



98TH ADVISORY FORUM
KONGENS LYNGBY, 03-04 DECEMBER 2025

6.1 - FEEDBACK ON THE ARCHITECTURE OF EFSA'S GUIDANCE DOCUMENTS



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PROJECT OBJECTIVES

The project aims at addressing a series of needs raised by EFSA's stakeholders and internally

Early Engagement

Involving stakeholders
in GD development



Clarity

Improving
understanding of EFSA
GD



Predictability

Enhancing the reliability
of EFSA's GD work



Retrievability

Making GD easier to
find and access



Cross-Cutting Implementation

Enhancing integration of cross-
cutting GD across EFSA sectors



Process

Streamlining GD
development and
revision



OVERVIEW OF DELIVERABLES

1. New, clarified definition of EFSA GD

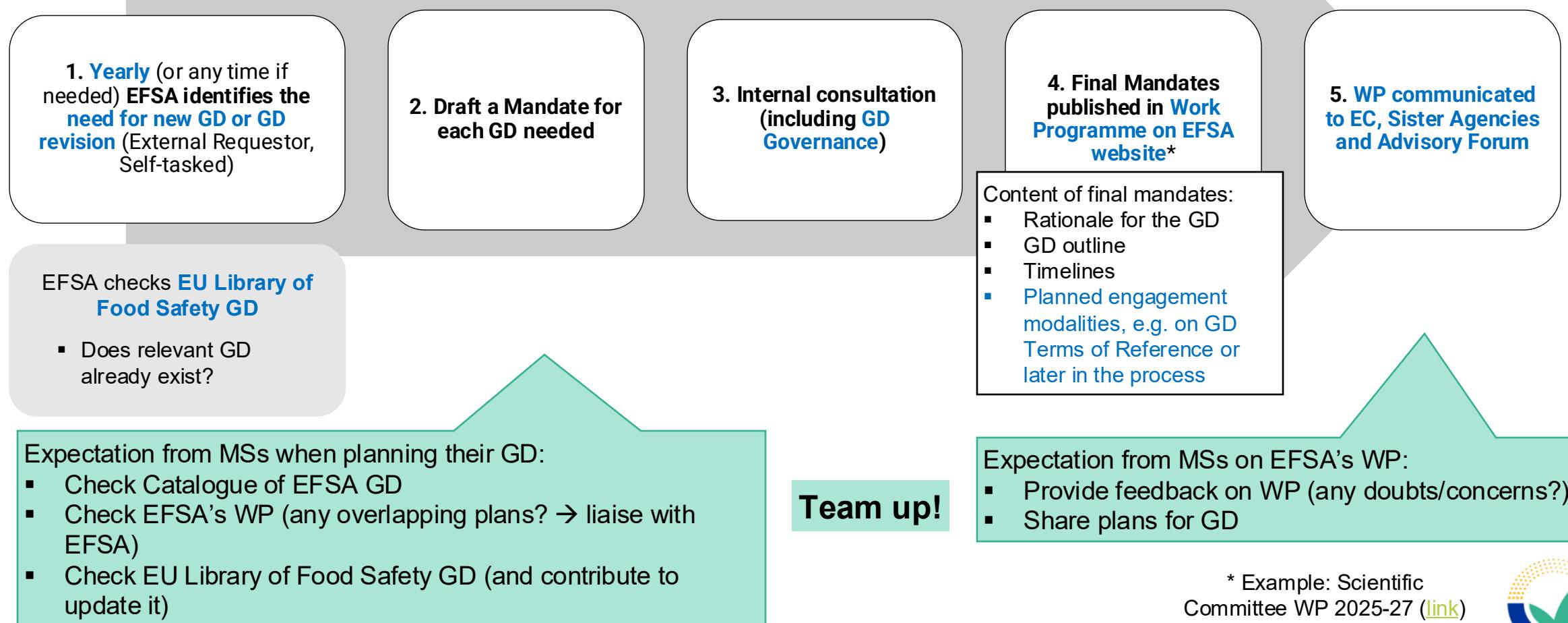
- Five GD categories

- 1 Cross-cutting GD (Scientific Committee)
- 2 Sector-specific GD (Scientific Panels)
- 3 GD on data standards (EFSA)
- 4 GD for data submission (EFSA)
- 5 Administrative GD (EFSA)

- 2. **New Management Scheme (Q2 2026):**
 - Governance and process for GD Work Programme (new)
 - Process for GD Lifecycle (revised)
- 3. **All GD organised into a Catalogue (Q1 2026)**
 - Complemented by the EU Library of Food Safety GD from AF members
- 4. **New way of publishing GD (2027)**



GOVERNANCE AND PROCESS FOR GD WORK PROGRAMME (WP) (Q2 2026)



* Example: Scientific Committee WP 2025-27 ([link](#))



PROCESS FOR GD LIFECYCLE (Q2 2026): ENGAGEMENT MODALITIES

8 phases

- **4 new (3 optional)**
- **4 revised**

MSs can be consulted on the GD ToRs

MSs experts can be part of the WG

- MSs consulted on draft GD
- If possible, MSs involved in piloting the GD

MSs can provide feedback on the GD at any time

0. Consultation on GD ToRs
Optional

1. Establishment of Engagement Platforms
Optional

2. Working Group establishment

3. GD Protocol

- Why
- What
- How

Optional

4. GD development & Implementation Plan

- Consultation on draft GD
- Pilot test the GD

5. GD Publication & Implementation

- Transition period
- Capacity building

6. Monitoring of GD usage

- Continuous collection of feedback

7. GD Evaluation

- Every 5 years (or at any time)

MSs can take part in *ad hoc* discussion groups, activated at the start and remaining active for consultation throughout GD Lifecycle

MSs can be consulted on draft protocol for GD

Training, info sessions on GD



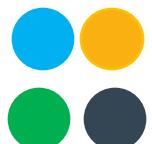
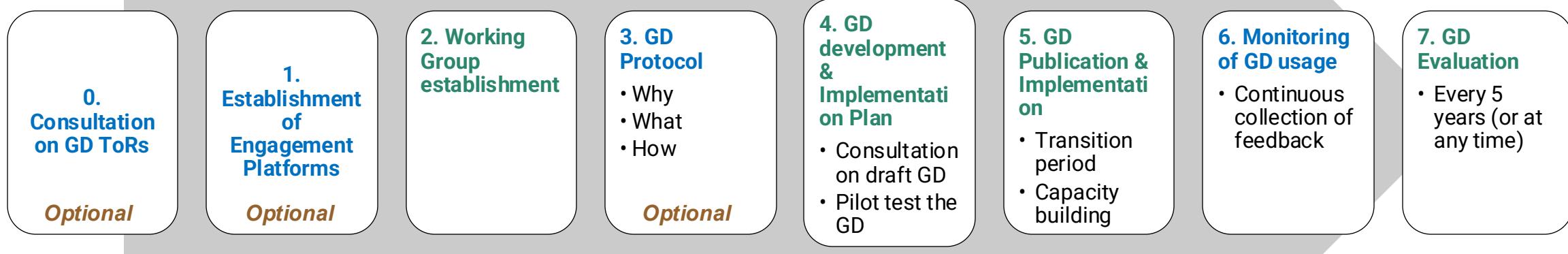
RECENT EXAMPLES OF ENGAGEMENT ACTIVITIES ON GD

Revision of Terrestrial ecotoxicology GD ([link](#); [link](#))

Revision of GD on Nanoparticles ([link](#))

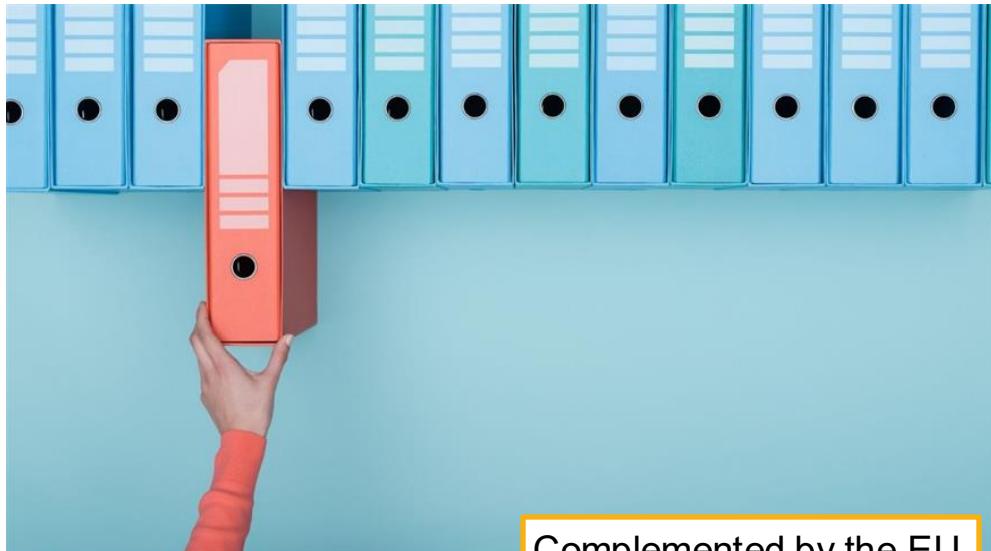
GD on Biomarkers of effects ([link](#))

Revision of GD on Weight of Evidence and Biological Relevance ([link](#))



GD CATALOGUE (Q1 2026)

GD CATALOGUE

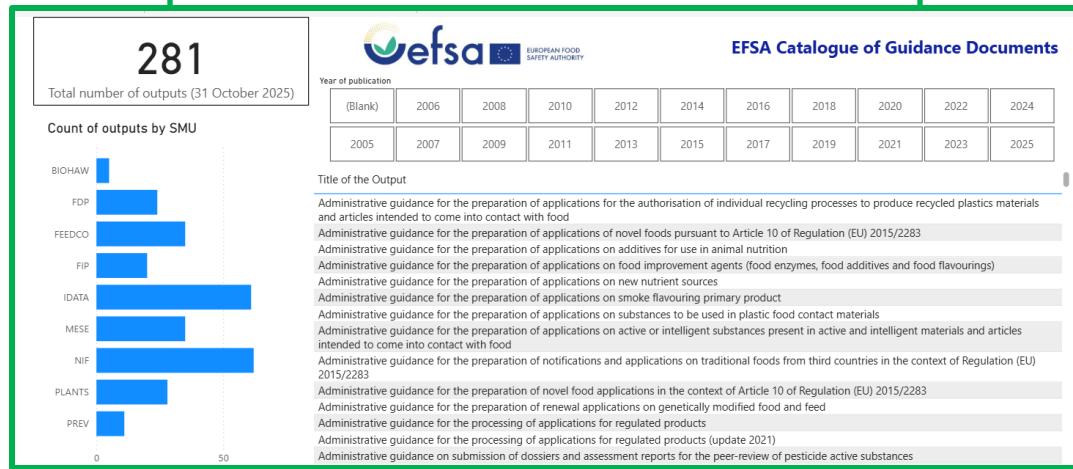


Complemented by the EU
Library of Food Safety GD

Benefits

- Single-entry point for GD
- Better GD retrievability, easy filtering by domain/authorisation type/...

First draft for internal use at EFSA



Prototype for publication on EFSA's website

The screenshot shows a prototype document listing on EFSA's website. At the top is a 'Filters & Sort' section with dropdowns for 'Food domain' (All food domains), 'Status' (All statuses), 'Data instructions' (All), and 'Applicability' (All applicability). Below it is a table with two rows of document details. The first row is for a document titled '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 from the Scientific Panels AFC/BIOHAZ'. The second row is for a document titled 'Statement on technical assistance on the format for applications for new alternative methods for animal by-products'.



NEW PUBLICATION FEATURES FOR EFSA GD (2027)



GD require regular review and update, and different publication features:

- ✓ **Versioning, better visualisation of major and minor GD revisions**
- ✓ Better **accessibility and link** with other GD and GD-related info
- ✓ More **interactive and user-friendly format**



New publication
platform (2027)

EU LIBRARY OF FOOD SAFETY GD - BACKGROUND



The EU Library of Food Safety GD is defined as *the curated collection of guidance documents, relevant to EFSA's scientific assessments ,developed by EU Member States' Competent Organisations and risk assessors.*



In the context of the One substance-One assessment and also the EFSA's Project on Guidance Architecture, the initiative of creating of EU Library of Food Safety GD was proposed at the end of 2023.



The initiative was discussed with the EFSA Advisory Forum in December 2024 and further on with Focal Points (February and November 2025).

OVERALL PROCESS

March-April 2025	Data collection
May-November 2025	Building the repository
December 25 to February 26	First Version of EU LIBRARY OF FOOD SAFETY GD
From February 2026	Library Maintenance (1/year)



NOVEMBER'25 – STATUS OF EU GUIDANCE REPOSITORY

Country	Docs submitted	Docs excluded	Docs on hold*	Docs included
Denmark	2	2	-	-
France	18	3	1	14
Germany	20	13	-	7
Hungary	1	1	-	-
Ireland	2	1	-	1
Italy	111	75	7	29
Latvia	2	1	-	1
Lithuania	1	1	-	-
Netherlands	4	1	-	3
Norway	1	1	-	-
Poland	2	2	-	-
Slovenia	1	-	-	1
Spain	1	-	-	1
Sweden	5	2	-	3
Switzerland	1	-	1	-
TOTAL	172	103	9	60

CRITERIA TO EXCLUDE DOCUMENTS [103 documents]	No. Docs
Obsolete	4
Not publicly available	2
Out of the EFSA's remit/Not Guidance Documents	97

* Documents not publicly available yet. Links to be provided.



REPOSITORY: SCREENSHOT

Country	Institution	Title of the output	Keywords	Abstract/Summary	Link	Year of Publication	Applicability	Food Domain	Status
France	ANSES	Évaluation du poids des preuves à l'Anses: revue critique de la littérature et recommandations à l'étape d'identification des dangers	Weight of Evidence, line of evidence, systematic review, transparency, evaluation planning, expert process, evidence integration	This guidance report by ANSES critically reviews existing literature on the "weight of evidence" (WoE) approach as applied in the hazard identification phase of risk assessment, and makes methodological recommendations to harmonize internal practices. It defines key concepts (e.g. line of evidence, WoE, systematic review), proposes a four-step framework (planning, establishment of evidence lines, integration, expression of conclusions), and evaluates ~25 methods from the literature according to criteria of directionality, relevance, and evaluates ~25 methods from the literature according to criteria of directionality, relevance,	https://www.anses.fr/fr/system/files/AUT_R2015SA0089Ra.pdf	2016	Cross-cutting	Animal Health;#Animal Welfare;#Biological Hazards;#Biological Hazards - Multiannual foodborne outbreaks;#Biological Hazards - ETRS zoonoses and AMR;#Biological Hazards - EURS - EURS TSE;#Contaminants;#Decontamination	Valid
Germany	Bundesinstitut für Risikobewertung (BfR)	Leitfaden für die Bewertung gesundheitlicher Risiken	Health risk assessment Hazard identification Exposure analysis Risk characterisation Risk communication Scientific transparency	The BfR's "Guideline for the Assessment of Health Risks" outlines a structured and scientifically grounded approach to evaluating risks to human health from food, feed, chemicals, microorganisms, and consumer products. The guideline defines four core steps: hazard identification, hazard characterisation, exposure assessment, and risk characterisation. It emphasizes transparency, reproducibility, and clarity in presenting risk assessments, referred to as "opinions." These assessments are intended to inform	https://www.bfr.bund.de/cm/350/leitfaden-fuer-gesundheitliche-bewertungen.62660711.pdf	2024	Cross-cutting	Contaminants Biological Hazards Veterinary Medical Products Residues (VMR) Pesticides Nutrition	Valid
Netherlands	NVWA	Animal welfare risk assessment methodology	Animal welfare Risk assessment Welfare Quality principles	This guidance document from the Office for Risk Assessment & Research (BuRo) of the Dutch Food and Consumer Product Safety Authority (NVWA) outlines the methodology used for assessing risks to animal welfare. Based on EFSA's framework and aligned with Codex Alimentarius principles, the method includes four key steps: hazard identification, hazard characterisation, exposure assessment, and risk characterisation. It integrates the Welfare Quality® principles to structure welfare-related hazards and consequences, focusing on	https://www.nvwa.nl/over-de-nvwa/documenten/nvwa/organisatie/buro/methodeijken/methodeijken-risicobeoordeling-dierenwelzijn	2022	Sector Specific	Animal Welfare	Valid
Slovenia	NIJZ	Instructions for assessing risk for human health due to exposure to chemical and microbiological hazards from the environment with selected chapters and practical examples, Part I	Risk assessment Chemical hazards Microbiological hazards Exposure evaluation Public health Predictive modeling	The document provides a comprehensive framework for assessing health risks from environmental chemical and microbiological exposures. It follows international standards, including EFSA, WHO, and Codex Alimentarius methodologies. Risk assessment steps include hazard identification, hazard characterization, exposure assessment, and risk characterization.	https://nijz.si/wp-content/uploads/2022/07/navodila_nijz_z_a_oceno_tveganja_kem_in_mikrobiol_dejavnikov.pdf	2022	Cross-cutting	Biological Hazards;#Contaminants;#Food Contact Materials (FCM);#Food improvement agents (FIA);#Pesticides monitoring;#Pesticides	Valid
Spain	AESAN	Guidelines of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) on the information required to perform the assessment of processing aids that are intended to be used in the preparation and production of food	Processing aids, assessment, guidelines, application, dossier.	The processing aids used in food preparation and production processes are regulated in Spain by Royal Decree 773/2023, which also defines them. There is also a specific regulation for the processing aids used in the production process of edible oils, which are regulated by Royal Decree 640/2015. As established in said Royal Decrees, the processing aids that do not appear in Annex I, and that are not referred to in sections 2 and 3 of Article 3 of Royal Decree 773/2023, and the processing aids used in the production process of edible oils that do not	https://www.aesan.gob.es/AFCOSAN/docs/documentos/publicaciones/revistas_comite_cientifico/LINFEAS_COADYUVANTES_TECNOLOGICOS.pdf	2023	Sector Specific	Other;#Processing aids	Valid
Ireland	Scientific Committee of the Food Safety Authority of Ireland	The Safety of Vitamins and Minerals in Food Supplements – Establishing Tolerable Upper Intake Levels and a Risk Assessment Approach for Products Marketed in Ireland	Vitamins, Minerals, Food Supplements, Tolerable Upper Intake Levels	The purpose of this report is threefold: (1) To provide scientific advice to the FSAI to develop guidance for the food industry on safety of vitamins and minerals in food supplements (2) To provide ULs and highest intakes of vitamins and minerals for population groups in Ireland to allow risk assessments of food supplements on Irish market, and (3) To outline the method for assessing the safety of food supplements for population groups	https://www.fsai.ie/getmedia/278afeef-0e80-492b-9aee-61ce44307cbf/9565_fsai_vitaminsandminerals_report_fa3(1).pdf?ext=.pdf	2020	Sector Specific	Nutrition	Valid
Sweden	Swedish Food Agency	Undeclared allergens in food - risk assessment guide	Undeclared allergens Risk assessment Food safety Dose-response Population exposure Cross-contamination	Food allergens are substances (often proteins) that commonly cause allergic reactions or other hypersensitivity issues. In food safety risk communication, as in this report, food that contains allergenic proteins (e.g., milk) are described as 'allergens' even though the specific food actually contains a number of different allergenic proteins. Allergens such as milk, peanut, or egg protein can go undeclared in food products due to mislabelling or contamination. Undeclared allergens can cause severe allergic reactions and a	https://www.livsmedelsverket.se/oms-publikationer/artiklar/2022/l-2022-nr-13-undeclared-allergens-in-food-risk-assessment-guide	2022	Cross-cutting	Other;#Allergens	Valid
Latvia	BIOR	Guidelines for the control of antimicrobial resistance development in agricultural production and veterinary practice in Latvia	Antimicrobial resistance (AMR) Veterinary medicine Responsible antibiotic use One Health Environmental contamination Zoonoses	This Latvian guidance document focuses on limiting the development of antimicrobial resistance (AMR) in agriculture and veterinary practice. It was developed under the AgroBioRes project and integrates international recommendations with national research findings. The document outlines the causes and spread of AMR, emphasizing the risks of improper antibiotic use, such as overuse, incorrect dosing, and lack of diagnosis. It highlights the environmental impact of antibiotic residues and the role of food in transmitting	https://lvb.lv/wp-content/uploads/2021/12/Vadlīnijas_VPP.pdf	2018	Cross-cutting	Biological Hazards - ETRS zoonoses and AMR	Valid
Italy	IZSLER	Valutazione del benessere animale nell'allevamento suino dallo svezzamento all'ingrasso - ClassyFarm	classyfarm, animal welfare, pig, weaning pig, fattening pig, self-assessment	"ClassyFarm is an IT platform of the Italian Ministry of Health, developed by the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna ""Bruno Ubertini"" (IZSLER), with the aim to categorise livestock farms based on their risk in animal welfare, biosecurity, and antimicrobial use. Within this platform, several data are inserted: in relation to Animal Welfare in pig farming, from the weaning phase to the fattening phase, a guidance and a checklist have been	https://www.classyfarm.it/images/documents/VET-AZIENDALE_AGGIORNATO_06-23/Manuale-SUINO-GRASSO-2018-LP-rev.3.pdf	2019	Sector Specific	Animal Welfare	Valid

EU LIBRARY OF FOOD SAFETY GUIDANCE DOCUMENTS



EU Library of Food Safety GD will be ready at the **end of February 2026** and then published with the EFSA Catalogue of GD



EU Library of Food Safety GD will be available from the **EFSA website**.
Branch of the EFSA Catalogue of GD



The Library will be organised and displayed on a **dashboard**.



The Library will be subject to Maintenance procedures



RECAP OF NEXT STEPS

Start piloting GD Governance and building EFSA GD WP

April 2026

March 2026

Publication of:

- Catalogue of EFSA GD
- EU Library of Food Safety GD



End 2026

Implementation

- **Governance**
- **GD Work Programme**
- **Process for GD Lifecycle**

2027

New way of publishing EFSA GD



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