議事（３）関係
鬼武専門委員提出資料

2018 年 5 月 30 日
食品安全委員会企画等専門調査会（第 24 回）

食品安全委員会　いわゆる「自ら評価」案件に関するメモ

日本生活協同組合連合会
鬼武一夫

１．EFSA（欧州食品安全機関）

EFSA でも self-tasking という言葉を使って、自身のイニシアティブで科学的作業を行っています。その内容は EFSA のウェブサイト How we work に記述されています。

Self-tasking の課題の決定は、事務局で行っていますが、重要な点は公開性（openness）と透明性を維持しています。（下記に引用）

私たちはまた、私たち自身のイニシアチブ、特に新興の問題や新たなハザードを調査し、評価方法やアプローチを更新するための科学的作業を行っています。 これはいわゆる「self-tasking（自己タスキング）」として知られています。

How we work

Most of EFSA’s work is undertaken in response to requests for scientific advice from the European Commission, the European Parliament and EU Member States.

We also carry out scientific work on our own initiative, in particular to examine emerging issues and new hazards and to update our assessment methods and approaches. This is known as “self-tasking”.

- EFSA organises its work programme – annual and multi-annual – according to priorities agreed with the European Commission and other partners, taking into account available resources.
- We consult closely to ensure that our programme complements those of our partners – particularly **national authorities and food safety**

agencies in EU Member States – and to avoid overlap and duplication of work and effort.

- EFSA's scientific advice is mostly provided by its Scientific Panels and Scientific Committee, members of which are appointed through an open selection procedure.
- EFSA staff may also produce scientific outputs on behalf of the agency, such as peer reviews of the assessment of active substances in pesticides, or responses to urgent requests for advice. EFSA staff also monitor and analyse information and data on biological hazards, chemical contaminants, food consumption and emerging risks.

EFSA adheres to a number of principles and practices aimed at ensuring the excellence of our work. These include:

- A commitment to openness and transparency in all our work.
- The development of a comprehensive body of good risk assessment practices to guide our Scientific Committee and Panel experts.
- A quality management system (QMS) that continually monitors and strengthens the quality of EFSA's scientific work. This includes self-review and customer feedback systems which ensure that scientific processes are developed consistently and continuously improved. EFSA's QMS has been awarded an ISO 9001:2015 certificate, the international standard for quality management.
- Reviews and inspections carried out by an internal auditor reporting to the EFSA's Management Board's Audit Committee, which advises senior management on possible improvements to work practices.
- External evaluation: EFSA's Founding Regulation obliges the Authority to commission independent external evaluations of its work and working practices. Based on these evaluations, the Management Board makes recommendations on EFSA's future management plans and strategies. The next evaluation will take place in 2017-2018 – a call for tenders to carry out the evaluation will be launched in March 2017.

In addition the Authority is legally bound by European Union legislation on issues such as public access to documents.

２． External Evaluation of　EFSA

EFSA の self-tasking の内容が Ernst & Young 社の作成した European Food Safety Authority External Evaluation of EFSA Final Report　（計 337 ページ）の page 40～に記載されています。この report は 2007-2010 年のものです。

新興の課題（Emerging issues）と今後の挑戦（future challenges）に分類され、前者には生物学的ハザードとしての食品媒介薬剤耐性（Food borne antimicrobial resistance as a biological hazard）が含まれます。

QUALITY ASSURANCE PROCEDURES

- To appreciate the quality and reliability of **FSA** work, the fact that the Parliament and Government give an external point of view is important. FSA, like EFSA, publishes each year a report on assurance of scientific quality.

QUALITY OF SCIENTIFIC OUTPUTS

- In the United Kingdom, specific quality assurance procedures to ensure the quality of **FSA**'s scientific advices and impartiality of scientific expertise have been implemented. Notably:
  - A peer-review assurance by the Chief Scientist Advisor and publication of everything FSA does with a risk assessment procedure.
  - An own internal science government check list to carry out proper procedures.
- **EMA** has implemented specific procedures to ensure the quality of selected experts. There is a list of criteria of quality standards shared and approved by the European Commission. When MS propose experts, they must comply with those criteria. The committees are also free to choose experts but according to the same criteria (highest possible standards). When it is difficult for small MS to cover the full range of expertise, there is support from another MS.
- **ECHA** has developed its management standards based on the Commission's Internal Control Standards for effective management and the internationally recognised ISO 9001 standard for quality management systems.

Evidence on the quality of EFSA's scientific outputs is provided by the increasing trend of **EFSA's outputs citations** in key relevant scientific journals[32] (Table 11): Food science and technology represents the most important thematic area in which EFSA's outputs are cited, followed by Toxicology and Veterinary Science.

As an additional evidence of the quality of EFSA's outputs, EFSA Journal is now indexed into 4 bibliographic databases[33].

Table 11: Number of citations of EFSA's publications

	2006	2007	2008	2009	2010	2011
N. of citations of EFSA publication in scientific papers	13	19	35	132	293	487

(Source: EY elaboration on EFSA Annual Activity Reports)

Effectiveness and scientific quality of self-tasking function to keep abreast of emerging issues

EFSA normally undertakes scientific work on its own initiative in fields where scientific knowledge and approaches are continually evolving. Over the period 2006-2011 two distinct processes have been used. Firstly, self-tasking occurs when EFSA, identifying a particular issue that requires further analysis and research, requests a self mandate directly to a Panel to produce a guidance, an opinion or data collection. Secondly, internal mandates could be used to assign tasks to Units, including outsourcing. These activities in general provide support to the work of the Panels in the form of exploratory or background work, and have been the principal processes used to task the EMRISK Unit to develop a procedure for the

[32] Progress report on the implementation of the MB Decision to further develop Impact Indicators within EFSA as appropriate tools for measuring the effectiveness of EFSA (MB 16-06-11).
[33] Annual Activity Report 2011.

formal identification of emerging risks. This procedure has been developed starting from recommendations made by the Scientific Committee in 2006 through a pilot study carried out in 2010-11.

Internal mandates and Self-tasking mandates have progressively increased their relevance in EFSA's activities, passing from 6% of EFSA's outputs (in terms of questions) in 2007 to 12% in 2011[34].

Self-tasking mandates represent a valuable instrument for EFSA to rapidly undertake on its own initiative, specific studies/activities on emerging issues or future challenges, in order to be able to anticipate future legislative works and to play an active role within the food safety system.

Around half of the self-tasking activities related to emerging issues and future challenges including developing methodologies, collection and analysis of experiences, technical specifications and risk assessment, as shown in **Error! Reference source not found.**.

Table 12: Scientific works undertaken under EFSA self-tasking function, 2007-2010

EFSA SELF-TASK QUESTIONS
Questions related to emerging issues
Blue Tongue Self mandate
The role of the tick vectors in the epidemiology of African Swine Fever and Crimean-Congo Hemorrhagic Fever in Eurasia
Bovine Besnoitiosis: an emerging disease in Europe
Self-tasking mandate on risk based control of biogenic amine formation in fermented foods
Assess the public health significance of meticillin resistant Staphylococcus aureus (MRSA) in animals and foods
Food borne antimicrobial resistance as a biological hazard
Surveillance and monitoring of Toxoplasma spp. In humans, food and animal
Monitoring and identification of human enteropathogenic Yersinia spp.
Monitoring of verotoxigenic Escherichia coli (VTEC) and identification of human pathogenic VTEC types
Food borne viruses
Mandate proposed to EFSA by the ANS Panel for a self-tasking safety assessment as a food additive of lutein preparations other than lutein with high concentrations of total saponified carotenoids at levels of at least 80 %.
PET recycling processes- evaluation criteria
Assessment of the use of cobalt compounds as additive in animal nutrition
Scientific Opinion on clustering and ranking of emissions of plant protection products from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments
Scientific Opinion on Risk Assessment for a Selected Group of Pesticides from the Triazole Group to Test Possible Methodologies to Assess Cumulative Effects from Exposure through Food from these Pesticides on Human Health
Cumulative and synergistic effects of pesticides
Questions related to future challenges
Geographical distribution of ticks with proven involvement in the transmission of animal diseases and zoonosis in Eurasia
Self-mandate on "Good Practice in Conducting Scientific Assessments in Animal Health Using Modelling
Risk Assessment Guidelines for Animal Welfare
Question for Scientific Opinion on the development of risk ranking tool on biological hazards
Question for Scientific Opinion on Reflecting the experience and lesson learnt from modelling on biological hazards
Future prospects that the BIOHAZ panel is facing
Self-tasking Working Group on the assessment of potential impacts of genetically modified plants on non-target organisms

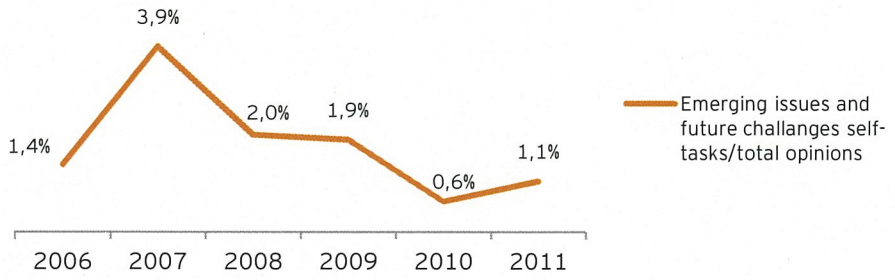
[34] Data provided by EFSA, 2012.

EFSA SELF-TASK QUESTIONS
Scientific Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations of plant protection products in soil.
Scientific Opinion on the importance of the soil litter layer in agricultural areas
Scientific Opinion on Proposal for scenario development and risk assessment of PPP use in protected crop systems
Scientific Opinion on emissions of plant protection products from greenhouses and crops grown under cover: outline for a new guidance
Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
Scientific Opinion on outline proposals for assessment of exposure of organisms to substances in soil
Scientific Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment
Opinion on FOCUS report on landscape and mitigation factors in ecological risk assessment
Exploring options for providing preliminary advice about possible human health risks based on the concept of Thresholds of Toxicological Concern (TTC).

(Source: EY elaboration on EFSA's data, 2012)

Despite Internal mandates and self-tasking mandates progressively increased their relevance in EFSA's activities, the production of scientific works on emerging issues and future challenges through self-task mandates is characterized by a decreasing trend (both in absolute terms and as a percentage of total opinions, see Chart 2).

Chart 2: Trend of emerging issues and future challenges self-tasks/Total opinions



(Source: EY elaboration on EFSA's data, 2012)

3.1.2.2 Stakeholders' point of view

Suitability of outputs to clients' needs

EFSA's outputs are globally suitable to the needs of its clients and more specifically complete and clear according to 88% of respondents (Q1.1). This positive evaluation is also confirmed by several interviewees (NRM, NRA, IOs, Cons., EP, EC[35]).

As regards the **needs of risk managers** (EC and NRM), information and comments received by these stakeholders show how scientific opinions are globally considered clear and well structured. In addition, the majority of European risk managers (EC, EP) think that EFSA's scientific outputs usually fully fit their needs to inform EU policy decisions[36].

Given that outputs are generally suitable to the needs of EFSA's clients, some differences emerge when looking at the variety of perception by MS: information collected during interviews (NRM, NRA) highlights that in countries with a strong risk assessment capacity (like Germany, UK or France), risk managers mainly rely on national agencies when dealing with

[35] This opinion is supported also by one FIR and one NGO.
[36] Progress report on the implementation on the MB decision to further develop impact indicators within EFSA as appropriate tools for measuring the effectiveness of EFSA (mb 16 06 2011).