TECHNICAL REPORT OF EFSA

Database of guidance on different toxicity end-points, risk assessment methodologies and data collection related to food, feed, animal health and welfare and plant health[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

The purpose of this document is to provide an inventory of guidance and test methodologies that have been developed or are in the process of being developed on risk assessment related to food and feed safety.

This document covers three main aspects:

- Scientific aspects
- Procedural aspects
- Quality assurance

Each item is broken down into specific subtopics. The information is based on the Scientific Committee opinions on transparency, the report of the Scientific Committee Secretariat on the list of guidance, guidelines and working documents developed or in use by EFSA and the Evaluation of the European Union Pesticide Safety Review Process.

The document lists the guidance documents, guidelines and working documents relevant for the risk assessment for a specific subtopic developed by organisations in Europe, international organisations and organisations in third countries.

This inventory confirms that a large body of guidance and procedural documents on topics within EFSA's already exists. More importantly, in various areas new guidance is under development or revision. In order for EFSA to identify how it can benefit from existing work (and thus avoid duplication) and identify areas that require new development, it is necessary to make the data in this inventory readily available by creating a database. For EFSA to obtain the maximum benefit of these on going activities it is important to maintain and regularly (e.g. annually) update its inventory.

KEY WORDS: Guidance documents, guidelines, working documents

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CONSIDERATION

1. Introduction

In the EFSA Strategic Plan 2009-2013 the use of Integrated Approach (IA) has been identified as a key strategic area for the delivering of scientific advice associated with food chain from field to plate. The Integrated Approach can have as a main objective to achieve consistency in risk assessment methods used throughout the food chain. It is however recognised that the IA could also be conceptualised in other ways:

- The IA could be considered as an evolution from "Farm to Fork" concept to an "Integrated Food Cycle". The former being a description of the food chain until it reaches the customers whereas the latter also includes the impact of humans and their dietary habits on the environment.

- Another dimension of the IA could be labelled comprehensive approach to risk assessment, whereby both risks and benefits are considered.

- Another aspect is to draw on approaches used in other disciplines or agencies i.e. outside the food area.

The 2000 White Paper, that establishes the basis for the creation of EFSA, puts forward the "Farm to Fork" as a key element in assuming food safety. However, at the same time, various elements of topical legislation are now in place. These allow to properly addressing specific subsection of what is a very complex food chain. In order to maintain consistency and credibility it is important though that EFSA makes sure that overall consistency is maintained as well.

2. Objectives

The purpose of this document is to provide an inventory of guidance and test methodologies that have been developed or are in the process of being developed on risk assessment related to food and feed safety.

3. Materials and methods

This document covers three main aspects:

- Scientific aspects (Table 2)
- Procedural aspects (Table 3)
- Quality assurance (Table 4)

Each item is broken down into specific subtopics.

The initial source of information were the Scientific Committee opinions on transparency (EFSA, 2006; EFSA, 2009b), the report of the Scientific Committee Secretariat on the list of guidance, guidelines and working document developed and in use by EFSA (EFSA, 2009a) and the Evaluation of the European Union Pesticide Safety Review Process (EFSA, 2008).

These documents were characterised for the following attributes (Table 1):

- Organisations that issued the document, or is developing it, indicated with abbreviated name and location information (European Union (EU), International and Third Countries). The EU-based institutions were further differentiated into European Commission, EFSA, Member States (with abbreviation of the name) and other organisations. The attribute to EFSA was further distinguished according to the issuing panel, network or unit. Part of the food chain for which they are relevant.

- Scope of the document and whether it is finalised or under (pre-) development.
- If available, the link to a website from which the document can be downloaded will be included

The languages considered are the official EFSA languages i.e. English, German, French and Italian.

Table 1. Overall structure

Items	Subitems
Scope	Scientific Aspects Procedural Aspects Quality Assurance
Organisation	Location Name Year
Food sector	Animal Health Animal Welfare Biological Hazard/Zoonoses Colourings Contaminants in Feed and Food Feed Additives Flavourings Food Additives Food Contact Materials Genetically Modified Organism Maximum Residue Levels Nutrition Pesticides Plant Health
Status of the document	Finalised Under development (with EFSA involvement) Under development (without EFSA involvement)
References	

Table 2. Overview of scientific aspects

Items	Sub-Items	Details
Physical-chemical and analytical methods		
Hazard Characterisation	Toxicokinetics and ADME	
	Mammalian toxicology	Acute toxicity
		Repeated dose toxicity
		In vitro and in vivo genotoxicity
		Carcinogenicity
		Reproductive toxicity
		Endocrine disruptors
		Neurotoxicity: general, delayed
		Other: immunotoxicology, allergenicity, intolerance
	Microbial resistance	
Residue and Exposure	Exposure Assessment	
Risk Characterisation		
Environmental Risk Assessment	Environmental fate and behaviour	
	Eco-toxicology	

Table 3. Overview of procedural aspects

Items	Sub-Items	Details
Validation of submitted dossier		
Scope, Objectives and Term of reference		
Materials and methods	Terminology(including Expression of risk/Terms and definition/presentation of findings, expression of assumptions, availability and uncertainty)	
	Data and information collection	Monitoring
	Use of confidential data	
	Data storage, validation and retrieval	
	Missing information, assumption and default values	
	Default values and assumptions	
	Results and discussion, Summary and conclusion	
	Test procedures	
Public consultation		
Adoption of Opinions (adopting a report, diverging opinions and updating opinions)		
Communication of RA work and results		

Table 4. Overview of quality assurance

Items	Sub-Items	Details
Selection of experts		
Establishing of a Working group and organising a meeting		
Archiving procedure		
Quality assurance of scientific output		
Interaction with stakeholders		

4. Results

Annex A lists the guidance documents, guidelines, test procedures and working documents relevant for a specific subtopic developed by organisations in Europe, international organisations and organisations in third countries.

In this document they are cited under each section for which they contain relevant information. As the documents may be relevant for several different sections, this means that the same information maybe repeated several times in this document. The contents of this inventory will be placed in a searchable database to enable identification of those documents relevant for a particular purpose.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSION

This inventory confirms that a large body of guidance and procedural documents on topics within EFSA's already exists. More importantly, in various areas new guidance is under development or revision. In order for EFSA to identify how it can benefit from existing work (and thus avoid duplication) and identify areas that require new development, it is necessary to make the data in this inventory readily available by creating a database which can be queried for key characteristics such as those listed in the Materials and Methods.

Therefore the information contained in this reports are stored into an MS Access database, an easy-to-use programme for creating and maintaining databases. It has been created according to the overall structure of the document. Suitable reports containing information on one single topic or a combination of different sub-items can be extracted from the database according to the needs of the users.

For EFSA to obtain the maximum benefit of these ongoing activities it is important to maintain and regularly (e.g. annually) update its inventory, including the most recently realised EU, international and third countries' guidance.

RECOMMENDATIONS

Following this initial inventory, a task force will be created to complete the list of documents and to review and finalise the attributes of each document in the database.

Next, the inventory will be submitted for review to the Scientific Committee and the Advisory Forum for review. Input from other organisations may be sought, as appropriate.

The database, when fully operational, will then allow to support

- The identification of areas of common interest across panels and agencies
- The nature of the most appropriate working groups: across EFSA panels, across agencies, international or third countries working groups

Occasionally, the need may be resided in the necessity to develop an approach by EFSA but more in the organisation of training to implement new technologies.

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EFSA (European Food Safety Authority), 2009b. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessment carried out by EFSA. Part 2: General Principles. *The EFSA Journal* (2009), 1050, 1-22.

APPENDICES

Appendix A

1. SCIENTIFIC ASPECTS

1.1. Physical-chemical and analytical methods

EU

European Commission

EC (2009) COMMISSION REGULATION (EC) No 761/2009 amending, for the purpose of its adaptation to technical progress, Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the EP and of the Council on the REACH.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:220:0001:0094:EN:PDF

EC (2008) Regulation 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). 30 May 2008
http://eur-lex.europa.eu/JOIndex.do?year=2008&serie=L&textfield2=142&Submit=Search&_submit=Search&ihmlang=en

EC (2008) Regulation 429/2008 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. 25 April 2008.
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:133:0001:0065:en:PDF

EC **DG SANCO** (2000) Guidelines for the implementation of Decision 2002/657/EC. SANCO/2004/2726 rev.1
http://products.ihs.com/Ohsis-SEO/793467.html

DG SANCO (2003) Guidance Document on the assessment of the equivalence of technical materials of substances regulated under council directive 91/414/EEC. SANCO/10597/2003 rev. 8.1 final.
http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc14_en.pdf

DG JRC (2003) CRL Feed Additives: Guidance for applicant seeking authorisation for feed additives under Regulation (EC) No 1831/2003, as regards the evaluation of methods of analysis.
http://www.irmm.jrc.be/html/CRLs/crl_feed_additives/authorisation/guidance_for_applicants/Administrative_Guidance_2009_ver1.00_w_annexes.pdf

EG JRC (2009) CRL Feed Additives: Explanatory Notes to the applicants concerning Methods of analysis and reference samples (Annex II of Regulation (EC) No 429/2008.
http://www.irmm.jrc.be/html/CRLs/crl_feed_additives/authorisation/guidance_for_applicants/Explanatory_notes_(February_2009).pdf

EFSA

EFSA **GMO** (2008) 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 by the Scientific Panel on Genetically Modified Organisms on 24 September 2008. ISBN: 92-9199-019-1.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902599947.htm

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http://www.efsa.europa.eu/cs/BlobServer/Guidance_of_Efsa/praper_epco_manual_e4_rev4_2005-september1.pdf?ssbinary=true

Others

ILSI (2003) Risk Characterisation of Chemicals in Food and Diet "Final part of Food Safety in Europe (FOSIE): Risk Assessment of Chemicals in Food and Diet. Food and Chemical Toxicology 2003; 41(9):1205-1271
http://www.ilsi.org/europe/Pages/ViewItemDetails.aspx?ID=190&ListName=Publications

International

UN FAO/WHO (2006) Updating the Principles and Methods of Risk Assessment: MRLs for Pesticides and Veterinary Drugs.
http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/DOWNLOAD/bilthoven_2005.pdf

1.2. Hazard Characterisation

1.2.1. Toxicokinetics and Absorption, Distribution, Metabolism and Excretions (ADME)

EU

European Commission

EC (2008) Regulation 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). 30 May 2008
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EC **DG SANCO** E1 (2004) Guidance Document on Dermal Absorption. SANCO/222/2000 rev.7.
http://ec.europa.eu/food/plant/protection/evaluation/guidance/wrkdoc20_rev_en.pdf

EC DG SANCO E1 (2001) Guidance for setting of an acute reference dose (ARfD). 7199/VI/99 rev. 5
http://ec.europa.eu/food/plant/protection/resources/7199_vi_99.pdf

EFSA

EFSA **FEEDAP** (2008) 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/en/scdocs/scdoc/801.htm

EFSA FEEDAP (2008) 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/en/scdocs/scdoc/803.htm

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http://www.efsa.europa.eu/cs/BlobServer/Guidance_of_Efsa/praper_epco_manual_e4_rev4_2005-september1.pdf?ssbinary=true

1.2.2. Mammalian toxicology

1.2.2.1. Acute toxicity

EU

European Commission

EC (2008) Regulation 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). 30 May 2008
http://eur-lex.europa.eu/JOIndex.do?year=2008&serie=L&textfield2=142&Submit=Search&_submit=Search&ihmlang=en

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EFSA

EFSA **SC** (2009) Existing approaches incorporating replacement, reduction and refinement of animal testing: applicability in food and feed risk assessment. Adopted on 8 April 2009. The EFSA Journal (2009) 1052, 1-77.
http://www.efsa.europa.eu/en/scdocs/scdoc/1052.htm

EFSA **FEEDAP** (2008) 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/en/scdocs/scdoc/801.htm

EFSA **PRAPeR** (2005) Working Document for preparation of the ”List of End points” for chemical active substances. EPCO Manual E4.
http://www.efsa.europa.eu/cs/BlobServer/Guidance_of_Efsa/praper_epco_manual_e4_rev4_2005-september1.pdf?ssbinary=true

EFSA **PPR** (2008) Risk Assessment for Birds and Mammals - Revision of Guidance Document under Council Directive 91/414/EEC (SANCO/4145/2000 – final of 25 September 2002) [1] - Scientific Opinion of the Panel on Plant protection products and their Residues (PPR) on the Science behind the Guidance Document on Risk Assessment for birds and mammals. Adopted on 17 June 2008. The EFSA Journal (2008), 734, 1-181.
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International

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http://who.int/ipcs/food/jmpr/arfd_guidance.pdf

1.2.2.2. Repeated Dose toxicity

EU

European Commission

EC (2008) Regulation 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). 30 May 2008
http://eur-lex.europa.eu/JOIndex.do?year=2008&serie=L&textfield2=142&Submit=Search&_submit=Search&ihmlang=en

EFSA

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International

OECD (2001) Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies. Series on testing and assessment no. 32 – Series on Pesticides no. 10.
http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/NT00002CCE/$FILE/JT00129312.PDF

1.2.2.3. In vitro and in vivo genotoxicity

EU

European Commission

EC (2008) Regulation 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). 30 May 2008
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Member States

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1.2.2.4. Carcinogenicity

EU

European Commission

EC (1999) Guidelines for setting specific concentration limits for carcinogens in Annex 1 of Directive 67/548/EEC. ISBN 9282874435.
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Member States

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1.2.2.5. Reproductive toxicity

EU

European Commission

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International

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EU

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EU

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EU

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1.3. Residues and Exposure

1.3.1. Residues

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EU

EFSA

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EU

EFSA

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EU

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1.4.1. Environmental fate and behaviour

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2.2. Scope, objectives and terms of reference

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2.3. Materials and methods

2.3.1. Terminology (including Expression of risk/Terms and definition/Presentation of findings including expression of assumptions, variability and uncertainty)

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2.3.2. Data and information collection

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Third Countries

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2.3.3. Monitoring and data reporting

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European Commission

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2.3.4. Use of confidential data

EU

EFSA

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2.3.8. Test procedures

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EU

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EU

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EU

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3. Quality Assurance

3.1. Selection of experts

EU

European Commission

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3.2. Establishing a Working Group and organising a meeting

3.3. Archiving procedure

3.4. Quality assurance of scientific output

EU

European Commission

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3.5. Interaction with stakeholders

EC

European Commission

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EFSA

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GLOSSARY / ABBREVIATIONS

AFC	Additives, Flavourings, processing aids and materials in Contact with food Panel
AFSSA	Agence Française de Sécurité Sanitaire des Aliments
AHAW	Animal Health and Animal Welfare Panel
ASTM	American Society for Testing and Materials
BIOHAZ	Biological Hazard Panel
CAC	Codex Alimentarius Commission
calEPA	California Environmental Protection Agency
CEF	Food Contact materials, Enzymes and Flavourings Panel
CIPAC	Collaborative International Pesticides Analytical Council
COC	Committee on Carcinogenicity
CSL	Central Science Laboratory
DATEX	Data Collection and Exposure Unit
DIN	Deutsches Institut für Normung eV *(German Institute for Standardization)*
EC	European Council
ECB	European Chemicals Bureau
EFCOSUM	European food consumption survey method
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EPPO	European and Mediterranean Plant Protection Organization
FAO	Food and Agriculture Organization
FEEDAP	Feed Additives Panel
GEMS	Graphical Exposure Modelling System
GMO	Genetically Modified Organisms Panel
HSA	Health Sciences Authority
IARC	International Agency on Research on Cancer
ICH	International conference of harmonisation
IFTS	International Federation of Teratology Societies
IGHRC	Interdepartmental Group on Health Risk from Chemicals
ILSI	International Life Science Institute
IPCS	International Programme on Chemical Safety
IPPC	International Plant Protection Convention
ISO	International Organization for Standardization
ISPM	International Standards for Phytosanitary Measures
IUPAC	International Union of Pure & Applied Chemistry
JECFA	Joint FAO/WHO Expert Committee on Food Additives

JRC	Directorate General Joint Research Centre
MB	Management Board
MRL	Maximun Residue Level
NDA	Nutrition Panel
NZFSA	New Zealand Food Safety Authority
OECD	Organisation for Economic Co-operation and Development
OIE	Organisation Mondiale de la Santé Animale
PLH	Plant Health Panel
PPR	Plant Protection Products Panel
PRAPeR	Pesticides unit
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Health and Environment)
SANCO	Directorate General for Health and Consumers
SC	Scientific Committee
SCF	Scientific Committee for Food
SETAC	Society of Environmental Toxicology And Chemistry
SSC	Scientific Steering Committee
TG	Technical Guidance
UN	United Nations
WHO	World Health Organization
ZOONOSES	Zoonoses Data Collection Unit