Annex IV – Scientific expertise

- **Microbiological characterisation and assessment of possible genetic modifications of the microorganisms used as additives or as production strains in the food or feed chain:** identification of the microorganism (including analysis of whole genome sequence), antimicrobial susceptibility (including use of whole genome sequencing and phenotypic testing), antimicrobial production, toxigenicity and pathogenicity, genetic modifications (including analysis of its purpose, characteristics and structure), absence of the production strain, presence of DNA from the production strain, impact on gut microbiota, compatibility with other additives showing antimicrobial activity.
- **Microbiological risk assessment of novel foods including expertise in the safety assessment of food enzymes.**
- **Chemistry and microbiology (viruses, bacteria, fungi, etc.)**.
- **Chemical and physicochemical characterisation of novel foods including expertise in NMR, mass spectrometry and in the characterisation of chemical complexes and/or nanomaterials**.
- **Physical-chemical properties of plant protection products and their active substances**.
- **Methods of analysis of plant protection products and of their residues**.
- **Toxicology and regulatory toxicology**: including ADME, short- and long-term toxicity, genotoxicity, reproductive and developmental toxicity, immunotoxicity, neurotoxicity, developmental neurotoxicity.
- **Non dietary exposure and risk assessment of plant protection products**: operator, worker, resident and bystander.
- **Environmental fate and behaviour of plant protection products**.
- **Ecotoxicology**.
- **Ecology and population dynamics**.
- **Ecological/Environmental exposure and risk assessment**.
- **New approach methodologies:** (e.g. in silico approaches, in chemico and *in vitro* assays, new testing tools, such as “high-throughput screening” and “high-content methods” e.g. genomics including where appropriate the analysis of (whole) genome sequencing, proteomics, metabolomics).
- **Physiology and metabolism of yeasts and filamentous fungi:** characterisation of strains of yeast and filamentous fungi in terms of production of toxins and/or secondary metabolites with potential toxicity to humans. Physiology and metabolism of yeasts and filamentous fungi during industrial fermentations, with emphasis of potential production of toxins and/or secondary metabolites.
- **Horizontal gene transfer (HGT) from genetically modified plant to micro-organisms**: molecular biology to identify the origin and biological function of the genetic elements included in the event/s under evaluation and to assess the outcome of the bioinformatic analysis requested to the applicant to identify cases in which HGT is facilitated. Specific expertise in microbiology, microbial ecology and soil ecology to identify the possible consequences of HGT. Familiarity with the main peculiarities of the GM crops and on the fate of DNA and proteins.
- **Agronomic and phenotypic characterisation of cultivated plants:** field trials are conducted to collect agronomic, phenotypic and compositional parameters of the GM plants and of its appropriate controls. Commission Regulation (EC) 503/2013 requires that the field trials are representative of the condition under which the GM crop will be cultivated. The individuals are required to have expertise in plant breeding to evaluate the quality and the appropriateness

selection of the starting materials used to conduct the field trials. Expertise in agronomy is required to appraise the quality and representativeness of the selected field trial sites, the applied management practices and the agrometeorological conditions in respect to the specific crop under assessment, its specific characteristics and its intended use. Expertise in plant physiology is also needed to identify the occurrence of specific environmental conditions (e.g biotic and abiotic stressors) and to assess the possible consequences for the plant growth. Expertise in weed management is required to evaluate the representativeness and the appropriateness of the applied herbicide regimes.

- **Efficacy studies of feed additives in target animals (covering both food-producing animals and pets and non-food producing animals)**: efficacy of the additive according to common feed manufacturing, animal husbandry and farming practices in the European Union, endpoint analysis of short and long-term (*in vivo*) studies.
- **Safety studies (e.g. toxicological studies) of food, feed additives food contact materials and GMO**: absorption, distribution, metabolism and excretion (ADME) and (marker and total) residue studies in target and laboratory animals, toxicology studies (including genotoxicity, sub-chronic oral toxicity, chronic oral toxicity, carcinogenicity, reproduction toxicity), determination of a safe dose, highest safe intake, consumer exposure, maximum residue limit (MRL) and withdrawal period, toxicological effects on the respiratory system/eyes and skin/blood, exposure via all routes.
- **Dietary exposure assessment for food enzymes:** preparation of input data to launch call-for-data. Collating and processing data of food consumption, food processing and recipes. Disaggregation of national dietary survey to FoodEx system. Familiarity with dietary surveys, preferably with direct experience in conducting those surveys, and with food composition tables. Knowledge about food processing technology.
- **Dietary exposure assessment – Plant protection products risk assessment**: the individuals are required to have scientific expertise in performing consumer dietary risk assessment in the framework of the setting of Maximum Residue Levels (MRLs) in the framework of Commission Regulation (EC) No 396/2005 and/or the peer review residues assessment under Regulation (EC) No 1107/2009, e.g. assessment of the metabolism of pesticides in plants and in livestock, assessment of the supervised residue field trials, setting of MRLs (refer to the 'Residues in or on treated products, food and feed' part of the data requirements for active substances: Commission Regulation (EU) No 283/2013 and Regulation (EU) No 544/2011).
- **Literature Review analysis in the field of feed:** extract critical data from the technical dossier and from systematic/extensive literature search where applicable and prepare a summary describing the study design (when relevant), key findings/study observations, indicating the relevance of critical data, highlighting uncertainties and inconsistencies identified and missing information applicable to different categories of additives (such as technological additives, sensory additives, nutritional additives, zootechnical additives, coccidiostats and histomonostats) as well as for the environment.
- **Statistical analysis in the field of feed:** assess the statistical analysis provided for tolerance and efficacy studies for feed additives including the design of the experiment, its sample size applicable to different categories of additives (such as technological additives, sensory additives, nutritional additives, zootechnical additives, coccidiostats and histomonostats).
- **Environmental risk assessment of feed additives**: phase I assessment (including calculation of PEC in soil, groundwater or sediment for sea cages) and phase II assessment (including physico-chemical properties, environmental fate, PEC and PNEC calculations and their estimated refinements values, toxicity tests for the terrestrial/fresh water/marine compartments).

- **Industrial fermentations and downstream processing:** production of substances by fermentation (submerged, semi-solid and solid state) using microorganisms at pilot and industrial levels. Downstream process including filtration, concentration, chromatography and other related purification processes, formulation.
- **Epidemiology, with experience in the analysis of animal health and welfare data for surveillance, outbreak investigation, vaccine efficacy estimation, sample size calculations and statistical and mathematical modelling for risk assessment purposes:** proficient knowledge and experience using statistical analysis software, such as R or SAS or any other application in line with EFSA strategy. Proven experience in all three packages will be needed, as adapting scripts from one package to another will be required. Solid demonstrated experience in analysing disease outbreak and surveillance data, sample size calculations and disease modelling. Experience in assessing the direct and indirect effects of vaccination strategies for disease control. Experience in the development of spread models and evaluation of different control measures (with vaccination among others). Knowledge and experience in estimation of the Basic reproduction ratios (R0) under different control strategies.
- **Scientific evaluation on animal health standards and animal disease control strategies (eradication measures, contingency planning, etc)**.
- **Animal welfare, with experience on the assessment of Animal Based Measures** for commonly farmed species (poultry, cattle, pig) and/or minor species (rabbits, horses, small ruminants, ratites, camelids). Proven experience in the application of welfare protocols based on the assessment of Animal Based Measures at farm level or during transport or during the slaughter process.
- **Expertise in the area of Geographical information Systems and analysis, model building in ArcGIS, Cartography and graphic design**
- **Proven experience in systematic or extensive literature searches in the areas of animal and plant health and plant protection products**.
- **Data science:** Design of data models, deep knowledge on international standards for animal health and welfare, data management, reporting.
- **Plant health risk assessment:** pest categorisation, pest risk assessment, commodity risk assessment, plant pest surveillance, horizon scanning
- **International standards on phytosanitary measures:** interpretation, compilation and analysis of phytosanitary measures; international standards for phytosanitary measures (ISPMs).
- **Plant pathology**; plant mycology, plant bacteriology, plant virology, plant nematology.
- **Entomology or acarology**: agriculture entomology, forest entomology, agriculture acarology, forest acarology.
- **Statistical and mathematical modelling for plant health risk assessment purposes:** plant disease epidemiology, insect population ecology, modelling plant pests' invasions, sample size calculations, including proficient knowledge and experience using statistical analysis software.
- **Statistical analysis with expertise in human study designs.**
- **Regulatory science:** experience in reviewing and assessing dossiers for regulated products in compliance with relevant legal framework, administrative and scientific guidance documents.

Indicative tasks according to scientific expertise

Tasks \ Scientific expertise	Microbiological characterisation and assessment of possible genetic modifications of the microorganisms used as feed additives or as production strains in the food or feed chain	Microbiological risk assessment of novel foods including expertise in the safety assessment of food enzymes	Chemistry and microbiology (viruses, bacteria, fungi, etc.)	Chemical and physicochemical characterisation of novel foods including expertise in NMR, mass spectrometry and in the characterisation of chemical complexes and-or nanomaterials	Physical-chemical properties of plant protection products and their active substance	Methods of analysis of plant protection products and of their residues	Toxicology and regulatory toxicology	Non dietary exposure and risk assessment of plant protection products	Environmental fate and behaviour of plant protection products	Ecotoxicology	Ecology and population dynamics	Ecological/Environmental exposure and risk assessment	New approach methodologies	Physiology and metabolism of yeasts and filamentous fungi	Horizontal gene transfer (HGT)	Agronomic and phenotypic characterisation of cultivated plants	Efficacy studies of feed additives in target animals	Safety studies (e.g. toxicological studies) of food, feed additives, FCM and GMO	Dietary exposure for food enzymes	Dietary exposure assessment – Plant protection products risk assessment	Literature review and/or Statistical analysis	Environmental risk assessment of feed additives	Industrial fermentations and downstream processing	Epidemiology	Scientific evaluation on animal health standards and animal disease control strategies (eradication measures, contingency planning, etc)	Animal welfare, with experience on the assessment of Animal Based Measures	GIS Expertise	Data science	Plant health risk assessment	International standards for phytosanitary measures	Plant pathology	Entomology or acarology	Statistical and mathematical modelling for plant health risk assessment purposes	Statistical analysis with expertise in human study designs	Regulatory science: Reviewing dossier for regulated products
Provide preliminary completeness check of dossiers, in compliance with EFSA administrative and scientific guidance document	X	X	X	X											X	X		x			X	X	X					X	X	X	X	X	X	X	
Analyse and extract critical data from dossier submitted (factual/key findings/ observations /uncertainties /missing information) and prepare summary reports	X	X	X	X											X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Perform additional literature search and/or statistical analysis, when needed		X	X	X														X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	
Prepare of input data to launch call-for-data. Collate and process data of food consumption, food processing and recipes. Disaggregate national dietary survey to FoodEx system																			X																
Preparation of draft assessments on the pesticide residues in plants, residues in livestock and consumer risk assessment, on the basis of the Member State Assessment report																				X															
Analyse the data provided in Draft/Renewal Assessment Report (DAR/RAR) provided by the responsible Rapporteur Member State and any supporting documents					X	X	X	X	X	X	X	X	X	X	X	X				X	X		X	X			X								X
Preparation of draft assessment on the specific chapter of the DAR/RAR					X	X	X	X	X	X	X	X	X	X	X	X				X	X		X	X			X								
Prepare summary report from literature for risk assessment purposes on animal health and animal welfare: data extracted from methodology and result section (key findings/uncertainty/conclusions/recommendations/gaps).																								X	X	X	X		X	X	X	X	X	X	
Perform GIS analysis on vector or raster data and apply a GIS workflow; making maps in a variety of ways and present the in a multitude of media																								X	X	X	X		X	X	X	X	X	X	

Attend meetings, either physically or via web-conference if necessary	X	X	X	X	X	X	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		X