



Fitness check

EFSA- Intermediate report

Why an intermediate report?

With regard to EFSA, it was decided to base the fitness check on the results of EFSA last external evaluation (2012 final report Ernst and Young).

The 2012 external evaluation covers the period Jan. 2006 to Dec. 2010. Some of the results had to be updated/completed on the basis of the results of the Impact Assessment on the establishment of fees for EFSA and updates provided by EFSA and MS (WG of 29 June on the cooperation with EFSA).

An intermediate report is necessary since the 2012 evaluation did not fully (or in some cases not explicitly) cover coherence, relevance and EU added value.

Elements of context (1)

EFSA is still a rather young agency as it became operational in 2003. It grew rapidly (budget increased from €10.3 Million in 2003 to a stable budget of around €79 Million and its staff increased from 72 in 2003 to 445 in 2014 (74% being allocated to operational activities and 26% to support activities)).

The significant size of EFSA's budget and staff was conceived to cope with the reform of the EU food safety system (White Paper) to take place but it also created a perception that EFSA was "big enough" to manage any new tasks however complex and time-consuming.

Context (2)

Its workload changed (more applications for authorisations) due to a high number of new legal texts on authorisations adopted since 2003.

Sharp increase in the number of requests for scientific opinions sent to EFSA (74.5% increase between 2006 and 2011)

High expectations from all stakeholders and Institutions on the ability of EFSA:

- to deliver an increased number of scientific opinions timely, fully independent and of high quality.*
- to support better the EU food safety system by its technical and scientific expertise in case of crisis, by an improved data collection, and its communication on risk.*

Main findings on effectiveness

1. EFSA scientific outputs

- *Globally, the establishment of EFSA allowed meeting the increasing demands that the reform of the food safety legislation put on scientific advice and support.*
- *EFSA also demonstrated its capacity to support the food safety system in cases of emergencies and crisis with timely and high quality scientific support.*

Scientific outputs (2)

- *EFSA was able to deliver adequate scientific outputs in terms of suitability to the needs, quality, independence and timeliness.*
- *But the timeliness of its advice has been a problem in certain areas of authorisations and does not always meet the needs of applicants/industry.*
- *There are backlogs in certain areas of authorisations.*

Data collection

- *EFSA's data collection complies with the requirements set in its Founding Regulation.*
- *Supported by positive views from stakeholders and risk assessors.*
- *Progress to be made on accessibility and rules for access, as identified in the 2012 evaluation, has been accomplished.*
- *International cooperation increased*
- *Still some concerns on the MS side on EFSA IT systems (friendliness)*

EFSA communication tasks

- *EFSA communication is effective and of good quality.*
- *The outreach is good.*
- *The target of the communication is rather an educated public but there are also new initiatives to transfer science to the public (videos, social media).*
- *Cooperation with national counterparts*

Independence

- *The 2012 evaluation concludes that "EFSA is generally independent and has one of the most advanced and robust systems for the prevention of conflicts of interests".*
- *EFSA even further refined its system.*
- *But it remains a sensitive issue and there are still misunderstandings (DoI not automatically meaning CoI, no full bullet-proof system possible).*

Networking with MS (1)

- *A specific WG was organised with MS on 29 June to discuss the networking.*
- *The current system of cooperation with MS delivers in terms of sharing of data and methodologies and in terms of cooperation on data collection.*
- *But one of the main aims of the system "a better sharing of tasks between EFSA and national agencies" has not yet been achieved in particular in the area of scientific opinions.*

Networking with MS (2)

- *The current system allows EFSA to be effectively supported by national experts as members of its SC/ Panels and WGs.*
- *However, there are limitations in the current system (grants and procurements considered as not sufficiently attractive, Article 36 list, ability of experts to participate in EFSA's work negatively impacted by time spent in EFSA, routine work, conflict with own employment).*
- *Not all MS having sufficient scientific capacity to support EFSA.*

Transparency and openness

EFSA fully meets the requirements of its founding Regulation in terms of transparency.

It is appreciated as a transparent organisation.

Its new policy on "open EFSA" is an attempt to satisfy the general trend in civil society for more openness (in particular improved tools to scrutinise the risk assessment process).

Efficiency (1)

- *No major problem of efficiency in terms of structure and allocation of resources.*
- *Internal financial and control systems corresponding to standards.*
- *Internal and external quality systems on scientific outputs.*
- *EFSA' structure demonstrated its ability to adapt to significant increase and change of workload.*

Efficiency (2)

- *Main problem of efficiency is the management of applications for authorisations with:*
 - Delays
 - Backlogs
 - High number of long "stop the clocks"
- *Causes are internal and external.*

Efficiency 3 (internal aspects)

EFSA's working processes:

- *Unsuitable guidance and lack of dialogue resulting in numerous and long stop the clocks.*
- *EFSA considers that its resources do not always allow for certain forms of dialogue but has taken steps to remedy these problems (new catalogue of services, better involvement of stakeholders in guidance)*

Efficiency 4 (internal aspects)

Elements identified as having a negative impact on the Panels' functioning:

- *Excessive routine work combined with a high workload in certain areas of authorisations.*
- *Insufficient sharing of work with MS and with EFSA staff.*
- *Too long/complex opinions in certain cases.*
- *Crossing the boundaries with risk management.*

Efficiency (5) external aspects

- *Sectorial legislations on authorisations adopted after the creation of EFSA resulted in to EFSA having to manage 39 different workflows, limiting its ability to standardise.*
- *Sectorial legislation created efficiency problems in the EFSA system because of the requirements to review old substances or new ones never assessed, leading to peaks of applications (more than 4000 claims to assess in 2008).*
- *Cost-efficiency issues linked to extra-costs not existing in other EU scientific agencies: selection process of experts based on open call, sharing of work based on grants and procurement and not imposed by legislation, costs linked to a very strict system on independence.*

Coherence (1)

Internal coherence

Tools are in place for internal coherence (guidance from EFSA Scientific Committee). Still room for improvement.

Coherence with national scientific bodies

Divergent opinions are limited and the Art. 30 procedure is working (only 4 cases out of 11 cases since EFSA's creation were confirmed as real divergences).

However, most of the remaining divergences are on sensitive issues.

Coherence (2)

- *with other EU scientific agencies*

Well established cooperation with ECDC on food-borne diseases, with EMA/ECDC (antimicrobial resistance) and ECHA.

- *with international bodies*

Cooperation increased in the last years with main third countries agencies and with international bodies

Coherence (3)

EFSA, Commission and MS have to promote consistency of the risk analysis process (RA/RM and risk communication)

The cooperation is effective and promote consistency of the risk analysis process.

Still work in progress on the following issue:

- Guidance: improved dialogue between RA and RM on guidance on the scientific "translation" of the acceptable level of risk which is a RM competence and reinforcement of the risk communication process with stakeholders.

Relevance (1)

- *EFSA tasks are relevant and complement each other.*
- *Wide scope relevant (enlarged EFSA scope on Plant Health and nutrition in relation to food law)*
- *EFSA structure relevant to address changes: increase and changes of workload, more independence, more openness, services to applicants.*

Relevance (2)

EFSA system is relevant but some aspects are not consistent with certain current trends:

- In a context of reduced resources, some MS consider that the financing of their contribution to EFSA is not satisfactory.
- Centralised authorisations are an EU responsibility and national agencies might give low priority to train and employ experts mostly contributing to EFSA's work.
- EFSA's strict rules on independence are not in line with the national and EU trend for public/private partnership.
- All those elements are aggravated by the current scarcity of scientific experts.

Added value (1)

- *EFSA's increased scientific capacity is an added value for the protection of health and the internal market. It provides sound and independent scientific advice for the harmonised EU food safety system.*
- *Added value for internal market and health since it contributes to the harmonisation of RA methodologies in non-harmonised areas (safety of botanicals).*
- *Added-value in case of crisis because of the specific expertise and tools EFSA developed (tracking, new database with ECDC)*
- *Added value for MS since the EFSA system ensures risk assessment, sharing of data and methodologies, support on risk communication throughout the EU.*

Added value (2)

However, MS with limited capacity of expertise benefit more than those with significant capacity of expertise as their contribution to EFSA's work can be considered as a cost.

Globally as expressed in the comment of one MS: "On balance EFSA's activities are essential to the operation of the agreed EU regime, especially for those MS who have limited national capacity to undertake work in areas covered by EFSA remit. From our knowledge of its working methods and performance to date we conclude that it is providing good value for money, is working hard to deliver improvements and we would not expect an alternative body to be able to provide the same service on a more cost-effective basis".

Thank you for your attention