegation of Switzerland presented this revision and explained the key change was the use of the multi-criteria analysis approach, which included the following steps: identification of hazard/feed/edible product combinations; identification and definition of the criteria by which each selected combination is quantified; assignment of the criterion-based values to the combinations; normalization of these values to make them comparable between criteria; weighting of the criteria to reflect their relative importance; combining the weighted normalised values for each combination to produce a score and ranking of the scores; and reporting. The risk-profiling step was removed as this was not a part of the prioritization process and was also not used by FAO/WHO in their work on parasites in food.

32. It was further explained that the example of prioritization in the annex was generic and for illustrative purposes only and did not apply to a specific hazard/feed/edible product combination. However, since it was based on the FAO/WHO parasite report, the example needed to be revised to apply to feed.

33. The Committee agreed to consider CRD 6 as the basis for discussion.

General discussion

34. The Task Force agreed that the revised document was a good basis for discussion, but that further work was needed on the example in the Annex, in particular to ensure its applicability to feed.

Specific comments

35. The Task Force accepted the majority of the changes proposed and, in addition to some editorial changes to improve clarity and consistency with the document on risk assessment (Agenda Item 4), made the following changes and comments.

Title, Introduction and Scope

36. The Task Force agreed with the revised more concise title that is “Guidance for Governments on Prioritizing Hazards in Feeds”.

37. The Introduction was amended to make clear that “preliminary risk management activities” are part of the risk management process and provide inputs leading to a risk management decision.

38. The Task Force amended the scope to indicate that approaches other than the multi-criteria analysis approach could also be used for prioritization.

Definitions

39. Consistent with the earlier decision on definitions in the risk assessment document (Agenda Item 4), the Task Force agreed: to revise the definitions to ensure consistency with other texts related to animal feed; to use to the extent possible Codex definitions; and to limit the list of definitions to only those terms which appear in the document.

40. The Task Force agreed to use the definition of “processing aid” for food from the Procedural Manual and to indicate that it was also applicable to feed.

41. The Task Force noted that the term “carry-over” when translated into French and Spanish did not clearly differentiate between “carry-over” and “cross-contamination” and could cause confusion. The Task Force therefore agreed to delete the definition for “carry-over” and to broaden the definition of “cross-contamination” to also cover contamination of feed originating from previous use of equipment.

Prioritization of hazards in the framework of Codex risk analysis

42. The Task Force agreed to amend this section to clarify that prioritization could also be undertaken at any point of the risk analysis process.

Prioritization Process

43. The Task Force introduced an introductory paragraph to explain the aim of prioritization.

Steps of the Prioritization Process

44. The Task Force introduced a reference to the risk assessment document (Agenda Item 4) to explain the link between the two documents.

45. The Task Force agreed to better describe Step 2 “Identification and definition of the criteria” using the information from the example. The Task Force agreed that the criteria which could be considered included : those related to the extent of the occurrence of the hazard; effect on human health; and other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

46. The Task Force agreed to amend Step 5 “Criterion weighting” to explain that weighting of criteria is typically done by the risk manager with support of experts when required; and introduced a new paragraph under Step 6 “Ranking of the hazard/feed/edible product combinations” to emphasize the need to demonstrate the impact of assumptions on the ranking.

47. The Task Force supported the deletion of the risk-profiling step, as it was a separate element of the preliminary risk management activities.

Annex 1: Examples of Hazards in Feed with Potential Relevance for Human Health

48. The Task Force discussed the need for this Annex. A number of delegations considered that the Annex was useful and that it made the document more complete and self-contained. The Annex provided, even though not exhaustive, a wide list of hazards in feed and information that countries could consider when starting their prioritization process. It was considered that this useful information could also contribute to a common understanding of these hazards in feed. These delegations also noted that the language used in the Annex was not prescriptive and that the introduction made it clear that its purpose was only to provide examples.

49. Some other delegations were not in favour of retaining the Annex. They pointed out that the information provided was not complete and would be difficult to maintain and update; and that the 2008 report of the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety already included information on hazards in feed. These delegations also questioned the validity of some of the information and expressed concern that countries could misinterpret the purpose of the Annex and use the examples as unjustified barriers to trade.

50. In view of the support by a large number of delegations to retain the Annex, the Task Force considered it in detail with a view to identifying and addressing those parts that could be of concern. It was agreed to focus on the information provided and not to add new information that could not be verified.

51. In particular, the Task Force amended the Title to only refer to hazards in feed to better reflect its content. The introductory section was revised to make it clearer that the Annex was not a comprehensive description of different situations related to feed and food safety; that the information might need to be updated; that the Annex was intended to provide only information for the initial steps of the prioritization process and should not be considered as a risk assessment of the cases mentioned; that the examples illustrated might not be relevant everywhere or at all times; and that the Annex was not covering rare and emerging hazards.

52. The Task Force further corrected some inaccuracies, such as: replacing *Cysticercus* spp with *Taenia* spp and deleting the example of *Trichinella*. It also deleted the section on viruses, which was relevant to animal health rather than feed, and included zearalenone as an example of mycotoxins, noting that it was not a major contaminant of edible products as it was rapidly metabolised and/or excreted.

53. The Task Force amended the section on organic chemicals to distinguish between dioxins and polychlorinated biphenyls (PCBs) and added the example of medicated feed as a potential source of cross-contamination of feed in the Section on pesticides, veterinary drugs, feed additives and processing aids.

54. In view of these amendments, the Task Force agreed to retain the Annex.

55. The delegations of Argentina, Brazil and Costa Rica expressed their reservation to the inclusion of the Annex in the Guidance noting that: the Annex could not be easily updated; the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety, published in 2008, addressed feed hazards of relevance to food safety; and that competent authorities could misinterpret the purpose of the Annex and use the information therein as unnecessary sanitary requirements that could compromise trade.

56. The Task Force recognizing that new information on hazards in feed of relevance to human health had become available since the FAO/WHO Expert Meeting (2008), requested FAO and WHO to provide updated

information. It was noted that FAO and WHO would consider this request in light of their work plans and availability of resources.

Annex 2: Example of the Prioritization Process

57. The Task Force agreed that it would be useful to have an example to illustrate the steps of prioritization and established an in-session working group to prepare a revised example more applicable to feed.

58. The Task Force considered the proposal of the in-session WG (CRD 7), which was based on fictitious hazard/feed/edible product combinations, applicable criteria, and hypothetical criterion-based values.

59. The Task Force revised the introductory part to indicate that the example was fictitious and that its only purpose was to illustrate the steps of the prioritization process; that the criteria used were applicable but not exhaustive; and the values used were illustrative.

60. The Task Force supported the example and made some editorial amendments to improve its readability and clarity and further agreed to re-order the two annexes for better flow of the document.

Conclusion

61. The Task Force noted the progress made on the text and that there were no outstanding issues that needed to be addressed and agreed to advance the proposed draft Guidance for Governments on Prioritizing Hazards in Feed to Step 5/8. The Task Force noted that Argentina, Brazil, Costa Rica, Saudi Arabia and Thailand required time to consult at national level on the changes made to the document.

Status of the proposed draft Guidance for Use by Governments in Prioritizing their National Feed Hazards

62. The Task Force agreed to forward the renamed proposed draft Guidance on Prioritizing Hazards in Feed to the 36th Session of the Commission for adoption at Step 5/8 with the omission of Steps 6 and 7 (*see* Appendix III).

OTHER BUSINESS (Agenda Item 6)

63. The Task Force noted that no other business had been put forward.

64. The Chairperson congratulated all delegations, which had actively contributed through the two sessions to develop comprehensive guidance documents for governments on the application of risk assessments of feed and on prioritization of feed hazards. The Chairperson further noted that, with the completion of these two documents, the Task Force had completed the task assigned to it by the 33rd Session of the Commission.

SUMMARY STATUS OF WORK

Subject Matter	Step	Action by:	Document Reference (REP13/AF)
Draft Guidelines on application of risk assessment for feed	8	36th CAC	Para. 27 and Appendix II
Proposed draft Guidance for use by governments in prioritizing the national feed hazards (renamed Guidance on Prioritizing Hazards in Feed)	5/8	36th CAC	Para. 62 and Appendix III

Appendix I

LIST OF PARTICIPANTS
LISTE DES PARTICIPANTS
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Chairperson:
Présidente:
Presidente:

Dr Eva REINHARD

Means of Agricultural Production Directorate
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 322 25 03
Fax: +41 31 323 54 55
E-mail:eva.reinhard@blw.admin.ch

Assistant to the Chairperson:
Assistante du Président:
Asistente del Presidente:

Mr Louis TAMBORINI

Means of Agricultural Production Directorate
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 322 27 13
Fax: +41 31 322 26 34
E-mail: louis.tamborini@blw.admin.ch

ARGENTINA – ARGENTINE

Dr Teresa BIANCHI
Department Senasa
Blanco Encalada 2387 piso 19 Dpto G
Capital Federal, Argentina
Tel: +54 011 478 686 32
E-mail: tbianchi@senasa.gov.ar

BELGIUM – BELGIQUE – BÉLGICA

Mr Diederik STANDAERT
Federal Public Service Health
Food Chain Safety and Environment
DG Animal, Plant and Foodstuffs
Place Victor Horta 40 bt. 10
1060 Brussels, Belgium
Tel:+ 32 252 473 54
E-mail: diederik.standaert@gezondheid.belgie.be

Mr Damien VAN OYSTAEYEN
Federal Agency for the Safety of the Food Chain
DG Control Policy
55 Bld du Jardin Botanique
1000 Brussels, Belgium
Tel: +32 (0)2 211 86 06
E-mail: damien.vanoystaeyen@afsca.be

BRAZIL – BRÉSIL – BRASIL

Mr Bruno Jean Adrien PAULE
Ministry of Agriculture,
Livestock and Food Supply
Esplanada dos Ministérios
Bloco D, Anexo A, Sala 443
70043-900 Brasilia
Tel: +55 613 218 23 07
E-mail: bruno.paule@agricultura.gov.br

Ms Angela PELLEGRINO-MISSAGLIA
Sindiraçoes
Avenida Paulista, 1313 – 10^{0}andar
01311-923 Sao Paolo , Brazil
Tel: +55 119 844 901 95
E-mail: apmissaglia@uol.com.br

CAMEROON – CAMEROUN – CAMERÚN

Ms Colette BOOTO A NGON-WOLIMOUM
Sous-Directeur de l'Alimentation Animale
Ministére de L' Elevage des Pêches et des Industries Animales
B.P. 5674
Yaoundé, Cameroun
Tel: + 237 99 612 471 / +237 776 597 50
E-mail: booto25@yahoo.fr

CANADA – CANADÁ

Ms Catherine ITALIANO
Risk Analysis & Toxicology Section
Animal Feed Division
Canadian Food Inspection Agency
59 Camelot Drive
K1A 0Y9 Ottawa, Canada
Tel: +613 773 7531
E-mail: Catherine.italiano@inspection.gc.ca

CHILE – CHILI

Mr. Juan ALARCÓN
Coordinador Unidad de Alimentos para Animalés del
Servicio Agricola y Ganadero
Departamento de Protección Pecuaria
Servicio Agricola y Ganadero
Bulnes 140, Santiago
Santiago, Chile
Tel: +56 2 234 513 86
E-mail: juan.alarcon@sag.gob.cl

Ms Roxana VERA
Servicio Agricola y Ganadero
Unidad de Acuerdos, Supdepartemento de Negociaciones Internationales
División de Asuntos Internacionales
Bulnes 140, Santiago
Santiago, Chile
Tel: +56 2 234 511 67
E-mail: roxana.vera@sag.gob.cl

CHINA – CHINE

Ms Yulian GAO
China National Center for Food Safety Risk Assessment
37 Guangqulu, Chaoyang
Beijing 100022, China
Tel: +86 10 521 655 78
E-mail: gaoyulian@cfsa.net.cn

Ms Zhe ZHANG
China National Center for Food Safety Risk Assessment
Division I of Food Standard
37 Guangqulu, Chaoyang
Beijing 100022, China
Tel: +86 10 521 654 06
E-mail: zhangzhe@cfsa.net.cn

COSTA RICA

Ms Isabel MONTERO
Ambassador of Costa Rica
Embassy of Costa Rica in Switzerland
Schwarztorstrasse 11
3007 Berne, Switzerland
Tel: +41 31 372 78 87
E-mail: costa.rica@bluewin.ch

Mr Roberto AVENDANO-SANCHO
Consul of Costa Rica
Embassy of Costa Rica in Switzerland
Schwarztorstrasse 11
3007 Berne, Switzerland
Tel: +41 31 372 78 87
E-mail: iaraya@meic.go.cr

Ms Roxana TINOCO
Counsellor
Mission of Costa Rica to the UN
23, Avenue de France
1202 Genève, Switzerland
Tel: +41 22 731 25 87
E-mail: mission.costa-rica@ties.itu.int

DENMARK – DANEMARK - DINAMARCA

Ms Birgitte BROESBØL-JENSEN
Danish Veterinary and Food Administration Chemicals and Food Quality Division
Stationsparken 31
DK-2600 Glostrup
Tel: +45 72 276 879
E-mail: bibje@fvst.dk

ESTONIA

Ms Eda ERNES
Ministry of Agriculture
Food Safety Department
Lai Street 39/Lai Street 41
Tallinn 15056, Estonia
Tel: +372 625 51 26
E-mail: eda.ernes@agri.ee

EUROPEAN UNION – UNION EUROPÉENNE – UNIÓN EUROPEA

Dr James MOYNAGH
Head of Unit
European Commission
Rue Froissart 101
1049 Brussels, Belgium
Tel:+32 229 580 86
E-mail: james.moynagh@ec.europa.eu

Mr Miguel Angel GRANERO ROSELL
DG Health and Consumers
European Commission
Rue Froissart 101
1049 Brussels, Belgium
Tel: +32 229 581 10
E-mail: miguel-angel.granero-rosell@ec.europa.eu

Ms Barbara MORETTI
DG Health and Consumers
European Commission
Rue Froissart 101
1049 Brussels, Belgium
Tel: +32 229 923 62
E-mail: barbara.moretti@ec.europa.eu

EGYPT – ÉGYPTE – EGIPTO

Bad AZZA
Ministry of Agriculture
Agriculture Research Center
Regional Center for Food and Feed
9 El Gamaa St.
Giza, Egypt
Tel: +020 1118 982 986
E-mail: azzabadr@yahoo.com

FINLAND – FINLANDE – FINLANDIA

Ms Marita AALTO
Ministry of Agriculture and Forestry
Department of Food
P.O. Box 30
00023 Government Helsinki, Finland
Tel: +358 405 930 136
E-mail: marita.aalto@mmm.fi

FRANCE – FRANCIA

Mr Tanguy BIDAUD
Coop de France
Nutrition Animale
43, rue Sedaine
75011 Paris, France
Tel: +33 144 175 714
E-mail: tanguy.bidaud@coopdefrance.coop

Ms Gaël CABASSUT
Ministère de l'Agriculture, de l'Agroalimentaire et de la Foret
Direction Générale de l'Alimentation
251, rue Vaugirard
75732 Paris Cedex 15, France
Tel: +33 149 558 453
E-mail: gael.cabassut@agriculture.gouv.fr

Ms Anne COULOMBE
Ministère de l'Economie et des Finances
Direction générale de la Concurrence, de la Consommation et la Répression des Fraudes
DGCCRF
59, Bd Vincent Auriol
75703 Paris Cedex 13, France
Tel : +33 144 972 564
E-mail : anne.coulombe@dgccrf.finances.gouv.fr

Ms Anne DEYGAS
Syndicat National des Producteurs d'Additifs et d'Ingrédients de la Chaîne Alimentaire
Adisseo France SAS
10, Place du Général de Gaulle
92160 Antony, France
Tel: +33 146 747 038
E-mail: anne.deygas@adisseo.com

GERMANY – ALLEMAGNE – ALEMANIA

Dr Sabine KRUSE
Federal Ministry of Food, Agriculture and Consumer Protection
Rochusstrasse 1
53123 Bonn, Germany
Tel: +49 (0) 228 - 99 529 4186
E-mail: sabine.kruse@bmelv.bund.de

Mr Peter RADEWAHN
Deutscher Verband Tiernahrung e.V. (DVT)
Beueler Bahnhofsplatz 18
53225 Bonn, Germany
Tel: +49 228 975 68 24
E-mail: radewahn@dvtiernahrung.de

Dr Helmut SCHAFFT
Federal Institute for Risk Assessment
Max-Dohrn-Str. 8-10
10589 Berlin, Germany
Tel: +49 308 412 34 75
E-mail: helmut.schafft@bfr.bund.de

Ms Dorothea SCHIEMANN
Arbeitsgemeinschaft für Wirkstoffe in der Tierernährung (AWT) e.V.
Avenue Louise, 130 A – Box 1
1050 Brussels, Belgium
Tel : +32 2 639 66 64
E-mail : dos@fefana.org

GHANA

Dr Musheibu Mohammed ALFA
Animal Products and Biosafety Department
Food and Drugs Authority
P.O. Box CT 2783 Cantonments
Accra, Ghana
Tel: +233 244 337 247
E-mail: mushalfa107@yahoo.co.uk

Ms Gloria ODOI
Food and Drugs Authority
Feed Safety Unit
P.O. Box CT 2783 Cantonments
Accra, Ghana
Tel: +233 277 412 912
E-mail: djoppus@yahoo.com

INDONESIA – INDONÉSIE

Dr Gardjita BUDI
Ministry of Agriculture
Director of Quality and Standardization
D Building 3rd Floor
Jl. Harsono RM No. 3 Ragunan
12550 Jakarta, Indonesia
Tel: +62 21 781 58 81
E-mail gbudi.jkt@gmail.com

Mr. Desianto Budi UTOMO
Charoen Pokphand Group
Jl. Ancol VIII/1
14430 Jakarta Utara, Indonesia
Tel: +62 21 691 99 99
E-mail: desianto@epjf.co.id

Ms Triastuti Andayani FATHONI
Ministry of Agriculture
Directorate of Animal Feed, Directorate General of Livestock and Animal Health Service
Forage Division
J1. Harsono RM No. 3 Ragunan
12550 Jakarta, Indonesia
Tel: +62 21 788 338 04
E-mail: andayanitriastuti@yahoo.co.id

Dr Mursyid MA'SUM
Ministry of Agriculture
Directorate General of Livestock and Animal Health Service, Directorate of Animal Feed
Jl. Harsono RM No. 3 Ragunan
12550 Jakarta, Indonesia
Tel: +62 21 7883 3805
E-mail: murma_sang@yahoo.com

Prof. Arnold P. SINURAT
Ministry of Agriculture
Indonesia Research Institute for Animal Production
Desa Banjarwaru 03/03 Ciawi
Bogor 16720, Indonesia
Tel: +62 251 824 0751
E-mail: arnoldst@cbn.net.id

Ms Tatie SRI PARYANTI
Ministry of Marine Affairs and Fisheries
Directorate of Production, Directorate General of Aquaculture
Jl. Harsono RM No. 3 Ragunan
12550 Jakarta, Indonesia
Tel: +62 21 7884 62 60
E-mail: tatsipa@gmail.com

IRAN, ISLAMIC REP OF

Mr Mohammadreza KOUHKANNEJAD
Ministry of Agriculture
Department of Livestock Products Affairs
Taleghani Avenue
P.O. Box 15934
16111 Tehran, Iran
Tel: +98 21 645 83 901
E-mail: kouhkannejad@gmail.com

IRELAND – IRLANDE – IRLANDA

Dr Liam HYDE
Department of Agriculture, Food and the Marine
Feeding Stuffs Division
Backweston Admin. Building
Celbridge
Co. Kildare, Ireland
Tel: +353 150 587 65
E-mail: liam.hyde@agriculture.gov.ie

Mr Gerry LOHAN
Departement of Agriculture, Food and the Marine
Backweston Admin. Building
Celbridge
Co. Kildare, Ireland
Tel: +353 150 587 66
E-mail: Gerry.lohan@agriculture.gov.ie

ITALY – ITALIE – ITALIA

Mr Ciro IMPAGNATIELLO
Italian Codex Contact Point
Ministry of Agricultural Food and Forestry Policy
Via XX Settembre, 20
00187 Roma, Italy
Tel: +39 064 665 60 46
Fax: +39 064 880 273
E-mail: c.impagnatiello@mpaaf.gov.it

Mr Carmelo CICERO
Ministero della Salute
Office VII
Animal Nutrition
Roma, Italy
Tel: +39 065 994 65 83
E-mail: c.cicero@sanita.it

JAPAN – JAPON – JAPÓN

Dr Takako KIMURA
Ministry of Agriculture, Forestry and Fisheries
Animal Products Safety Division, Food Safety and Consumer Affairs Bureau
1-2-1 Kasumigaseki Chiyoda-ku
100-8950 Tokyo, Japan
Tel: +81 335 028 111
E-mail: takako_kimura@nm.maff.go.jp

Dr Yumiko SAKURAI
Ministry of Agriculture, Forestry and Fisheries
Animal Products Safety Division, Food Safety and Consumer Affairs Bureau
1-2-1 Kasumigaseki Chiyoda-ku
Tokyo, Japan
Tel: +81 335 028 111
E-mail: yumiko_sakurai2@nm.maff.go.jp

KENYA

Dr Purity NGUHIU
Ministry of Livestock Development
Department of Veterinary Services
Veterinary Laboratories, Kabete
P.O. 00625, Kangemi
Nairobi, Kenya
Tel: +254 722 737 711
Email: puritynguhiu@yahoo.com

KUWAIT – KOWEÏT

Mr Abdul Jaleel ALKHUDDARI
Sabah al – Salim B6 S1 h5, Kuwait
Tel: +965 9000 33 99
E-mail: vet-dr@hotmail.com

LITHUANIA – LITUANIE - LITUANIA

Ms Natalija GUSEVA
Permanent Representation of Lithuania to the EU
Rue Belliard 45, Office 3.15
1040 Brussels, Belgium
Tel: +32 278 81 899
E-mail: Natalija.guseva@eu.mfa.lt

MOROCCO – MAROC

Dr Abdelwahed Douk
Office National de Sécurité Sanitaire des Produits Alimentaires
Avenue Hadj Ahmed Cherkaoui
Agdal – Rabat, Morocco
Tel: +212 537 676 583
E-mail: a_8douk@hotmail.com

Mr Abdellatif Sahnoun
Direction de Développement des Filiaires de Production
Ministère de l'Agriculture et de la Pêche Maritime
Najah 40 Guiche Oudaya
Témara, Morocco
Tel: +212 618 140 505
E-mail: abdelsahnoun@gmail.com

Mr Mohamed TANNAOUI
Laboratoire Officiel d'Analyse et de Recherches Chimiques
25, rue Nichakra Rahal
Casablanca, Morocco
Tel: +212 522 302 007
E-mail: tannaoui1@yahoo.fr

NETHERLANDS – PAYS-BAS – PAÍSES BAJOS

Ms Astrid BULDER
National Institute for Public Health and the Environment (RIVM)
Centre for Nutrition, Prevention and Health Services (VPZ)
P.O. Box 1
3720 BA Bilthoven, Netherlands
Tel: +31 302 747 048
E-mail: astrid.bulder@rivm.nl

Mr Rob THEELEN
Food and Consumer Product Safety Authority
Office for Risk Assessment
P.O. Box 43006
3540 AA Utrecht, Netherlands
Tel: +31 611 88 2558
E-mail: r.m.c.theelen@vwa.nl

NEW ZEALAND – NOUVELLE-ZÉLANDE – NUEVA ZELANDIA

Ms Janice ATTRILL
Ministry for Primary Industries
Animal & Animal Products Directorate
25 The Terrace
6011 Wellington, New Zealand
Tel: +64 489 426 32
E-mail: Janice.attrilla@mpi.govt.nz

NIGERIA – NIGÉRIA

Mr Adekunle ADEBAMBO
Federal Ministry of Trade and Investment (FMTI)
Federal Produce Inspection Service
Area 1 Old Federal Secretariat
Garki
Abuja, Nigeria
Tel: +234 803 248 17 88
E-mail: adebambo_adekunle@yahoo.com

Mr Julius Oreyemi APANISILE
Federal Ministry of Trade and Investment (FMTI)
Federal Produce Inspection Service
FMTI, Area 1 Old Federal Secretariat
Garki
Abuja, Nigeria
Tel: +234 803 312 42 56
E-mail: mrapanisile@yahoo.com

Ms Preye Olive EDOTIMI
National Agency for Food and Drug Administration and Control
Plot 2032 Olusegun Obasanjo Way
Wuse 7
Abuja, Nigeria
Tel: +234 803 302 48 23
E-mail: edotimi.p@nafdac.gov.ng

Mr Godwin Oyedele OYEDIJI
Nigerian Institute of Animal Science
Federal Ministry of Agriculture and Rural Development FMARD
Area 11, Garki
Abuja, Nigeria
Tel: +234 803 320 12 72
E-mail: oyedeleoyediji@yahoo.com

Mr Mshelbwala Gideon MBURSA
Federal Ministry of Agriculture and Rural Development
FMARD Area 11
Garki
Abuja, Nigeria
Tel: +234 803 786 38 43
E-mail: gidmm@yahoo.com

Mr Sikiru Ishola OLOWO
National Agency for Food and Drug Administrative & Control
Plot 2032, Olusegun Obasanjo Way
Wuse 7
Abuja, Nigeria
Tel: +234 807 367 70 43
E-mail: solowo_2000@yahoo.com

Mr John Toyin TAIWO
Federal Ministry of Agriculture and Rural Development (FMARD)
Departement of Livestock & Pest Control Services
FMARD AREA 11, Garki
Abuja, Nigeria
Tel: +234 803 323 53 75
E-mail: jonsolt@yahoo.ca

NORWAY – NORVÈGE – NORUEGA

Ms Jorunn MADSEN
Norwegian Food Safety Authority
Head Office
P.O.B. 383
N.2381 Brumunddal, Norway
Tel: +47 232 165 69
E-mail: jorunn.madsen@mattilsynet.no

Mr Karl-Erik SLINNING
Norwegian Food Safety Authority
Head Office
P.O.B. 383
N.2381 Brumunddal, Norway
Tel: +47 232 167 02
E-mail: karl-erik.slinning@mattilsynet.no

PHILIPPINES – FILIPINAS

Ms Estherlina D. ARIFALO
Philippines / National Codex Organization
Department of Agriculture
Visayas Avenue, Diliman
Quezon City, Philippines
Tel: +632 924 79 54
E-mail: esther_arifalo@yahoo.com

POLAND – POLOGNE POLONIA

Mr Krzysztof KWIATEK
Chair of the Coordinating Committee for Europe
National Veterinary Research Institute
Departement of Hygiene of Animal Feedingstuffs
57 Partyzantow Avenue
24-100 Pulawy, Poland
Tel: +48 818 893 082
E-mail: kwiatekk@piwet.pulawy.pl

PORTUGAL

Mr José COSTA
Ministry of Agriculture, Sea, Environment and Spatial Planning
Animal Feeding Unit
Tapada da Ajuda, Edificio 1
1349-018 Lisboa, Portugal
Tel: +351 213 613 200
E-mail: josecosta@dgav.pt

REPUBLIC OF KOREA – RÉPUBLIQUE DE CORÉE – REPÚBLICA DE COREA

Mr Hong Sik MOON
Director of Feed Industry Research Institute
KFA BLDG
1581-13 Seocho-Dong Seocho-Gu
Seoul, Republic of Korea
Tel: +82 258 157 23/4
E-mail: keoul@hanmail.net

Mr Hyung Sik KIM
Korea Livestock Products HACCP Accreditation Service
Gyeonggi Venture Yeonsung University, Anyang & dong,
Manau-gu, Anyang-Si
Gyeonggi-do, Republic of Koreda
Tel: +82 10 5393 9562
E-mail: ommdaeil@gmail.com

Mr Eung-Gu LEE
Experiment & Research Institute, NAQS
Republic of Korea
Tel: +82 221 656 131
E-mail: 2eung9@korea.kr

Mr Juhyung SEO
Formulator
NH Feed
451, Sungnae-Dong
Gangdong-Gu
Seoul, Republic of Korea
Tel: +82 10 6334 7941
E-mail: joo.hyung.seo@hotmail.com

Mr Kyoungmin SO
Rural Development Administration
Republic of Korea
Tel: +82 31 290 1676
E-mail: ls2273@korea.kr

Mr Young-Bae SON
Experiment & Research Institute, NAQS
Republic of Korea
Tel: +82 221 656 131
E-mail: 2788@korea.kr

SAUDI ARABIA – ARABIE SAOUDITE – ARABIA SAUDITA

Dr Zohair MULLA
Saudi Food and Drug Authority
Food Sector
SFDA 3292 North Ring Road
13312-6288 Riyadh, Saudi Arabia
Tel: +966 120 38 222
E-mail: zsmulla.c@sfda.gov.sa

SPAIN – ESPAGNE - ESPAÑA

Ms Patricia PERTEJO ALONSO
Técnico Veterinario de Red de Alerta Sanitaria
D.G. de Producciones y Mercados Agrarios
Ministry of Agriculture, Food and Environment
C/Almagro, 33 – 4ª Planta
28010 Madrid, Spain
Tel: +34 913 471 799-66 12
E-mail: ppertejo@magrama.es

SWEDEN – SUÈDE – SUECIA

Dr Kjell WEJDEMAR
Swedish Board of Agriculture
Dragarbrunnsgatan 35
75320 Uppsala, Sweden
Tel: +46 70 342 47 61
E-mail: kjell.wejdemar@jordbruksverket.se

SWITZERLAND – SUISSE – SUIZA

Mr François PYTHOUD
Head of International Sustainable Agriculture Unit
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 323 44 45
Fax: +41 31 322 26 34
E-mail: francois.pythoud@blw.admin.ch

Ms Awilo OCHIENG PERNET
Codex Vice-Chairperson
Division of International Affairs
Swiss Federal Department of Home Affairs
Swiss Federal Office of Public Health
CH-3003 Bern, Switzerland
Tel: +41 31 322 00 41
Fax: +41 31 322 11 31
E-Mail: awilo.ochieng@bag.admin.ch

Mr. Jacques CHAVAZ
Deputy Director General
Head of Markets and International Affairs Directorate
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 322 25 02
Fax: +41 31 322 26 34
E-Mail: jacques.chavaz@blw.admin.ch

Mr Elkin AMAYA
Global Regulatory Affairs Manager
DSM Nutritional Products / Nutrition Innovation Center
Wurmisweg 576
4303 Kaiseraugst, Switzerland
Tel: +41 79 264 38 22
Fax: +41 61 815 87 70
E-mail: elkin.amaya@dsm.com

Dr Rex FITZGERALD
Regulatory Toxicology Expert
Swiss Centre for Applied Human Toxicology
University of Basel
Klingelbergstrasse 61
4056 Basel, Switzerland
Tel: +41 61 267 19 58
E-mail: rex.fitzgerald@unibas.ch

Mr Michel GEINOZ
Responsable contrôle officiel des aliments pour animaux
Agroscope Liebefeld-Posieux Research Station ALP
P.O. Box 64
1725 Posieux, Switzerland
Tel: +41 26 407 73 92
Fax: + 41 26 407 73 00
E-mail: michel.geinoz@alp.admin.ch

Mr Thomas JÄGGI
Swiss Farmer's Union
Laurstrasse 10
5201 Brugg, Switzerland
Tel: +41 56 462 51 11
E-mail: Thomas.jaeggi@sbv-usp.ch

Mr Martin MÜLLER
Swiss Codex Contact Point, Scientific Adivsor
Division of International Affairs
Swiss Federal Office of Public Health
Seilerstrasse 8
3003 Bern, Switzerland
Tel: +41 31 324 93 16
Fax: +41 31 322 11 31
E-mail: martin.mueller@bag.admin.ch

Ms Ursula TRÜEB
Representative of the Swiss Consumer Organizations
Bölzli 1
4312 Magden, Switzerland
Tel: + 41 61 841 12 56
E-mail: ursula.trueb@vtxmail.ch

Dr Ludovica VERZEGNASSI
CT-Regulatory and Scientific Affairs
Nestec S.A.
55, Av. Nestlé
1800 Vevey, Switzerland
Tel: +41 21 924 25 36
E-mail: ludovica.verzegnassi@nestle.com

Mr Jean VIGNAL
Regulatory Affairs
Nestec Ltd
55, Avenue Nestlé
1800 Vevey, Switzerland
Tel: +41 21 924 35 01
E-mail: jean.vignal@nestle.com

Mr Pascal ZAFFARANO
Means of Agriculture Production Directorate
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 322 26 10
Fax: +41 31 323 26 34
E-mail: pascal.zaffarano@blw.admin.ch

Mr Paul ZWIKER
Representative of the Swiss Consumer Organizations
Westliche Lettenstrasse 4
9220 Bischofszell, Switzerland
Tel: +41 71 420 06 44
Fax: +41 71 420 06 43
E-mail: zwiker@bluewin.ch

THAILAND – THAÏLANDE – TAILANDIA

Ms Wimolporn THITISAK
Deputy Director General
Department of Livestock Development
69/1 Phayathai Rd., Rajthevi
Bangkok 10400, Thailand
Tel: +66 2653 4403
Fax: +66 2953 4900
E-mail: wimolporn2000@yahoo.com

Mr Krit BOONYAWATTANA
Ministry of Agriculture and Cooperatives
National Bureau of Agricultural Commodity and Food Standards (ACFS)
50 Phaholyotin Rd, Ladyao Chatuchak
10900 Bangkok, Thailand
Tel: +66 2561 2277 Ext. 1410
E-mail: kritku@yahoo.com

Ms Yupa LAOJINDAPUN
Ministry of Agriculture and Cooperatives
National Bureau of Agricultural Commodity and Food Standards (ACFS)
50 Phaholyotin Rd. Ladyao Chatuchak
10900 Bangkok, Thailand
Tel: +66 256 122 77 Ext. 1458
E-mail: yupa@acfs.go.th

Mr Anurojana PUNYAWAN
Thai Feed Mill Association
CP Tower 313 Silom Road
10900 Bangkok, Thailand
Tel: +66 891 191 229
E-mail: dr.max@cpf.co.th

Mr Thanabadee RODSOM
Bureau of Livestock Standard and Certification
Department of Livestock Development
69/1 Phayathai Rd. Ratchathevi
10900 Bangkok, Thailand
Tel: +66 265 344 44 Ext. 3156
E-mail: nuifgc9@hotmail.com

TURKEY – TURQUIE – TURQUIA

Ms Gonca OZTAP
Ministry of Food, Agriculture and Livestock
Department of Feed
Eskisehir Yolu 9, km Lodumlu
06060 Ankara, Turkey
Tel: +9031 2258 76 50
E-mail: gonca.oztap@tarim.gov.tr

UNITED KINGDOM – ROYAUME-UNI – REINO UNIDO

Mr Keith MILLAR
Hygiene & Microbiology Division
Food Standards Agency
Room 3C, Aviation House
125 Kingsway
London WC2B 6NH, United Kingdom
Tel: +44 207 276 8472
Fax: +44 207 276 8910
E-mail: keith.millar@foodstandards.gsi.gov.uk

Ms Mandy JUMNOODOO
Hygiene & Microbiology Division
Food Standards Agency
Room 3C, Aviation House
125 Kingsway
London, WC2B, 6NH, United Kingdom
Tel: +44 207 276 84 68
E-mail: mandy.jumnoodoo@foodstandards.gsi.gov.uk

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

Dr Daniel McCHESNEY
Office of Surveillance and Compliance
FDA/Center for Veterinary Medicine
7529 Standish Place
Rockville, MD
US 20853
Tel: +1 240 453 68 30
E-mail: daniel.mcchesney@fda.hhs.gov

Mr Kyd D. BRENNER
DTB Associates, LLP
1700 Pennsylvania Ave NW
Suite 200
Washington, DC 20006, USA
Tel: +1 202 684 25 08
E-mail: kbrenner@dtbassociates.com

Ms Doreen CHEN-MOULEC
US Department of Agriculture, U.S. Codex Office
1400 Independence Ave SW
20250-3700 Washington DC, USA
Tel: +1 202 205 77 60
E-mail: doreen.chen-moulec@fsis.usda.gov

Mr Randall GORDON
National Grain and Feed Association
1250 I St.
N.W. Suite 1003
Washington, DC 20005, USA
Tel: +1 202 289 08 73
E-mail: rgordon@ngfa.org

Dr Jennifer KOEMAN
National Pork Board
Science & Technology
1776 NW 114th
50325 Clive, USA
Tel: +515 223 2633
E-mail: jkoeman@pork.org

Dr Christine NAVARRE
Louisiana State University Agricultural Center
131 Dalrymple Building, LSU
70803 Baton Rouge, USA
E-mail: cnavarre@agcenter.lsu.edu

Mr Joel NEWMAN
American Feed Industry Association (AFIA)
2101 Wilson Blvd., Suite 916
22201 Arlington, USA
Tel: +1 703 558 35 62
E-mail: jnewman@afia.org

Dr Elizabeth WAGSTROM
National Pork Producers Council
122 C St. NW Suite 875
Washington, DC 20001, USA
Tel: +1 202 347 36 00
E-mail: wagstroml@nppc.org

INTERNATIONAL NON GOVERNMENTAL ORGANIZATIONS – ORGANISATIONS NON-GOUVERNEMENTALES INTERNATIONALES – ORGANIZACIONES NO GUBERNAMENTALES INTERNACIONALES

ASSOCIATION OF AMERICAN FEED CONTROL OFFICIALS (AAFCO)

Mr Tim HERRMAN
AAFCO
445 Agronomy Rd
College Station TX USA 77845
Tel: +1 979 845 11 21
E-mail: tjh@otsc.tamu.edu

EUROPEAN FEED MANUFACTURERS' FEDERATION (FEFAC)

Mr Alexander DÖRING
FEFAC
Rue de la Loi 223
1040 Brussels, Belgium
Tel: +32 228 00 50
E-mail: fefac@fefac.eu

INTERNATIONAL FEDERATION FOR ANIMAL HEALTH (IFAH)

Ms Barbara FREISCHEM
Executive Director
IFAH
rue Defacqz, 1
1000 Brussels, Belgium
Tel: +32 2 541 0112
Fax +32 2 541 0119
E-mail: b.freischem@ifahsec.org

Dr Olivier ESPEISSE
Vetérinaire Responsable
IFAH
Elanco
24, Boulevard Vital Boubot
92200 Neuilly/ Seine, France
Tel: +33 155 493 535
E-mail: espeisse_olivier@lilly.com

INTERNATIONAL FEED INDUSTRY FEDERATION (IFIF)

Ms Alexandra DE ATHAYDE
Executive Director
IFIF
Freier Weg 6
53177 Bonn, Germany
Tel: +49 228 2861 7802
E-mail: alexandra.athayde@ifif.org

Mr Philippe BECQUET
Head of Regulatory Affairs Europe
DSM Nutritional Products / Animal Nutrition and Health
Wurmisweg 576
4303 Kaiseraugst, Switzerland
Tel: +41 61 815 77 92
E-mail: philippe.becquet@dsm.com

Ms Monica FANTI
IFIF
Alltech Inc.
3031 Catnip Hill Pike
Nicholasville, KY, USA
Tel: +1 (210) 861-4170
E-mail: mfanti@alltech.com

Mr Didier JANS
FEFANA
Secretary General
Avenue Louise, 130A-Box 1
1050 Brussels, Belgium
Tel: +32 363 966 60
E-Mail: dja@fefana.org

Mr Colm MORAN
IFIF
14 Place Marie-Jeanne Bassot
92300 Levallois-Perret, France
Tel: +33 141 340 170
E-mail: cmoran@alltech.com

INTERNATIONAL DAIRY FEDERATION (IDF)

Mr Koenraad DUHEM
Scientific Director
Institut de l'élevage
149, rue de Bercy
75595 Paris Cedex 12, France
Tel: +33 (0)1 40 04 53 37
Fax: +33 (0)1 40 04 52 75
E-mail: koenraad.duhem@idele.fr

Dr Maxim BOBKOV
Nestec S.A.
Avenue Nestlé 55
1800 Vevey, Switzerland
Tel: +41 21 924 36 95
E-mail: maxim.bobkov@nestle.com

Dr Jamie JONKER
National Milk Producers Federation
2101 Wilson Blvd
Suite 400, Arlington
Virginia USA 22201
Tel: +1 703 243 61 11
E-mail: jjonker@nmpf.org

Mr Jörg SEIFERT
Technical Director
International Dairy Federation
70, Boulevard Auguste Reyers
1030 Brussels, Belgium
Tel: +32 272 567 43
E-mail: jseifert@fil.idf.org

FOOD AND AGRICULTURAL ORGANIZATION – ORGANISATION DES NATIONS UNIES POUR L'ALIMENTATION ET L'AGRICULTURE – ORGANIZACIÓN DE LAS NACIONES UNIDAS PARA LA AGRICULTURA Y LA ALIMENTACIÓN (FAO)

Daniela A. BATTAGLIA
Livestock Production Officer
Animal Production and Health Division, FAO
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: +39 065 705 67 73
Fax: +39 065 705 57 49
E-mail: daniela.battaglia@fao.org

Sarah CAHILL
Food Safety Officer
FAO/JEMRA Secretariat
Food Safety and Codex Unit
Agriculture and Consumer Protection
Department, FAO
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: +39 065 705 36 14
Fax: +39 065 705 45 93
E-mail: sarah.cahill@fao.org

WORLD HEALTH ORGANIZATION (WHO) – ORGANISATION MONDIALE DE LA SANTÉ (OMS) – ORGANIZACIÓN MUNDIAL DE LA SALUD (OMS)

Ms Mina KOJIMA
Technical Officer
World Health Organization
Department of Food Safety and Zoonoses
20, Avenue Appia
1211 Genève 27, Switzerland
Tel: +41 22 791 29 20
Fax: +41 22 791 48 07
E-mail: kojimam@who.int

CODEX SECRETARIAT – CODEX SECRÉTARIAT – SECRETARÍA CODEX

Annamaria BRUNO
Senior Food Standards Officer
Joint FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: +39 06 570 56254
Fax: +39 06 570 54593
E-mail: annamaria.bruno@fao.org

Verna CAROLISSEN-MACKAY
Food Standards Officer
FAO/WHO Food Standards Programme
Viale delle Terme di Caracalla
00153 Rome, Italy
Tel: +39 06 570 55629
Fax: +39 06 570 54593
E-mail: verna.carolissen@fao.org

SWISS SECRETARIAT – SECRÉTARIAT SUISSE – SECRETARÍA SUIZA

Ms Miriam ANDONIE
International Sustainable Agriculture Unit
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 322 19 51
Fax: +41 31 322 26 34
E-mail: miriam.andonie@blw.admin.ch

Mr Michael HARTMANN
International Sustainable Agriculture Unit
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 322 25 95
Fax: +41 31 322 26 34
E-mail: michael.hartmann@blw.admin.ch

Ms Lucie Künzle
Legal Affairs Unit
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 322 50 69
Fax: +41 31 322 26 34
E-mail: lucie.kuenzle@blw.admin.ch

Ms Veronika LINSMAYER
Rural Construction and Business
Assistance Unit
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 324 84 22
Fax: +41 31 322 26 34
E-mail: veronika.linsmayer@blw.admin.ch

Ms Isabella NEUHAUS
International Sustainable Agriculture Unit
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 322 25 69
Fax: +41 31 322 26 34
E-mail: isabella.neuhaus@blw.admin.ch

Mr Armand STUMP
Communication Unit
Swiss Federal Office for Agriculture
Mattenhofstrasse 5
3003 Bern, Switzerland
Tel: +41 31 323 08 87
Fax: +41 31 322 26 34
E-mail: armand.stump@blw.admin.ch

Appendix II

DRAFT GUIDELINES ON THE APPLICATION OF RISK ASSESSMENT FOR FEED

(at Step 8 of the Procedure)

INTRODUCTION

1. These guidelines provide guidance for feed and feed ingredients risk assessment by governments in accordance with Codex principles for risk analysis.[1] They address the potential risks to human health associated with the presence of hazards in the feed of food-producing animals and the subsequent transfer of hazards to edible products.

2. These guidelines should enable risk assessment of hazards in feed based upon local conditions considering the impact on food safety and human health. The application of these guidelines should also enable international comparability of feed risk assessments and thereby promote fair practices in food and feed trade.

3. Implementation of these guidelines requires specialised support and training of experts on animal feeding and risk analysis.

4. These guidelines should be read in conjunction with the *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004).

5. Codex guidance on risk assessment of food additives, food contaminants, natural toxicants, residues of pesticides and veterinary drugs, and microbiological hazards is also provided in:

- Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[2];
- Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods[2];
- Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues[2];
- Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods[2];
- *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007);
- *Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007);
- *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (CAC/GL 77-2011);
- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30- 1999).

6. Further information is provided in the WHO Principles and Methods for the Risk Assessment of Chemicals in Food[3] and the FAO/WHO Microbiological Risk Assessment Series (MRA)[4].

7. Annex 1 lists other references that have been used when developing this document.

SCOPE

8. These guidelines are applicable to all hazards in the feed of food-producing animals, which may adversely affect human health. Agents which may adversely affect animal health but which have no impact on food safety are not considered in these guidelines, as they are not within the scope of the Codex Alimentarius.

9. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered as it is not within the scope of the Codex Alimentarius.

DEFINITIONS

10. The following definitions are included to establish a common understanding of the terms used in these guidelines.

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[1] Throughout the text the term “feed” refers to both feed and feed ingredients, unless otherwise stated
[2] Codex Alimentarius Commission: Procedural Manual
[3] http://www.who.int/foodsafety/chem/principles/en/index1.html
[4] http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/

Biotransformation product: Product resulting from the transformation of a chemical or biological agent in the body of the food-producing animal (e.g. via metabolic processes).

Contaminant: Any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.[2]

Edible product: Any tissue or product from a food-producing animal which is intended for human consumption, including for example meat, fish, eggs and milk.

Exposure assessment: The qualitative and/or quantitative evaluation of the likely human intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant.[2] In these guidelines, it may also refer to the consideration of the exposure of a food-producing animal to a hazard and to an evaluation of the likely amount of a hazard in feed that can transfer to an edible product.

Feed (Feedingstuff): Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food-producing animals.[5]

Feed additive: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, that affects the characteristics of feed or animal products (micro- organisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration).[5]

Feed ingredient: A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances.[6]

Food: Any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.[2]

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.[2] In these guidelines, it refers to an agent in feed, which has the potential to cause an adverse human health effect after transfer into an edible product.

Hazard characterization: The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.[2]

Hazard identification: The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.[2]

Qualitative risk assessment: A risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk.[6]

Quantitative risk assessment: A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties.[6]

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.[2] In these guidelines, it may also refer to the probability that a hazard in feed eaten by a food-producing animal will transfer to an edible product at a level which may cause an adverse health effect in humans.

Risk analysis: A process consisting of three components: risk assessment, risk management and risk communication.[2]

Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.[2]

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[5] *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004)
[6] *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CAC/GL 30-1999)

Risk characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.[2]

Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.[2]

Risk estimate: The quantitative estimation of risk resulting from risk characterization.[2]

Risk management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.[2]

Risk profile: The description of the food safety problem and its context.[2]

Transfer: Passing of a chemical or biological hazard (including hazardous biotransformation products) from feed of a food-producing animal to an edible product of the animal.

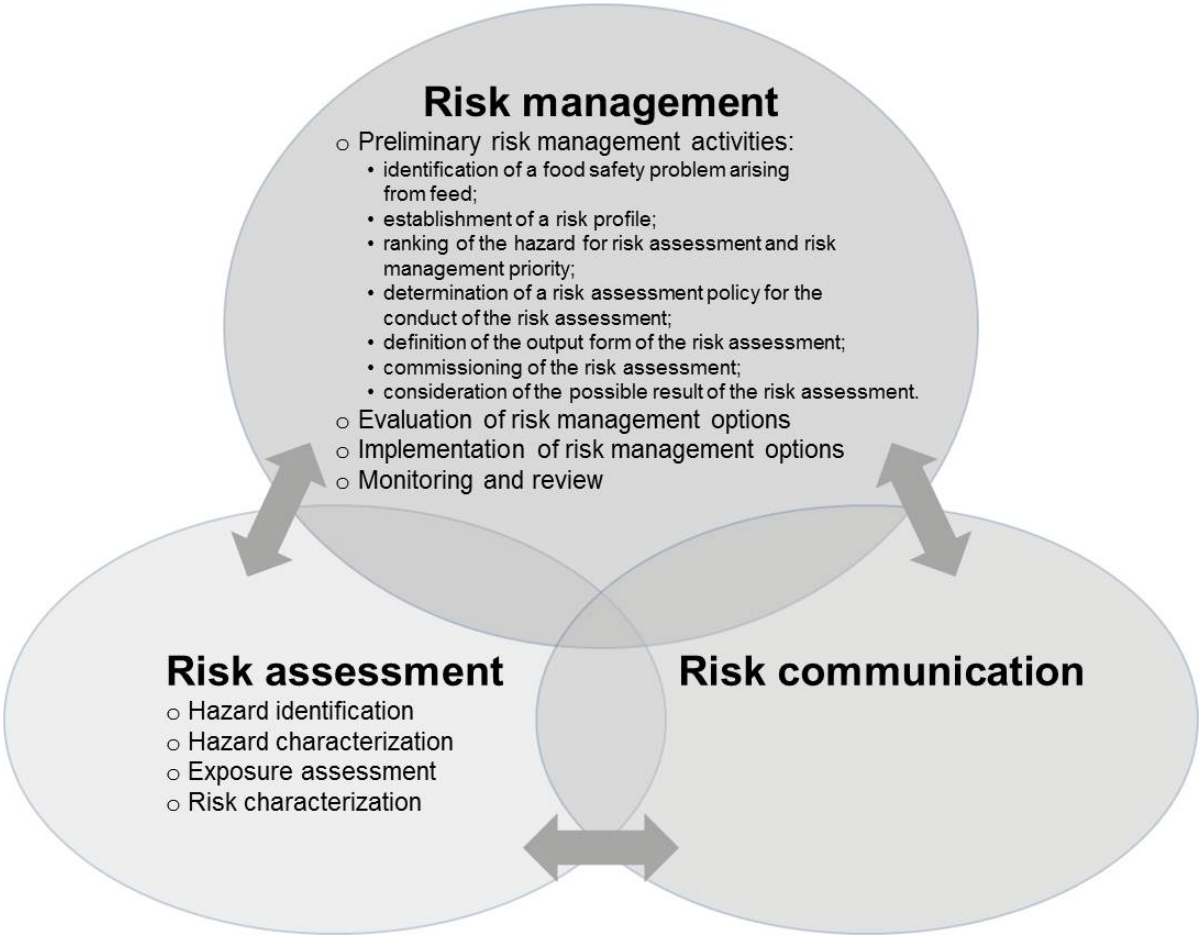
Transparent: Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review.[6]

Undesirable substances: Contaminants and other substances, which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues.[5]

RISK ASSESSMENT IN THE CODEX RISK ANALYSIS FRAMEWORK

11. Risk assessment is one of the three components of the risk analysis framework together with risk management and risk communication. This is illustrated in Figure 1.

Figure 1. Risk analysis framework



12. A risk assessment is commissioned by the risk manager. Preliminary risk management activities include in particular: identification of a food safety problem arising from feed; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority (for further details see Guidance for Government on Prioritizing Hazards in Feed); determination of a risk assessment policy for the conduct of the risk assessment; definition of the output form of the risk assessment; commissioning of the risk assessment; and consideration of the possible results of the risk assessment.

13. The risk assessment policy should be established by the risk manager 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, documented, unbiased and transparent. The mandate given by the risk manager to the risk assessor should be as clear as possible.

RISK ASSESSMENT PROCEDURE

14. 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.

15. Experts involved in risk assessment should be objective in their scientific work and selected in a transparent manner on the basis of their expertise.

16. Risk assessment is a science based process and should follow a structured approach incorporating the following four steps: hazard identification, hazard characterization, exposure assessment and risk characterization.

17. 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.

18. 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.

Hazard identification

19. Hazards in feed can include biological and chemical agents (such as "heavy metals", dioxins, excessive levels of pesticides, veterinary drugs and additives), radionuclides and other undesirable substances. Biotransformation products present in edible products also need to be considered.

20. Feed additives, veterinary drugs and pesticides used in feed, which have been assessed for safety and which have been used under stated conditions of use as pre- approved by the competent authorities, should not be *prima facie* considered as hazards.

21. Physical agents in feed are not known to be hazards reasonably likely to cause food safety risks, but rather may cause a risk to animal health, which is outside the scope of these guidelines.

22. Factors to be considered include those which can markedly influence the occurrence of a given hazard in feed and which may be specific to a locale, country, or region, include environmental conditions and interactions with other materials during growth, harvesting, drying, processing, storage, handling and transport.

23. Useful information on the presence of the hazard in feed may be obtained from regulatory surveillance samples and investigative work, published data from government agencies and scientific peer-reviewed publications, and from international programs such as the WHO Global Environment Monitoring System (GEMS/Food), the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN), and other reliable rapid alert systems, and industry self-monitoring programmes.

24. In order to evaluate which feed ingredients may contain a given hazard, consideration should be given to the source of feed ingredients and environmental conditions and interactions, and the potential for introduction of hazards during their manufacture, preparation, transportation, handling, storage and use. Many feed ingredients are produced as co-products or by-products from other production processes, including industrial processes, and an evaluation may need to be made of these processes and their potential for introducing hazards in feed.

Hazard characterization

25. Hazard characterization refers to the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with hazards in feed, which may be present in edible products as a result of transfer. For any hazard identified, including biotransformation products, a hazard characterization should be conducted.

26. Information on characterization of specific hazards may be obtained in international reports and monographs from risk assessment bodies and/or in peer-reviewed scientific literature. Sources of information should be documented.

27. For the hazard characterization of chemicals the relevant reference value especially for an oral route of exposure is identified, e.g. Acceptable Daily Intake (ADI), Tolerable Daily Intake (TDI), Acute Reference Dose (ARfD). For biological hazards, a dose-response relationship is established if possible.

28. If available scientific data are inadequate to characterize a hazard, it may be necessary to consider generating such data. The risk manager may request action to resolve the data gaps. Any generation of new data should be based on relevant scientific principles and procedures.

Exposure assessment

29. Human exposure assessment is the qualitative and/or quantitative evaluation of the likely intake of the hazard(s) via food. The aim of the exposure assessment in feed risk assessment is to estimate the level or prevalence of hazard(s) in edible product(s) after transfer from feed. Subsequently, these estimated levels of hazard in edible product arising from feed are used as input for human exposure assessment.

30. The final edible product(s) in the exposure assessment should be defined as precisely as necessary.

31. Exposure assessment should use quantitative data on the level of hazard(s) or prevalence in feed and/or edible product(s). If quantitative data are not available, a semi-quantitative or qualitative risk assessment approach may be useful in assessing the potential food safety risk. If necessary, the assessment should be reconsidered when scientific quantitative data are obtained.

32. Data obtained from sampling and testing of feed and edible product may be useful for quantifying the exposure. Sampling plans for feed and edible products should use scientifically recognized principles and procedures in accordance with the *General Guidelines on Sampling* (CAC/GL 50-2004). The sampling plan should take into consideration possible non-homogeneous distribution of the hazard. Analytical laboratory methods should be validated using scientifically recognized principles and procedures in accordance with the *General Criteria for the Selection of Methods of Analysis Using the Criteria Approach*[1].

33. Exposure assessment for a hazard in feed is a two-step process. The first step concerns the exposure of the food-producing animal to hazard(s) through feed. If such exposure is present, the second step is to evaluate the transfer of hazard(s) to edible product(s) of the food-producing animal.

First Step: *Animal exposure assessment*

34. The first step involves:

(a) Identification of feeds which may contribute to intake of a given hazard;

(b) Determination of the concentration of the hazard in feed;

(c) Calculation of hazard intake by the food-producing animal from relevant feed sources, based on information on feeding practices (quantity, frequency and duration of feed intake) as appropriate.

(d) Identification, and if possible quantification, of other sources of the hazard which may contribute to exposure to the hazard in the food-producing animal (e.g. bedding materials, soil, water, air or others).

35. Animal exposure will differ as a result of the formulation of the feed, the use patterns for the animal, and the exposure scenarios.

Second Step: *Transfer*

36. Modelling and measurements are used to calculate transfer through the food-producing animal and the resulting hazard level and/or prevalence in edible product.

37. Transfer of a hazard from feed to edible product depends on its kinetics in the food-producing animal, including absorption, biotransformation, distribution, excretion, and the potential for accumulation or proliferation in tissues.

38. The kinetics may be influenced, in particular, by:

- Biological or chemical properties of the hazard;

- Species, breed, gender, life stage**,** and health status of the food-producing animal;
- Frequency and duration of feed intake;
- Formulation of the feed and potential interaction between the hazard and feed components.

39. Published, peer-reviewed, toxicokinetic or other models that can predict the transfer of hazard from feed to edible products, may be used or adapted for a given exposure assessment. Sources of information should be documented.

40. The feed exposure assessment should result in the determination of the predicted level or prevalence of a hazard in edible product. This result is then incorporated as a starting point in the human exposure assessment for food. The evaluation of the human exposure to the hazard should be done using relevant foods and food groups and/or specific human populations to account for feed as a source of exposure, (e.g. by modelling).

Risk characterization

41. Risk characterization, in a feed risk assessment, considers the outcomes from the hazard characterization and the exposure assessment to derive a risk estimate for food safety.

42. A first risk estimate may be performed by a comparison of the predicted levels of the hazard in edible product with existing national or international maximum levels for food commodities.

43. If a more extensive risk assessment is required, a risk estimate could be, for example: (a) an estimate of the probability that a given concentration of hazard in feed may result in a concentration in edible product, the human consumption of which may lead to exceeding a national or international health based guidance value (e.g. ADI, TDI); or (b) an estimate of the probability that an infectious agent in feed could lead to an infection in an animal, which may result in an unacceptable contamination of edible product.

44. When the hazard is also present in environmental sources such as water and air, or in foods of non-animal origin, other exposure assessments on these sources should be taken into consideration for the risk characterization and subsequent risk management options.

45. Additional outputs of a risk assessment, which would have been defined in the initiation of the risk assessment, can include evaluation of the effect of different risk management options on the estimated health risk.

REPORTING

46. The risk assessment should be fully and systematically documented and communicated to the risk manager.

47. 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 assessor.

48. The conclusions of the risk assessment should be presented in a readily understandable and useful form to the risk manager and made available to other risk assessors and interested parties so that they can review the assessment.

ANNEX I

WHO Human Health Risk Assessment Toolkit: Chemical Hazards. IPCS Harmonization Project Document No. 8. WHO, Geneva, 2010. ISBN 978 92 4 154807 6. (http://www.who.int/entity/ipcs/publications/methods/harmonization/toolkit.pdf)

FAO/WHO Expert Meeting report on Animal Feed Impact on Food Safety. FAO/WHO, Rome, 2008. ISBN 978-92-5-105902-9. (ftp://ftp.fao.org/docrep/fao/010/a1507e/a1507e00.pdf)

FAO/WHO Microbiological risk assessment publications (http://www.who.int/foodsafety/publications/micro/en/) including Hazard Characterization for Pathogens in Food and Water (MRA Series 3); Exposure Assessment of Microbiological Hazards in Food (MRA Series 7); Risk Characterization of Microbiological Hazards in Food (MRA Series 17).

Relevant sections of: OIE Terrestrial Animal Health Code (http://www.oie.int/en/international-standard-setting/terrestrial-code/)
OIE Aquatic Animal Health Code (http://www.oie.int/en/international-standard-setting/aquatic-code/)

FAO Good Practices for the Feed Industry. FAO Animal Production and Health Manual No. 9. FAO/IFIF, Rome, 2010. ISBN 978-92-5-106487-0. (http://www.fao.org/docrep/012/i1379e/i1379e00.htm)

Joint FAO/WHO Expert Committee on Food Additives (JECFA) (http://www.who.int/foodsafety/chem/jecfa/publications/en/ and http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/en/

Joint FAO/WHO Meeting on Pesticide Residues (JMPR) (http://www.who.int/foodsafety/chem/jmpr/en/ and http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/)

Joint FAO/WHO expert meetings on microbiological risk assessment (JEMRA) (http://www.who.int/foodsafety/micro/jemra/en/ and http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/en/

WHO International Programme on Chemical Safety (IPCS) (http://www.inchem.org/)

WHO Concise International Chemical Assessment Documents (CICAD) (http://www.who.int/ipcs/publications/cicad/)

The Gateway to Animal Feeding provides additional references and documents relevant to risk assessment of animal feed (http://www.fao.org/animalfeeding).

Appendix III

PROPOSED DRAFT GUIDANCE FOR GOVERNMENTS ON PRIORITIZING HAZARDS IN FEED

(at Step 5/8 of the Procedure)

INTRODUCTION

1. Hazard prioritization is part of the risk management process within the risk analysis framework.

2. The purpose of prioritizing hazards in feed as described in this document is to contribute to the safety of edible products by optimizing allocation of the resources required for risk assessment and risk management.

SCOPE

3. This document provides guidance to governments on prioritizing hazards in feed and feed ingredients[1] using the multi-criteria analysis approach. However, it is recognized that other approaches to prioritize hazards might be used.

4. This guidance is applicable to all hazards in the feed of food-producing animals which may adversely affect human health. Agents which may adversely affect animal health but which have no impact on food safety are not considered in this guidance, as they are not within the scope of the Codex Alimentarius.

5. Direct human exposure to hazards in feed, for example occupational exposure during feed production and processing, is not considered, as it is not within the scope of the Codex Alimentarius.

DEFINITIONS

6. The following definitions are included to establish a common understanding of the terms used in this guidance.

Biotransformation product: Product resulting from the transformation of a chemical or biological agent in the body of the food-producing animal (e.g. via metabolic processes).

Contaminant: Any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.[2]

Cross-contamination: Contamination of a material or product with another material or product, including contamination originating from the previous use of equipment.

Edible product: Any tissue or product from a food-producing animal which is intended for human consumption, including for example meat, fish, eggs and milk.

Feed (Feedingstuff): Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food-producing animals.[3]

Feed additive: Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, that affects the characteristics of feed or animal products. Micro- organisms, enzymes, acidity regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration.[2]

Feed ingredient: A component part or constituent of any combination or mixture making up a feed, whether or not it has a nutritional value in the animal's diet, including feed additives. Ingredients are of plant, animal or aquatic origin, or other organic or inorganic substances.[2]

Food: means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which have been used in the manufacture, preparation or treatment of "food" but does not include cosmetics or tobacco or substances used only as drugs.[2]

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[1] Throughout this document the term "feed" refers to both feed and feed ingredients, unless otherwise stated
[2] Codex Alimentarius Commission: Procedural Manual
[3] *Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004)

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.[2] In this guidance, it refers to an agent in feed which has the potential to cause an adverse human health effect after transfer into an edible product.

Medicated feed: Any feed which contains veterinary drugs as defined in the Codex Alimentarius Commission Procedural Manual.[3]

Processing Aid: Any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, food or food ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.[2] (In this guidance this definition applies to feed and feed ingredients).

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.[2] In this guidance, it may also refer to the probability that a hazard in feed eaten by a food-producing animal will transfer to an edible product at a level which may cause an adverse health effect in humans.

Risk analysis: A process consisting of three components: risk assessment, risk management and risk communication.[2]

Risk assessment: A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.[2]

Risk characterization: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.[3]

Risk communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.[2]

Risk management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.[2]

Transfer: Passing of a chemical or biological hazard (including hazardous biotransformation products) from feed of a food-producing animal to an edible product of the animal.

Undesirable substances: Contaminants and other substances, which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including food safety related animal health issues.[3]

PRIORITIZATION OF HAZARDS IN THE FRAMEWORK OF CODEX RISK ANALYSIS

7. Risk analysis comprises three distinct but closely linked components: risk assessment, risk management, and risk communication.[2]

8. Risk management comprises preliminary risk management activities (including: identification of a food safety problem arising from feed; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; determination of a risk assessment policy for the conduct of the risk assessment; definition of the output form of the risk assessment; commissioning of the risk assessment; and consideration of the possible results of the risk assessment), evaluation of risk management options, implementation of risk management options, monitoring and review[4]. Prioritization of hazards in feed is part of preliminary risk management activities but can also be undertaken at any point of the risk analysis process.

9. Annex 3 lists references that have been used when developing this document.

[4] *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007)

10. Details of the steps are described below. An example of the prioritization process based on these steps is given in Annex 1 for illustrative purposes only.

PRIORITIZATION PROCESS

11. The prioritization process provides ranking for different combinations of hazard, feed and edible product in a risk analysis framework. A defined prioritization process ensures transparency and repeatability, and facilitates re-evaluation when new data are available without repeating all steps.

12. The prioritization process in this guidance comprises the following steps:

Step 1. Identification of the hazard, the feed and the edible product potentially associated with food safety problems.

Step 2. Identification and definition of the criteria by which each selected hazard/feed/edible product combination will be quantified.

Step 3. Assignment of criterion-based values to the hazard/feed/edible product combinations.

Step 4. Normalization of these values to make them comparable between criteria.

Step 5. Weighting of the criteria to reflect their relative importance.

Step 6. Combining the weighted normalized values for each hazard/feed/edible product combination to produce a score, and ranking of the scores to obtain the order of priority.

Step 7. Reporting of the process, methods and results.

Step 1. Identification of the hazard, the feed and the edible product potentially associated with food safety problems

13. In this initial screening step, the risk manager identifies hazard/feed/edible product combinations which are potentially associated with food safety problems, and which may need to be prioritized for risk assessment and risk management. Further guidance on risk assessment of feed is provided in the Guidelines on Application of Risk Assessment for Feed.

14. Useful information on the presence of the hazard in feed and/or edible product may be obtained from existing risk profiles and risk assessments, and from regulatory surveillance programs/data, published data from government agencies and scientific peer-reviewed publications, and from international programs such as the WHO Global Environment Monitoring System (GEMS/Food); the Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) (references in Annex 3); and other reliable rapid alert systems, and industry self-monitoring programs.

15. Information which may be useful includes:

- Descriptions of the hazard, the feed and edible product;
- Description of the food safety problem potentially associated with the hazard/feed/edible product combination;
- Chemical or biological characteristics and toxicology profile of the hazard;
- Levels of hazard in feed and edible products;
- Possible sources of hazard during production, processing, packing, packaging, transport, storage and use;
- Relevant legislation;
- Information on economic impact;
- Information on knowledge gaps.

16. If the data obtained in this step indicate that the association of a specific hazard/feed/edible product combination with a food safety problem is negligible, it may be decided to exclude that combination from further steps. Such screening should use defined exclusion/inclusion decision rules (for example, no occurrence in the area under consideration during a given time-frame).

17. Examples of hazards with potential relevance for human health are given in Annex 2.

Step 2. Identification and definition of the criteria by which each selected hazard/feed/edible product combination will be quantified

18. The criteria to be used to prioritize the hazard/feed/edible product combinations should be relevant and reflect the purpose of the prioritization.

19. Criteria which could be considered include those related to the extent of occurrence of a hazard in feed and edible product, effects on human health, and other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.

20. Each criterion should be defined so that there is no ambiguity in interpretation and so that it can be described quantitatively (e.g. number of illnesses, concentration of a hazard). Semi-quantitative descriptions (e.g. low, medium, high) should be clearly explained.

21. Identification and definition of the criteria should be done with the assistance of experts.

Step 3. Assignment of criterion-based values to the hazard/feed/edible product combinations

22. For each of the criteria, a value is assigned by experts to the hazard/feed/edible product combinations. Depending on the hazard/feed/edible product combinations and the criteria, different specialized experts may be needed.

Step 4. Normalization of these values to make them comparable between criteria

23. To permit comparison of values between criteria, they need to be normalized to a common scale with defined levels.

24. The method used for normalizing should be developed by experts and fully documented.

Step 5. Weighting of the criteria to reflect their relative importance

25. Criterion weighting is done independently from the previous steps, typically by risk managers with the support of experts, when required.

26. Each criterion is assigned a weighting which reflects its relative importance. The sum of the weightings is 100%.

Step 6. Combining the weighted normalized values for each hazard/feed/edible product combination to produce a score, and ranking of the scores to obtain the order of priority

27. For each hazard/feed/edible product combination, the weighted normalized values are combined to obtain a score, e.g. (C1*W1)+(C2*W2)+...(Cn*Wn), where C are the normalized criteria values and W are the criteria weights.

28. Ranking of the scores of each of the hazard/feed/edible product combinations yields the prioritized list, which reflects both the normalized criteria values and the weighting of the criteria.

29. It is important to demonstrate the influence of any assumptions used in the ranking process. This could be done for example by using sensitivity analyses (e.g. weighting all criteria equally or weighting which reflects the relative importance of each criterion).

Step 7. Reporting of the process, methods and results

30. The prioritization process, methods and results should be documented and reported fully, systematically and transparently. This should include:

- The rationale for the choice of hazard/feed/edible product combinations;
- The rationale for the criteria;
- The rationale for the normalization method;
- The rationale for the weightings;
- An estimate of the sensitivity of the ranking to the normalization method and the weightings, if conducted;
- Identification of all data gaps, assumptions and uncertainties.

ANNEX 1

EXAMPLE OF THE PRIORITIZATION PROCESS

The following is a fictitious example, which is intended only to illustrate the steps in the prioritization process. This example uses applicable but not exhaustive criteria and the values used are illustrative. In a real-life situation, details of the procedure, particularly the criteria definitions, quantification, normalization of the values and weighting of the criteria, must be developed on a case-by-case basis in consultation with experts.

Step 1. Identification of the hazard, the feed and the edible product potentially associated with food safety problems

For simplicity, this example uses only three hazard/feed/edible product combinations ("combinations 1, 2 and 3") to demonstrate the prioritization procedure. The process is however primarily intended to be used with a larger number of combinations.

Step 2. Identification and definition of the criteria by which each selected hazard/feed/edible product combination will be quantified

This example uses four criteria (C1-C4). The descriptions/definitions of these criteria are briefly summarized in Table 1.

Table 1: Criteria chosen for this example

Criterion	**Description/definition**
C1. Occurrence level in feed	% of feed samples exceeding a defined level for the hazard
C2. Transfer from feed to edible product	%, based on measurement or modeling
C3(a) Toxicity of chemical hazard or C3(b) Health effects of biological hazard	(a) Health-based guidance value (e.g. ADI[5] or TDI[6]) (b) Number of hazard-related illnesses
C4. Impact on feed availability	Replacement feed available (easy, difficult, impossible)

Step 3. Assignment of criterion-based values to the hazard/feed/edible product combinations

For each of the criteria C1 to C4, a value is assigned to each hazard/feed/edible product combination, and categorized as shown in Table 2.

Step 4. Normalization of these values to make them comparable between criteria

An example of normalization is summarized in Table 2. In this example, each criterion value is assigned to one of a range of levels chosen for this example and then normalized to a scale of 0, 0.5, 1.0.

Table 2: Normalization of values

Normalized value	**0**	**0.5**	**1.0**
	Low	*Medium*	*High*
C1. Occurrence level in feed (% of feed samples exceeding a defined level for the hazard)	*<10%*	*10–25%*	*>25%*
C2. Transfer from feed to edible product (based on measurement or modeling)	*<5%*	*5-50%*	*>50%*
C3(a). Toxicity of chemical hazard (health-based guidance value (e.g. ADI[5] or TDI[6])	*>1 mg/kg bw/day*	*1 µg-1 mg/kg bw/day*	*<1 µg/kg bw/day*
C3(b). Health effects of biological hazard (number of hazard-related illnesses per 100'000 of population)	*<0.1*	*0.1-1*	*>1*
C4. Impact on feed availability (replacement feed available)	*Replacement easy*	*Replacement difficult*	*Replacement impossible*

[5] Acceptable Daily Intake (ADI)
[6] Tolerable Dietary Intake (TDI)

Step 5. Weighting of the criteria to reflect their relative importance

The weightings chosen for the criteria C1 to C4 in this example are summarized in Table 3.

Table 3: Criterion weighting chosen for this example

Criterion	Weighting code	Average weighting decided by experts
C1. Occurrence level in feed	W1	15%
C2. Transfer from feed to edible product	W2	40%
C3. Health hazard ((a) or (b), depending on the hazard*)	W3	30%
C4. Impact on feed availability	W4	15%
Sum		100%

* C3(a) for chemical hazards, C3(b) for biological hazards

Table 3 shows that the criterion related to transfer from feed to edible product in this example is assigned the greatest weight (40%), followed by health hazard, occurrence level, and impact on feed availability.

Step 6. Combining the weighted normalized values for each hazard/feed/edible product combination to produce a score, and ranking of the scores to obtain the order of priority

The score for each hazard/feed/edible product combination in this example is calculated using the following equation:

Score = C1*W1 + C2*W2 + C3(a or b)*W3 + C4*W4

where C are the combination-specific normalized values and W are the criteria weightings.

An example of the calculation of the score for one hazard/feed/edible product combination is shown in Table 4.

Table 4: Example of scoring of a hazard/feed/edible product combination for Combination 1 (for a chemical hazard)

Criterion	Value	Normalized value (C)	Criterion Weight (W)	C *W
C1. Occurrence level in feed	<10%	0	15%	0
C2. Transfer from feed to edible product	5-50%	0.5	40%	0.2
C3(a). Health hazard	<1 µg/kg bw /day	1.0	30%	0.3
C4. Impact on feed availability	Low	0	15%	0
Score				**0.5**

This scoring is performed for each hazard/feed/edible product combination to be prioritized.

Scores and the resulting ranking/prioritization of Combination 1 with two other hypothetical hazard/feed/edible product combinations are summarized in Table 5.

Table 5: Prioritization of three hazard/feed/edible product combinations based on ranked scores

Hazard/feed/edible product combination	Score	Ranking / priority
Combination 1	**0.5**	**2**
Combination 2	**0.475**	**3**
Combination 3	**0.75**	**1**

Step 7. Reporting of the process, methods and results

The report should include full documentation as described in paragraph 30 of the Guidance.

ANNEX 2

EXAMPLES OF HAZARDS IN FEED WITH POTENTIAL RELEVANCE FOR HUMAN HEALTH

1. This Annex is not a comprehensive description of the different situations related to feed and food safety. The information included in this Annex may need to be updated as more scientific knowledge becomes available on these issues. By illustrating hazards which may occur in different parts of the world, this Annex is intended to provide additional information on how to use the prioritization procedure in practice as described in the guidance. Therefore, this Annex should not be taken as a risk assessment of the cases mentioned.

2. This Annex should be considered in conjunction with the report of the FAO/WHO Expert Meeting on Animal Feed Impact on Food Safety (FAO/WHO, Rome, 2008) when making the initial step of the prioritization process.

3. The examples may not be relevant everywhere or at all times; they simply illustrate the range of hazards, feeds and edible products which may need to be considered in a given location at a given time. In addition, rare and emerging hazards are not covered.

4. The following examples are listed according to the types of hazards.

Biological hazards

Bacteria

5. The primary microbiological hazards in feed that can transfer to edible products of food-producing animals are zoonotic microorganisms contaminating feeds. These microorganisms may be introduced into feed by, for example, crops, forages and water from contaminated pasture land or cross-contamination from infected animals (including carcasses) during feed production, processing, transport, storage and use.

6. *Salmonella* is a worldwide human health concern. Contaminated feed can represent a route of exposure of food-producing animals to *Salmonella*. Edible products affected can include eggs, meat and meat products. However, the correlation between contaminated feed and infection by a given *Salmonella* strain and the contamination of edible products from these animals needs to be established on a case-by-case basis. Adequate strain typing is necessary to establish such correlations. Strain typing is also important to identify strain types that are more commonly associated with human pathogenicity. In the absence of the establishment of such correlation or of strain typing, any contamination of feed with *Salmonella* could be considered as a hazard, particularly if not adequately heat-treated prior to its use.

7. *Brucella*: In countries where *Brucella* is endemic, pasture may be contaminated by ruminants which deliver or abort offspring there, because the placentas of infected animals contain high levels of these microorganisms. Milk-producing animals may become infected by eating forage from contaminated pastures and excrete the microorganisms in their milk. This milk may be a risk to human health if not pasteurized prior to use.

Endoparasites

8. Some animal endoparasites, such as *Toxoplasma* and *Taenia* spp., are human health hazards. Various life stages of these organisms may contaminate pasture and forages and the derived feed via infected animals. Ingestion of contaminated feed by food-producing animals can result in the presence of infective cysts in edible products (e.g. meat), which may pose a risk to human health, particularly if not adequately heat treated prior to consumption.

Prions

9. Prions are infectious agents composed of protein in a misfolded form which induces existing, properly-folded prion protein (PrPc, a constituent of normal mammalian cells) to convert into the disease-associated, prion form (PrPSc). Prions are responsible for the transmissible spongiform encephalopathies in a variety of mammals, including bovine spongiform encephalopathy in cattle and variant Creutzfeldt–Jakob disease in humans. Prions are extremely resistant to denaturation by chemical and physical agents including heat. Exposure of food-producing animals can occur via feed contaminated with material from prion-infected carcasses. Transfer from prion-contaminated feed to edible products has been demonstrated.

Chemical hazards

Elements

10. A number of elements may present a hazard to humans. This includes radionuclides and elements commonly referred to as "heavy metals", such as arsenic, cadmium, lead and mercury.

11. Radionuclides including caesium-134, caesium-137, strontium-90 and iodine-131 present in animal feed and forages may transfer to edible products. Major sources are contaminated soil, water and forage. Transfer of radioiodine to milk, radiostrontium to bone, and radiocesium to milk, eggs and meat has been demonstrated.

12. The following are non-exhaustive examples of “heavy metals”:

- Arsenic is a naturally-occurring contaminant found in minerals and (mainly in the less toxic organic form) in marine plants, fish and shellfish and other farmed aquatic animals.
- Cadmium is a naturally-occurring contaminant in soil minerals (such as phosphate and zinc sources), and in forages and cereals grown near smelting and mining areas, or where the soil has been treated with contaminated manure, sewage, sludge or phosphate fertilizers; edible products affected include shellfish, oysters, salmon, also kidney and liver.
- Lead contamination may occur naturally or from industrial waste in, for example, feed minerals (e.g. copper sulphate, zinc sulphate, zinc oxide) and in forages and cereal via air, soil or water contamination; it is found in edible products such as fish, milk, bone, brain and kidney.
- Mercury from industrial sources, which contaminates soil and water can produce secondary contamination of forages, crops and aquatic organisms; edible products affected have included liver, kidney, fish, and other aquatic animals.

Toxins

13. Toxins are naturally occurring hazards that include:

- Mycotoxins, e.g. aflatoxins, ochratoxins, zearalenone;
- Bacterial toxins, e.g. botulinum toxin and staphylococcal enterotoxin;
- Terrestrial plant toxins, e.g. solanine in potatoes, gossypol in cottonseed;
- Marine toxins, e.g. toxins from certain algae, particularly dinoflagellates.

Mycotoxins

14. Mycotoxins are produced by fungi commonly found in cereals (especially wheat, sorghum and maize), oilseed meals and cakes, and silage.

15. Transfer from feed to edible products has been demonstrated for various mycotoxins including aflatoxins and ochratoxins.

16. Aflatoxins can occur in e.g. copra, peanut cake, sunflower cakes, corn, corn gluten, rice bran, cottonseed, palm kernel and soy beans. Aflatoxin B_1 is metabolized in some food-producing animals to aflatoxin M_1 which transfers to milk. Aflatoxin M_1 is a human carcinogen.

17. Ochratoxin A is most commonly found in cereals such as rye, barley, maize and wheat, and to a lesser extent in peanuts and soybeans. It transfers to edible products such as blood, liver and kidney and to a lesser extent meat, fat and milk. Ochratoxin A is nephrotoxic in humans.

18. Fumonisins, deoxynivalenol, T-2 and HT-2 toxin and zearalenone are rapidly metabolized and/or excreted by food-producing animals and are therefore not major contaminants of edible products.

Bacterial toxins

19. A limited number of toxins produced by bacteria such as *Clostridium botulinum, C. tetani* and *C. perfringens, Vibrio cholerae, Staphylococcus aureus, Yersinia enterocolitica,* and *Shigella dysenteriae* are acutely toxic to food-producing animals when ingested with feed but transfer of toxin to edible products is unlikely.

Terrestrial plant toxins

20. Toxin-producing plants may occur in grasslands used for forage. Naturally occurring toxins can include pyrrolizidine alkaloids (e.g. jacoline from *Senecio jacobaea*) and other alkaloids (e.g. atropine, cocaine, ephedrine, morphine, nicotine, solanine), terpenes (e.g. camphor, pinene), tetrahydrocannabinol, gossypol, isoflavones, and glycosides (e.g. cyanogenic glycosides, digitalis). Transfer of some of these toxins to edible products such as milk and meat has been demonstrated.

Marine toxins

21. Dinoflagellates such as *Gambierdiscus toxicus* in tropical and subtropical waters produce marine toxins including heat-resistant ciguatoxin, maitotoxin, scaritoxin and palytoxin. Small filter-feeding fish which can accumulate such biotoxins and their predators may be harvested and used to make fish meal. Transfer of ciguatera toxin to human milk after maternal poisoning has been reported, so transfer from feed to milk of food-producing animals is a possibility.

Organic chemicals

22. Of the many organic chemical contaminants that are present in the environment and therefore are potentially present in feed, it is the lipophilic compounds that have the greatest tendency to accumulate in edible products of food-producing animals.

23. Polychlorinated dibenzodioxins (PCDD) and polychlorinated dibenzofurans (PCDF) commonly known as dioxins, and organochlorine pesticides such as aldrin, dieldrin, and dichlorodiphenyltrichloroethane (DDT), are lipophilic and have long half-lives in the environment. Dioxins in feed may arise by contamination, for example from dioxin-containing preservatives in wood, or from combustion sources (e.g. waste incineration plants, fossil fuel power stations, bush fires, exhaust gases) or by chemical reactions during processing involving solvents containing chlorine. Dioxins may be present as contaminants in mineral sources, such as clays, recuperated copper sulphate, zinc oxide, and in food by-products, including fish by-products such as fish meal and fish oils. Dioxin contamination of edible products has been reported for fish, fat of meat, milk, and egg yolk.

24. Polychlorinated biphenyls (PCBs) have been widely used in a number of industrial and commercial applications. Although the manufacture, processing and distribution of PCBs have been prohibited in almost all industrial countries since the 1980s, their entry into the environment still occurs. Following exposure of farmed animals, including aquaculture, PCBs will accumulate in meat, liver and particularly in fat tissues. PCBs have been reported to be associated with an increased risk of cancer of the digestive system and possibly other sites.

Pesticides, veterinary drugs, feed additives and processing aids

25. Cross-contamination of feed by pesticides, veterinary drugs, medicated feed, feed additives and processing aids may occur during production, processing, transport or storage.

26. Unapproved use of pesticides**,** veterinary drugs, medicated feed, feed additives and processing aids, or the presence of undesirable substances, may lead to excessive levels in feed and edible products (e.g. clenbuterol in meat).

ANNEX 3

ADDITIONAL REFERENCES

Useful sources of information on potential hazard/feed/edible product combinations include:

WHO Global Environment Monitoring System (GEMS) (WHO Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food). (http://www.who.int/foodsafety/chem/gems/en/)

Joint FAO/WHO International Food Safety Authorities Network (INFOSAN) (WHO International Food Safety Authorities Network (INFOSAN); (http://www.who.int/foodsafety/fs_management/infosan/en/).

Notifications from the European Rapid Alert System for Food and Feed (EU RASFF); (https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=notificationsLis t)

Some examples of prioritization frameworks, processes and methods are given in:

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Humblet MF, Vandeputte S, Albert A, Gosset C, Kirschvink N, Haubruge E, Fecher-Bourgeois F, Pastoret PP, Saegerman C (2012). Multidisciplinary and evidence-based method for prioritizing diseases of food-producing animals and zoonoses. Emerg Infect Dis 18(4):e1. doi: 10.3201/eid1804.111151

Lake R, Hudson A, Cressey P, Nortje G (2000). Risk Profiles For The Foods New Zealanders Eat: Project F13ra3. Prepared as part of a Ministry of Health contract for scientific services by ESR Risk Profile Project Team, November 2000. (http://www.foodsafety.govt.nz/elibrary/industry/Risk_Profiles-Science_Research.pdf

New Zealand Ministry for Primary Industries, Food safety science group. Risk ranking. (http://www.foodsafety.govt.nz/science-risk/risk-assessment/risk-ranking.htm)

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