



## DISCUSSION DOCUMENT<sup>1</sup>

### GFL Expert group 29 June 2015

#### Fitness check on Regulation 178/2002(EFSA chapter)

##### Introduction

The purpose of the fitness check is to assess the fitness for purpose of Regulation 178/2002. Such an evaluation implies to address the effectiveness, efficiency, coherence, the EU added value and the relevance of EFSA.

The fitness check addresses both the adequateness of the EFSA system with the provisions and objectives of Regulation 178/2002 and the concrete implementation of these provisions (EFSA's processes in particular) since it is important to identify which problems/concern result from the legal provisions and which problems/concerns come from modalities of implementation.

With regard to EFSA, it was decided to base the evaluation on the last EFSA external evaluation report (2012). Given that the results of this external evaluation cover the period January 2006 to December 2010, some of the results need to be updated, completed and cross-checked on the basis of the results of the Impact Assessment on the establishment of fees for EFSA (SWD (2013) 45 final), the results concerning EFSA coming from the two studies (GFL and RASFF/crisis management) and other relevant documents on the functioning of EFSA (in particular EFSA management plans, EFSA budget, EFSA annual reports, EFSA stakeholders' comments).

One of the principles established by Regulation 178/2002 is that one of the bases for EFSA's effective functioning is the networking and cooperation with its national counterparts and other scientific bodies. Other provisions of the Regulation such as the recourse to external members for the membership of EFSA Scientific Committee and Panels and of their working groups also provide for the involvement of national experts in EFSA's work. A large number of the experts contributing to EFSA being employed by national public bodies, their involvement in EFSA implies that these national public bodies consider the cooperation with EFSA as part of their activities. EFSA has since its creation built on these bases to further refine the systems (focal points in the MS, expert database, externalisation of work through grants and procurements, EFSA networks).

**The first aim of the cooperation with MS is to evolve towards a more "collaborative system"** pooling knowledge and expertise throughout the EU with the support of the networking of organisations operating within the fields of EFSA's mission. It is the main mission of the Advisory Forum as foreseen in Article 27 and a specific network was established by Article 36..

In practice, EFSA's scientific activities strongly involve the participation of external scientific experts mainly based in Member States through various procedures:

- Selection of experts to participate in scientific committee and panels, every 3 years;
- Recourse to external scientific experts to assist EFSA Scientific Committee, Scientific Panels and their Working Groups, EFSA networks and respective working groups to contribute to EFSA assignments (provision of scientific advice, data collection) or assignments to scientific projects;
- Allocation of grants and procurements to competent national organizations in order to support EFSA in the following tasks: data collection, preparatory work for scientific opinions, other scientific and technical assistance.

**The second aim of the cooperation with MS is coherence.** According to Article 22(8) of Regulation 178/2002, EFSA, Commission and Member States shall promote the effective coherence between risk assessment, risk management and

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<sup>1</sup> This document does not necessarily represent the views of the Commission's services.



risk communication function. The cooperation and networking should facilitate the early exchange of scientific information, the sharing of data, best practices and methodologies. They thus contribute to common understanding and views on the scientific issues linked to the EU food chain. to facilitate convergences and to minimise the risk of divergences more specifically addressed in Article 30 of Regulation 178/2002.

The objective of the meeting is to discuss the main findings of the 2012 external evaluation of EFSA in relation to the cooperation with Member States.

DG SANTE underlines that an in-depth discussion with MS on these issues is needed since some of these findings might need to be updated in the light of the following:

- the EFSA 2012 external evaluation results cover the period January 2006 to December 2010 (sometimes extending to 2011). EFSA has since changed and made progress.
- the MS' situation and views might also have changed since this period. In particular, the members of EFSA's Advisory Forum have signalled problems of declining resources in the national risk assessment agencies/bodies making it more difficult to participate to EFSA's work.
- the results of the EFSA 2012 external evaluation in particular in terms of workload for the Panels and the national experts need to be cross-checked with the updated results below provided by EFSA as well as other elements coming from the 2013 results of the impact assessment on fees for EFSA. In particular, this impact assessment showed that half of the applications for authorisation (the sector generating the highest workload for EFSA and the national experts) were due at the time to reviews/re-evaluations (review/re-evaluation of substances authorised at EU level since a long time such as old food and feed additives or review/re-evaluation of substances (such as enzymes) or claims already on the market but which had never been authorised at EU level. Given that reviews are limited in time, the mid-term workload of EFSA has to be assessed in more detail

#### Questions<sup>2</sup> received 2008-2014 by food sector area

Row Labels	2008	2009	2010	2011	2012	2013	2014
Animal By-Products	1	1	3	2			1
Dietetic products				1			
Enzymes					4	19	69
Feed additives - applications linked to 1831/2003	6	6	3	3	5	10	7
Feed additives - applications under 1831/2003	45	49	178	153	105	64	60
Feed additives - others				1	1		
Flavourings	785	643	109	54	90	250	68
Food additives	8	6	7	348	8	5	7
Food Allergy		1	2	1			
Food contact materials	12	45	81	60	29	28	30
Food Hygiene				3		1	
GMO notification under Directive (EC) 2001/18/EC						2	1
GMOs applications for renewal under Reg. 1829/2003			4				
GMOs applications under Reg. 1829/2003	19	17	24	21	12	9	4
Health claims Art. 13/2	4187		452		91		
Health claims Art. 13/5	12	15	19	18	47	30	21

<sup>2</sup> A question is defined as an autonomous scientific issue identifiable within a mandate and leading to the adoption of a scientific opinion of an EFSA Scientific Committee or Panel.



Health claims Art. 14	231	22	10	8	5	3	6
Novel Foods	8	7	4	4	5	4	8
Nutrient sources	1	2	2	3	1	1	1
Pesticides	7	3	113	3	10	51	70
Pesticides MRL Application (Reg. 396/2005 - Art. 10)							1
Pesticides peer review - confirmatory data			1	1	8	4	22
Pesticides peer review - included active substances	29						
Pesticides peer review - new active substances	28	9	5	11	13	19	14
Pesticides peer review - renewal Annex I inclusion		6	2			5	
Pesticides peer review - re-submission	2	20	62	1			
Processing aids				2			1
Smoke Flavouring			1	2	2		1
TSE	7						
Upper Levels Vitamins and Minerals		1					
<b>Grand Total</b>	<b>5388</b>	<b>853</b>	<b>1082</b>	<b>700</b>	<b>436</b>	<b>505</b>	<b>392</b>

- it needs to be identified which work processes of EFSA are prescribed by legislative provisions and cannot be changed by EFSA on its own and which work processes are linked to modalities of implementation that could be changed more easily.
- EFSA's updated figures included below

## I. Cooperation linked to the support of MS to EFSA's scientific activities

### Main problems identified by the 2012 EFSA external evaluation

#### *Global findings*

- Not all MS have a developed capacity for scientific expertise and risk assessment, thus the support provided to EFSA's scientific tasks by each MS varies.
- The quality of EFSA scientific outputs relies on the contribution of experts. MS with stronger risk assessment capacity are perceived to participate more significantly to EFSA's work. This is confirmed by the figures in the expert database, as of April 2015: experts from Italy, United Kingdom, Germany, France, Spain and The Netherlands amount to 55% of all experts from EU MS and EEA/EFTA countries included in the Expert Database. The countries with most experts in comparison with their population as part of the total EU population are Denmark (3.3), Luxembourg (2.8) and Ireland (2.5) and the most underrepresented ones are: Poland (0.2), Romania (0.4) and Czech Republic (0.5).<sup>3</sup>(External evaluation, point 3.4.7). However, DG SANTE notes that this analysis does not take into account the fact that experts are selected on the basis of the quality of their expertise and that the geographical repartition mentioned in the 2012 external evaluation is in line with the level of research expenses in the different MS.

#### *Findings on the Advisory Forum (AF)*

- The AF mainly supports the sharing of data, in particular work programme outputs, risk assessment practices and methodologies but does not effectively ensure the sharing of work between MS and EFSA (External evaluation point 3.4).

<sup>3</sup> Reference value calculated by dividing the relative size of the country population (%) by the proportion of experts in the EDB (%) for well represented countries; and inversely for underrepresented countries.



- These issues are the subject of the current review of the AF by EFSA. The EFSA initiative on the establishment of an EU agenda is aimed at being a better tool to share planning on new projects and agree on common priorities.

#### *Findings on participation via grants and procurements*

- The share of EFSA budget allocated to externalization/outsourcing to MS via grants and procurement steadily grown (from 6% of EFSA budget in 2009 to 11% in 2011). Updated data show that in the last four years, EFSA has allocated an increasingly large budget to support the grants and procurements projects (Annex). In 2009 - 2014, 77 grants agreements for a total of € 11,726,024 and 789 procurement contracts for a total of € 36,623,168 were successfully awarded.
- 14% of the procurements remained unsuccessful between 2007 and 2009 and less than 25% of the Article 36 organisations have been involved at least once in Article 36 grants (External evaluation, point 3.4). Updated data show that in 2009-2014, 38% of Article 36 organisations have been involved in at least one grant or procurement project.
- The 2014 external evaluation conducted by EFSA to determine the impact of its science grant and procurement projects on delivery of its tasks<sup>4</sup> found that the most common reason why entities did not apply was that the published science grant and procurement calls were not relevant to their organisation's area of work (29 per cent of respondents cited this reason). Other reasons are illustrated in annex (Figure 2)<sup>5</sup>:
- The 2014 external evaluation also revealed that EFSA's conflict of interest requirements placed a much higher burden on its contractors (procurement) and to a lesser extent on beneficiaries (grants) than did those of any of the other institutions. Other institutions dealt with the issue through a simple declaration of honour.
- The Article 36 list has been reviewed and includes now 330 organisations from 30 countries (MS and the 2 EFTA States participating to EFSA)
- The 2014 External Evaluation found that the EFSA grants and procurements projects had a strong networking and cooperation benefit, facilitating collaboration between MS organisations and forging new, lasting relationships, particularly for Article 36 organisations. The evaluation also indicated that the impact of EFSA's science spending could be increased further, by greater use of longer term, larger research (grant-funded) projects. As a result, since 2014, EFSA has broadened the elements under its grant scheme to include thematic grants and framework partnership agreements<sup>6</sup>. Furthermore, EFSA science projects were also useful to organisations for publications, to support existing or to develop new research programmes, and to support teaching activities (Figure 3).

#### *Findings on participation of external experts*

- Independent scientific experts that compose Scientific Panels/ Committee have a major role in EFSA's activity but the 2012 external evaluation points out that "the more experts spend time on EFSA's activities, the less they have time to do their usual work for their original institutions" (External evaluation, point 3.6.2.2).
- Some stakeholders (Scient.Org, FIR, one NRM, one NRA (External evaluation, point 3.6.2.2) point out that some members of the Panels are overloaded. The external evaluation also indicates (External evaluation point 3.6.3.1) that some national authorities (NRA) signal that EFSA's engages experts they employ for 50% of their time. Some (one stakeholder per group NRA, Scient.Org, NGOs) indicate the need that the time spent by experts of the panel is optimized (to act as peer-reviewers) in order to concentrate their time in EFSA on added value activities. The last available data in EFSA (Expert Survey 2011) indicated that 40% of EFSA experts are employed by a national government authority. In the Expert survey, the experts indicated an average estimate of 4 days per month, with Chairs and vice-Chairs of the Scientific Committee and Panels providing higher estimate (around 6.5 days per month).

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<sup>4</sup> Available on EFSA's website: <http://www.efsa.europa.eu/en/supporting/pub/695e.htm>.

<sup>5</sup> External review of the impact of scientific grant and procurement projects on delivering EFSA's tasks – Comprehensive Report, Figure 30

<sup>6</sup> Available on EFSA's website: <http://www.efsa.europa.eu/en/search/doc/amp1517.pdf>, p.55.



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- Some stakeholders (NRM, NRA, FIR, EP/external evaluation point 3.6.2.2) consider the reliance of EFSA on external experts is one of EFSA's main strengths, since it guarantees a wide "portfolio" of expertise. They consider as a consequence that it is inconceivable that EFSA develops internally all needed competence.
- The external review (External evaluation, point 3.5.4) points out that there are a series of challenges for the mobilisation of experts in the short/medium term: (geographical location and time for travels, experts having to deal with conflicting priorities (their own job and their involvement in EFSA), criticisms on the independence of experts, small financial compensation even if the attractiveness of EFSA is still positive (high quality of EFSA outputs, contacts with other experts, EU work recognised internationally, opportunity to measure different approaches, public interest work, good on CV)
- the results of recent calls on the membership of Panels showed that the average age of experts participating to EFSA (from 53.6 years in 2012 to 55.3 years in 2015) is increasing and that some Panels in the area of applications for authorisations have problems in attracting new members

## General questions

- Which are the main positive points of the cooperation between EFSA and your country?
- Which are the main negative points of the cooperation between EFSA and your country?
- To what extent is the participation to EFSA's activities important for your country?
  - How is this priority translated in concrete terms (cooperation with EFSA is included in the mission statement of your national risk assessment agency/body, political guidelines have been issued by your authorities on the cooperation with EFSA to public scientific bodies competent for the safety of the food chain, others tools? Can you specify the tools and procedures in place?
  - In which tools of cooperation with EFSA is your country involved in (Advisory Forum (AF), Working Group of the AF, focal points, sending external experts, grants, procurements)? Can you specify to what extent?
- Can you provide information on the issue of declining resources in national public bodies and its impact on the cooperation with EFSA (quantitative information/examples)?

## Specific questions

### Grants and procurements

- Which conclusions can we draw from the updating of the Article 36 list in particular with regard to a better adequacy between the projects subject to Article 36 grants and the organisations now included on the list?
- Which conclusions can we draw from the updated data above on the causes restricting the participation of national organisations to grants and procurements (figure 2 in annex)? Can you indicate whether you consider that the causes are different for Article 36 grants and for procurements? If yes, specify.
- Which conclusions can we draw from the updated data above on the benefits that national scientific organisations draw from the participation to EFSA grants and procurements projects (figure 3 in annex)?
- Which conclusions can we draw from the increase of budget allocated to grants and procurements (figure 1 in annex)?

### On the participation of national experts employed by public bodies in EFSA's work

- Which concrete actions are in place at the level of your MS to facilitate the participation of national experts employed by public bodies to EFSA?
- Some limiting factors for the participation of national experts to EFSA are specified in the 2012 external review, can you provide views on the following ones below and identify their importance from very important, important, not very significant, significant to not significant?
  - To what extent the amount of time spent in EFSA by your national expert is a limiting factor? If considered as an important limiting factor, what could be the acceptable amount of time for the concerned organisations in your country? Can you confirm or infirm that the amount of time spent by experts is significantly more important for some Panels or some specific tasks and indicate for which



- ones? If specific Panels or specific tasks are at stake, can you identify which ones and the specific problems leading to excessive time requested from external experts?
- To what extent is the context of decreasing resources in the national scientific organisations a limiting factor for the participation of national experts to EFSA?
- To what extent the EFSA rules on independence hinder the participation of some of your national experts?
- Do you identify other significant limiting factors?

## II. Cooperation, recognition of EFSA and coherence

### Results on recognition of EFSA by MSs (External evaluation point 3.5.3.2 page 124)

There is a large consensus on the fact that EFSA is a leader to perform risk assessment. Two thirds of the respondents to the survey carried out in the framework of the 2012 EFSA evaluation consider that EFSA is at the forefront of the risk assessment methodologies in Europe, and this figure rises to 91% of the respondents when including those who gave a rate equal or higher than 3 out of 4.

The needs of the MS and the correlated expectations on EFSA's role vary in each MS according to the existence or not of a developed national risk assessment system.

### Results on coherence (External evaluation 3.4.3.2 and 3.3.3.1)

Globally, EFSA's efforts to promote coherence between risk assessment, risk management and risk communication are well-perceived (79% of respondents give a rating equal or higher than 3 in the online survey – EC, NRA, NRM). In particular, the efforts to align EFSA risk assessment methodologies and National Risk assessment ones are recognized by 86% of NRA (3.4.3.2 page 110)

Nonetheless about 48% of respondents NRA declared in the survey that they had situations of misalignment with EFSA's advice (3.4.3.2 page 111).

This is demonstrated in particular by the figures on the implementation of the Article 30 procedures (3.3.3.1 page 89) included in the 2012 EFSA external evaluation, even if the cases of effective divergences are only two.

Table 1: Procedures for divergent opinions art.30 (updated by EFSA for 2012-2014)

YEAR	TOPIC OF THE CONTROVERSIAL ISSUE	UNIT RESPONSIBLE	RESULT OF DIVERGENCE
2006	QRA tallow	BIOHAZ	Solved
2008	MON 810	GMO	Solved
	Threshold of Toxicological Concern	Scientific Committee	Solved
2009	Risk assessment of lycopene	ANS	Confirmed
2011	Sweeteners	ANS	Solved
	Coumarin	NDA	Solved
	Bisphenol A	CEF	confirmed
2012-2014	Bisphenol A	FIP	Confirmed
	Caffeine	Nutrition	Solved
	Perchlorate	BIOCONTAM	Solved



## Questions

- Which conclusions can we draw on the basis of the updated evidence?
- Are specific procedures or guidelines in place in your country to promote the complementarity between the national risk assessment activities with EFSA's activities?
- Do you consider that in certain cases it is useful and complementary to work on the same scientific issues/risk assessments as EFSA? If yes, in which cases?
- What is your concrete experience with Article 30 (procedure in case of divergent scientific opinions) procedures, what could be improved in the functioning of the procedure?

### III. Added value of EFSA for MS/Costs for MS (external evaluation point 3.4.3.1)

The number of EFSA's mandates received by Member States to perform risk assessments has doubled between 2007 and 2008 and remained steady (about 100 mandates/year) since 2008.

#### Questions received 2008-2014 by Mandate requestor (updated by EFSA)

	2008	2009	2010	2011	2012	2013	2014
<b>Commission</b>	<b>310</b>	<b>374</b>	<b>150</b>	<b>777</b>	<b>455</b>	<b>689</b>	<b>556</b>
<b>Member State</b>	79		2	113	93	73	58
<b>Application</b>	79		2	102	91	69	57
<b>Art 29 – Scientific opinion</b>				2	1	2	1
<b>Art 31 – Scientific and technical assistance</b>				1			

77% of national risk assessors and risk managers consider that their National Food Safety Authority benefits from EFSA's activities in terms of costs: due to EFSA inputs and sharing of expertise as well as operational support (risk assessments, communication, methodologies and trainings), national authorities can reduce some of their expenses. For example, costs related to identifying the best methodology are reduced. However, 23% consider that EFSA's activities do not reduce their national agencies' costs.

The impact on National Agencies' budget and activities highly depends on the Agency's expertise. For countries where there is no Risk Assessment Agency the impact of EFSA is significantly positive (it carries out work that the country would not be able to do alone). For countries with large scientific capacity, the impact is controversial and sometimes brings duplication and an increase of work to "translate" EFSA's opinions to a national level to support risk managers.

EFSA sometimes causes a problem to the efficiency of National Authorities because it engages National Authorities' experts (NRA), even for 50% of their time.

## Questions

- In which cases does your country send mandates to EFSA (lack of risk assessment capacity; sending of mandate prescribed by EU legislation in the case of certain authorisation procedures; other cases)? Can you specify the proportion between the different types of mandates your country has sent to EFSA?



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- Do you consider that the points of views expressed in the 2012 external evaluation on the ratio cost/benefit of the cooperation in particular the differences of point of views between countries having different scientific capacity remain the same or have they evolved? Can you provide data/evidence justifying your reply?
- Which are the main benefits of EFSA's activities for your country?
- Which are the main costs related to EFSA's activities for your country?

#### List of acronyms

Cons. Consumer Organizations  
EFSA: European Food Safety Authority  
FIR Food Industry Representatives  
MS: Member States  
NGOs Non-Governmental Organizations (other than Consumer Organizations)  
NRM National Risk Managers  
NRA National Risk Assessors  
Scient. Org. Scientific organizations





ANNEX (updates provided by EFSA)

Figure 1: EFSA budget under EFSA's grant and procurement schemes from 2009 to 2014

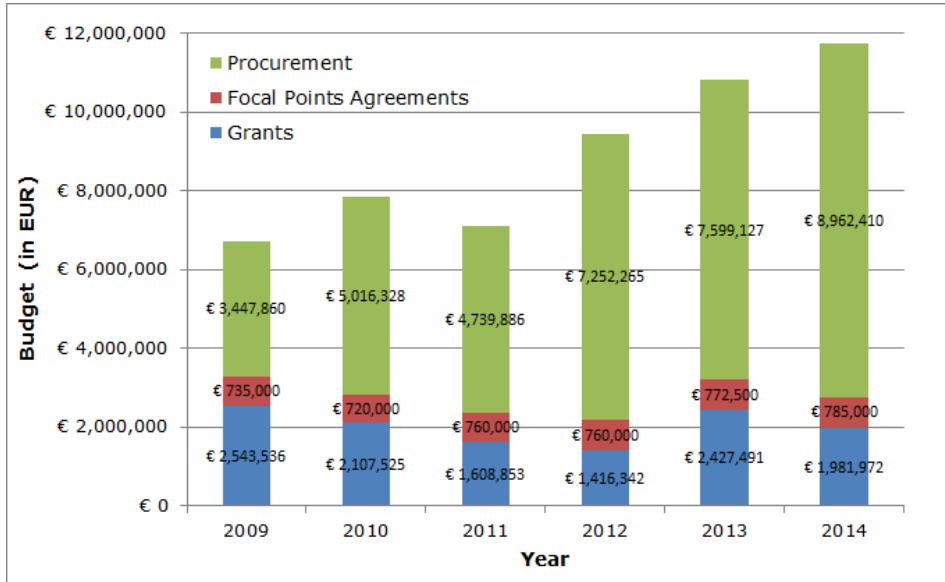




Figure 2: Reasons why entities did not apply for an EFSA science project (grant or procurement)

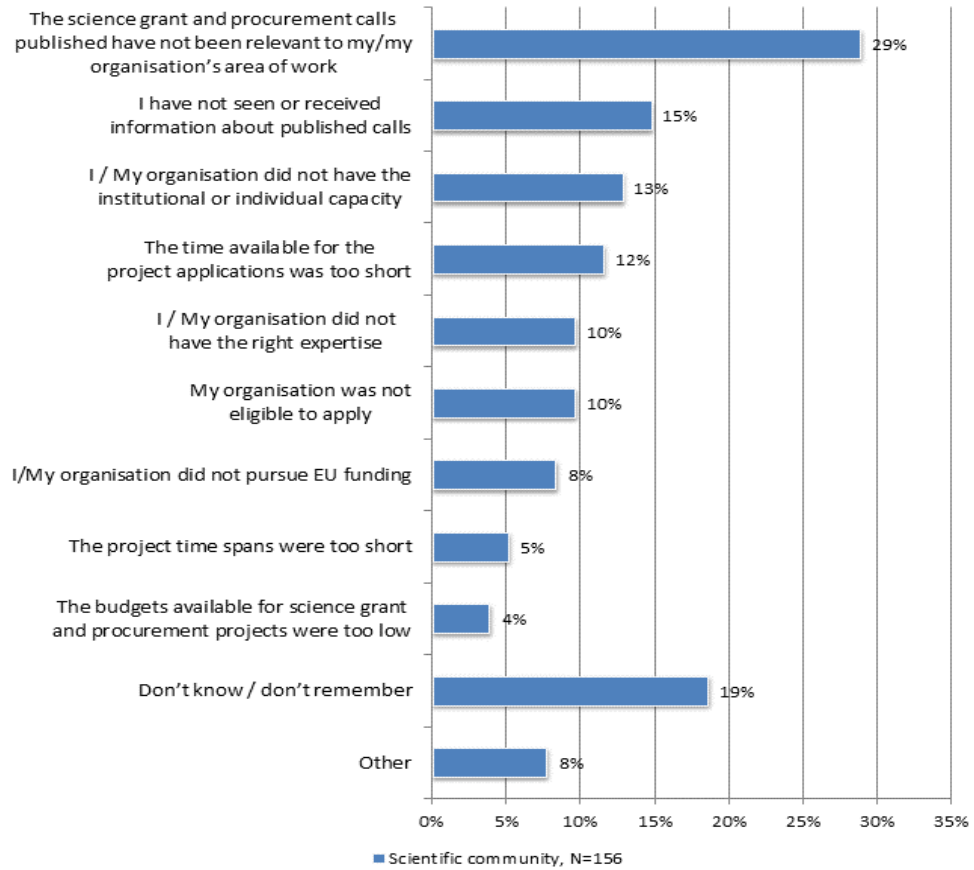




Figure3: How organisations used the data and other results from EFSA science projects in their work

