

# Organisation Information Collection Form

This is a template for the collection of information at national level, to assess if an organisation complies with the criteria of inclusion in the List of Competent Organisations<sup>1</sup> (ref. [eligibility criteria – Commission Regulation \(EC\) No 2230/2004](#)). The information requested in this form is the minimum information for the assessment of organisations; Member States may require further information to assess organisation, considering their particularities and needs at national level.

The form is to be used by an interested organisation to provide information to the respective EFSA national Focal Point. The collected information consists of two main parts: Parts 1-4: identification information, called "Organisation details", Parts A-D: "Information for Member State Assessment" providing information and referencing to documents to support verification of an organisation compliance with the criteria set out in the Regulation (EC) 2230/2004, Art.1 a) - d). There is an indicative link between questions numbering (A-D) and the information collected to support assessment of compliance against the respective criteria set out of the Regulation. In addition, the form needs to be accompanied by documents supporting the data/information provided by the organisation.

The collected information will then be used, at national level supported by the Focal Point, to assess the organisation's compliance with the inclusion criteria. The information provided by an organisation to the Focal Point is stored by the Focal Point in accordance with national regulation and rules in their organisation, **for at least seven years.**

Following a positive assessment, at national level, on compliance of the organisation with the criteria, the organisation profile/account is created by the Focal Point in the online tool (Competent Organisations Database). This tool/Database is provided by EFSA for the maintenance of the List of Competent Organisations. The Focal Point provides to EFSA a summary of the Member State assessment, which has previously been performed at national level.

EFSA reviews the provided information in the tool to ensure compliance. The organisation then needs to be formally designated to EFSA by the Member State via its Permanent Representation/Mission to the EU. Upon approval of EFSA's Management Board, the organisation is included in the List of Competent Organisations.

The List of Competent Organisations is published at the EFSA website and notified in the Official Journal of the European Union ('C' series) upon each Management Board decision on updating the List.

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<sup>1</sup> The "competent organisations" are legal entities established in the EU Member States, operating in the fields within the EFSA's mission, complying with a set of legally established criteria, which are designated by Member States to be in a position to assist EFSA in its mission [please, refer further to Art.36 of the General Food Law - Regulation (EC) 178/2002 and the corresponding implementing rules - Regulation (EC) 2230/2004].

**Structure of the Information Collection Form**

**Organisation details .....3**  
**Information for Member State Assessment .....6**  
**Declaration .....12**

## Organisation details (Parts 1-4)

### 1. Details on the legal entity

1.1 Official Name of the organisation in original language	
1.2 Abbreviation of the organisation`s name	
1.3 Name of the organisation in English	
1.4 Abbreviation of the organisation in English	
1.5 Street name and number	
1.6 Postal code	
1.7 Town / City	
1.8 Country	
1.9 Website / URL	
• 1.10 Institutional Publication Repositories, i.e. reference to org. publications on major scientific portals, e.g. on Research Gate	
1.11 Legal Entity Form (LEF) Number	

• not mandatory information

### 2. Details of the Organisation`s Administrative Contact Person

2.1 First name	
2.2 Last name	
2.3 Title	
2.4 Position / Role	
2.5 Phone	
• 2.6 Phone 2	
• 2.7 Fax	
2.8 e-mail	
• 2.9 e-mail 2	

### • 3. Organisation`s remit(s):

(not mandatory information, possible to choose more than one option)

- 3.1  risk assessment
- 3.2  risk management
- 3.3  risk communication
- 3.4  risk-benefit assessment
- 3.5  regulatory science
- 3.6  research

#### 4. Organisation's competences with regard to food and feed chain

Specific fields of competences (for your organisation, chose at least one of following areas within the EFSA's mission):

- 4.1  **plant health:** covers the risks of plant pests and pathogens to agriculture, landscape or forestry plants and biodiversity
- 4.2  **plant protection products and/or their residues:** covers evaluation of potential risks to humans, animals and the environment; MRLs of pesticides in food; pesticide residue levels in food and related human exposure
- 4.3  **genetically modified organisms (GMOs):** covers GM plants, GM microorganisms and GM animals and the evaluation of their impact on food, feed or the environment
- 4.4  **food additives, flavourings and smoke flavourings** and covers their safety
- 4.5  **food contact materials, enzymes and/or processing aids** covers used in food production: safety of food enzymes (including those from genetically modified microorganisms), substances used to manufacture food packaging / other food-contact materials, and processing aids used in food production
- 4.6  **products or substances used in animal feed:** covers safety and/or efficacy of additives and products and/or substances used in animal feed for target species, consumers and users
- 4.7  **animal health and/or welfare:** covers animal diseases and well-being of food-producing animals during breeding, rearing, transportation and slaughter; includes impact analysis that the conditions and treatment of animals can have on both animal and human health
- 4.8  **biological hazards:** covers hazards (bacteria, viruses, fungi, parasites – also those causing food spoilage) transmitted from animals/other sources to humans via food; food hygiene; antimicrobial resistance; TSEs e.g. BSE, scrapie; animal-by product processing
- 4.9  **chemical contaminants** in the food chain: covers chemicals unintentionally in food/feed via food production, distribution, packaging, consumption, or in the environment naturally or via human activity; mycotoxins; biotoxins; veterinary drug residues; unauthorised substances in food / animals
- 4.10  **human nutrition, dietetic products, allergens and/or novel foods:** covers human nutrition, diet and allergens; food products with nutrition or health benefit claims; dietary reference values for nutrients and energy intake; novel foods
- 4.11  **environmental risk assessment (ERA):** covers impact of plant protection products, feed additives, GMOs, invasive alien species, etc. on biodiversity, ecosystems and the environment, in general
- 4.12  **nanotechnology:** covers nanoscience and nanotechnologies in relation to food / feed safety, including engineered nanomaterials in

food additives, enzymes, flavourings, food contact materials, novel foods, food supplements, feed additives and pesticides

- 4.13  **emerging risks:** covers identification of emerging risks in the food chain, i.e. risks from newly identified hazards to which a significant exposure may occur, or from unexpected new or increased significant exposure and/or susceptibility to known hazards

Note: For each selected competence, the organisation will need to specify **at least one contact person** in the online tool later when the Organisation's Administrative Contact Person will be asked to enter the organisation's details. One contact can cover also more than one competence.

## Information for Member State Assessment (Parts A-D)

A.1 Does your organisation carry out **scientific** support tasks in the field within EFSA's mission?

A.1.1  Yes

A.1.2  No

A.2 Does your organisation carry out **technical** support tasks in the field within EFSA's mission?

A.2.1  Yes

A.2.2  No

A.3 Specifically, does your organisation perform activities, **which include:**

A.3.1  collection and analysis of data connected with risk identification

A.3.2  exposure to risks

A.3.3  risk assessment

A.3.4  food or feed safety assessment

A.3.5  scientific or technical studies

A.3.6  scientific or technical assistance for risk managers

If so, please provide reference, e.g. by sending the relevant documents or the link to the documents, or providing links if publically available, and indicate in the table below where the information can be found.

Information (in brief)	Document name	Date of the document	Page(s) where the information is found
A.1.1			
A.2.1			
A.3. ....			

Note: add lines as necessary to list all documents;

Examples of documents to be provided:

**Statute:** Statute of the organisation from where to analyse, *inter alia*, the exact activities, mission of the organisation purpose and the authoritative power.

**Establishment act:** Public legal act establishing the entity in question or failing that, any other official document attesting the establishment of the entity, clearly indicating it pursues public interest objectives.

**Annual / Activity report:** Annual report indicating the exact activities carried out by the organisation.

Please note that documents considered in the assessment of an organisation's compliance should, in general, be official / formal documents not having, been created for the sole purpose of this designation.

Please indicate if your organisation is:

- B.1  a **Government Authority/body/entity**: the organisation is a government authority, such as a ministry, or is directly and fully affiliated with such a government authority.

or

- B.2  **not a Government Authority/body/entity**  
(if so, please chose at least one from the below options):
- B.2.1  **Public law**: the organisation has been established under public law, e.g. through an act of public law, government decree, or similar.
- B.2.2  **Private law**: the organisation has been established under private law, e.g. as a limited company or private foundation.
- B.2.2  **Control**: the organisation remains under direct and full operational and/or budgetary control by a public authority, e.g. a ministry.

and also if the organisation is:

- B.3  **for-profit**
- B.3.1  profit has to be entirely re-invested into the organisation or returned to its founder (public domain)
- B.3.2  profit is NOT entirely re-invested into the organisation
- B.3.2  profit is provided to / shared with its founder (in the private domain)

or

- B.4  **not-for-profit** [more than one option may be ticked:]
- B.4.1  recognised as non-profit organisation by national law
- B.4.2  any profit made, has to be entirely re-invested into the organisation or returned to the government / founder (in the public domain)
- B.4.2  any profit made is provided to / shared with its founder (in the private domain)

B.5 In the **year** \_\_\_\_ the organisation's **budget** was derived from:

- B.5.1 \_\_\_% **public** sources of funding [i.e. governmental funding plus other public funding, including funding from local, regional or international/ intergovernmental sources, e.g. EU funding]

and

- B.5.2 \_\_\_% **private** sources of funding [i.e. all funding from non-public sources, including income from exploitation of assets, rent of property, provision of services and IP royalties, interest earned, etc.].

Please provide reference, e.g. by sending the relevant documents or the link to the documents, or providing links if publically available, and indicate in the table below where the information can be found.

Information (in brief)	Document name	Date of the document	Page(s) where the information is found
B.1 or B.2			
B.3 or B.4			
B.5			

Note: add lines as necessary to list all documents

Examples of documents to be provided: Establishment Act or Decree, Statute or Mission statement, Annual or Activity Report, Annual budget or Financial Statement / Report.

**B.6** Please indicate if your organisation has **measures in place** to ensure:

- B.6.1  Integrity
- B.6.2  Independence of the organisation and staff
- B.6.3  Non-disclosure / confidentiality

B.6.1 Procedures/Rules on **integrity** are contained in the following binding documents:

- B.6.1.1  staff rules, or ethic code/guidelines/rules
- B.6.1.2  applicable federal, state or regional laws
- B.6.1.3  organisation statute
- B.6.1.4  other, please specify:.....

B.6.2 Procedures/Rules on **independence** are contained in the following binding documents:

- B.6.2.1  staff regulations
- B.6.2.2  ethics code/guidelines/rules
- B.6.2.3  applicable federal, state or regional laws
- B.6.2.4  organisation statute
- B.6.2.5  the organisations enforces a policy to avoid and manage conflicts of interest
- B.6.2.6  other, please specify:.....

B.6.3 Procedures/Rules on **non-disclosure** and **confidentiality** are contained in the following binding documents:

- B.6.3.1  staff regulations
- B.6.3.2  staff contract of employment
- B.6.3.3  ethics code/guidelines/rules
- B.6.3.4  non-disclosure agreements
- B.6.3.5  applicable federal, state or regional laws
- B.6.3.6  organisation statute
- B.6.3.7  certified quality management system
- B.6.3.8  other, please specify:.....



Please provide reference, e.g. by sending the relevant documents or the link to the documents, or providing links if publically available, and indicate in the table below where the information can be found.

Information (in brief)	Document name	Date of the document	Page(s) where information is found
B.6.1			
B.6.2			
B.6.3			

Note: add lines as necessary to list all documents

Examples of documents to be provided: as examples above - Establishment Act or Decree, Statute or Mission statement, Annual or Activity Report, Annual budget; and Financial Statement / Report or specific documents like guidelines/rules/code of Conduct, Ethics, Deontology rules or other supporting documentation demonstrating that the organisation`s arrangements include specific procedures and rules ensuring that any tasks entrusted to it by EFSA will be performed with independence and integrity.

C.1 Does your organisation have a proven or recognised high level of **scientific** or **technical** expertise in one or more field(s) of EFSA's remit?

C.1.1  Yes

C.1.2  No

If so, please provide reference, e.g. by sending the relevant documents or the link to the documents, or providing links if publically available, and indicate in the table below where the information can be found.

Information (in brief)	Document name	Date of the document	Page(s) where information is found
C.1.1			
C.1.1			

Note: add lines as necessary to list all documents

Examples of documents to be provided: specifically showing if your organisation is a national authority / body responsible for one or more field(s) of EFSA's remit, and/or formally used at national level to provide scientific or technical expertise (capacities, information/data, infrastructure) in one or more field(s) of EFSA's remit; e.g. Establishment Act or Decree, Statute or Mission statement of the designated entity, Annual / Activity Report, Publications in scientific peer-reviewed journals, Accreditation or certification of working procedures (please specify type of accreditation / certification and by who/which entity accredited/certified) or others.

D.1 Does your organisation have the capacity (in terms of needed **expertise, financial resources** and **infrastructure**) to operate in a network of the Competent Organisations in the fields of EFSA's remit?

D.1.1  Yes

D.1.2  No

D.1.1 Which networks is your organisation involved in?

Name of network	Field of competence of network	Geographical distribution of network partners
Examples: EU Reference Laboratories PULSE-NET MED-VET-NET EFSA Scientific Networks	(choose <b>from</b> the <b>above 13</b> competence fields under point <b>4.1.-13.</b> )	(EU / global / national / regional)

D.2 Is there a restriction when your organisation works in a network (e.g. data sharing restrictions)?

D.2.1  Yes

D.2.2  No

D.2.1 If so, please specify: .....

D.3 Would your organisation have the capacity to efficiently perform tasks allocated by EFSA (in terms of needed expertise, financial resources and infrastructure)?

D.3.1  Yes

D.3.2  No

D.4 Would there be any restrictions for your organisation to perform the tasks efficiently (e.g. data sharing restrictions)?

D.4.1  Yes

D.4.2  No

D.4.1 If so, please specify: .....

D.5 Is your organisations certified or accredited?

D.5.1  Yes

D.5.2  No

D.5.1 If yes, please specify the type of accreditation/certification, by which entity and when it was accredited/certified.

Please provide reference, e.g. by sending the relevant documents or the link to the documents, or providing links if publically available, and indicate in the table below where the information can be found.

<b>Information (in brief)</b>	<b>Document name</b>	<b>Date of the document</b>	<b>Page(s) where information is found</b>
D.1.1			
D.5.1			

Note: add lines as necessary to list all documents

Examples of documents to be provided: Establishment Act or Decree, Statute or Mission statement, Annual or Activity Report, Annual budget or Financial Statement / Report, Publications in scientific peer-reviewed journals, Accreditation or certification of working procedures (please specify type of accreditation / certification and by who/which entity accredited/certified) or others.

## Declaration

*[Please fill-in and send to the national Focal Point this declaration only when asked to by the Focal Point]*

I, hereby, confirm that the information provided herein is, to the best of my knowledge, correct. I also confirm that I have the authority or I have been granted the authority to express the interest of the organisation described herein in being included in the list of Competent Organisations.

Name: .....

Function: .....

Date: .....

Signature (unless the documents is electronically signed): .....