

27 November 2024

09:00-13:00

Minutes agreed on 24 January 2025

**Location:** Webconference**Chair:** Ana Afonso (Head of the Nutrition and Food Innovation Unit)**Attendees:**

- o Network Participants:

Country	Name
Austria	AGES - Austrian Agency for Health and Food Safety Environment Agency Austria
Belgium	Sciensano VIB
Bulgaria	National Center of Public Health and Analyses Agrobioinstitute Risk assessment center on food chain
Croatia	Croatian Agency for Agriculture and Food
Cyprus	State General Laboratory
Czech Republic	Ministry of the Environment Crop Research Institute Výzkumný ústav rostlinné výroby, v.v.i.
Denmark	DTU FOOD National Food Institute
Estonia	Ministry of Climate Agriculture and Food Board
Finland	Ministry of Social Affairs and Health / Board for Gene Technology Finnish Food Authority
France	ANSES
Germany	Federal Agency for Nature Conservation Federal Office of Consumer Protection and Food Safety
Greece	HELLENIC FOOD AUTHORITY (EFET) Ministry of Rural Development and Food
Hungary	Ministry of Agriculture
Ireland	Food Safety Authority of Ireland Environmental Protection Agency
Italy	Inail
Latvia	Institute of Food Safety, Animal Health and Environment "BIOR"
Lithuania	Ministry of Environment
Luxembourg	ALVA
Malta	Malta Competition & Consumer Affairs Authority (MCCAA)
Netherlands	Wageningen Food Safety Research National Institute for Public Health and the Environment
Norway	Norwegian Scientific Committee for Food and Environment (VKM)



Romania	National Sanitary Veterinary and Food Safety Authority
Slovak Republic	Biomedical research centre, SAS Ministry of Agriculture and Rural Development of the Slovak Republic
Slovenia	Ministry of the Environment, Climate and Energy
Spain	National Commission of Biosafety Consejo Superior de Investigaciones Científicas (CSIC)
Sweden	Swedish Board of Agriculture Swedish Food Agency

- Observers:  
Federal Food Safety and Veterinary Office FSVO (Switzerland); National Food Authority (Albania); Food Safety Agency (Bosnia and Herzegovina); Food and Veterinary Agency (Kosovo); Field Crops Central Research Institute, General Directorate of Agricultural Researches and Policies, Ministry of Food and Agriculture (Turkey)
- European Commission/Other EU Agencies representatives: DG Sante
- EFSA:
  - Nutrition and Food Innovation (NIF) Unit; Ana Afonso (chair), Michele Ardizzone, Giacomo De Sanctis, Antonio Fernandez Dumont, Arianna Ferrari, Tilemachos Goumperis, Sara Jacchia, Paolo Lenzi, Aleksandra Lewandowska, Franco Maria Neri, Ana Martin Camargo, Nikoletta Papadopoulou, Pietro Piffanelli, Silvija Kolosevska, Tommaso Raffaello, Elena Sanchez Brunete, Reinhilde Schoonjans
  - ED Team Chief Scientist Office: Konstantinos Paraskevopoulos

## 1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Spain.

## 2. Adoption of agenda

The agenda was adopted without changes.

## 3. Agreement of the minutes of the 17<sup>th</sup> Network meeting held on 30-31 May 2024, in Brussels

The minutes of the 17<sup>th</sup> Network meeting had been previously agreed by written procedure on 10 July 2024.

## 4. Request to provide scientific and technical assistance for a regular horizon scanning to assess new scientific data on plants, animals, microorganisms and products thereof obtained by new genomic techniques

**Knowledge sharing - Possible MS involvement**



## **Abstract**

EFSA presented the recently received mandate from the European Commission, in which it is requested to i) periodically screen scientific literature to identify studies relevant for food and feed and environmental safety of GMOs obtained by New Genomic Techniques; ii) assess evidence present in the literature to see if it has any implications on EFSA scientific opinions; iii) critically assess the relevance and quality of papers. The mandate started in November 2024; the first deliverable is estimated in June 2025 and the next ones every six months after that until December 2026. At the end of the mandate its extension could be considered, based on need. The purpose of the exercise is to remain up to date with the fast progress in the research field of NGTs and ensure that EFSA's opinions of the topic remain up to date.

## **Discussion**

The Netherlands enquired to what extent grey literature, such as reports, assessments from non-EU authorities, and newsletters, would be screened in the proposed systemic search as part of the horizon scanning. EFSA clarified that to ensure the quality of the data collected, the initial intent is to include only scientific literature but broadening the scope would be considered.

Based on previous experience, The Netherlands emphasized the importance of screening not only scientific literature but also new developments, assessment reports from foreign authorities, magazine articles, and news items. The Netherlands highlighted the need to stay informed about what is happening in the field by incorporating a broad range of sources. EFSA clarified that the search will mainly focus on the assessment of food and feed, and environmental safety, rather than taking into considerations all possible new developments in NGTs. The aim of this mandate is to maintain a structured and up-to-date horizon scan to support future activities related to NGTs, focusing on risks and hazards identification based on new, reliable, and validated high quality scientific data. It was noted that the literature searches are expected to retrieve a significant number of papers, but not all of them would be relevant. EFSA emphasized that focusing on papers directly related to risks and hazards is important, as proof-of-concept papers may not be relevant. It was also emphasized that quality standards, including critical appraisal tools, would need to be considered, especially for validating the relevance of grey literature. EFSA raised the question of which languages, in addition to English, should also be included within the scope of the search.

Belgium agreed with the Netherlands on the inclusion of grey literature for the topic of risk assessment. Belgium also asked what input EFSA would require from the member states for this mandate. EFSA clarified that a preliminary discussion was taking place at this meeting and that future meetings could focus specifically on the protocol development. However, EFSA encouraged the Member States to provide input on the protocol's construction and to share literature searches on related topics. It was also specified by EFSA that assessment of the literature identified by the search would be performed internally.

France agreed with the idea of including grey literature, such as national institution publications. France also asked whether the scope would be similar to what was done by the Joint Research Centre (JRC) in 2021, listing NGT applications (and eventually focusing on the risks posed by such applications), or centred only around the risk. France highlighted that a scope centred only around the risks would probably limit the number of relevant publications. France also asked about the involvement of the Subgroup on NGTs.

EFSA explained the experience gained in conducting extensive literature searches, both internally and through external contractors, e.g. for developing EFSA's opinions on synthetic biology and cisgenesis. These opinions also included papers brought to EFSA's attention during public consultations by experts and Member States.



The plan to establish and test protocols and search strings, with an initial focus on plant NGTs, was discussed. The objective is to refine these methods to ensure they retrieve relevant publications, including those previously brought to EFSA's attention by the Member States, industry, NGOs and experts. High-quality criteria are essential to avoid irrelevant information. The goal is to create one set of strings that could be reused in six-month intervals.

During the first months of the mandate, EFSA will focus on developing and refining these search protocols and will involve Member States and other stakeholders to gather feedback and ensure the relevance of the search protocols. Finally, the concern about the vast amount of available literature and the need to establish strict selection criteria and quality standards to avoid wasting resources was discussed. EFSA reminded that the coming few months will be dedicated to establishing the protocol and testing search strings, focusing first on plants obtained by NGTs which are a priority. The first deliverable is estimated in June, and will include a description of the methodology to be reiterated every 6 months.

Until the next GMO Network meeting in May/June 2025, EFSA and Member States may exchange information via digital communications (e.g., emails, Teams meetings). Member States were invited once more to share work/studies from other related and already completed literature searches. EFSA may also apply AI tools to the initial screening steps (i.e., title and abstract screening), which will be later validated by internal reviewers' checks.

Slovenia considered the likely rise in NGT products placed on the market in the near future and posed a question on EFSA's plan for horizon scanning once this 2-year mandate will be closed in 2026. EFSA shared the plan to consider extending the mandate in two years, when future developments in AI may allow for an automated approach. Slovenia asked clarifications about the EFSA's plan for using AI in the literature screening step, and to what extent such tools would be implemented. EFSA clarified that the DistillerSR platform currently used already contains an in-built AI language model for initial steps such as title and abstract screening. Establishing high-quality criteria and a training dataset remains crucial for achieving good results with DistillerSR.

Ireland shared its experience on performing horizon scanning projects conducted over the past years, although on broader topics, by their team which could also be approached by EFSA if necessary. Ireland suggested to include grey literature in the search to be as comprehensive as possible and then apply established quality criteria for its assessment.

EFSA agreed with Ireland and emphasized that establishing quality criteria is necessary. The concept of ranking evidence, as described in EFSA's guidance for literature reviews, was also highlighted. Literature reviews conducted on emerging risks, which includes horizon scanning, was acknowledged as previous experience on the ranking approach.

## **5. Updates from Member States on GMO risk assessment:**

### **New genomic techniques - BfN activities**

The BfN presented an overview of important completed, ongoing and upcoming R&D projects on NGTs. They cover a broad field and range from environmental risk assessment, monitoring, traceability and technology assessment to horizon scanning. The projects deal with different organisms, namely crops, wild plants, animals and microorganisms. A recently launched project investigates the ecological impact of GMOs becoming established in natural habitats and how these could be assessed prior to approval. Another recent project examines the current state of knowledge for the application of synthetic biology, taking into account artificial intelligence, to microorganisms to support risk assessment and policy advice. The



presentation includes a list of selected peer-reviewed publications resulting from recent R&D and other projects.

### **Discussion**

EFSA thanked Germany for the presentation on BfN activities and suggested to keep EFSA updated on progress of the projects mentioned, especially related to NGTs and RNAi. EFSA proposed to use a common channel (e.g. Teams channel) to share publications of relevance for the GMO network, also including current advances in synthetic biology and other technologies.

The Netherlands asked Germany for the possibility to participate in some of the projects or workshops mentioned in the presentation. Germany agreed to discuss this possibility with colleagues involved in the organization of these events.

Slovenia also expressed interest in following the progress of the mentioned projects and participating in the related meetings and requested an explanation of the definition of near-natural ecosystems, which was mentioned in the presentation. German suggested that a definition will be provided within the project itself.

Belgium has also asked for clarification on operationalization of technology assessment for GMOs. Germany explained that the scope of the project goes beyond what is in the legal requirements for the risk assessment of GMOs and it includes the evaluation of the impact on the society and economy of countries where GMOs are grown.

### **Updates from other MS**

EFSA encouraged Member States to communicate activities on areas that are relevant to EFSA and the GMO Network.

The Netherlands shared information regarding two commissioned studies by the Dutch Government. The first study, carried out by Perseus, focused on the interpretation of the GMO definition in the EU Member States. It examined specific elements of the definitions provided in the European directives on contained use and deliberate release and included a hypothetical case study. Contributions were made by many EU Member States, and the study was published the week before the network meeting. The study can be accessed at this link <https://www.rijksoverheid.nl/documenten/rapporten/2024/11/20/interpretation-of-the-gmo-definition-in-eu-member-states>.

The second study, also commissioned by the Dutch Government, involved sampling the vicinity of industrial settings for pathogens and GMO identification. This project was still ongoing and was expected to be published very soon.

An update was also shared from Hungary, noting that Hungary held the Presidency for the Council this semester. It was mentioned that there were two NGT working party meetings in progress. At the last meeting, where EFSA was also in attendance, two funded projects representatives were invited to discuss detection and identification issues. The Detective and Darwin projects can be accessed at the following links:

DARWIN: <https://data.consilium.europa.eu/doc/document/ST-15818-2024-INIT/en/pdf>

DETECTIVE: <https://data.consilium.europa.eu/doc/document/ST-15819-2024-INIT/en/pdf>

Slovenia informed that in early 2024, two scientific committees issued an opinion regarding the proposed Commission proposal on NGTs. The scientific committees welcomed the Commission proposal on regulation on NGT plants and were supportive of the introduction of the two categories for plants obtained by NGTs. It was suggested that a summary of the



scientific opinion from the two scientific committees involved in national level processes could be shared.

## **6. EFSA OMICS roadmap – Discussion on possible relevance of OMICS data in GMO risk assessment**

### **Abstract**

EFSA presented an overview of the recently completed procurement to develop a comprehensive roadmap for action on implementing omics and associated bioinformatics approaches in risk assessment (RA), addressing a strategic objective for the wider application of these technologies in the future. The scope of the roadmap spanned across seven key areas including GMOs, novel foods, plant and animal health etc, focusing on five risk assessment development areas that intersect with the various omics technologies.

The roadmap identified several knowledge gaps and challenges for the broader incorporation of Omics in RA, focusing on the key omics approaches: advancing the use of genomics, incorporating proteomics/metabolomics/transcriptomics as well as metagenomics, and multiomics. Key challenges include regulatory constraints, lack of standardization, data access issues, and the need for fit for purpose reference databases.

The roadmap recommended several future actions/projects with varying levels of regulatory readiness, from high-priority items like harmonising hybrid sequencing approaches to moderate-priority items like metagenomics adoption. Two specific project proposals were highlighted in detail:

- a) Omics-based risk assessment of GM plants, which aims to complement traditional assessment methods with comprehensive molecular profiling approaches.
- b) Allergenicity assessment for novel foods, focusing on using untargeted proteomics to identify potential allergenic risks.

In addition, some information on the next steps was presented on how the Implementation will proceed and steps highlighted included: through expert exchange in EFSA's KIC BIOTECH, internal and external discussions and stakeholder engagement at the European and international level to ensure wide alignment on the priorities.

This initiative represents a significant effort to shift toward more comprehensive, data-driven risk assessment methodologies in food safety, particularly emphasising the need for standardisation and integration of modern analytical techniques into regulatory frameworks.

### **Discussion**

The Netherlands emphasised the relevance of the work to the OECD working party on the safety of foods and feeds. It was suggested that this work should also be presented there. The importance of framing the issue correctly was highlighted, as there was concern about overburdening applicants and authorities with additional requirements beyond of what is already mandated. The need to present new methods as facilitators for risk assessment, rather than complicating the process, was underlined. An additional comment was made regarding animal studies, suggesting that hypothesis-driven approach could be useful in the frame of omics data. For instance, in the case of a crop that produces pro-vitamin A, focusing the assessment on specific carotenoids rather than conducting a holistic profile assessment would be preferred.

EFSA acknowledged that the request for additional/new requirements to the applicants should be indeed carefully considered. However, the inevitable need to progress to a more



informative and holistic approach should also be taken into account, considering the increased complexity of products that need to be risk assessed.

Ireland noted that different omics approaches have been used in the past, and while a targeted omics approach can be preferred on a case-by case basis, the holistic approach is still relevant in risk assessment. Ireland has also voiced concerns about a lack of a harmonised system for sampling and reporting of food allergens in EU and for the over focus on allergens in GMOs. Ireland acknowledged that identifying allergens is a relevant part of the risk assessment; however, upon discovery, questions would remain about the resulting impact on product labelling. Reference was made to the WHO/FAO expert group that reassessed the priority allergens for Codex, noting that soya was removed due to low prevalence, along with other allergens. Ireland also suggested that if a new allergen was to be identified, it would need to be assessed in terms of prevalence, potency, etc., before taking further action. Finally, it was recommended to focus on the 14 priority allergens currently recognized in Europe, rather than searching for potential new allergens without solid evidence of their presence in GMOs seen so far.

EFSA also mentioned the upcoming omics-related discussion at the Advisory Forum meeting, encouraging feedback on the risk assessments areas needing further advancement as identified by the roadmap and which would require prioritising.

Belgium pointed out the need to firstly identify current risk assessment challenges that new tools such as omics could help addressing. Belgium also asked whether feedback on the questions posed during the presentation could be provided after the meeting.

EFSA highlighted the need to broaden the discussion, aiming to engage (and align) on the European and international levels to define the next steps.

## **7. Tackling challenges in recycling GMM fermentation waste**

### **Abstract**

Finding environmentally friendly solutions for treating Class 1 GM micro-organism waste from large scale fermentation processes poses certain challenges due to the properties of the processed fermentation mass. In order to recycle the mass for further purposes using a composting process, several different requirements from different regulations (e.g. GMO, waste, fertilizer and environmental legislation) must be fulfilled without causing excessive costs to the operators involved. In practice, the GM micro-organisms have to be inactivated either before or during the composting process, and this has to be confirmed. The risk assessment involved as well as sampling from the composting process have some features that proved challenging for the Finnish authorities and operators when trying to simultaneously fulfil several legal obligations.

### **Discussion**

Denmark asked whether any concern was given to residual DNA and genes of concern (e.g., AMRs). Finland confirmed that AMRs were taken into consideration, while residual DNA was not considered a problem due to the type of enzymes produced. Finland further explained that the main point of interest was the viable organisms, rather than pure DNA and or nucleic acids. While horizontal gene transfer was considered as a possible issue, the origin of the strains used and the related genetic inserts were not different from what is already present in the soil.



Netherlands asked some clarifications on the use of the term 'waste' to refer to byproducts, as often the biomass or the co-/by-products of fermentation can still have alternative uses. Finland agreed that the term should only be used for products with no additional possible uses.

EFSA mentioned that the guidance for the risk assessment of genetically modified organisms which was published in 2011 will be soon replaced for the molecular characterization and the environmental risk assessment parts. The updated guidance, called the 'Draft guidance on the characterisation and risk assessment of microorganisms used in the food chain', is expected to be open for consultation soon. This overarching guidance applies to all EFSA units dealing with microorganisms, both GM and non-GM. The environmental risk assessment chapter has been significantly developed and for GMMs are to be aligned with the areas of concern of the Directive 2001/18 /EC and it is based on a problem formulation approach. It was also suggested to monitor the public consultation of this document and inspect the relevant chapters to see what is applicable for the cases presented by Finland.

Germany asked clarifications on the fact that inactivating GMMs in contaminated material is optional for GMMs of risk class 1, and whether GMMs containing AMRs could still be categorized as class 1. Finland clarified that most of the microbial or bacterial strain used in the contained use do contain AMR genes for selection purposes. Finland also explained that they have always been labelled as risk class 1 in contained use. However, the risk classification depends on the facilities and the uses.

EFSA asked whether there were any specific considerations on the legal routes and applicability of the directive, especially focusing on any actions required by companies. Finland specified that so far the decisions were taken at the national level and specific conditions for the companies involved were set by the national competent authority. However, it was noted that similar issues would be faced when future cases occur. The European Commission has proposed initiatives to address some challenges caused by the horizontal legislation on biotechnology, although it is unclear whether this issue will be among them. Ambitious goals related to the Green Deal and circular economy in the future Commission were acknowledged, suggesting that it might take time to solve all these challenges. Finland welcomed comments and suggestions on how to handle such scenarios.

The Netherlands informed that some activity is planned to sample the vicinity of industrial settings (including medical companies) to identify pathogens and GMOs. The collected data may be analysed by applying AI and machine learning techniques in order to link environmental and water parameters to the presence or absence of harmful organisms. This work will improve risk assessment and management strategies.

EFSA provided more information on the 'Draft guidance on the characterisation and risk assessment of microorganisms used in the food chain' mentioned above. The initiative originated from the feed additive area, where extensive experience in risk assessment of fermentation products from GM and non-GM organisms exists. Since 2018, guidances have been developed and updated, for example with the whole-genome-sequencing approach. Similar experience exists for food enzymes, and from the biohazard area experiences with qualified presumption of safety (QPS) organisms are built up, and the pesticides area is now covering microorganisms as well. As a result, microorganisms are frequently characterized in EFSA. Therefore, EFSA considered that a single guidance should be developed to align the risk assessment strategies across different Units. This new draft will be published soon. The main part the document is focusing on updates for the characterization of microorganisms and incorporates a newly developed section for environmental risk assessment. The food and feed risk assessment part remained closely linked to the intended product use. Therefore, the aspects related to ingestion by animals or humans are not as elaborated in this document



since the requirements remained those applicable to feed additive, food enzyme, and possibly novel food.

EFSA acknowledged that challenges were faced when developing the environmental part of the new guidance due to limited experience, particularly with GMMs. The existence of intrinsic and acquired AMR genes also is well acknowledged. The new guidance informs when the presence of such genes is considered to pose a risk or a hazard, e.g. by considering exposure scenarios and degradation. This may be more investigated in specific environments such as composting. Fermentation products are (partially) purified and void of viable cells. The guidance includes information on inactivated cell biomasses, fermentation products, biomasses, as well as active agents (living cells), thus covering biomass in various ways.

The guidance can be informative if a national authority would need to assess the safety of a specific use of a microorganism (such as contained use). The guidance is expected to be completed by June 2025, with public consultation expected before the end of 2024. The outcome of the public consultation is to be published with the draft document. A more detailed presentation on the guidance contents is planned to be included during the next meeting.

The participants were encouraged to forward answers to questions sent by the Finland's representative.

Update after the meeting: public consultation is available via this link: <https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0ITk0000035F1V/p/c1221>

## 8. Updates on previously presented topics

- **Scientific opinion on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques)**

### **Abstract**

EFSA presented an updated on the mandate on the application of New Genomic Techniques (NGTs) to animals for agricultural, food, and feed purposes. EFSA summarized the structure of the draft scientific opinion which reports potential novel hazards and risks posed by these biotechnological developments compared to conventional breeding and established genetic modification techniques and assesses the adequacy of relevant existing EFSA guidelines for risk assessment of GM animals. EFSA outlined the timeline for finalizing the draft opinion, with public consultation planned for early 2025 with the final scientific opinion expected by June 2025.

### **Discussion**

No questions were received during the meeting. EFSA agreed to inform the GMO Network when the public consultation will be opened.

Update after the meeting: public consultation is available via this link: : <https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0ITk000003Wxsr/pc1293>

- **Scientific opinion on new developments in biotechnology applied to microorganisms**

EFSA informed the GMO Network that the scientific opinion of the GMO Panel was published. The document can be accessed [at this link](#).



- **Request for placing on the market of Soy Leghemoglobin produced from genetically modified *Pichia pastoris* (EFSA-GMO-NL-2019-162)**

EFSA informed the GMO Network that the scientific opinion of the GMO Panel was published. The document can be accessed [at this link](#).

- **Mandate of the Panel on proteins' safety**

**Abstract**

EFSA presented the current state of the mandate and summarised the key elements of the document. EFSA highlighted the importance of the public consultation step in the process. It is expected that the draft document will be launched for public consultation by mid-January 2025. All participants were encouraged to participate to the consultation for the benefit of the activity.

**Discussion**

No questions were received during the meeting. EFSA agreed to inform the GMO Network when the public consultation will be opened.

- **Development of risk assessment methodology for RNAi-based GMPs**

**Abstract**

EFSA has established a risk assessment approach in compliance with the Commission Implementing Regulation (EU) No 503/2013 to assess GM plants designed to induce gene silencing through RNA interference (RNAi), based on available scientific evidence ([Pačes et al., 2017](#); [Christiaens et al., 2018](#); [Dávalos et al., 2019](#)). In the frame of the developmental project "Review of risk assessment methodology for RNAi-based GM plants" and related internal mandate M-2024-00157, EFSA investigated whether updates are needed to improve the current risk assessment methodology based on more recent studies and new evidence from the evolution of the scientific knowledge in this area in the last seven years. EFSA updated the GMO Network on the progress made and informed that a bioinformatic script was developed to identify plant RNAi off-targets and a EFSA guidance (EFSA-Q-2024-00613) is currently being developed, to be published in the first quarter of 2025.

**Discussion**

The Netherlands expressed some concerns regarding the uploading of the sequences to an external server, as this step may be a problem for confidential data such as the sequences of the events.

EFSA explained that the tool would be designed to be downloaded and run in the user's own secure environment, without the use of any web interface requiring the data to be uploaded to an external server. This process will safeguard the confidentiality of the applicant's data.

The Netherlands asked whether the bioinformatic tool is intended for use in all double-stranded RNA applications, including those not related to GM plants, such as plant protection products. EFSA clarified that the project aims at fulfilling the requirements of the Implementing Regulation 503/2013 related to GM plants. In case the tool was to be used for biopesticide risk assessment, it would likely need to consider non-target organisms. However, the parameters as set for this project are established to assess the off-target effects in plants, and the parameters for animals and other organisms



would need to be adjusted accordingly. However, the tool could potentially be modified to accommodate different parameters since it is open source.

## **Closure of the meeting**

The Chair thanked the GMO Network members for their active participation and the fruitful discussion. The chair informed that the next meeting will be held in presence, in Poland (dates to be communicated). The chair informed that the draft minutes of the 18th GMO Network meeting will be shared with the participants and published on the EFSA website together with the presentations within 15 working days. The meeting was closed at 13:00.