

Parma, 5 December 2008

**Review of the work carried out under Article 36 and
proposed contract and grant activities for 2009**

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Summary of the work carried out under Article 36 and proposed contract and grant activities for 2009

Article 36 of EFSA's Founding Regulation sets the basis for the networking with and among Member State organisations operating in the fields within EFSA's mission, and is a cornerstone of the scientific cooperation between EFSA and the Member States at the level of organisations.

In the two years following the establishment of the list of competent organisations under Article 36, activities have focused first on setting up and then further improving the tools and processes necessary for implementing Article 36. Besides the key task of making functional the list of competent organisations itself, this required the development of a set of detailed implementing procedures towards carrying out scientific cooperation projects, implemented in the form of grant agreements between EFSA and the Member State organisations.

As a result of the inclusion of organisations from Bulgaria and Romania, the list now includes 243 entries. This number may be substantially increased following the current updating for which the EFSA Management Board will decide on new organisations to be added. The number of additional institutions submitted for consideration by the Management Board is 128. In addition, five organisations requested to be removed from the list. This would bring the total number to 366.

A total of 37 competent organisations from 17 Member States have entered – or are about to enter - into 26 grant agreements with EFSA thus far. The total budget allocated to Article 36 projects has increased from €1.7 million (related to 8 calls) in 2007, to €2.0 (related to 18 calls) million in 2008, and a proposed €3.9 million in 2009.

Scientific cooperation with Member State organisations also takes place via public procurement procedures and other specific agreements. This has thus far involved 30 organisations from 10 Member States. Similar to projects under Article 36, the total budget allocated to these activities has substantially increased since EFSA's establishment in 2003, from approximately €2.1 million for the entire period 2003-2006, to €1.2 million in 2007, €3.8 million in 2008 and a proposed €3.6 million for 2009.

In the Work Programmes for 2009, the total budget allocated to cooperation between EFSA and Member State organisations is around 7.5 million €. The table below shows the distribution of this budget for the different activities as well as the type of contract. It will be noted that the 2009 increase goes to grants (whereas there is no increase for contracts). The availability of an expanded list of organisations should indeed facilitate the use of this mechanism of cooperation. It will also be noted that the majority of the resources is to be spent on support for risk assessment, either assessment of applications or other risk assessments.

Budget proposed to be allocated in 2009 to scientific cooperation with organisations in Member States for the main scientific activities of EFSA.

| Activity | Grants (€) | Procurement (€) | Total (€) |
|---|-----------------------|----------------------------|----------------------|
| 1. Support for evaluation of application dossiers | 775 000 | 1 638 000 | 2 413 000 |
| 2. Risk assessment | 1 595 000 | 120 000 | 1 715 000 |
| 3. Data collection | 1 020 000 | 940 000 | 1 960 000 |
| 4. Horizontal issues and Scientific Cooperation | 475 000 | 50 000 | 525 000 |
| Total | 3 865 000 | 2 748 000 | 6 613 000 |

In addition, it is intended to conclude Focal Point agreements for a total amount of 860 000 € thus bringing the total budget to **7 473 000 €**

Within the context of the interim review of the strategy on cooperation and networking, the Advisory Forum provided positive feedback regarding the activities under Article 36. While the foundations are in place and a significant amount of progress has been made, the following improvements are proposed:

- to update the list of organisations every 2 years at a pre-defined period as well on an *ad hoc* basis should a new area be identified.
- to allow the Executive Director of EFSA to continuously introduce updates and modifications of the listed organisations (*i.e.* “technical changes”), provided that this does not affect the criteria for inclusion into the list as laid down in Commission Regulation No. (EC) 2230/2004.
- to further foster the networking of these organisations via additional initiatives *i.e.* develop the Article 36 list into a broadly available database with a dedicated extranet space for the Article 36 network.

1. Introduction

Collaboration between EFSA and the Member States is carried out at various levels. At the level of the Member State the collaboration takes place through the Advisory Forum, which is assisted by the Focal Points network. Scientific cooperation also takes place with individual organisations and individual experts.

Cooperation with selected “competent” organisations in Member States is described in Article 36 of EFSA’s founding Regulation and in Regulation (EC) 2230/2004, according to which a list of competent organisations capable of assisting EFSA in its tasks was adopted by EFSA’s Management Board in December 2006. According to the provisions of Regulation (EC) 2230/2004, financial support is provided in the form of grants.

Scientific cooperation with organisations is also carried out via public procurement procedures (contracts), according to the provisions laid down in Article 32 of EFSA’s Founding Regulation on scientific studies, as well as through the establishment of other specific agreements, such as with the Focal Points.

The objective of this paper is to provide an activity report to the Management Board on the implementation of the scientific cooperation and networking activities under Article 36. Scientific cooperation activities via procurement and other agreements are also included where appropriate.

2. Establishing the list of competent organisations

The Article 36 list (hereafter referred to as the “list”) was originally established on 19 December 2006, following the procedure indicated in Articles 1 and 2 of Regulation (EC) 2230/2004, whereby EFSA’s Management Board adopted the list, acting on a proposal from the Executive Director of EFSA and following the official nominations by the Member States’ Permanent Representations. Further details on the practicalities of nominations are provided in Appendix 1. At the time of its establishment, the list included 234 entries from 23 Member States. There were no nominations from Malta and Luxembourg.

3. Overview of scientific cooperation activities with organisations

The planning of the scientific cooperation activities with Member State organisations is implemented on an annual basis and through specific annual Work-Programmes (WP), which are developed following proposals from EFSA's Scientific Committee, EFSA's Scientific Panels and Networks and EFSA's Scientific Directorates. There have been two such WPs to date, for 2007 and 2008, while the WP for 2009 has been submitted to the Management Board for adoption.

The proposed work programmes are discussed at the Advisory Forum. EFSA seeks to identify scientific issues of common interest to be undertaken under the network. When doing so, Member States and the Authority strive to avoid any duplication of efforts by the Member States and EFSA. EFSA also cooperates with the Commission to avoid overlaps with existing work at Community level. The overall proposal is submitted to the Management Board for endorsement.

Calls for proposals on grants and calls for tender on public contracts are published on EFSA's website. In addition, for grants, all organisations on the list are notified by e-mail immediately following the publication of a call for proposals.

In 2007, the first operational year of the Article 36 list, eight grants were signed for a value of approximately €1.7 million. For the 2008 work-programme, 18 grants are expected to be signed by year-end, for an estimated budget of €2.0 million. For the 2009 WP, grants are currently foreseen for a budget of €3.9 million.

Procurement activities (contracts) with individual organisations on scientific issues have been carried out since 2003 and Focal Point agreements since 2007. For the period 2003-2006, the total was €2.1 million¹. The figure for 2007 was €1.2 million, while for 2008 it is €3.8 million². For 2009, the estimated budget for contracts/Focal Point agreements is €3.6 million.

Figure 1 provides an overview of the budget allocated to grants and contracts/agreements from 2003 to 2009. More details on the scientific activities carried out under grants and contracts from 2003 to 2008 can be found in Tables 1A-3A in the main body of the report on the interim review of the strategy on cooperation and networking.

¹ Some early procurement activities may be missing from the figures; efforts are currently in place to ensure that these figures are all inclusive.

² This involves standard procurement activities for contracts of approximately 2.3 million (1.4 for new calls and 0.9 for contract renewals), as well as agreements (€0.9 million for collaboration agreements with Member State organizations for the provision and processing of food consumption data, €0.4 million for Service Level Agreements with the JRC and €0.2 million for the Focal Point agreements).

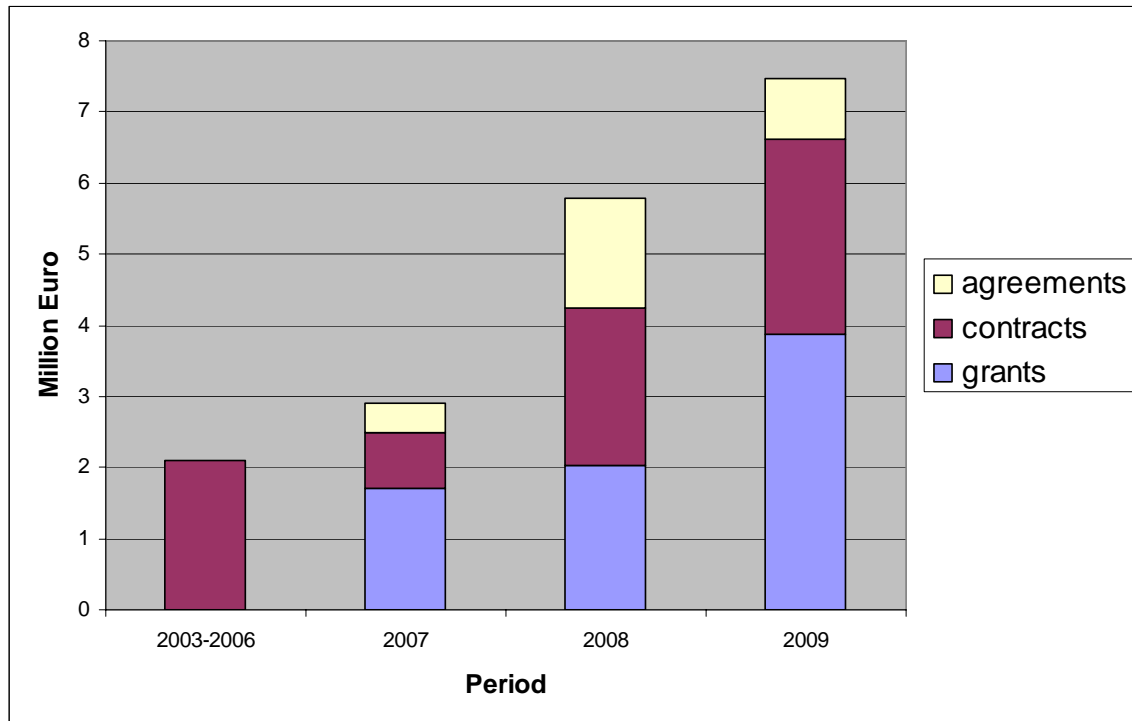


Figure 1: Budget allocated to grants, contract and agreements for the period 2003 – 2009.

In order to promote networking with and amongst Member State organisations, EFSA encourages the formation of consortia for carrying out the projects. Indeed, eleven out of the 26 grant agreements (i.e. 42%) signed to date or expected to be signed soon are carried out by consortia, including up to 10 partner organisations. The average is 2.5 partners per awarded grant. In comparison, only three out of the 40 procurement contracts (i.e. 8%) have been awarded to consortia³. The average is 1.4 partners per awarded contract

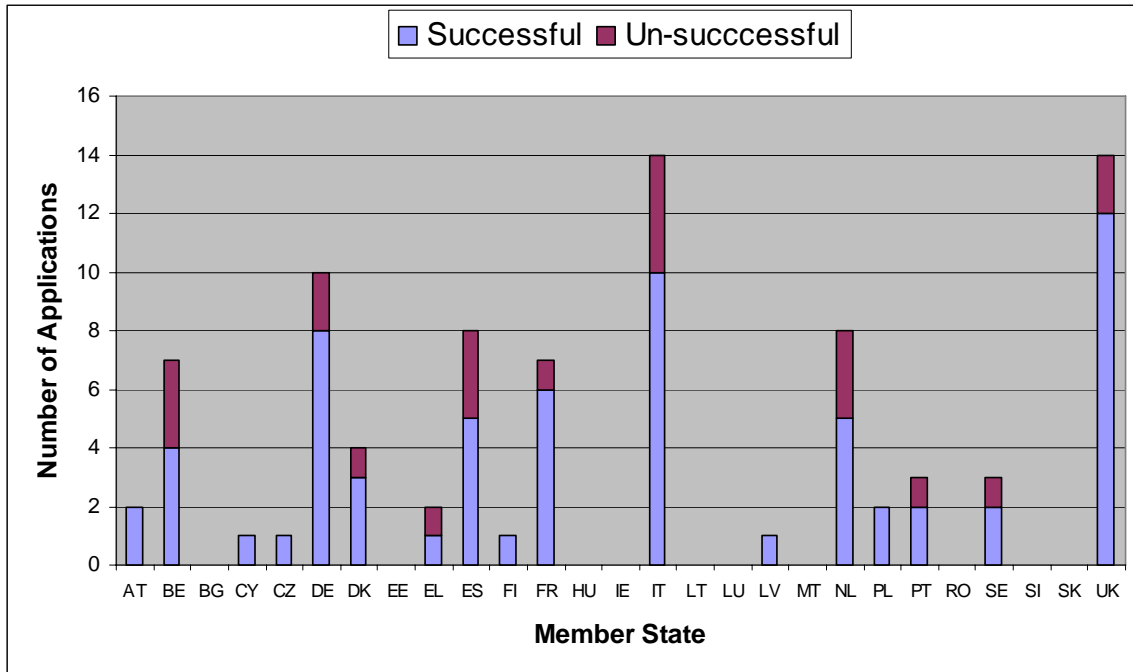
Figure 2 shows a breakdown, by Member State, of organisations that applied and organisations that were awarded a grant or contract⁴(2A and 2B, respectively). In the case of grants, 45 organisations from 17 MS have submitted applications, with 37 organisations from 17 MS being successful in participating in at least one grant. In procurement, organisations from 13 Member States have submitted applications, and organisations from 10 Member States have been successful. The average number of applicants per awarded grant and contract is 1.7 and 2.8 respectively.⁵

³Framework contracts with more than one organisations but in which there is no collaboration among the individual organizations are not considered as consortia.

⁴ Data on the unsuccessful applicants for the already signed contracts were available only for the running contracts (mainly contracts signed in 2007 and 2008).

⁵ For procurement, all procedures are included (open and negotiated); the rate of applicants per call only for the open procedures is higher, at approximately 6.8.

A



B

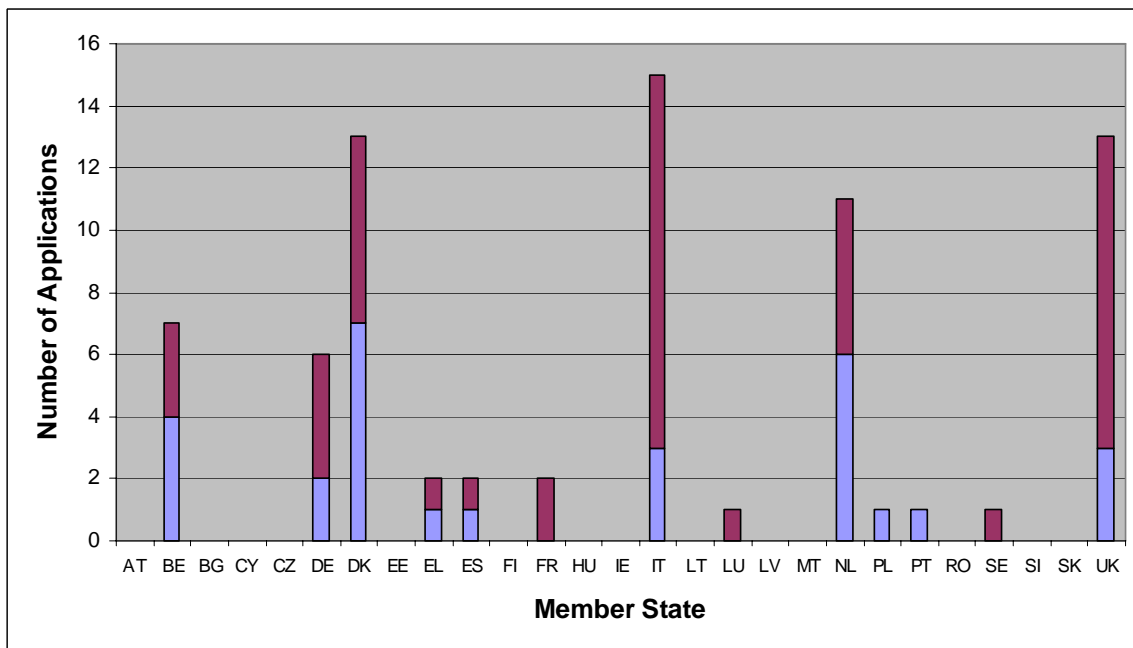


Figure 2: Applications for grants (A) and procurement (B) - breakdown by Member States.

4. Updating the list of competent organisations

Regulation (EC) 2230/2004 foresees that the list shall be updated regularly, taking account of reviews or new designation proposals from the Member States. The list has already been updated by the addition of competent organisations from new Member States, namely Bulgaria (with 6 organisations) and Romania (with 4 organisations), as adopted by the Management Board on December 2007, as well as with the withdrawal of one organisation, as adopted by the Management Board on June 2008, bringing the total number of entries to 243⁶ (Figure 3).

A procedure for updating the list by new nominations and/or withdrawals for all 27 Member States was launched in June 2008, and is foreseen to be completed with the adoption of the new list by EFSA's Management Board in December 2008. The number of additional institutions submitted for approval to the Management Board is 128. In addition, five organisations requested to be removed from the list. This may bring the total number to 366.

It is proposed that the list shall continue to be updated regularly and when specific needs arise. The EEA-EFTA States applying the EU Food Law (Norway, Liechtenstein and Iceland) will also be able to designate competent organisations once the amended EEA agreement has entered into force.

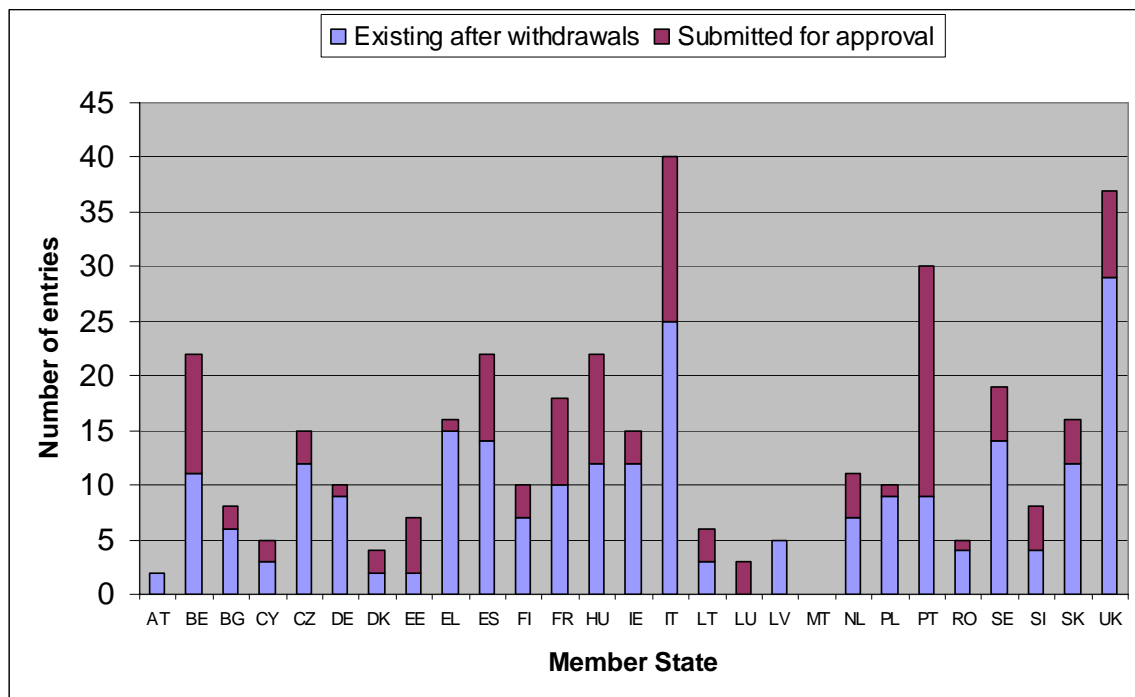


Figure 3: Entries on the Article 36 list - breakdown by Member State.

⁶ This is the current situation; the list of existing organisations as it stands now can be found at http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_article_36_cooperation.htm

More details on the updating and maintenance of the list, as well as on the procedures that EFSA has put in place to take care of these are provided in Appendices 1 and 3. Focal Points – in support of the Advisory Forum member - have an important role in informing and stimulating competent organisations to apply to be added to the list when the formal procedure is open. In addition, they support EFSA staff in keeping the list functional by highlighting any necessary changes to be made regarding organisations from their country already on the list.

Out of a total of 30 grants that were evaluated thus far three were unsuccessful⁷:

Two GMO calls launched in 2007 failed in the evaluation:

- Cry proteins and their expression in micro organisms and genetically modified plants
- Study on the state-of-the-art on the impact of Genetically Modified Herbicide Tolerant plants on non-target organisms

One PLH call launched in 2008 received no proposals:

- Development of a harmonised approach to the characterisation of risk in pest risk assessment

For contracts launched in 2008 one GMO call received no proposals:

- Defining environmental risk assessment criteria for genetically modified fishes to be placed on the EU market

This experience indicates the need for a better representation of all fields of competence within EFSA's remit. Table 1 below demonstrates the strengthening of all the fields of competence, and in particular in the areas of plant health and new technologies, when comparing the current and the proposed list.

⁷ One call launched in 2008 will be signed in 2009

Table 1: Number of organisations in the Article 36 list with main competences represented in the current and in the proposed list

| Area of competence | Current list | Proposed list | % increase |
|---------------------------------------|---------------------|----------------------|-------------------|
| General research capacities | 226 | 354 | 57 |
| Food including nutrition | 198 | 313 | 58 |
| Feed | 144 | 224 | 56 |
| Animal production, health and welfare | 107 | 179 | 67 |
| Plant health | 35 | 93 | 166 |
| Plant protection products | 92 | 151 | 64 |
| Biological hazards | 164 | 257 | 57 |
| Food production and food supply | 144 | 237 | 65 |
| GMO | 85 | 142 | 67 |
| Toxicology | 95 | 161 | 69 |
| Exposure assessment | 121 | 184 | 52 |
| New technologies ⁸ | 0 | 42 | n/a ⁹ |
| Others | 97 | 203 | 109 |

⁸ This has been added only to the questionnaire in the recent call for nominations

⁹ Not applicable

5. Implementing conditions and monitoring the performance of tasks

EFSA implements grants under Art. 36 compliant with Title VI of the EU General Financial Regulation and with Art. 160 – 184a of the related Implementing Rules. A comparison of the main principles applicable to grants and public contracts (procurement) can be found in Appendix 3.

To ensure that the performance of tasks EFSA entrusts to the organisations on the list follow a set of harmonised quality criteria, these criteria are always specified in each call. The calls are assessed against these criteria by evaluation committees consisting of representatives from at least two different units in EFSA, thus ensuring compliance with Art. 6 of Regulation (EC) 2230/2004). Similar procedures, with the same type of quality criteria apply to public procurement.

EFSA has put in place detailed implementing procedures for preparing and launching the calls for proposals under Art. 36, for evaluating the received proposals, for awarding grants to the successful applicants and for managing the resulting grant agreements. These include the “Vademecum” for preparing and launching of the Art. 36 calls for proposals, the “Call and guide for applicants” for evaluating the received proposals, the “Call and guide for applicants” and the “Template for evaluation minutes” for awarding grants to the successful applicants, the “Guide on administrative management of grant agreements” for managing the resulting grant agreements and a series of templates prepared for each step of the procedure. All these detailed implementing rules were agreed upon with the European Commission legal services.

The Financial Regulation of the EU with its implementing rules foresees a series of criteria for the evaluation of calls for proposals:

- eligibility criteria: for evaluating the eligibility of the applicant and its possible partners, the eligibility of the project for which the EFSA grant may be awarded, and the eligibility of the proposed costs.
- selection criteria: once proposals have met the eligibility criteria, they are evaluated against the selection criteria, which are used to evaluate the applicants (and its possible partners) financial and operational capacity.
- award criteria: once proposals have satisfied the requirements of the eligibility and selection criteria, they are evaluated against the award criteria, which have been standardised in EFSA and are: quality of the proposal, quality of the management (including consortium if applicable) and cost effectiveness (however the award criteria - contrary to the eligibility and selection criteria - may be different on a case by case basis (i.e. depending on the particularities of each call). The weighting of the award criteria is decided on a case by case basis.

To ensure the highest quality in the final outcome of the project, EFSA monitors the performance of the tasks entrusted to the organisations on the list from the very early stages. Steering committees (with representatives from EFSA’s scientific units and

Panel/Working Group members) follow the projects carefully. Reporting and meeting requirements, such as:

1. Meetings (kick-off, interim and final meeting)
2. Reports (interim and final reports)

are specified in the call for proposals and ensure that the projects meet the requirements and specifications.

The reports are subject to approval and the grant is paid in full only once the project is finalised at the required quality level. In addition, grant agreements contain some dissuasive penalties to be applied in the case of departure from the required quality standards. Similar procedures apply to public procurement. Of importance in the monitoring of the work under article 36 is also the assessment of the impacts of the Article 36 projects to the work of EFSA. However it is currently too early for such an assessment to take place, as thus far only one Article 36 project has been (recently) finalised. Such an assessment will be possible in 2009 once the first set of Article 36 project reports have been finalised.

6. Proposed measures for improving the work under article 36

6.1. List of competent organisations

According to Regulation (EC) 2230/2004, EFSA shall regularly update the list taking account of reviews or new designation proposals from the Member States, while Member States shall review their designations at least every 3 years. Experience has shown that regular updating will indeed be beneficial for optimising the necessary expertise on the list, taking into account the changing scientific needs and demands as well as changes occurring in research organisations in Member States. While necessary, the process of updating the list requires considerable resources both from EFSA and the Member States and thus needs to be well planned.

To facilitate this process, it is proposed:

- to update the list *every 2 years* at a pre-defined period. This provides sufficient flexibility towards adjusting the list according to the needs of the Authority and Member States.
- to update the list on an *ad hoc* basis if a new area of competence is identified.
- to allow the Executive Director to introduce technical updates and modifications of the listed organisations, provided that this does not affect the criteria for inclusion into the list as laid down in Commission Regulation No. (EC) 2230/2004 (see Appendix 2).

6.2. Networking under Article 36

According to Regulation (EC) 2230/2004, EFSA shall foster networking with the organisations on the list so as to promote active scientific cooperation in the fields within its mission.

Within the context of the interim review of the strategy on cooperation and networking, the Advisory Forum was recently asked to provide Member States' views on the implementation of the Strategy. The feedback concerning activities under Article 36 indicates that respondents consider these activities to be important, to have been well done, and suggest that they should continue at the same level. Specific comments were made, such as i) that it is important to avoid duplication of activities, e.g. through Article 36 projects and ESCO working groups, and ii) for new Member States, in the first five post-accession years, to participate in such projects without national financial contribution. Experience gained so far has therefore indicated that networking is already successfully taking place.

Nevertheless, this networking can be strengthened through the provision of appropriate tools and by further streamlining the processes that are already in place.

To facilitate the process, it is proposed:

- to further develop the Article 36 list into a broader database and to create a dedicated extranet space for the Article 36 network, thus providing an electronic forum for networking and facilitating the formation of consortia.
- to invite the organisations on the list to one of the major scientific events organised by EFSA, thus providing an additional forum for networking.
- to continuously improve the existing guidelines for applicants, including the development of a FAQ document.
- to further develop collaborative scientific activities under Article 36 beyond the scope of the grants tool, i.e. for activities not financially supported by EFSA.

Appendices

Appendix 1

Procedural steps for the nomination of new Member State organisations

Further details on the practicalities of nominations were described in the “Request to Member States to nominate competent national organisations operating in the fields of EFSA’s mission” (letter of 25 July 2005 from the Authority’s Executive Director to the Permanent Representation of Member States to the European Union). The procedural steps are as follows:

- i) EFSA launches the procedure and provides a Questionnaire to assist the Member States and EFSA with the selection of appropriate candidates;
- ii) the Permanent Representations of Member States officially channel the submission of the applications for organisations which are in compliance with the essential criteria (and Questionnaires) to EFSA;
- iii) upon receipt, EFSA reviews the compliance of the nominated organisations with the set criteria and prepares the decision of the Management Board;

EFSA’s Management Board adopts the list with the organisations that met the set criteria by the set deadline.

Appendix 2

Changes regarding organisations already on the Article 36 list

Since the establishment of the list, a number of requests for changes to the list have been received by EFSA, either through the Members States' Competent Authorities, their Permanent Representatives or via the organisations themselves. In order to deal with these requests, and according to the provisions of Regulation (EC) 2230/2004, EFSA has established a procedure to ensure that this is done efficiently and transparently.

Throughout this period, EFSA has received more than 100 requests for changes concerning organisations that are already on the list. These requests were sent via different channels, mainly through emails and in some cases through the submission of new questionnaires, reflecting the updated situation.

EFSA has been screening these requests on a regular basis following the procedure described in the below section "procedure for the maintenance and updating of the Article 36 list". The large majority of these requests concern non-substantial changes, e.g. for editorial changes related to contact information, while several of them concern more substantial changes, e.g. the notification of structural, organisational, or other changes that have taken place. For the more substantial changes, new questionnaires were requested (if they weren't submitted directly by the relevant organisations) for assessing the new situation. In some cases, EFSA has had to request more information and/or clarifications. In most of these cases, the assessment revealed that the more substantial changes were in compliance with the selection criteria, and could therefore be implemented.

The list has been continuously revised for organisations that are already on it. The revisions were initiated following a request by the Authority's Executive Director to Member States, made at the meeting of the Advisory Forum held in Lisbon on 20 September 2007 and a subsequent request to all Article 36 organisations via e-mail on 29 November 2007.

In the future, the maintenance of the adopted list regarding organisations that are already on it shall take place on a continuous basis, and via the liaising between the Member State Focal Points and EFSA.

The procedure used by EFSA is described below (see Figure 4):

- i) requests for revisions may come from the Focal Points and the Advisory Forum, the Article 36 organisations themselves, or the Permanent Representations.
- ii) requests are assessed by the Article 36 committee¹⁰ and are placed in two categories:
 - a) requests for non-substantial changes, i.e. “technical changes”: these refer mainly to editorial changes, such as related to the contact information, internal operational rearrangements and other changes that do not impact on the structure of the organisation. They are dealt with immediately and the Article 36 list is updated accordingly following a decision by EFSA’s Executive Director. The Management Board must be informed of the technical change at the next Management Board meeting.
 - b) requests for more substantial changes: these refer to all other requests, which involve changes to the structure, funding, competence, etc. of the organisations (i.e. related to the criteria set out in Article 1 of Regulation 2230/2004 for the inclusion of organisations on the list). In these cases, the submission of an updated questionnaire, eventually via the Permanent Representation, may be required. EFSA’s Grant Committee¹¹ will then assess these changes. The outcome of the assessment is brought to the attention of EFSA’s Executive Director, who then may make a proposal to the Management Board for possible adoption.

¹⁰ Representatives of EFSA’s Legal, Finance and Scientific Cooperation Units.

¹¹ EFSA’s Scientific Directors and EFSA’s Director of Administration

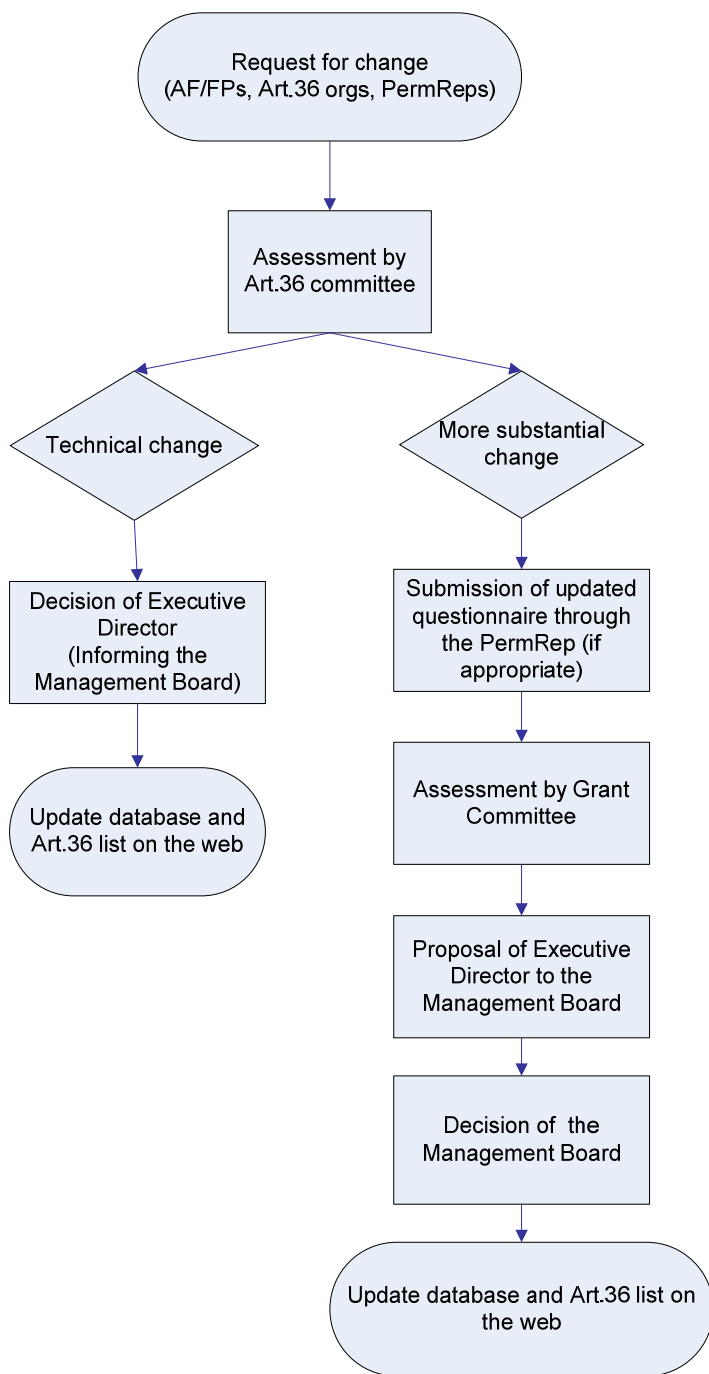


Figure 4. Proposed procedure for updating the Art.36 list for already existing organisations.

Appendix 3 Comparison between Grants and Public Contracts¹²

Grants are “*direct financial contributions, by way of donation, from the budget in order to finance:*

- a) either an action intended to help achieve an objective forming part of a European Union policy;*
- b) or the functioning of a body which pursues an aim of general European interest or has an objective forming part of a European Union policy”.*

In the case of a contract the Authority obtains a product or service it needs in return for payment, while in the case of a grant it makes a contribution either to a project carried out by an external organisation or direct to that organisation because its activities contribute to Community policy aims.

The Table below shows the main features and differences of grants and public contracts (procurement):

¹² This information is taken from Titles V and VI of the EU Financial Regulation (COUNCIL REGULATION (EC, Euratom) No 1605/2002; OJ L 248 of 25 June 2002)

| Public contract | Grant |
|--|---|
| Purpose | |
| <p>The purpose of the expenditure is to acquire a product or service^[1] which the Authority needs for its own activities.</p> | <p>The purpose of the expenditure is to encourage actions recognised as useful by the Authority, but which fall primarily within the scope of the beneficiary's activities.</p> |
| Initiative and control | |
| <p>Initiative and control lie entirely with the Authority: it is the Authority that places the initial order for a product or service and produces detailed specifications. The successful tenderer must comply with the specifications.</p> | <p>The application for financing originates with the beneficiary, who submits a proposal to the Authority for support for activities he is carrying out or planning to carry out in response to a Authority call for proposals. The proposal sets out the specifications for the action to be performed within the framework laid down in advance by the Authority.</p> |
| Ownership | |
| <p>Since the product or service has been purchased and paid for by the Authority, in general it belongs to the Authority in its entirety.</p> | <p>Ownership as a rule is with the beneficiary of the grant.</p> |
| Community contribution | |
| <p>The Authority usually pays 100% of the contract price.</p> | <p>The grant may not be used to finance the total costs of the action save in duly substantiated exceptional cases involving external actions.</p> |
| Mutual obligations, monitoring | |
| <p>The contract is bilateral: it imposes reciprocal obligations on the Authority and on an economic operator, with the operator providing the Authority with a product or service it has ordered.</p> | <p>Conditions are attached to the award of a grant but there is no direct specific link between individual obligations on either side (Authority and beneficiary).</p> |

| | |
|---|--|
| The Authority monitors the provision of the product or service it has ordered. | The Authority has the right to monitor the technical implementation of the action and the use made of the funds granted. |
| Profit | |
| The Authority pays the economic operator. It is natural that the operator's remuneration should include an element of profit. | The grant must not have the purpose or effect of producing a profit for the beneficiary. |
| Procedures | |
| Tenders are received as part of an open, restricted or negotiated procedure. | Grant applications are normally received in response to a call for proposals. |