

# Riskihindamise valdkonna juhendmaterjalid

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## Terminoloogia

EFSA Glossary <http://www.efsa.europa.eu/en/glossary-taxonomy-terms>

Scientific Opinion on Risk Assessment Terminology. EFSA Journal 2012; 10 ( 5):2664, 43 pp.  
<https://doi.org/10.2903/j.efsa.2012.2664>

WHO/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, 2004  
<http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf>

## Andmete kogumine, arvamuste koostamine ja läbivaatus

30.10.23. EFSA. Guidance on protocol development for EFSA generic scientific assessments.  
<https://www.efsa.europa.eu/et/efsajournal/pub/8312>

Asendab 2020.a. dokumendi ‘Draft framework for protocol development for EFSA's scientific assessments’

1.09.23. BfR. Guideline for the assessment of health risks.  
<https://www.bfr.bund.de/cm/364/guideline-for-the-assessment-of-health-risks.pdf>

Scientific report on Principles and process for dealing with data and evidence in scientific assessments. EFSA Journal 2015; 13( 5):4121, 35 pp.  
<https://doi.org/10.2903/j.efsa.2015.4121>

Guidance on Statistical Reporting. EFSA Journal 2014; 12( 12):3908, 18 pp.  
<https://doi.org/10.2903/j.efsa.2014.3908>

Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment. EFSA Journal 2014; 12( 6):3734. [278 pp.] <https://doi.org/10.2903/j.efsa.2014.3734>

Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637. 90 pp. <https://doi.org/10.2903/j.efsa.2010.1637>

## Läbipaistvus

Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain  
<http://data.europa.eu/eli/reg/2019/1381/oj>

Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessment carried out by EFSA. Part 2: general principles, EFSA Journal (2009) 1051, 1-22.  
<https://doi.org/10.2903/j.efsa.2009.1051>

## Määramatuse hindamine

Guidelines for Uncertainty Analysis: Application of the respective documents of EFSA and BfR for exposure assessments. EFSA supporting publication 2018: EN-1472. 113 pp.  
<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2018.EN-1472>

Guidance on Uncertainty Analysis in Scientific Assessments. EFSA Journal 2018;16(1):5123, 39 pp.  
<https://doi.org/10.2903/j.efsa.2018.5123>

Scientific Opinion on the principles and methods behind EFSA's Guidance on Uncertainty Analysis in Scientific Assessment. EFSA Journal 2018;16(1):5122, 235 pp.  
<https://doi.org/10.2903/j.efsa.2018.5122>

## Muud valdkondade ülesed juhendid

Joint Risk Assessment Operational Tool. FAO/WOAH/WHO. 2020.  
<https://www.who.int/initiatives/tripartite-zoonosis-guide/joint-risk-assessment-operational-tool>

Draft for internal testing Scientific Committee guidance on appraising and integrating evidence from epidemiological studies for use in EFSA's scientific assessments. EFSA Journal 2020;18(8):6221, 83 pp.  
<https://doi.org/10.2903/j.efsa.2020.6221>

Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. EFSA Journal 2019;17(3):5634, 77 pp.  
<https://doi.org/10.2903/j.efsa.2019.5634>

Emerging risks identification on food and feed – EFSA. EFSA Journal 2018;16(7):5359, 37 pp.  
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5359>

Scientific Opinion on the guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971, 69 pp. <https://doi.org/10.2903/j.efsa.2017.4971>

Guidance on the assessment of the biological relevance of data in scientific assessments. EFSA Journal 2017;15(8):4970, 73 pp. <https://doi.org/10.2903/j.efsa.2017.4970>

Overview of existing methodologies for the estimation of non-dietary exposure to chemicals from the use of consumer products and via the environment. EFSA Journal 2016;14(7):4525, 19 pp. <https://doi.org/10.2903/j.efsa.2016.4525>

Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012; 10( 3):2579, 32 pp. <https://doi.org/10.2903/j.efsa.2012.2579>

Statistical Significance and Biological Relevance. EFSA Journal 2011; 9( 9):2372,17 pp. <https://doi.org/10.2903/j.efsa.2011.2372>

Collection and routine analysis of import surveillance data with a view to identification of emerging risks EFSA Journal 2010; 8 (3): 1531  
<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2010.1531>

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. EFSA Journal 2005; 3( 10):282, 33 pp. <https://doi.org/10.2903/j.efsa.2005.282>

## Loomatervis

Methodological guidance for the development of animal welfare mandates in the context of the Farm to Fork Strategy <https://www.efsa.europa.eu/en/efsajournal/pub/7403>

Guidance on good practice in conducting scientific assessments in animal health using modelling <https://www.efsa.europa.eu/en/efsajournal/pub/7346>

Technical guidelines on rapid risk assessment for animal health threats. FAO Animal Production and Health Guidelines No. 24, FAO 2021 <https://doi.org/10.4060/cb3187en>

Human Animal Infections and Risk Surveillance (HAIRS) group. Processes of risk assessment. Public Health England. 2018.  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/761106/HAIRS\\_risk\\_assessment\\_processes.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761106/HAIRS_risk_assessment_processes.pdf)

Terrestrial Animal Health Code Chapter 2.1 Import Risk Analyses, WOAH, viimane uuendus 2018  
[https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre\\_import\\_risk\\_analysis.htm](https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_import_risk_analysis.htm)

Scientific opinion on an *ad hoc* method for the assessment on listing and categorisation of animal diseases within the framework of the Animal Health Law. EFSA Journal 2017; 15( 7):4783, 42 pp. <https://doi.org/10.2903/j.efsa.2017.4783>

Manual of Procedures for Wildlife Disease Risk Analysis. OIE and IUCN. 2014.  
<https://doc.woah.org/dyn/portal/digidoc.xhtml?statelessToken=MkAZ4dBQ8zR8-9kMhXWtgW0->

[9JIlmdJuQFfnMh6coo=&actionMethod=dynamic%2Fportal%2Fdigidoc.xhtml%3AdownloadAttachment.openStateless](#)

Dufour, B., Plee, L., Moutou, F., Boisseleau, D., Chartier, C., Durand, B., Ganiere, J. P., Guillotin, J., Lancelot, R., Saegerman, C., Thebault, A., Hattenberger, A. M., & Toma, B. 2011. A qualitative risk assessment methodology for scientific expert panels: -EN- -FR- Une méthodologie d'évaluation qualitative du risque destinée aux comités scientifiques d'experts -ES- Método de determinación cualitativa del riesgo para comisiones científicas. Revue Scientifique et Technique de l'OIE, 30(3), 673–681. <https://doi.org/10.20506/rst.30.3.2063>

Handbook on import risk analyses for animals and animal products. Introduction and qualitative risk analyses. 2nd edition. OIE, 2010. [https://rr-africa.oie.int/wp-content/uploads/2018/03/handbook\\_on\\_import\\_risk\\_analysis\\_-\\_oie\\_-\\_vol\\_\\_i.pdf](https://rr-africa.oie.int/wp-content/uploads/2018/03/handbook_on_import_risk_analysis_-_oie_-_vol__i.pdf)

Guidance on Good Practice in Conducting Scientific Assessments in Animal Health using Modelling. EFSA Journal 2009; 7(12):1419. 38 pp.  
<https://efsajournal.wiley.com/doi/10.2903/j.efsa.2009.1419>

Phylum. Listing and Categorisation of Priority Animal Diseases, including those Transmissible to Humans. Report for OIE. 2009. [https://ec.europa.eu/food/system/files/2016-10/ah\\_policy\\_strategy\\_study\\_oie\\_2010\\_pt2.pdf](https://ec.europa.eu/food/system/files/2016-10/ah_policy_strategy_study_oie_2010_pt2.pdf)

## Antibiotikumiresistentsus

Terrestrial Animal Health Code Chapter 2.1 6.11. Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in animals, WOAH, viimane uuendus 2015.  
[https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre\\_antibio\\_risk\\_ass.htm](https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_antibio_risk_ass.htm)

## Toidu ja sööda ohutus

25.10.22 EFSA. Guidance on the use of the benchmark dose approach in risk assessment.  
<https://www.efsa.europa.eu/et/efsajournal/pub/7584>

Technical report on handling occurrence data for dietary exposure assessments. EFSA supporting publication 2021:EN-7082. 28pp. <https://doi.org/10.2903/sp.efsa.2021.EN-7082>

Guidance Document on Scientific criteria for grouping chemicals into assessment groups for human risk assessment of combined exposure to multiple chemicals. EFSA Journal 2021;19(12):7033, 37 pp.  
<https://doi.org/10.2903/j.efsa.2021.7033>

Microbiological risk assessment - Guidance for food. Microbiological Risk Assessment Series No. 36. FAO and WHO, 2021 <https://doi.org/10.4060/cb5006en>

Guidelines for rapid risk analysis following instances of detection of contaminants in food where there is no regulatory level. CXG 92-2019 [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B92-2019%252FCXG\\_092e.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B92-2019%252FCXG_092e.pdf)

Scientific Opinion on a Qualified Presumption of Safety (QPS) approach for the safety assessment of botanicals and botanical preparations. EFSA Journal 2014; 12( 3):3593, 38 pp.  
<https://doi.org/10.2903/j.efsa.2014.3593>

Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL 30-2014  
PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK ASSESSMENT (fao.org)

Guidelines on the Application of Risk Assessment for Feed. CAC-GL 80-2013 [www.fao.org/fao-who-codexalimentarius/sh-proxy/it/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B80-2013%252FCXG\\_080e.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/it/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B80-2013%252FCXG_080e.pdf)

Scientific Opinion 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. EFSA Journal 2012; 10( 3):2578, 5 pp. <https://doi.org/10.2903/j.efsa.2012.2578>

Overview of the procedures currently used at EFSA for the assessment of dietary exposure to different chemical substances EFSA Journal 2011; 9( 12):2490, 33 pp.  
<https://doi.org/10.2903/j.efsa.2011.2490>

Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011; 9( 3):2097, 34 pp. <https://doi.org/10.2903/j.efsa.2011.2097>

Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance. CAC/GL 77-2011 [GUIDELINES FOR RISK ANALYSIS OF FOODBORNE ANTIMICROBIAL RESISTANCE \(fao.org\)](#)

FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies. 2011, <http://www.fao.org/3/ba0092e/ba0092e00.pdf>

Guidance on human health risk-benefit assessment of food. EFSA Journal 2010; 8( 7):1673, 41 pp.  
<https://doi.org/10.2903/j.efsa.2010.1673>

Principles and Methods for the RA of chemicals in food; WHO, Environmental health criteria 240, 2009 [Principles and methods for the risk assessment of chemicals in food \(who.int\)](#)

EFSA Scientific Committee; Guidance on safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements, on request of EFSA. EFSA Journal 2009; 7 (9):1249. 19 pp. <https://doi.org/10.2903/j.efsa.2009.1249>

FAO/WHO. Risk Characterization of Microbiological Hazards in Food: Guidelines. Microbiological Risk assessment. 2009. Series No 17. Rome 116 pp. <http://www.fao.org/3/i1134e/i1134e.pdf>

Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal (2007) 587, 1–16 <https://doi.org/10.2903/j.efsa.2007.587>

## Uued tehnoloogiad (bio- ja nanotehnoloogia, GMO, uuendtoit)

Guidance on risk assessment of nanomaterials to be applied in the food and feed chain: human and animal health. EFSA Journal 2021;19(8):6768, 111 pp. <https://doi.org/10.2903/j.efsa.2021.6768>

Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health. EFSA Journal 2018;16(7):5327, 95 pp.  
<https://doi.org/10.2903/j.efsa.2018.5327>

Scientific Opinion on guidance for the risk assessment of the presence at low level of genetically modified plant material in imported food and feed under Regulation (EC) No 1829/2003. EFSA Journal 2017;15(11):5048, 19 pp. <https://doi.org/10.2903/j.efsa.2017.5048>

Scientific Opinion on Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. EFSA Journal 2011; 9( 5):2140, 36 pp.  
<https://doi.org/10.2903/j.efsa.2011.2140>

Codex Alimentarius biotehnoloogiaid puudutavad juhendid <http://www.fao.org/fao-who-codexalimentarius/thematic-areas/biotechnology/en/>

## Riskikommunikatsioon

Scientific report on technical assistance in the field of risk communication. EFSA Journal 2021;19(4):6574, 113 pp. <https://doi.org/10.2903/j.efsa.2021.6574>

Future directions for risk communications at EFSA. EFSA Journal 2021;19(2):e190201, 6 pp.  
<https://doi.org/10.2903/j.efsa.2021.e190201>

When Food Is Cooking Up a Storm – Proven Recipes for Risk Communications 2017, EFSA  
[https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/riskcommguidelines170524.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/riskcommguidelines170524.pdf)

Guidance on Communication of Uncertainty in Scientific Assessments. EFSA Journal 2019;17(1):5520, 73 pp. <https://doi.org/10.2903/j.efsa.2019.5520>

Täiendavaid riskihindamise valdkonna juhendeid leiab:

[Guidance and other assessment methodology documents | EFSA \(europa.eu\)](#)

[Scientific advice | Food safety and quality | Food and Agriculture Organization of the United Nations \(fao.org\)](#)

[Publications - OIE - World Organisation for Animal Health](#)