



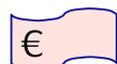
## **Collaboration between Art 36 organizations and EFSA**

**Riitta Maijala  
Director of Risk Assessment**

**Finish EFSA Focal Point Seminar – EVIRA  
Helsinki, Finland, 03 June 2009**

# Article 36 and Procurement for scientific projects

Article 36,  
procurement



Scientific  
Projects

Data and  
Information



Scientific Institutes  
in the Member States

# Annual Work Programmes Grants and Procurement

- Grants – Article 36 of EFSA’s Founding Regulation (Regulation (EC) No 178/2002) and Implementing rules (Regulation (EC) No 2230/2004)
  - Promote networking
  - Competent organisations designated by Member States
- Procurement (contracts)– For scientific studies, Article 32 of EFSA’s Founding Regulation
- Grants and Procurement: based on EU Financial Regulation and Implementing rules
- Cooperation with Member State organisations - supporting the scientific work of EFSA

## Article 36 of EFSA's Founding Regulation states:

*EFSA "...shall promote the European networking of organisations operating in the fields within the Authority's mission."*



**List of competent organisations established**



**These may undertake work on behalf of EFSA, e.g.:**

- data collection;
- preparatory work for development of scientific opinions;
- other scientific and technical support, e.g. on emerging issues and crisis situations.

# Comparison of Grants vs Procurement

## Procurement

## Grant

<b>Buying things</b>		<b>Purpose</b>		<b>Giving money</b>
<b>EFSA</b>	←	<b>Ownership of outputs</b>	→	<b>Beneficiary (restricted)</b>
<b>Agreed price</b>	←	<b>Financial contribution</b>	→	<b>% Share of costs</b>
<b>Profit</b>	←		→	<b>Non-profit</b>
<b>F.R, Title V, Directive, <i>vade mecum</i></b>	←	<b>Rules applying</b>	→	<b>F.R, Title VI, guide on grants</b>
<b>Call for tender (open/restricted/ negotiated)</b>	←	<b>Procedures</b>	→	<b>Call for proposals - restricted to Art. 36 list</b>
<b>Contract</b>	←	<b>Legal form</b>	→	<b>Grant agreement</b>

# Article 36 list

- Applicants for grants need to be on the Art. 36 list (currently **371** competent organisations on the list)
- Permanent Representations of the MS to the EU propose organisations
- EFSA's Management Board adopts the list (defined criteria)

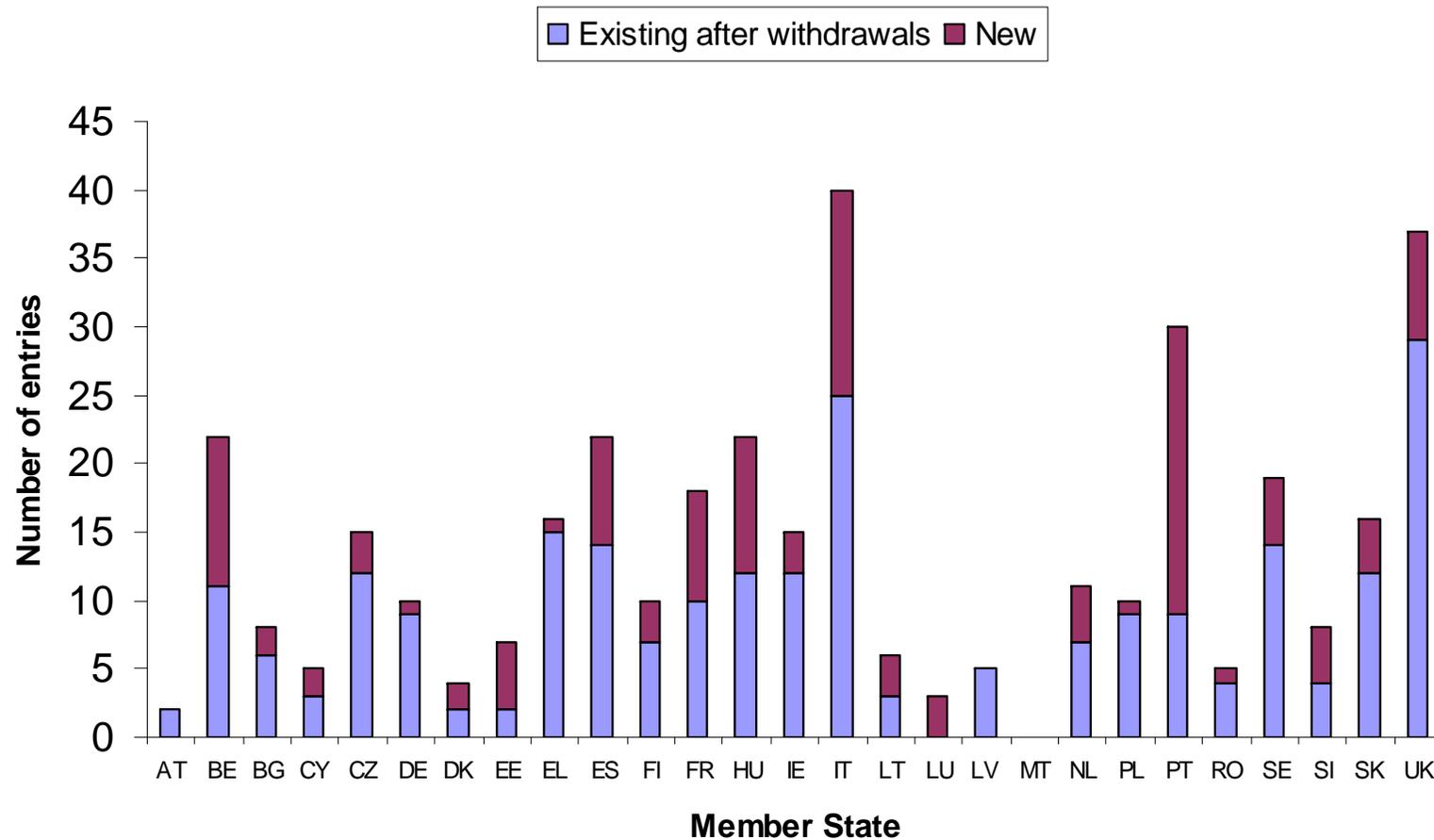
- designated by Member States based on essential criteria as stipulated in **Regulation (EC)2230/2004**
  - “must carry out scientific and technical support tasks in the fields within the mission of EFSA...”
  - “must be legal entities pursuing public interest objectives, and their organisational arrangements must include specific procedures and rules ensuring that any tasks entrusted to them by the Authority will be performed with independence and integrity”
  - “must possess a high level of scientific or technical expertise in one or several fields within the Authority’s mission,...”
  - “must have the capacity to operate in a network on scientific actions...and/or the capacity to perform efficiently the types of task ... which may be entrusted to them by the Authority.”

# Organisations on the Art 36 list

- May apply to calls for proposals launched by EFSA (if they so wish)
- Should ensure that the information held by EFSA (as submitted in the questionnaires) is up-to-date (e.g. contact information, organisational changes, etc)
- If awarded a grant, need to fulfill their tasks as stipulated in the grant agreement

# Article 36 list – Member States

## Entries on the Article 36 list – breakdown by Member State



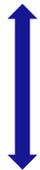
## The role of Focal Points:

- To **stimulate** Article 36 organisations to apply
- To act as an **interface** between EFSA and the Article 36 organisations.

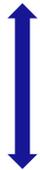
# Information flow between Art36 organisations and EFSA

- **General correspondence**

Article 36 organisation  
contact person



EFSA Focal Points



EFSA Scientific  
Cooperation unit

(Cooperation.Article36  
@efsa.europa.eu)

- **Grant specific correspondence  
(signature of grant agreement - end  
of project)**

Art36 project beneficiaries



EFSA responsible  
scientific unit

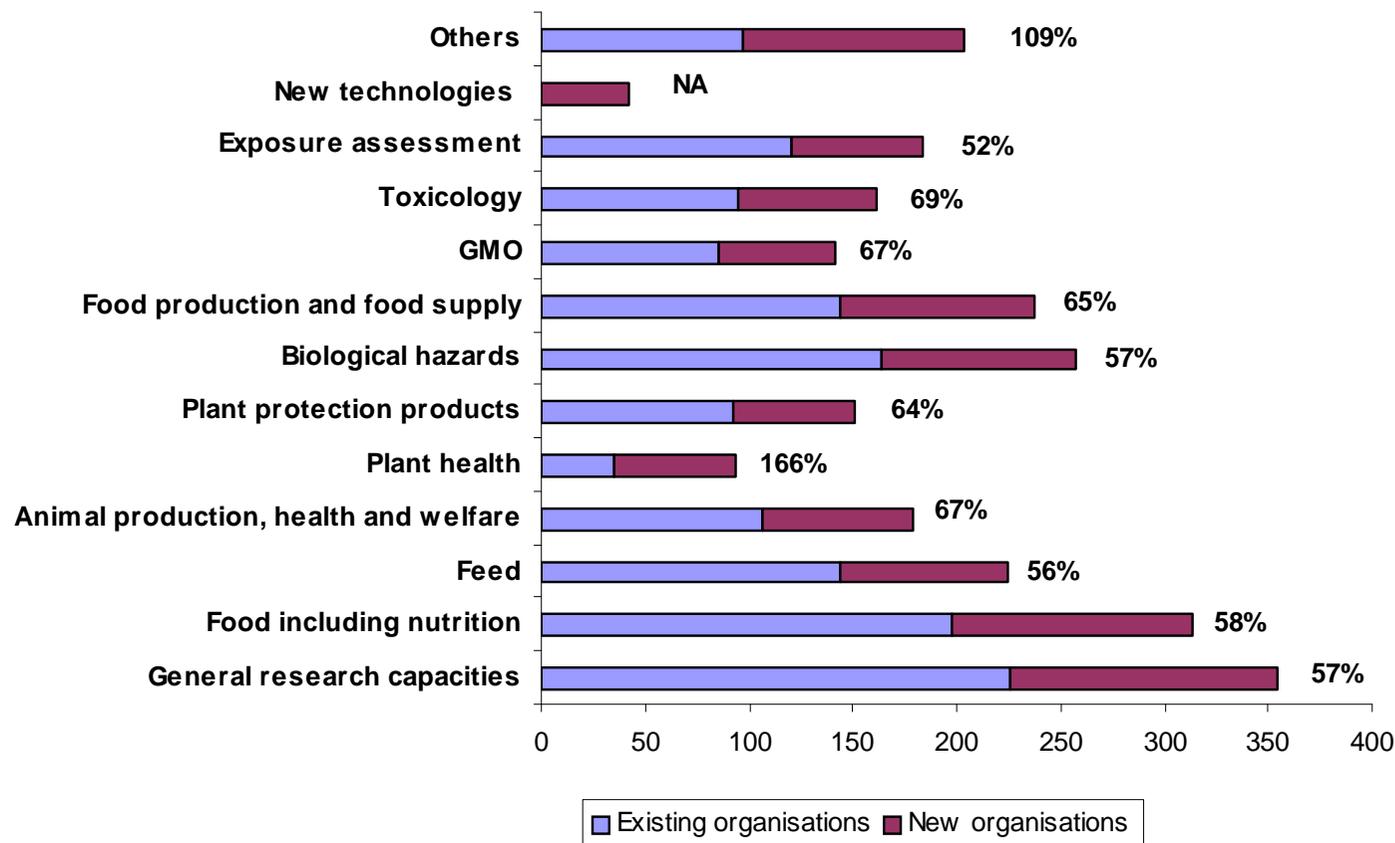
# a “living” list, to be regularly updated:

- New designations: via the MS Permanent Representations
  - 1<sup>st</sup> update December 2008
  - Regular updates are foreseen, e.g. every 2 yrs
  - Ad hoc updates depending on the needs (e.g. to strengthen new fields of competence)
- Organisations already on the list
  - Technical changes, e.g. in contact information, editorial changes on the list
    - notification to EFSA via contact person/Focal Point; may require official notification via the MS Permanent Representation
  - Substantial changes, for any changes that may affect the evaluation against the set criteria, e.g. restructuring, mergers, etc,
    - requires the submission of an updated questionnaire via the MS Permanent Representation
  - Withdrawals: via the MS Permanent Representation

- Out of a total of 30 grants that were evaluated thus far, 27 were successful (signed)
- Three unsuccessful calls were in the area of GMOs and plant health, before the list was updated
- The recent update of the Article 36 list significantly strengthened the GMO and plant health areas of competence (70 and 170% increase in coverage, respectively)

# • Article 36 list - competences

## • Number of organisations with main competences in the original and in the updated list (% change)





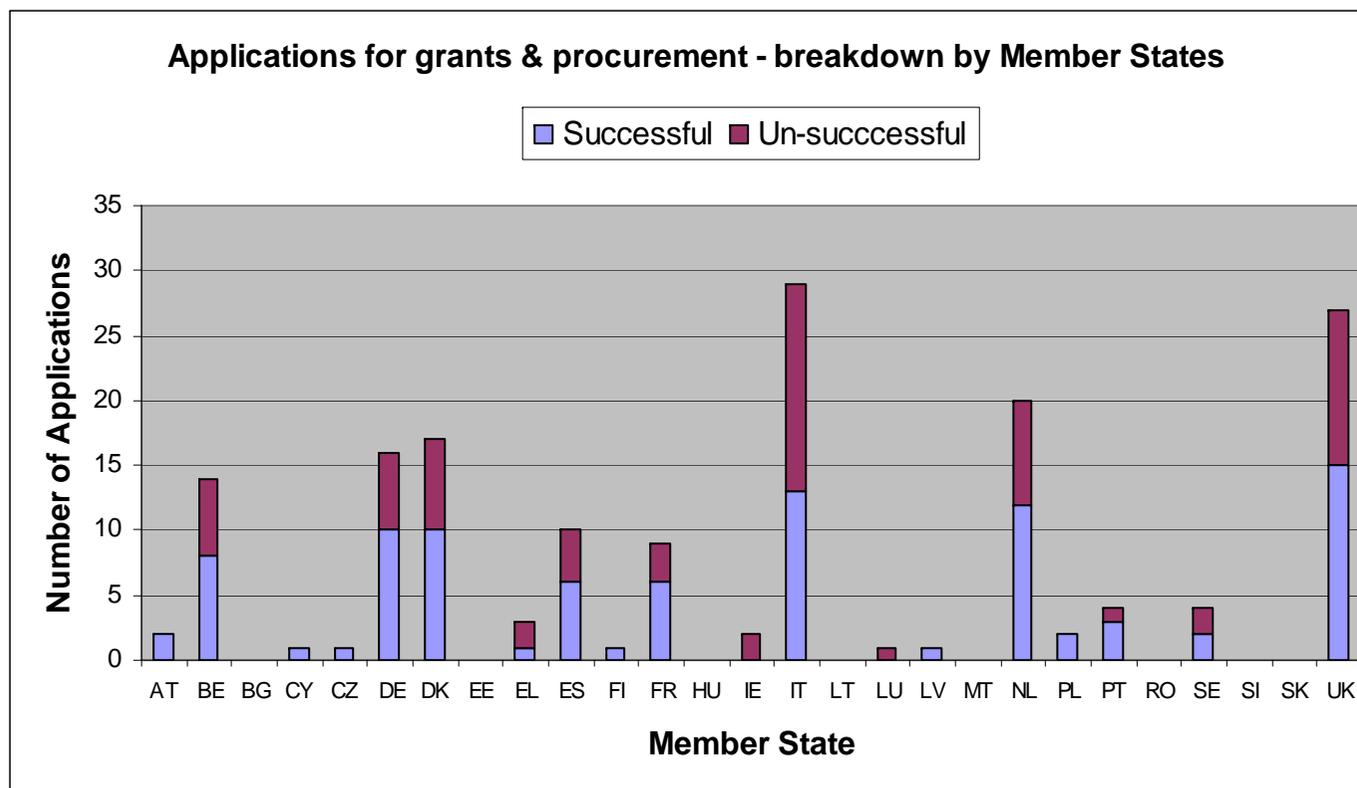
## Funding for research via Art. 36

# Comparison between grants and procurement

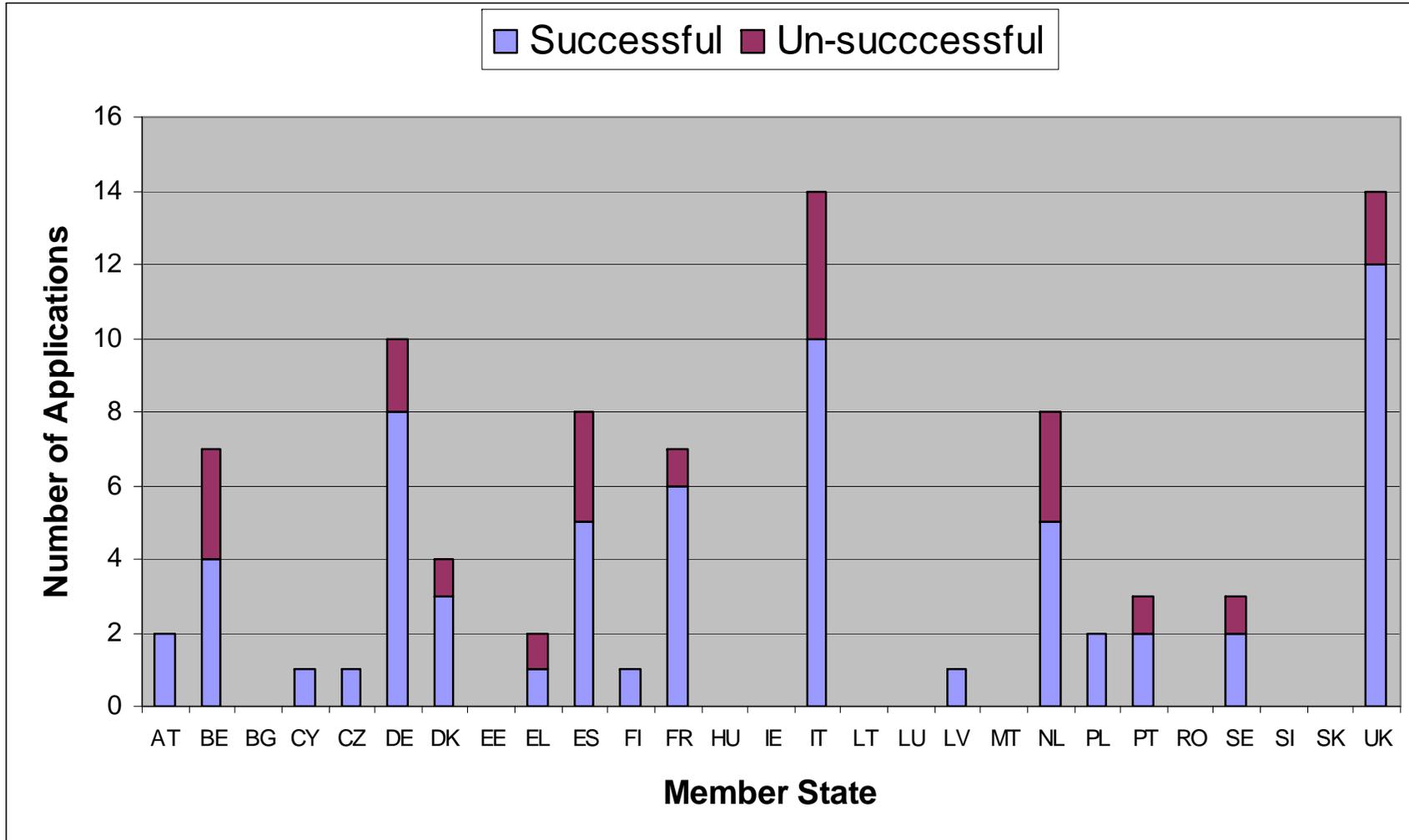
- Both are based on the EU Financial Regulation and its Implementing Rules
- Similar provisions and implementing procedures to ensure the highest quality, mainly through:
  - Harmonised quality criteria and implementing conditions
  - Monitoring the performance of tasks

# Annual Work Programmes Grants and Procurement

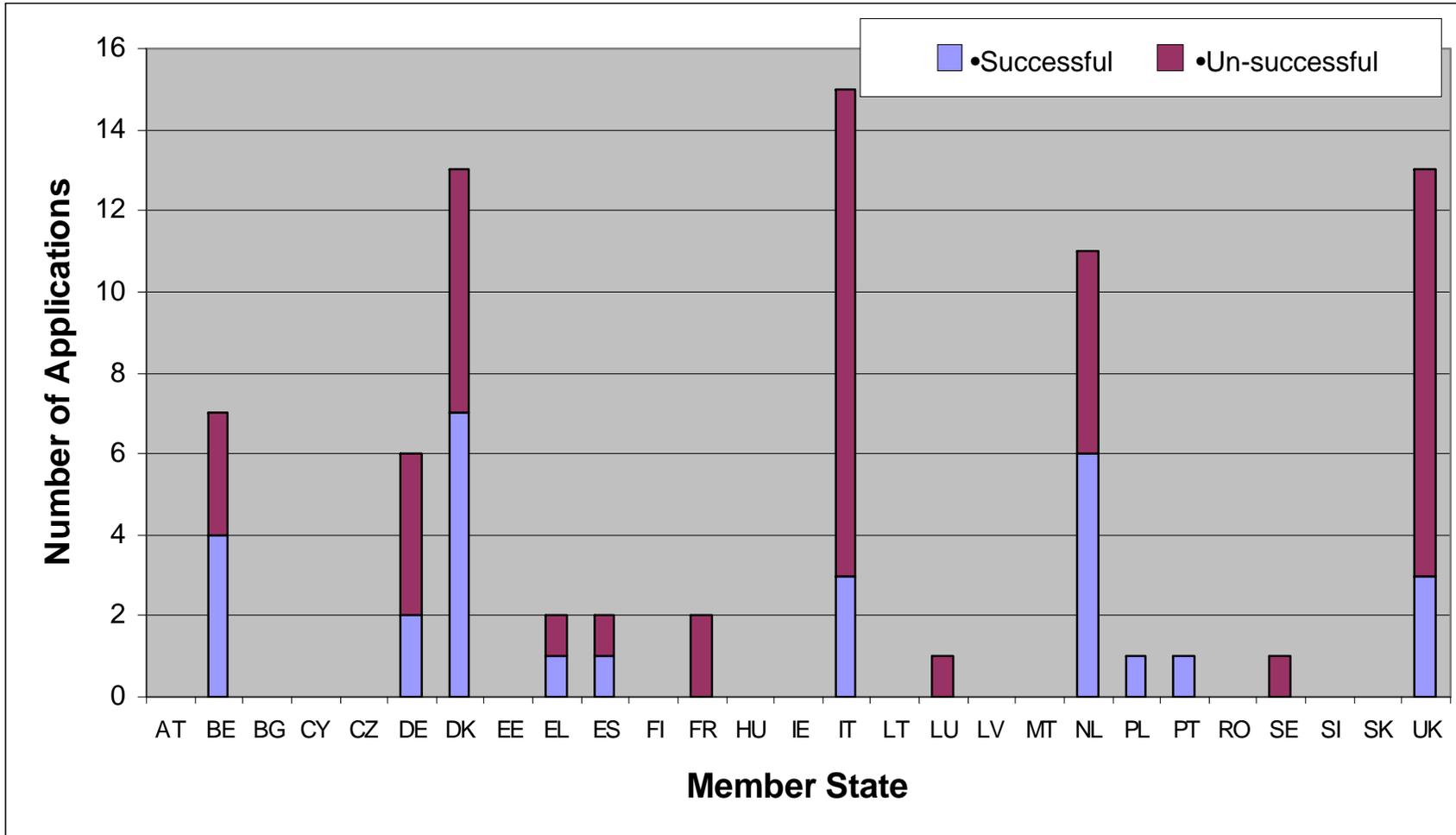
## • Applications for grants and procurement by end 2008



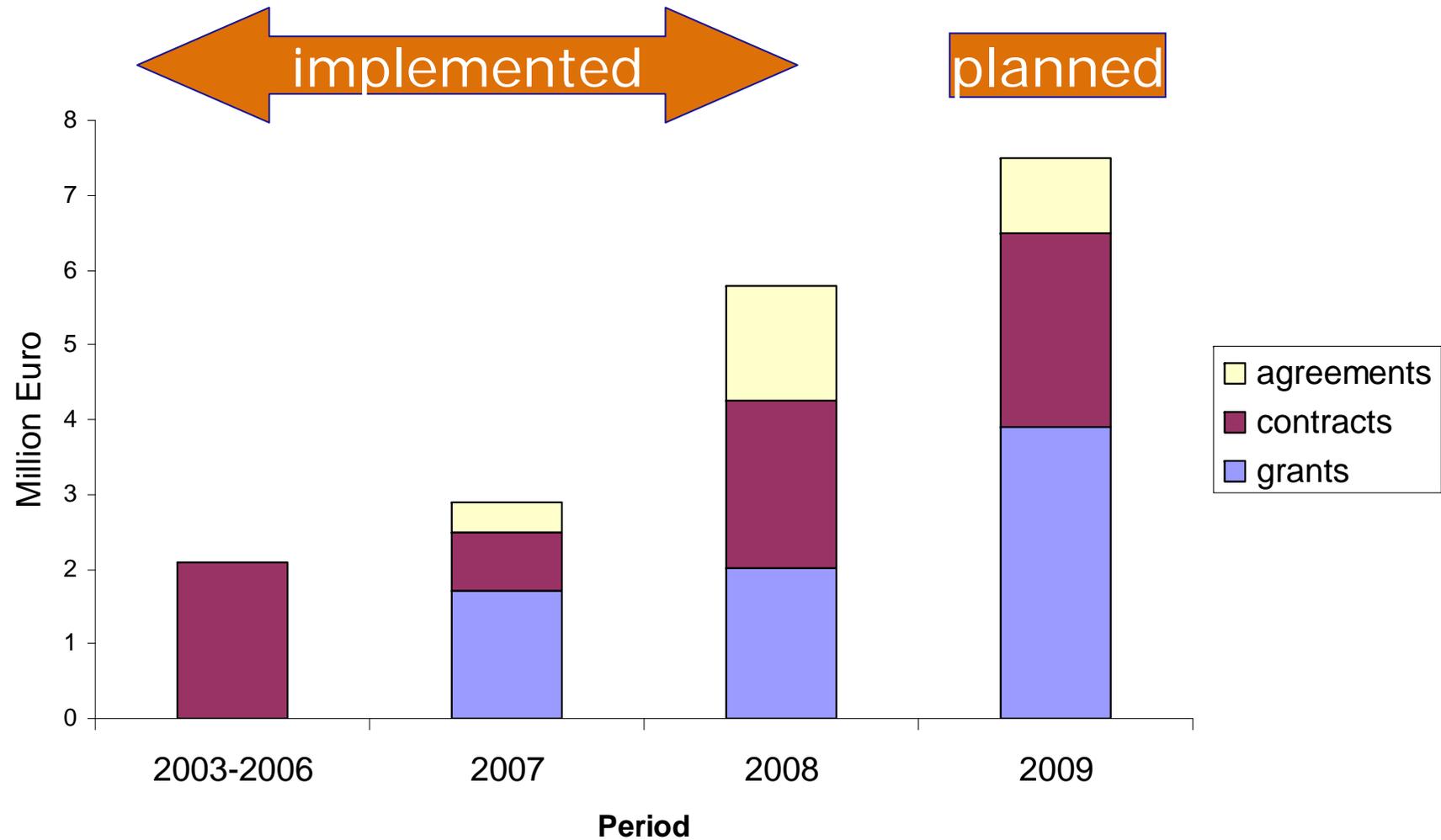
# Applications for grants by end 2008 – breakdown by Member States



# Applications for procurement by end 2008 – breakdown by Member States



# Work-programme – 2003- 2009



# Annual Work Programmes Grants and Procurement (areas to be funded)

- Preparation and adoption:
  - proposals from EFSA's Scientific Committee, Panels and Networks and Scientific Directorates
  - reviewed by the Advisory Forum and the Scientific Committee
  - endorsed by EFSA's Management Board
- Efforts towards identifying issues of common interest and avoiding duplication of activities

# Selection of areas to be funded

- Follow the scheme that was presented in the previous slide
- MS are consulted at the level of the EFSA Advisory Forum
- The final decision on the WP is taken by the EFSA Management Board when the WP is adopted
- Changes at the level of individual planned calls may occur due to unforeseen reasons
- Decision before launching the calls by the authorising officers: EFSA's Director of Risk Assessment or EFSA's Director of Scientific Cooperation and Assistance

# Grants signed so far (since 2007)

- **Support for the examination of authorisation dossiers**
  - Pesticides
- Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents
- Applicability of thresholds of toxicological concern in the dietary risk assessment of metabolites, degradation and reaction products of active substances of plant protection products
- Impact of metabolic and degradation processes on the toxicological properties of residues of pesticides in food commodities
  - Feed additives
- Post-market monitoring of feed additives
- Selected trace and ultratrace elements: Biological role, content in feed and requirements in animal nutrition - Elements for risk assessment
- Review of mycotoxin detoxifying agents used as feed additives: mode of action, efficacy and feed/food safety

# Grants signed so far (since 2007)

- **Preparatory work for risk assessment**
  - Animal Health and Welfare
- Scientific reviews on the three specific animal diseases and an evaluation of the distribution of arthropod vectors and their potential for transmitting exotic or emerging vector-borne animal diseases and zoonoses
- Epidemiology of different agents causing disease in aquatic animals: scientific review and database development
- Scientific review on Tuberculosis in wildlife in the EU
- Scientific reviews on Crimean-Congo Hemorrhagic Fever and Epizootic Hemorrhagic Disease
- Project to develop Animal Welfare Risk Assessment Guidelines on Stunning and Killing
- Animal Welfare Risk Assessment Guidelines on Transport

# Grants signed so far (since 2007)

- **Preparatory work for risk assessment (contd)**
  - Biological Hazards
- Quantitative microbiological risk assessment on Salmonella in slaughter and breeder pigs
  - Contaminants
- Scientific information on mycotoxins and natural plant toxicants
- Survey on use of veterinary medicinal products in third countries
  - Plant Health
- Inventory of data sources for phytosanitary pest risk assessment in the European Community

# Grants signed so far (since 2007)

- **Data collection and analysis supporting risk assessment and risk monitoring**
  - Assessment Methodology
- Systematic review of pest risk models using climatic data and plant phenology
- Bee Mortality and Bee Surveillance in Europe
  - Exposure Assessment
- Support to complete EFSA's food consumption concise database
- Small research projects on furan in food
- Individual food consumption data and exposure assessment studies for children
- Research project on exposure to furan during food preparation
- Development of a standard food classification and sample description system for chemical occurrence data storage
  - Pesticides - MRL
- Collection of Codex Maximum Residue Limits and related information for active substances to be evaluated under Article 12(2) of Regulation (EC) No 396/2005<sub>26</sub>

# Grants signed so far (since 2007)

- **Data collection and analysis supporting risk assessment and risk monitoring**
  - Zoonoses
- Development of harmonised schemes for monitoring and reporting of Echinococcus, Trichinella, Cysticercus and Sarcocystis in animals and foodstuffs in the EU
- "Development of harmonised schemes for monitoring and reporting of rabies and Q fever in animals in the European Union"
- Development of survey methods for food-borne pathogens in foodstuffs in the European Union
- **Horizontal issues and scientific cooperation**
- Development of a framework for the risk assessment of chemical mixtures – A toxicological database on relevant chemical mixtures to food safety

# Work Programme 2009

## Grants and Procurement

- Annual Work-Programme approved by the EFSA Management Board in December 2008

- WP is published on EFSA website:

[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_article\\_36\\_cooperation.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_article_36_cooperation.htm)

- 1<sup>st</sup> call launched in February 2009
- Subsequent calls under preparation

# Work Programme 2009

## Grants and Procurement

### •2009 budget: €7.47 million

- Support for the examination of authorisation dossiers, in the areas of plant protection products, genetically modified organisms, food additives and nutrient sources added to food, food contact materials, enzymes, flavourings and processing aids, feed additives, human nutrition and health claims - budget: €2.41 M
  - *Pesticides* (budget: € 0.80 M) *Other* (budget: € 1.61 M)
- Preparatory work for risk assessment, in the areas of biological hazards, animal health and welfare, plant health, contaminants - budget: €1.72 M
- Data collection and analysis supporting risk assessment and risk monitoring, in the areas of emerging risks, occurrence of contaminants and food consumption - budget: €1.96 M
- Horizontal issues and scientific cooperation - budget: €1.38 M

# Draft Work Programme 2010

## Grants and Procurement

- **Preliminary** planning of EFSA units for 2010
- Based on the Preliminary Draft Budget 2010
- Similar planning/consultation process as in 2009
- No major shifts on budget/areas compared to 2009
- Similar number of calls compared to 2009

**•Draft Work Programme 2010**  
**Grants and Procurement**

- **Consultations with EFSA Advisory Forum and Scientific Committee**
- **EFSA MB to approve WP 2010 in autumn**
- **Evaluation of the impact of grants/procurement projects to EFSA's work beginning of 2010**

# Grants - The “project cycle”

- Identifying the need for scientific/technical support: *one year before launching (exceptions for urgent mandates)*
- Planning in the Annual WP/budget: *one year before launching (exceptions for urgent mandates)*
- Preparing the calls for launching (e.g. terms of reference, other internal procedures)
- Launching the call
- Reception and evaluation of proposals (quality criteria: exclusion, selection, award)
- Signature of the grant agreement
- Implementation of the tasks, reporting , publication

- calls are published on EFSA's website
- organisations on the list are notified by e-mail
- procedures according to the EU Financial Regulation (Title VI) and related Implementing Rules (Art. 160 – 184a)

- Call launched on the web – with deadline
- Art. 36 organisations submit proposals
- Questions for clarifications sent to dedicated email address:  
[grants@efsa.europa.eu](mailto:grants@efsa.europa.eu)
- Clarifications published on the call-specific website (EFSA)
- Opening and Evaluation committees for each call (EFSA staff)
- Evaluation committee assesses the proposals against the eligibility, selection and award criteria (as published in the call): based on EU Financial Regulation
- Further clarifications may be requested from the applicants
- Evaluation committee proposes successful applicant based on the evaluation
- Authorising officer (Director of RA or SCA) authorises the award of a grant to the successful applicant(s)

- **eligibility criteria (section 3.2 of CfP):**
  - eligibility of the applicant and its possible partners, e.g.
    - Need to be on the article 36 list
    - Declaration of honour that they are not under a list of exclusion situations (e.g. bankruptcy or liquidation, convicted of an offence, etc.)
  - eligibility of possible consortium and subcontracting, e.g.
    - Partnership statement defining technical/intellectual and financial involvement of each member
  - eligibility of the project, e.g.
    - respecting restrictions on size and duration , type of activities to be undertaken
  - eligibility of the proposed costs, e.g.
    - provide an estimated budget that needs to be in accordance to the stipulated rules: ensuring that all proposed cost items are eligible for funding, ensuring consistency with the project and specific objectives, mandatory applicants direct financial contribution to the project

- **selection criteria (section 3.3 of CfP):**
- 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** capacity, demonstrating stable and sufficient financial resources to
    - maintain their activity throughout the project (via appropriate extracts of annual budgets)
    - participate in its funding (via letter of commitment of public body)
  - **operational** capacity, demonstrating adequate management, professional competences and qualifications for the completion of the project, e.g. via
    - annual activity report, CVs, similar projects undertaken in the past, references

- **award criteria (section 3.4 of CfP):**
- 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:
    - achieving the objectives of the Call, guaranteeing an excellent level of science output , and added value to the existing knowledge
  - quality of the management (including consortium if applicable):
    - project management and the internal project communication is described and is demonstrably of high quality,
    - the implementation of the project by the experts involved and their real participation have been clearly described and appear to be suitable to the tasks/objectives targeted
  - cost effectiveness:
    - the Estimated budget is cost-effective (comparison between the costs and the anticipated achievement of the objectives and results obtained)
  - The weighting of the award criteria is decided on a case by case basis.

# Article 36 –finalised projects

- **The first Article 36 project was finalised in October 2008**
- **6 projects in total have been finalised to date**
- **with the experience accumulating, EFSA will perform an assessment of the activities carried out under Article 36, and their impact to EFSA's work, by the beginning of 2010**

**Thank you for your attention!**