

TECHNICAL REPORT OF EFSA

List of guidance, guidelines and working documents developed or in use by EFSA¹

Prepared by the Secretariat of the Scientific Committee

(Question No EFSA-Q-2005-00299)

Issued on 24 April 2009

SUMMARY

This technical report summarises the guidance documents, guidelines and working documents developed or in use by EFSA for the risk assessment. The report has been compiled in the framework of the activities of the Scientific Committee on transparency in risk assessment and can be read together with the document “Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessment carried out by EFSA. Part 2: general principles”. The report lists general as well as specific documents in use by the different EFSA panels.

EFSA will review and update this document regularly.

Key words: Guidance documents, guidelines, working documents

¹ For citation purposes: Technical report of EFSA prepared by the Secretariat of the Scientific Committee on List of guidance documents, guidelines and working documents developed or in use by EFSA. *EFSA Technical Report* (2009) 294, 1-13.

TABLE OF CONTENTS

Summary	1
Table of Contents	2
General guidance documents.....	3
Scientific Committee	3
Animal health animal welfare panel (AHAW).....	4
Food additives and nutrient sources (ANS) – Food contact material, enzymes and flavourings (CEF) ..	5
Biological hazards (BIOHAZ)	6
Feed additives (FEEDAP)	6
Genetically Modified Organisms (GMO)	10
Nutrition (NDA)	11
Plant health (PLH).....	12
Plant protection products (PPR) and pesticides risk assessment peer review Unit (PRAPeR)	12
Zoonoses Data Collection	12

GENERAL GUIDANCE DOCUMENTS

Codex Alimentarius (2003) Principles for Risk Analysis and Guidelines for Safety Assessment of Foods derived from Modern Biotechnology.

Rome: Joint FAO/WHO Food Standards Programme, Food and Agriculture Organization.
ftp://ftp.fao.org/codex/Publications/Booklets/Biotech/Biotech_2003e.pdf

Codex Alimentarius Commission. Principles and guidelines for the conduct of microbiological risk assessment factor(s) to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables. Codex Alimentarius Commission - WHO (1999) CAC/GL-30.

ftp://ftp.fao.org/es/esn/jemra/CAC_GL30.pdf

Codex Alimentarius Commission (2008). Procedural Manual - 17th Edition.

http://www.codexalimentarius.net/web/procedural_manual.jsp

FAO/WHO (1995). Application of Risk Analysis to Food Standards Issues, Report of the Joint FAO/WHO Expert Consultation, Geneva, Switzerland, 13-17 March 1995, WHO/FNU/FOS/95.3. World Health Organisation, Geneva.

<http://www.who.int/foodsafety/publications/micro/march1995/en/index.html>.

FAO/WHO (1997). Risk Management and Food Safety, Report of a Joint FAO/WHO Consultation, Rome, Italy, 27 to 31 January 1997, FAO Food and Nutrition Paper 65. Food and Agriculture Organisation of the United Nations, Rome.

<http://www.fao.org/docrep/W4982E/W4982E00.htm>.

IPCS (1996) Principle for the safety assessment of food additives and contaminants in food WHO, International programme on chemicals safety (Environmental Health Criteria 70)²

http://www.who.int/ipcs/food/update_project/en/index.html

WHO (2004). IPCS risk assessment terminology. Part 1: IPCS/OECD key generic terms used in chemical hazard/risk assessment. Part 2: IPCS glossary of key exposure assessment terminology. International Programme on Chemical Safety, World Health Organization, Geneva.

<http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf>

SCIENTIFIC COMMITTEE

Opinion of the Scientific Committee on a request from EFSA related to a harmonised approach for risk assessment of substances which are both genotoxic and carcinogenic.

Adopted 18/10/ 2005. The EFSA Journal (2005) 282, 1-31

http://www.efsa.europa.eu/EFSA/Scientific_Opinion/sc_op_ej282_gentox_en3.pdf

Guidance of the Scientific Committee on a request from EFSA related to uncertainties in dietary exposure assessment. Adopted 14/12/2006. The EFSA Journal (2006) 438: 1-54

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_uncertainty%20exp_en.pdf

² Update in progress

Transparency in risk assessment carried out by EFSA: Guidance Document on procedural aspects. Endorsed 11/04/2006 by the Scientific Committee. The EFSA Journal (2006) 353, 1-16.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/sc_guidance_transpaproc_en1_0.pdf

Opinion of the Scientific Committee on the “Introduction of a qualified presumption of safety (QPS) approach for assessment of selected microorganisms referred to EFSA”³. Adopted 19/11/2007. The EFSA Journal (2007) 587, 1-16.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej587_qps_en.pdf

Scientific Advise by the Scientific Committee “Internal and external review: proposal for a review system for EFSA’s scientific activities”. Adopted 3/08/2007. The EFSA Journal 526, 1-15.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/biohaz_op_ej923_qps_en.pdf

Opinion of the Scientific Committee on the “Approach to enhance EFSA’s responsiveness to urgent questions”. Adopted 10/07/2007. The EFSA Journal (2007), 525, 1-4.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623591901.htm

Guidance document on the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. Publication date: 20/06/2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178717026833.htm

Guidance of the Scientific Committee on Transparency in the scientific aspects of risk assessment carried out by EFSA. Part 2: general principles. Adopted 07/04/2009 by the Scientific Committee. The EFSA Journal (2009) 1051, 1-22.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902513151.htm

ANIMAL HEALTH ANIMAL WELFARE PANEL (AHAW)

AHAW has no specific guidance documents. The following documents are considered to be the most important:

OIE (2000) Guidelines for risk analysis, in *International Animal Health Code*. Chapter 1.3.2.

OIE (2004a) Handbook on Import Risk Analysis for Animals and Animal Products. Volume 1. Introduction and qualitative risk analysis. p. 57.

OIE (2004b) Handbook on Import Risk Analysis for Animals and Animal Products. Volume 2. Quantitative risk assessment. p. 126.

Opinion of the Scientific Panel on Animal Health and Welfare (AHAW) on the Framework for EFSA AHAW Risk assessments. The EFSA Journal (2007) 550, 1-46.

http://www.efsa.europa.eu/EFSA/Scientific_Opinion/ahaw_op_ej550_framework_en.1.pdf

³ This opinion has been prepared by a Working Group of the Scientific Committee and updated by the BIOHAZ panel. It is also of interest of the FEEDAP panel.

FOOD ADDITIVES AND NUTRIENT SOURCES (ANS) – FOOD CONTACT MATERIAL, ENZYMES AND FLAVOURINGS (CEF)

The documents developed by EFSA before July 2008 refer to both panels. The documents developed after July 2008 are assigned to the appropriate panel ANS or CEF.

Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council. OJ L 180/8, 19/07/2000.

http://ec.europa.eu/food/fs/sfp/addit_flavor/flav01_en.pdf

Regulation (EC) no 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directive 80/590/EEC and 89/109/EEC. OJ L 338/4; 13/11/2004.

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_338/l_33820041113en00040017.pdf

Council Directive 89/109/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs OJ L 40, 11/02/1989, p. 38 – 1989 L0109; 10/01/1989. Corrected by: "C1 Corrigendum, OJ L 347, 28/11/1989, p. 37 (89/109).

<http://www.foodplast.com/upload/documents/document11.pdf>

Guidance on Submissions for Food Additive Evaluations by the Scientific Committee on Food. SCF/CS/ADD/GEN/26 Final 12/07/2001.

http://ec.europa.eu/food/fs/sc/scf/out98_en.pdf

Guidance from the AFC Panel on submission of a dossier on a Smoke Flavouring Primary Product for evaluation by EFSA. Adopted 7/10/2004; Last update: 27/08/2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902030797.htm

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/guidancedocument1.0.pdf

Guidance Documents on the submission of a dossier on a substance to be used in Food Contact Materials for evaluation by EFSA by the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC). Last update 27/08/2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902030817.htm

Guidance on submission for safety evaluation of sources of nutrients or of other ingredients proposed for use in the manufacture of foods (opinion expressed on 12/07/2001).

SCF/CS/ADD/NUT/21 Final, 12/07/2001.

http://ec.europa.eu/food/fs/sc/scf/out100_en.pdf

The AFC Panel endorsed these guidelines in the 2nd meeting in July 2003 and added comments on how to interpret this guidance with respect to the need for toxicological studies:

http://www.efsa.europa.eu/EFSA/Event_Meeting/minutes_afc_02_adopted_en1.0.pdf

Joint AFC/BIOHAZ guidance document on the submission of data for the evaluation of the safety and the efficacy of substances for the removal of microbial surface contamination of foods of animal origin. Adopted 13/07/2006 BIOHAZ panel and 28/08/2006 by AFC panel. The EFSA Journal (2006) 388, 1-9.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/biohaz_op_ej388_decontam_guidance_en,0.pdf

CEF: Guidelines on submission of a dossier for safety evaluation by the EFSA of a recycling process to produce recycled plastics intended to be used for manufacture of materials and articles in contact with food - Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC). Adopted date: 21/05/2008. The EFSA Journal (2008) 717, 1-12.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178717811412.htm

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/afc_ej717_efsa_guidelines_recycling_en.pdf

BIOLOGICAL HAZARDS (BIOHAZ)

Joint AFC/BIOHAZ guidance document on the submission of data for the evaluation of the safety and the efficacy of substances for the removal of microbial surface contamination of foods of animal origin. Adopted 13/07/2006 BIOHAZ panel and 28/08/2006 by AFC panel. The EFSA Journal (2006) 388, 1-9.

http://www.efsa.europa.eu/EFSA/Scientific_Document/biohaz_op_ej388_decontam_guidance_en.pdf

Opinion of the Scientific Panel on biological hazards (BIOHAZ) on microbiological criteria and targets based on risk analysis. Adopted 7/03/2007. The EFSA Journal (2007) 462, 1-29.

http://www.efsa.europa.eu/EFSA/Scientific_Opinion/biohaz_op_ej462_micro_criteria_en.pdf

Opinion of the panel on Biological Hazards on “The maintenance of the list of QPS microorganisms intentionally added to food or feed”. Adopted 10/10/2008. The EFSA Journal (2008) 923, 1-48.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/biohaz_op_ej923_qps_en.pdf

Guidelines for applications for new alternative methods of disposal or use of Animal By-Products under Regulation (EC) No 1774/2002 prepared jointly by the Health and Consumer Protection Directorate-General and the European Food Safety Authority. SANCO/10060/2006.

http://ec.europa.eu/food/food/biosafety/animalbyproducts/disposal0604_en.pdf

Principles and Guidelines for the Conduct of Microbiological Risk Assessment CAC/GL-30 (1999)

http://www.codexalimentarius.net/download/standards/357/CXG_030e.pdf

FEED ADDITIVES (FEEDAP)

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18/10/2003 pp 29-43.

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_268/l_26820031018en00290043.pdf

Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the

preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22/05/2008, p. 1-65.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:133:0001:0065:EN:PDF>

Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition. OJ L 213, 21/07/1982, p. 8.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31982L0471:EN:HTML>

Council Directive 83/228/EEC on the fixing of guidelines for the assessment of certain products used in animal production (Bioproteins CD 82/471/EEC). OJ L 126, 13/05/1983, p.23-27. Amendments incorporated by 294A0103 (51) (OJ L 001 03.01.1994 p.220).

http://ec.europa.eu/food/food/animalnutrition/labelling/marktlab12_en.pdf

Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes. OJ L 237, 22/09/1993, p. 23-27.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31993L0074:EN:HTML>

Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes. OJ L 62, 6/03/2008 p. 9-22.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:062:0009:0022:EN:PDF>

Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition. OJ L 064 , 07/03/1987, pag 19-28.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31987L0153:EN:HTML>

Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorizations of feed additives. OJ L 59, 5/03/2005 p. 8-15.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:059:0008:0015:EN:PDF>

Guidelines for the assessment of additives in feedingstuffs Part II: enzymes and micro-organisms. DG Health and Consumer Protection.

http://ec.europa.eu/food/fs/sc/scan/out68_en.pdf

Guidance document of the scientific panel on genetically modified organisms (GMO) for the Risk Assessment of genetically modified microorganisms and their derived products intended for food and feed use. Adopted 17/05/2006. The EFSA Journal (2006) 374, 1-115.

http://www.efsa.europa.eu/EFSA/Scientific_Document/comm_Guidance%20doc_GMM_en.pdf

Opinion of the Scientific Committee on the Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. Adopted 19/11/2007. The EFSA Journal 2007, 587, 1-16.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej587_qps_en.pdf

Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) for the establishment of guidelines on the assessment of safety and efficacy of silage

additives, on a request from the Commission under Article 7(5) of Regulation (EC) No 1831/2003. Adopted 20/04/2006. The EFSA Journal (2006) 349, 1-10.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej349_silage_guidelines_en1.pdf

Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the development of an approach for the environmental risk assessment of additives, products and substances used in animal feed. Adopted 08/03/2007. The EFSA Journal (2007) 529, 1-73.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178626084619.htm

Technical Guidance for assessing the safety of feed additives for the environment. Prepared by the Panel on Additives and Products or Substances used in Animal Feed. Adopted 22/10/2008. The EFSA Journal (2008) 842, 1 – 28.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902153679.htm

Guidance for the preparation of dossiers for technological additives prepared by the Panel on additives and products or substances used in animal feed. Adopted 16/07/2008. The EFSA Journal (2008) 774, 1-21.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej774_technological_en,0.pdf

Guidance for the preparation of dossiers for sensory additives prepared by the Panel on additives and products or substances used in animal feed. Adopted 16/09/2008; The EFSA Journal (2008) 799, 1-15.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902094248.htm

Guidance for the preparation of dossiers for nutritional additives prepared by the Panel on additives and products or substances used in animal feed. Adopted 16/07/2008. The EFSA Journal (2008) 775, 1-15.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej775_nutritional_en,0.pdf

Guidance for the preparation of dossiers for zootechnical additives prepared by the Panel on additives and products or substances used in animal feed. Adopted 16/07/2008. The EFSA Journal (2008) 776, 1-18.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej776_zootechnical_en,0.pdf

Guidance for the preparation of dossiers for coccidiostats and histomonostats prepared by the Panel on additives and products or substances used in animal feed. Adopted 16/07/2008. The EFSA Journal (2008) 777, 1-11.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej777_coccidiostats_en,0.pdf

Guidance for the preparation of dossiers for additives already authorised for use in food prepared by the Panel on additives and products or substances used in animal feed. Adopted 16/09/2008. The EFSA Journal (2008) 800, 1-3.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej800_food_feed_en,0.pdf

Technical Guidance Tolerance and efficacy studies in target animals prepared by the Panel on additives and products or substances used in animal feed. Adopted 17/07 2008. The EFSA Journal (2008) 778, 1-13.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej778_tolerance_efficacy_en,0.pdf

Technical Guidance for establishing the safety of additives for the human consumer prepared by the Panel on additives and products or substances used in animal feed. Adopted 16/09/2008. The EFSA Journal (2008) 801, 1-12.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej801_consumer_safety_en,0.pdf

Technical Guidance Studies concerning the safety of use of the additive for users/workers prepared by the Panel on additives and products or substances used in animal feed. Adopted 17/09/2008. The EFSA Journal (2008) 802, 1-2.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej802_user_en.pdf

Technical Guidance: Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition prepared by the Panel on additives and products or substances used in animal feed. Adopted 17/09/2008. The EFSA Journal (2008) 803, 1-5.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej803_minor_species_en,0.pdf

Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC prepared by the Panel on additives and products or substances used in animal feed. Adopted 17/07/2008. The EFSA Journal (2008) 779, 1-10.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej779_re-evaluation_en,0.pdf

Technical guidance - Compatibility of zootechnical microbial additives with other additives showing antimicrobial activity prepared by the Panel on additives and products or substances used in animal feed. Adopted 5/03/2008. The EFSA Journal (2008) 658, 1-5.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/feedap_guidance_ej658_compatibility_en.pdf

Technical guidance: Update of the criteria used in the assessment of bacterial resistance to antibiotics of human or veterinary importance prepared by the Panel on additives and products or substances used in animal feed⁴. Adopted 18/06/2008. The EFSA Journal (2008) 732, 1-15.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej732_tg_antimicrobial_resistance_en.pdf

⁴ This guidance document replaces the previous EFSA opinion on the updating of the criteria used in the assessment of bacteria for resistance to antibiotics of human or veterinary importance, adopted May 2005.

Technical Guidance on Microbial Studies. Prepared by the Panel on Additives and Products or Substances used in Animal Feed. Adopted 21/10/2008. The EFSA Journal (2008) 836,1- 3.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902139277.htm

Opinion of the scientific committee on animal nutrition on the safety of use of *Bacillus* species in animal nutrition. Opinion expressed by DG Health and Consumers Protection on 17/02/2000.
http://ec.europa.eu/food/fs/sc/scan/out41_en.pdf

Administrative guidance to applicants on the preparation and presentation of applications for authorisation of additives for use in animal nutrition. Last updated: 29/09/2008.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178625242905.htm

GENETICALLY MODIFIED ORGANISMS (GMO)

Regulation (EC) No 258/97 of the European parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. OJ L 43, 14/02/1997, p. 1-6.
http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31997R0258&model=guichett

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 17/04/2001, p. 1-39.
http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&numdoc=32001L0018&model=guichett&lg=en

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18/110/2003, p.1-23.
http://europa.eu/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf

Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use. Adopted 17/05/2006; The EFSA Journal (2006) 374, 1-115.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775770.htm
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/comm_Guidance%20doc_GMM_en.pdf

Guidance document of the Scientific Panel on Genetically Modified Organisms for renewal of authorisations of existing GMO products lawfully placed on the market, notified according to Articles 8 and 20 of Regulation (EC) No 1829/2003. Adopted 6/12/2006; The EFSA Journal (2006) 435, 1-4.
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/gmo_guidance_ej435_renewal_of_authorisations_en.pdf

Guidance document of the scientific panel on Genetically Modified Organisms for the risk assessment of genetically modified plants containing stacked transformation events. Adopted 16/07/2007; The EFSA Journal (2007) 512, 1-5.

http://www.efsa.europa.eu/EFSA/Scientific_Document/gmo_guidance_ej512_GM_stacked_events_en.pdf

Guidance document for the risk assessment of genetically modified plants and derived food and feed by the Scientific Panel on Genetically Modified Organisms (GMO) - including draft document updated in 2008. Adopted 24/09/2004. Last updated: 16/06/2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775747.htm

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/gmo_guidance_gm_plants_en_0.pdf

Report on the Safety and Nutritional assessment of GM Plant and derived Foods/Feeds - The role of animal feeding trials.

Adopted 12/09/2007; Food and Chemical Toxicology 46 (2008) S1; Publication date: 10/03/2008

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178660555237.htm

http://www.efsa.europa.eu/cs/BlobServer/Non_Scientific_Document/gmo_report_feedingtrials.pdf

Working Document of the GMO Panel on the interplay between Directive 2001/18/EC and Directive 91/414/EEC (Plant Protection Products). GMOs Published 10/10/2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902125247.htm

NUTRITION – (NDA)

Final scientific and technical guidance for applicants for preparation and presentation of the application for authorization of a health claim. Adopted 6/07/2007. Last updated: 01/02/2008.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178623592471.htm

Pre-submission guidance for applicants intending to submit applications for authorisation of health claims made on foods. Publication date: 14/03/2007. Last updated: 08/08/2007.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620768319.htm

SCF: Report on the revision of essential requirements of infant formulae and follow-on formulae. SCF/CS/NUT/IF/65 Final. Opinion adopted 4/04/2003.

http://ec.europa.eu/food/fs/sc/scf/out199_en.pdf

Contains a corrigendum made on 17/09/2007 on page 60, chapter 4.7.2 Carnitine mulae.

SCF: Opinion on the Assessment of Novel Foods. Recommendations concerning the scientific aspects of information necessary to support applications for placing on the market of novel foods and novel food ingredients (part II e part III). Adopted 7/06/1996; Published 1997.

http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_40.pdf

Guideline of the Scientific Committee on Food for the development of tolerable upper intake levels for vitamins and minerals. SCF/CS/NUT/UPPLEV/11 Final. Adopted 19/10/2000.

http://ec.europa.eu/food/fs/sc/scf/out80a_en.pdf

PLANT HEALTH (PLH)

International Plant Protection Convention (New Revised Text), FAO, 1997.

https://www.ippc.int/servlet/BinaryDownloaderServlet/13742_1997_English.pdf?filename=/publications/13742.New_Revise...

Framework for pest risk analysis. 2007. International Standards for Phytosanitary Measures (ISPM) No.2, FAO, Rome.

https://www.ippc.int/servlet/BinaryDownloaderServlet/184204_ISPM02_2007_E.pdf?filename=1179929048771_ISPM02_2007_E.pdf&refID=184204

Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms. 2004. International Standards for Phytosanitary Measures (ISPM) No.11, FAO, Rome.

https://www.ippc.int/servlet/BinaryDownloaderServlet/34163_ISPM_11_E.pdf?filename=1146658377367_ISPM11.pdf&refID=34163

Guidelines on Pest Risk Analysis: Decision-support scheme for quarantine pests PM 5/3 (3). 2007. European and Mediterranean Plant Protection Organization (EPPO), Paris.

http://archives.eppo.org/EPPOStandards/PM5_PRA/PRA_scheme_2007.doc

Guidance on the evaluation of pest risk assessments prepared by third parties to justify phytosanitary measures under the Council Directive 2000/29/EC. Scientific Opinion of the EFSA Panel on Plant Health. Endorsed for public consultation on 18 December 2008. Finalisation is in progress.

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902260573.htm

PLANT PROTECTION PRODUCTS (PPR) AND PESTICIDES RISK ASSESSMENT PEER REVIEW UNIT (PRAPER)

The list of the guidance documents for the implementation of the Council Directive 91/414/EEC (Plant Protection Products) and the EU pesticide residue legislations have been annexed to the following EFSA's Technical Report: "Evaluation of the European Union Pesticide Safety Review Process". The EFSA Journal (2008) 157, 1-110.

http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/praper_rep_ej157_pesticide_review_process_en.pdf?ssbinary=true

ZOONOSES DATA COLLECTION

Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:325:0031:0040:EN:PDF>

Regulation (EC) 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:325:0001:0015:EN:PDF>

Regulation (EC) No 2073/2005 on microbiological criteria in foodstuffs as amended by Regulation (EC) No 1441/2007.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:338:0001:0026:EN:PDF>