Annex B

In this guide

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Lists of guidance documents by EFSA, the US FDA and US EPA

Secretariat

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EFSA Guidance

Cross-cutting guidance

Guidance on the use of the **benchmark dose approach** in risk assessment

Guidance on **aneugenicity** assessment.

Guidance on risk assessment of **nanomaterials** to be applied in the food and feed chain: human and animal health.

Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including **nanoparticles**.

Guidance on the use of the **Threshold of Toxicological Concern** approach in food safety assessment.

Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of **combined exposure** to multiple chemicals.

Genotoxicity assessment of chemical **mixtures**.

Clarification of some aspects related to **genotoxicity** assessment.

Guidance on **uncertainty analysis** in scientific assessments.

Guidance on the risk assessment of substances present in food intended for **infants below 16 weeks** of age.

Guidance on the use of the **weight of evidence approach** in scientific assessments.

Guidance on the assessment of the **biological relevance** of data in scientific assessments.

Guidance on **statistical reporting.**

Guidance on **Expert Knowledge Elicitation** in Food and Feed Safety Risk Assessment.

Statement on the applicability of the **Margin of Exposure approach for the safety assessment of impurities** which are both genotoxic and carcinogenic in substances added to food/feed.

Guidance on selected **default values** to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data.

Scientific opinion on **genotoxicity testing strategies** applicable to food and feed safety assessment.

Guidance on **risk–benefit assessment** of foods.

Application of **systematic review methodology** to food and feed safety assessments to support decision making.

Transparency in risk assessment carried out by EFSA: Guidance Document on procedural aspects.

Guidance of the Scientific Committee on **transparency** in the scientific aspects of risk assessments carried out by EFSA. Part 2: General Principles.

Opinion of the Scientific Committee related to **uncertainties in dietary exposure assessment**.

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**.

Scientific Committee guidance on **appraising and integrating evidence from epidemiological studies** for use in EFSA's scientific assessments.

Sector-specific guidance

Guidance for submission for **food additive** evaluations.

Scientific Guidance for the submission of dossiers on **food enzymes**.

Scientific Guidance for the preparation of applications on **smoke flavouring primary products**.

Scientific Guidance on the data required for the risk assessment of **flavourings** to be used in or on foods.

Guidance on the scientific requirements for an application for authorisation of a **novel food** in the context of Regulation (EU) 2015/2283.

Guidance on the scientific requirements for a notification and application for authorisation of **traditional foods** from third countries in the context of Regulation (EU) 2015/2283.

Guidance on the renewal of the authorisation of **feed additives**.

Update: methodological principles and scientific methods to be taken into account when establishing Reference Points for Action (RPAs) for **non-allowed pharmacologically active substances** present in food of animal origin.

Guidance on the assessment of the safety of **feed additives** for the consumer.

Guidance on the assessment of the safety of **feed additives** for the target species.

General approach to assess the safety for the target species of botanical preparations which contain compounds that are genotoxic and/or carcinogenic when used as **feed additives**.

Guidance for establishing and applying tolerable upper intake levels for **vitamins and essential minerals**.

Note for guidance for the preparation of an application for the safety assessment of a substance to be used in **plastic food contact materials**.

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**.

Scientific Guidance on the criteria for the evaluation and on the preparation of applications for the safety assessment of **post-consumer mechanical PET recycling processes** intended to be used for manufacture of materials and articles in contact with food.

Guidelines on submission of a dossier for safety evaluation by the EFSA of active or intelligent substances present in **active and intelligent materials and articles intended to come into contact with food**.

Guidance on conducting repeated-dose 90-day oral toxicity study in rodents on **whole food/feed**.

Explanatory statement for the applicability of the Guidance of the EFSA Scientific Committee on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed for **GMO** risk assessment.

Scientific Opinion on a Qualified Presumption of Safety (QPS) approach for the safety assessment of **botanicals and botanical preparations**.

Guidance on safety assessment of **botanicals and botanical preparations** intended for use as ingredients in food supplements.

Introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected **microorganisms** referred to EFSA.

Guidance for **establishing and applying tolerable upper intake levels** for vitamins and essential minerals.

Guidance on scientific principles and data requirements for the **safety and relative bioavailability assessment of new micronutrient sources**.

FDA toxicology guidance documents for food ingredients

Preparation of **food contact substance** notifications (toxicology recommendations).

Toxicological principles for the safety assessment of **food ingredients**: Redbook 2000.

Toxicological principles for the safety assessment of direct **food additives and color additives**: 1993 Draft Redbook II. Sections of Draft Redbook II not yet finalized in Redbook 2000 are available.

Summary table of recommended toxicological testing for **additives** used in food.

EPA toxicology guidance

Framework for human health risk assessment to inform decision making.

Guidance for applying quantitative data to develop **data-derived extrapolation factors** for interspecies and intraspecies extrapolation.

Benchmark dose technical guidance.

Recommended **use of body weight**$^{3/4}$ as the default method in derivation of the oral reference dose

Framework for **metals** risk assessment.

Guidelines for **carcinogen** risk assessment.

Supplemental guidance for assessing susceptibility from **early-life exposure to carcinogens**.

Guidelines for **neurotoxicity** risk assessment.

Guidance on **cumulative risk assessment**: part 1. planning and scoping.

Guiding principles for **Monte Carlo analysis**.

Guidelines for **reproductive toxicity** risk assessment.

Guidelines for **developmental toxicity** risk assessment.

Guidelines for **mutagenicity** risk assessment.

Guidelines for the health risk assessment of chemical **mixtures.**

Note: only clear guidance documents (not other scientific opinions, reviews, case studies or white papers) that are relevant to the remit of the COT have been listed here.

Guidance related to the regulatory risk assessment of pesticides has not been listed, though some relates to combined exposures and may be of relevance to the COT's work. These are:

Guidance on **cumulative risk assessment** of pesticide chemicals that have a common mechanism of toxicity.

Guidance for identifying pesticide chemicals and other substances that have a **common mechanism of toxicity**.

Risk Assessment Guidance | US EPA.