



# MS COMPETENT ORGANISATIONS

## ART.36 LIST UPDATE DISCUSSION

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# IS IT (STILL) A COMPETENT ORGANISATION?

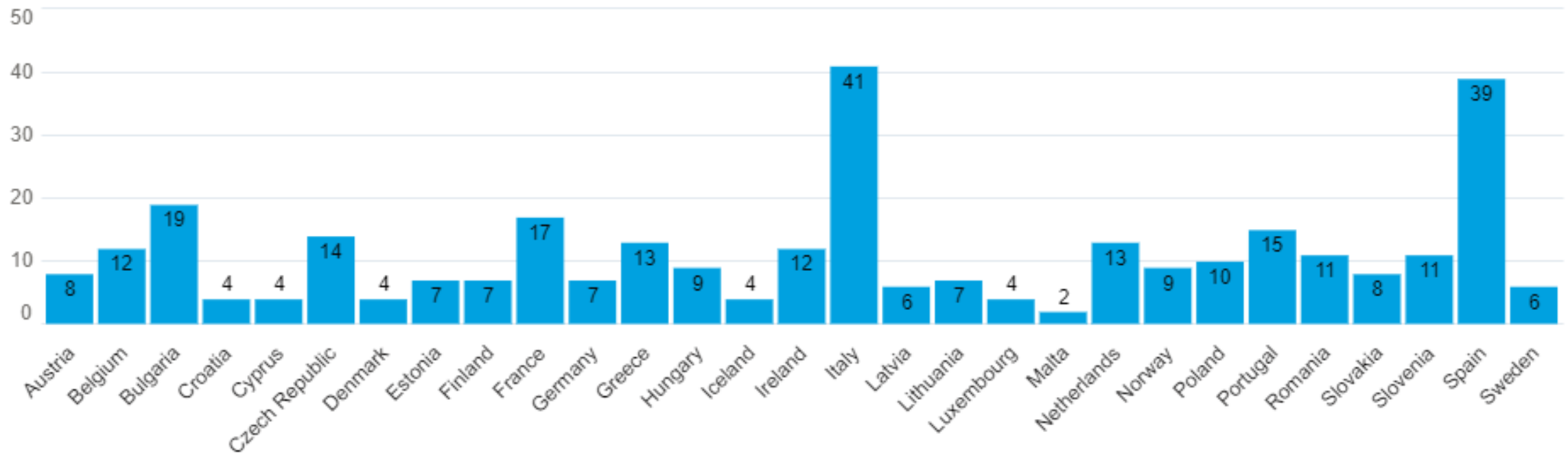
Today:  
recap  
clarity – understanding  
discussion





# 323 CURRENTLY INCLUDED ART.36 MS ORGANISATIONS (EU27/29)

- **National** organisations
- **Compliant** with the criteria (status, expertise, capacity,...)
- Interested & **designated** by MS



# ART.36-TOOL DATABASE

## Searchable:

- Countries (29: EU27+ Iceland and Norway),
- Organisations (323)
- Competences (13 areas)
- Contacts (@3,000+)

Available to: EFSA and MS –  
AF / Focal Points

## ESFA remit competences / expertise

Plant Health  
Plant Protection Products / Residues  
Genetically Modified Organisms  
Food Additives, Flavourings  
Food Contact Materials, Enzymes  
Products / Substances in Animal Feed  
Animal Health / Welfare  
Biological Hazards  
Chemical Contaminants  
Nutrition, Dietetic Products, Novel Food  
Environmental Risk Assessment  
Nanotechnology  
Emerging Risks



You can search in the List of Art.36 List competent organisations selecting from the options (one or several) under the available filters (by country, competence or remit) or by name of an organisation:

Country  
 Select an Option ▼

- Food and Feed Chain competences
- Animal Health / Welfare
  - Biological Hazards
  - Chemical Contaminants
  - Emerging Risks
  - Environmental Risk Assessment
  - Food Additives, Flavourings
  - Food Contact Materials, Enzymes
  - Genetically Modified Organisms
  - Nanotechnology
  - Nutrition, Dietetic Products, Novel Food
  - Plant Health
  - Plant Protection Products / Residues
  - Products / Substances in Animal Feed

- Organisation's remits
- Risk Assessment
  - Risk Management
  - Risk Communication
  - Risk Benefit Assessment
  - Regulatory Science
  - Research

Organisation Name  
 Search this list...

You can export the results of your search in a file by clicking on Export. For more contact details to organisations and their competences reach to your EFSA national Focal Point ([here](#)) or EFSA ([cooperation.article36@efsa.europa.eu](mailto:cooperation.article36@efsa.europa.eu)).

Export

Search results: 323 of 323 Competent Organisations

| Country | Orga... | N | E. | Engli... | Food and feed chain competences | Org... | Contact Informa... | Approval/Last Update... |
|---------|---------|---|----|----------|---------------------------------|--------|--------------------|-------------------------|
|---------|---------|---|----|----------|---------------------------------|--------|--------------------|-------------------------|

|         |              |       |        |           |  |          |  |          |
|---------|--------------|-------|--------|-----------|--|----------|--|----------|
| Belgium | Katholiek... | KU... | Kat... | KU Leuven | - Plant Health<br>- Plant Protection Products / Residues<br>- Genetically Modified Organisms<br>- Food Additives, Flavourings<br>- Food Contact Materials, Enzymes<br>- Products / Substances in Animal Feed | -        | Oude Markt 13<br>Leuven<br><a href="https://www.kuleuven.be">https://www.kuleuven.be</a> | 4/9/2023 |
|         |              |       |        |           | - Animal Health / Welfare<br>- Biological Hazards<br>- Chemical Contaminants   | Research |  |          |



# CRITERIA OF INCLUSION

A **competent organisations** of MS must

1. Carry out **scientific and technical support tasks**
2. Be **legal entities** pursuing **public interest objectives** and have specific procedures and rules ensuring tasks will be performed with **independence** and **integrity**
3. Possess a high level of scientific or technical **expertise** in one or more fields of EFSA's mission
4. Have the capacity to operate in a **network** and/or to **perform efficiently the tasks** in the Regulation (Reg. EC No 2230/2004) laying down detailed rules for the implementation of Art.36 (Reg 178/2002) regarding to the network of organisations operating in the fields within EFSA with EEA relevance.



# PROCESS AND TIMING

**Regular** EFSA MB meetings

(Mar, Jun, Dec)

**in-between**

**Written** procedure (min. 3 weeks open for approval)

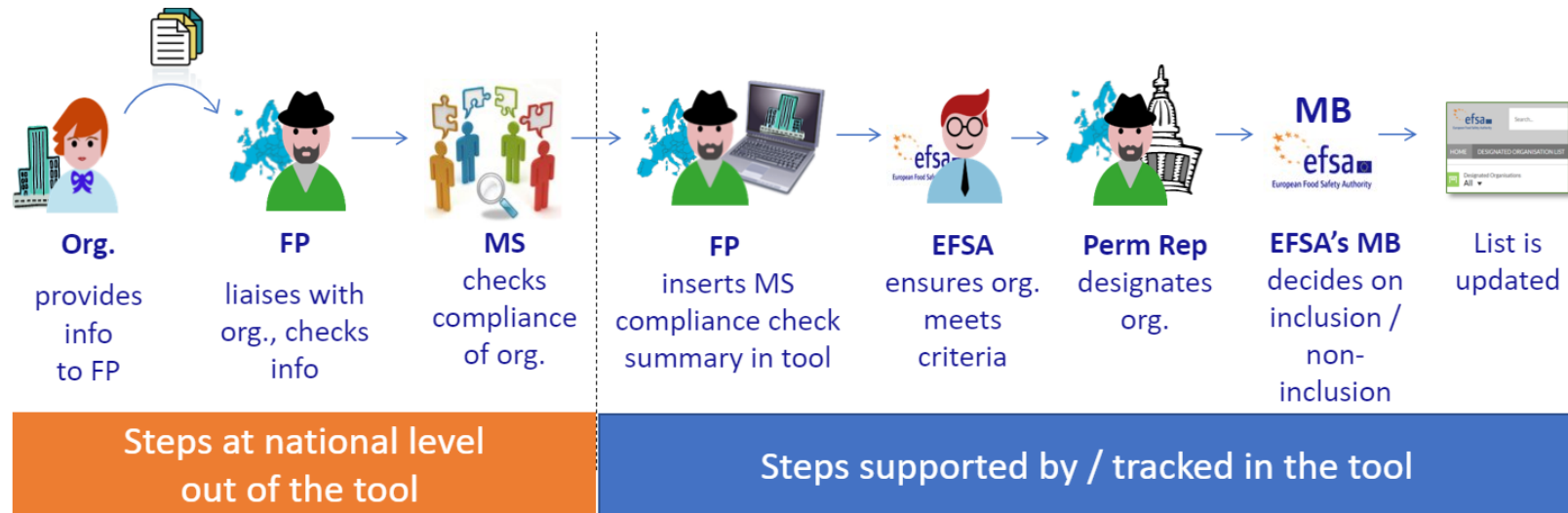
(5x in 2023; next planned early 2024)

**Time:**

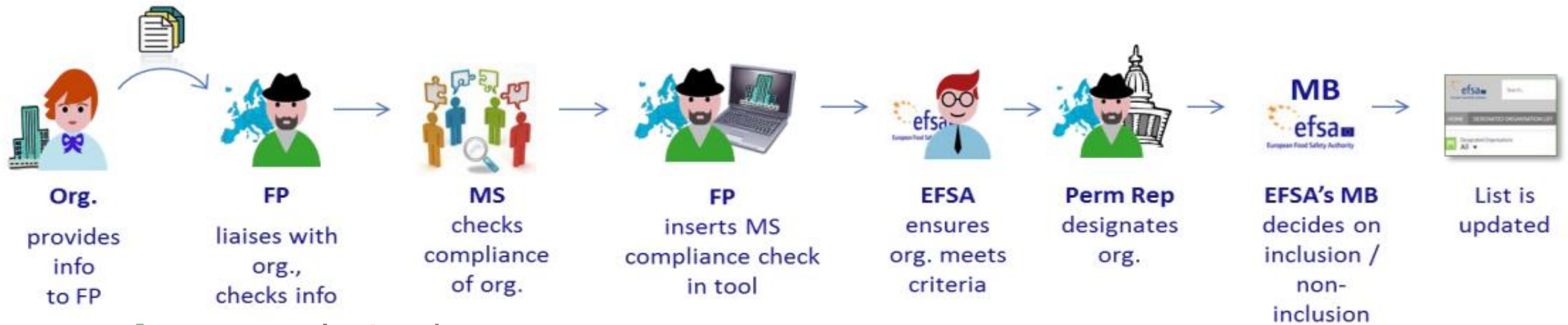
Plan 'unexpected',  
e.g. tool bugs to be  
solved by EFSA



**Workflow (tool):**



# PROCESS OF ART.36 LIST UPDATE



**Key players** role in the process:

Organisation / Focal Point / Member State (PermRep/Mission to the EU in Brussels)

EFSA / Administrator / Management Board

**Information:** to be provided when a change occurs; annually or min. every 3 yrs.

EFSA provides a **tool/database** (CRM) to collect and share information





# ART.36-DATABASE (TOOL)

## Access to Art.36-DB:

- ✓ MS -> FP Users (2 per country)
- ✓ Organisation -> Admin Contact (1)



↓ ↓ (ad hoc, when needed OR annually (advised) or min every 3 years)

## Update of Art.36 List of competent organisations designated by MS:

- new (designation of **inclusion** , EFSA MB approval)
- old (designation of **withdrawal**, EFSA notification)
- changes (2 kinds):
  - update covered by present MS assessment – ‘technical’ – direct EFSA approval,
  - update needing new MS assessment – ‘substantial’ – new **MS designation**



# UPDATE OF THE ART.36 LIST

*“Where designated organisations no longer meet the criteria ..., Member States shall withdraw their designation and immediately inform EFSA ...*

*Member States shall review the list of organisations they have designated regularly, and at least every three (3) years.”*

Art.1 (3), Implementing rules Reg. (EC) No 2230/2004

Practice:

**ongoing** Art.36 List update

✓ as of today **98.45% up-to-date** (i.e. 5 organisations pending update)



# LAST UPDATE INFORMATION

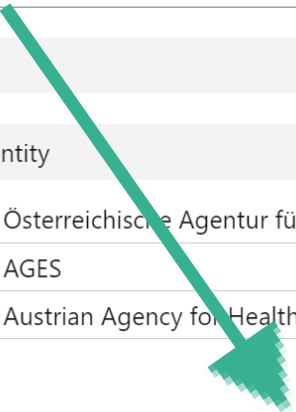
- View of the previous 'MS Assessment Summary' to the organisation's Admin CP
- under 'Related' tab, chronologically

**Details** **Related**


> Account Information

∨ Details on the legal entity

|                  |  |
|------------------|--|
| Account Name     | Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH |
| Name Abbreviated | AGES   |
| English Name     | Austrian Agency for Health and Food Safety                           |



**Details** **Related**

 **Assessment Requests (2)**


| Assessment Name                                    | Record Type                     | Request Status | Created Date     |   |
|--|---------------------------------|----------------|------------------|---|
| <a href="#">AGES - Change Request - 2022-09...</a> | <a href="#">Change / Update</a> | Approved       | 01/09/2022 16.34 | ▼ |
| <a href="#">AGES - New Request - 2019-04-26</a>    | <a href="#">New Request</a>     | Approved       | 26/04/2019 9.27  | ▼ |

# USER GUIDES & SUPPORT

**Competent Organisations (Art.36) management** Posts Files ▾ CompOrg Tool CompOrg List (

+ New ▾ Upload ▾ Edit in grid view Share Copy link Sync Add shortcut to O

Art.36 - exchange of views



✓ List update – process

MS Teams folder

Advise:

**FP Community**

Cooperation.article36@efsa.europa.eu

Name ↓ ▾

- User Guide for Organisations \_\_2022-02-07.pdf
- User Guide for Focal Points\_2022-02-07.pdf
- Pixi User Guide Pixi for FPs\_Tool-Intro\_2020-01.pptx
- Pixi User Guide for FPs\_ Withdraw\_2020-01.pptx
- Pixi User Guide for FPs\_ NewOrg\_2020-01.pptx
- Pixi User Guide for FPs\_ Changes\_2020-01.pptx
- MS\_Designation-letter\_Perm-Reps\_TEMPLATE\_2020.docx
- List\_changes\_\_ FP\_Workshop-Vilnius, 26-02-2020.pptx
- InformationCollectionForm\_forMS.docx
- EFSA's MFA registration UserGuide - since 8 Apr.2021.pdf
- EFSA Art\_36 -DB\_ new features \_ updated User Guide.msg
- Competence\_Mapping\_ Activities\_\_FP\_Workshop-Vilnius,27-02-2020.pptx
- Assessment Guidelines Competent Organisation\_\_ver.17May2021.pdf
- Art.36 list UPDATE - CHECK-LIST - ver.16-02-2022.docx
- 2018 Training Workshop Session2 - new tool.pptx



# SUPPORT

FP unique role:

**Contacts** to organisations

in addition to the public display information in [Search tool](#)

Project collaboration / consortia / follow-up / exchange / networking

Apply for funding:

<https://www.efsa.europa.eu/en/calls/art36grants>

## EFSA grants: why, what, HOW

EFSA may award grants to organisations which are designated by their Member State to assist EFSA with its mission and which are included on the Article 36 list of Competent Organisations. The list of eligible organisations to whom EFSA grants may be awarded is updated regularly and details of how new organisations can be included on the list is available at <https://www.efsa.europa.eu/en/partnersnetworks/scorg>.

When applying for EFSA grants, organisations may apply alone or in consortium with other Article 36 organisations, unless specified differently in the call for proposals. Applications may also involve some subcontracting, including with non-Art.36 organisations under certain conditions specified in the call.

### WHAT TASKS ARE ELIGIBLE?

Only tasks defined in Article 4 Regulation (EC) No 2232/2004 and Article 1 point 5e of Regulation (EU) 2019/1381 can be entrusted to organisations via a grant agreement to assist EFSA with its mission.

#### RISK ASSESSMENT SUPPORT

- ▶ Data delivery - collection/production
- ▶ Support in RA methodologies update/creation
- ▶ Preparatory work leading to drafting EFSA Scientific Opinion

Previous correlation: SPECIFIC GRANTS; TASKING GRANTS

#### CAPACITY BUILDING

- ▶ Dissemination of best practices
- ▶ Information exchange
- ▶ Knowledge sharing
- ▶ Create new scientific knowledge

Previous correlation: PARTNERING; FELLOWSHIP; THEMATIC; FOCAL POINT GRANTS

### METHODS OF FUNDING

A higher rate of funding (co-financing) is given for tasks directly supporting risk assessment compared to a lower rate of funding for projects ideated by the beneficiary. Co-financing may be provided up to a maximum of 99% of the total eligible costs. Alternatively, grants using "financing not linked to costs" may cover all project costs and may even result in a profit to the beneficiary. Sorted below by ease of processing.



### HOW IS THE GRANT AWARDED?

#### OPEN CALL FOR PROPOSALS

- ▶ Open to all article 36 organisations which meet the requirements in the call for proposals.

#### NO CALL FOR PROPOSALS

- ▶ Exceptional and duly substantiated emergencies;
- ▶ Organisation with a de jure or de facto monopoly;
- ▶ For activities with specific characteristics requiring a particular type of organisation due to its technical competence, high degree of specialisation or administrative powers.

### TYPE OF GRANT AGREEMENT

#### FRAMEWORK PARTNERSHIP AGREEMENT

Exact deliverables & timing NOT known

- ▶ Single - One EPA signed with one beneficiary (individual organisation or consortium).
- ▶ Cascade - EPAs signed in order of ranking with different beneficiaries.

#### DIRECT AGREEMENT

Exact deliverables & timing known

#### SPECIFIC AGREEMENTS

Exact deliverables & timing known

### WHO OWNS GRANT DELIVERABLES?

When EFSA is owner of deliverables produced under the grant, EFSA can make use of those deliverables without consulting the beneficiary.

When the beneficiary is owner of deliverables produced under the grant, they must request permission from EFSA prior to publishing or communicating information about the project.

For more details about rules related to EFSA grants, consult Title VIII EU Financial Regulation 2018 and <https://www.efsa.europa.eu/en/calls/art36grants>. EFSA also awards contracts for services through public procurement procedures. For more details about rules related to EFSA procurement, consult Title VII EU Financial Regulation 2018 and <https://www.efsa.europa.eu/en/calls/procurement>.

EFSA is the keystone of EU risk assessment regarding food and food safety. In close collaboration with national authorities in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks.  
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European Food Safety Authority



# THE VALUE OF PARTNERSHIP FOR MS COMPETENT BODIES



- **Synergies:**
  - Support to any ongoing work or task
  - Utilisation of available resources (staff, experts, knowledge, data, etc.)
  - Maintenance of staff expertise, relevant to the organisations' work
- **Strategy, Mission or Role** relevance
- **Visibility** (national, European, etc.)
- **Networking**
- **Funding**
- ...



Additional factors:

- **Prioritisation** differs across types of organisations (e.g., Univ. vs. Ministry services)
- **Organisations vs. People**



# IN SUMMARY

## ONGOING Art.36 List UPDATE and USAGE

FP community approach:

- ✓ exchange, support and sharing

with EFSA:

- ✓ improving guides and guidelines, best practices
- ✓ learning from verification / assessment / ad-hoc checks (new)
- ✓ dealing with identified issues (e.g. tool bugs, new areas of interest)

Reference:

MS Teams channel -> [Art.36 - exchange of views](#) & [cooperation.article36@efsa.europa.eu](mailto:cooperation.article36@efsa.europa.eu)



# THANK YOU & STAY CONNECTED

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