

# The the FP task force on Art. 36



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# Background

1. Overarching aim: to develop a more efficient and effective approach to implementing Article 36.
2. New EFSA project on Art. 36, which aims to:
  1. establish a more agile up-to-date List covering the needed spectrum of scientific excellence
  2. enhance the engagement of MS and competent organisations in networking and collaboration,
3. Innovative approach for Article 36 networking and management of the List
4. Alignment with EFSA 2020 Strategy for cooperation and networking
5. Inclusion in the "under development" new EFSA IT framework



Task Force of Focal Points is established to support the new EFSA project and vision on art. 36 by:

1. undertaking a proof-of-concept
2. providing input and feedback during the development of the procedures and IT tool,
3. participating in a simulation exercise
4. contributing to the development of guidelines and training materials for MS,
5. training other people,
6. continuing to be available as Article 36 mentors/coaches



# The Focal Point Task Force on Article 36

Members elected during the 28<sup>o</sup> FP meeting are:

- Birgitte Helwigh *FP Denmark*
- Cristina Alonso-Andicoberry *FP Spain*
- Gisle Solstad *FP Norway*
- Gorgias Garofalakis *FP Greece*
- Kirsi-Maarit Siekkinen *FP Finland*
- Luca Busani *FP Italy*

*Supported by EFSA AFSCO unit staff:*

- Dominic Christian
- Kerstin Gross-Helmert
- Martina Kurisova



# FP TS activities

1. Preliminary SWOT analysis on the actual process and tool for the Art. 36 management
2. Kick off meeting (Rome, 5-6 October)
3. Teleconference (EFSA, 17 October)
4. 1° Activity Report





# Preliminary SWOT analysis

- Was considered an effective way to collect information about the points 1 and 2 of the FP TS mandate:
- Was divided in two parts:
  - current process for managing the Article 36 List and networking with/among competent organisations;
  - current IT tool (Art.36-Database) for managing the Article 36 List and networking with/among competent organisations.
- FPs have been required to provide recommendations
- A SWOT form, background information and details on how to perform the SWOT analysis were sent to all FPs on 20<sup>th</sup> of September
- Deadline 14<sup>th</sup> of October 2016.
- Preliminary analysis on 5<sup>th</sup> of October during the Kick off meeting



# SWOT analysis conclusion i

## Representativeness:

- 18/30 replied representing 67% of the Art. 36 organizations
- all EU areas, North, South, Centre, East and West were covered
- differences regarding country size, internal organisation and functionality were included



# SWOT analysis conclusions: known issues

- To require a regular update of the information in the DB
- To simplify the process and to reduce the administrative burden
- To ensure a clear and effective management of the process
- To increase the benefits and to support the return of the investment for the organisations, the MS and EFSA
- To facilitate the support from AF and National authorities, also through supporting FPs, concerning the issues related to the Art36 process





# SWOT analysis conclusions: new issues

- Valuable analysis of the “state of the art” of the Art.36 process and tool with opportunities and threats related to the new concept.
- Potential CoI of the FPs as Art.36 themselves, if they have to evaluate their peers (the other Art.36); clarification mainly at the MS level.
- Regular evaluation of the cooperation activities of the organisations in the list



# SWOT analysis conclusions

- **Opportunities:** transition of the Article 36 Organisations into a European Risk Assessment hub and the interoperability of the new tool with other systems.
- **Threats:** less Art. 36 on the list
- **Recommendations:** to simplify and reduce the burden, ensuring at the same time the accomplishment of the requirements
- **Limitation of the SWOT:** this analysis involved FPs only. Other stakeholders plays important roles in the process, like the Art.36 organisations themselves, AF, national authorities...



# Kick off meeting

## Agenda:

- Welcome
- ToR of the Task Force, time table and main deliverables
- Analysis of the SWOT exercise
- Summary and main advices from the analysis
- Overview of Italian Art.36 management system and tools
- Example of the new concept: “competent authority” meaning
- Discussion on the new concept and role of the main actors
- Details of the upcoming activities and closure of the meeting



# The Kick off meeting

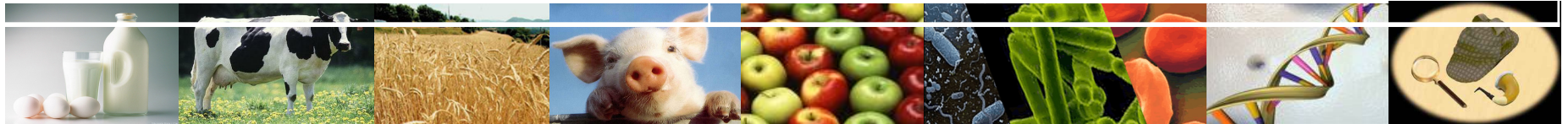
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## Participants:

Camilla Marchiafava	FP Italy
Dominic Christian	AFSCO unit, EFSA
Emiliano Bergamo	Ministry of Health
Gisle Solstad	FP Norway
Gorgias Garofalakis	FP Greece
Kerstin Gross-Helmert	AFSCO unit, EFSA
Luca Busani	FP Italy
Martina Kurisova	AFSCO unit, EFSA

## Apologies from:

Birgitte Helwich	FP Denmark
Cristina Alonso-Andicoberry	FP Spain
Kirsi-Maarit Siekkinen	FP Finland















# The Teleconference

- Agreement on the ToR of the Task Force
- Final discussion of the results of the SWOT analysis and approval of the minutes of the kick off meeting
- Insight into the new concept for art. 36
- Stakeholders: role and expectations from the new concept
- Tasks for the next meeting/deadline and Closure

## Participants:

Dominic Christian	AFSCO unit, EFSA
Gisle Solstad	FP Norway
Gorgias Garofalakis	FP Greece
Kerstin Gross-Helmert	AFSCO unit, EFSA
Kirsi-Maarit Siekkinen	FP Finland
Luca Busani	FP Italy
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# Future activities

Collection of national surveys on Art.36 organisations made by the FPs 15.11.2016

Draft of the procedures and questionnaire to elicit the AF opinion on the new concept of the Art. 36 1.12.2016



# Thank you

## Questions?

