Background Note to EFSA’s Advisory Forum

Project to develop a new concept for implementing Article 36 of EFSA’s Founding Regulation

Aim of the project
To strengthen European networking with and amongst competent organisations, through:
- Establishing, as the base for networking and collaboration, a more agile up-to-date List covering the needed spectrum of scientific expertise; and
- Enhancing engagement of Member States (MS) and organisations in networking.

This initiative supports Strategic Objective 3 of EFSA’s Strategy 2020: to “build the EU’s scientific assessment capacity and knowledge community”.

Rationale
Over the years, a number of barriers to cooperation have been identified by MS and EFSA, including:
- Long procedures, high administrative burden and duplication of work;
- Inefficient means of identification of (potential) partners; and
- Lack of incentives for organisations to join the list.

To overcome them, EFSA is developing a new concept to implement Art.36, based on:
- Almost 10 years of experience at EFSA and in MS;
- Exploring opportunities to more efficiently use the existing legal framework of Art.36; and
- Becoming an integral part of EFSA’s new IT landscape.

Central to this initiative, is the involvement of key players, i.e. Advisory Forum members, Focal Points and Art.36 organisations. A Focal Point Task Force was established to work closely together with EFSA.

Annexes
1. Article 36 of EFSA’s Founding Regulation
2. Roles and responsibilities as stipulated in Implementing Rules for Article 36
3. Project status and timeline
4. Terms of Reference of Focal Point Task Force on Article 36

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Annex 1: Article 36 (1, 2 & 3) of EFSA’s Founding Regulation

Article 36

Networking of organisations operating in the fields within the Authority’s mission

1. The Authority shall promote the European networking of organisations operating in the fields within the Authority’s mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Authority's mission.

2. The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public of competent organisations designated by the Member States which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

3. The implementing rules for the application of paragraphs 1 and 2 shall be laid down by the Commission, after consulting the Authority, in accordance with the procedure referred to in Article 58(2). Those rules shall specify, in particular, the criteria for inclusion of an institute on the list of competent organisations designated by the Member States, arrangements for setting out harmonised quality requirements and the financial rules governing any financial support.
Annex 2: Roles and responsibilities stipulated in Implementing Rules

Article 1

Competent organisations designated by the Member States

1. The competent organisations designated by the Member States in accordance with Article 36(2) of Regulation (EC) No 178/2002 shall meet the following criteria: (…)

2. Member States shall forward to the Authority, with a copy to the Commission, the names and details of the designated organisations, evidence that they comply with the criteria set out in paragraph 1, and details of their specific fields of competence. (…)

Where a designated organisation operates as part of a network, this shall be mentioned, and the network operating conditions shall be described.

In cases where it is a specific part of the designated organisation which has the ability and the capacity to operate in a network on scientific actions and/or perform the tasks which may be entrusted to them by the Authority, this shall be stipulated by the Member States.

3. Where designated organisations no longer meet the criteria set out in paragraph 1, Member States shall withdraw their designation and immediately inform the authority, with a copy to the Commission, accompanied by the relevant evidence.

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

Article 2

Establishing of the list of competent organisations

1. The Authority shall ensure that the organisations designated by the Member States comply with the criteria set out in Article 1(1). Where necessary, the Member States shall be asked, by reasoned request, to add to the evidence referred to in Article 1(2).

2. The Authority’s Management Board, acting on a proposal from the Executive Director, shall draw up the list of competent organisations, stating their specific fields of competence, (…)

4. The list shall be updated regularly, on the basis of proposals from the Authority’s Executive Director, taking account of reviews or new designation proposals from the Member States.

Article 4

Tasks to be entrusted to organisations on the list

2. The Advisory Forum shall ensure that there is a good general match between the requests for contributions which the Authority puts to the organisations on the list and the scope of those organisations to respond favourably. (…)
Annex 3: Project status and timeline
Annex 4: Terms of Reference of the Focal Point Task Force on Article 36
New concept for Article 36 networking and management of the List

Background
Since their creation in 2008, Focal Points have been involved in networking and managing the Article 36 List at national level, dealing with the regulatory requirements linked to Article 36 of EFSA’s Founding Regulation. The accumulated knowledge and experience in Member States (MS) and EFSA will be used to develop a more efficient and effective approach to implementing Article 36.

To this end, a Task Force of Focal Points is established to support a new EFSA project\(^1\), which aims at developing an innovative approach to strengthen European networking and collaboration amongst competent organisations and with EFSA. The project’s specific objectives are to:

1. Establish, as the base for European networking and collaboration, a more agile up-to-date List covering the needed spectrum of scientific excellence, through:
   - developing a more efficient solution (procedures and IT tool) for managing the List; and
   - increasing consistency and engagement of MS in managing the List;

2. Enhance the engagement of MS and competent organisations in networking and collaboration, by:
   - simplifying the assignment of tasks to competent organisations;
   - supporting organisations to identify potential partners;
   - including members of EFSA scientific networks in the List;
   - strengthening liaison of MS with competent organisations; and
   - fostering partnerships between MS.

The project is composed of three Phases:

Phase 1: Development of the new concept; by end December 2016;

Phase 2: Development of a new solution (policy, procedures, templates and IT tool) to manage the List of Competent Organisations and support networking; by end December 2017;

Phase 3: Newly drawing-up the List of Competent Organisations; by end December 2018.

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\(^1\) Innovative approach for Article 36 networking and management of the List
Tasks

As part of the Focal Point Task Force on Article 36, members will support the project by:

a) undertaking a proof-of-concept, leading to recommendations on efficiently maintaining the List of Competent Organisations and enhancing the engagement of MS and organisations in European networking and collaboration (Project phase 1);

b) providing input and feedback during the development of the new Article 36 solution (procedures and IT tool), as needed (Project phase 2);

c) participating in a simulation exercise of the new Article 36 solution and providing feedback (Project phase 2);

d) contributing to the development of guidelines and training materials for MS, including a set of best practices, on the new Article 36 processes and IT tool (Project phase 2);

e) training other people, who are involved in assessing organisations against criteria and maintaining the List, in dedicated trans-national workshops (Project phase 2);

f) continuing to be available as Article 36 mentors/coaches to other MS, creating an Article 36 community (Project phase 3).

Timeline and expected deliverables

<table>
<thead>
<tr>
<th>Item</th>
<th>Timeline</th>
<th>Deliverable</th>
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<tbody>
<tr>
<td>Proof-of-concept</td>
<td>October-November 2016</td>
<td>Recommendations</td>
</tr>
<tr>
<td>Input to new Article 36 solution</td>
<td>June-September 2017</td>
<td>Input and feedback</td>
</tr>
<tr>
<td>Simulation</td>
<td>October-November 2017</td>
<td>Completed validation</td>
</tr>
<tr>
<td>Training materials, etc.</td>
<td>October 2017-January 2018</td>
<td>Guidelines, training materials</td>
</tr>
<tr>
<td>Workshops</td>
<td>beginning 2018</td>
<td>Workshops</td>
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Membership

The Task Force was proposed during the 28th Focal Points meeting in Parma on 15-16 September 2016, and the members were elected by the Focal Point representatives.

Chair:
Luca Busani  
Focal Point Italy

Focal Point members:
Birgitte Helwigh  
Focal Point Denmark
Cristina Alonso-Andicoberry  
Focal Point Spain
Gisle Solstad  
Focal Point Norway
Gorgias Garofalakis  
Focal Point Greece
Kirsi-Maarit Siekkinen  
Focal Point Finland

Secretariat:  
EFSA / AFSCO unit