EUROPEAN
COMMISSION

Brussels, 11.2.2013
SWD(2013) 45 final

Part I/III

COMMISSION STAFF WORKING DOCUMENT

Impact Assessment on the Revision of Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety on the establishment of fees for EFSA

TABLE OF CONTENTS

1. PROCEDURAL ISSUES AND CONSULTATION PROCESS 3

1.1. Procedural issues 3

1.2. Consultations 3

1.2.1. Online public Consultation 4

1.2.2. Advisory Group on the Food Chain, and Animal and Plant Health and other Associations 4

1.2.3. Small and Medium Enterprises – European Enterprise Network (SMEs) 5

1.2.4. Member States (MS) 5

1.2.5. European Parliament (EP), Council 5

1.2.6. European Food Safety Authority (EFSA) 5

1.2.7. Impact Assessment Steering Group (IASG) 6

1.3. Discarded section on work sharing in EFSA's Panels 6

1.4. Modifications following the opinion of the Impact Assessment Board 6

2. POLICY CONTEXT, PROBLEM DEFINITION AND SUBSIDIARITY TEST 7

2.1. Background 7

2.2. Problem definition 8

2.3. Underlying drivers 11

2.4. Who is affected, in what ways and to what extent? 11

2.5. Baseline scenario (Annex V) 11

2.6. Subsidiarity test 17

3. OBJECTIVES 17

3.1. General 17

3.2. Specific 17

3.3. Operational 17

3.4. Consistency with horizontal objectives of the EU 18

4. POLICY OPTIONS 18

4.1. Options discarded at an early stage 19

4.2. Options selected for in-depth analysis 22

4.2.1. Description of option 1: No policy change 22

4.2.2. Description of option 2: Application fee for all applicants for risk assessment of new and renewal applications 23

4.2.3. Description of sub - option 2: Application fee for all applicants for risk assessment of new and renewal applications, excluding sectors where initial assessment is performed by MS. 23

4.2.4. Description of option 3: Application fee only for applicants who are authorisation holders for risk assessment of new and renewal applications 24

4.2.5. Description of sub-option 3: Application fee only for applicants who are authorisation holders for risk assessment of new and

renewal applications excluding sectors where initial assessment is performed by MS 24
4.2.6. Description of option 4: Fees for additional services for all applicants and for new and renewal applications 24
5. ANALYSIS OF IMPACTS 25
5.1. Economic Impact 25
5.1.1. Economic Impact on applicants of the food and feed chain 29
5.2. Impact on SMEs (the SMEs Test) 33
5.3. Impact on competitiveness and innovation 34
5.4. Impact on international competitiveness 36
5.5. Social Impacts 36
5.5.1. Impact on the perception of EFSA's independence 36
5.5.2. Impact on consumers 37
6. COMPARISONS OF THE OPTIONS 37
6.1. Cost-effectiveness analysis 37
6.2. Views of industry, consumers and Non-Governmental Organizations (NGOs) 42
6.3. Preferred option: No Policy change 44
7. MONITORING AND EVALUATION 45

1. PROCEDURAL ISSUES AND CONSULTATION PROCESS

1.1. Procedural issues

The work concerning the possible introduction of fees with regard to the processing of authorisation applications[1] submitted by industry to the European Food Safety Authority (EFSA) was characterized by two phases.

The first phase was devoted to the development of a Report from the European Commission to the European Parliament and the Council on the advisability and feasibility of establishing fees for EFSA, adopted on the 23 September 2010.

In line with the conclusions of this report and confirmed by the European Parliament (EP) and Council, the second phase focussed on the Impact Assessment (IA) on the possible introduction of fees for EFSA.

The first Roadmap was published in June 2011 and updated in November 2011.

The Impact Assessment process started in March 2011 when a data gathering exercise was performed within all interested Directorate General for Health and Consumers (DG SANCO) Units and EFSA.

Consultations were carried out throughout 2011/2012 in accordance with the Commission's minimum standards (Annex I).

Taking into account the vast number of sectors interested by this initiative, a significant effort was made to gather reliable and valid data through in-house data collection and surveys. However, it should be noted that data on the size and structure of the markets related to the 19 sectors are limited. Official statistics are not available at the disaggregated level needed, nor were the Associations able to furnish reliable data on such substances/products which have many different uses and are used in numerous final products.

1.2. Consultations

The consultation tools used by the European Commission reflected the different phases of the work concerning the possible introduction of fees for EFSA.

During the first phase, the open consultation tool was chosen in order to allow for a broader discussion on the advisability and feasibility of the introduction of fees for EFSA.

During the second phase, other consultation tools were chosen to meet the needs of the Impact Assessment analysis: targeted consultations of identified affected actors and a survey for socio-economic data gathering were carried out.

All actors directly and indirectly affected by the possible introduction of fees and their related aspects were consulted.

In line with the recommendation to reduce the regulatory burden on very small companies as a core objective of the Smart Regulation Agenda, particular attention was devoted to Small and Medium Enterprises (SMEs).

[1] The processing of authorisation applications is the scientific assessment of regulated products. It is the procedure by which EFSA assesses the applications submitted by applicants who seek to obtain an authorisation to put a product/substance/process/claim on the market.

1.2.1. Online public Consultation

On 11 November 2006, DG SANCO launched an online public consultation on SANCO's website to gather views of interested parties on the feasibility and advisability of presenting a legislative proposal enabling EFSA to receive fees for the processing of authorisation applications.

A detailed summary of the written comments received is available on the Commission's website at http://ec.europa.eu/food/consultations/sum_cons_efsa_fees_en.pdf. Most of the comments acknowledged that, in principle, fees are a useful tool for good governance and can contribute to ensuring that public money is spent on activities carried out in the public interest. However, the main concerns were, on the one hand, the feasibility of a fee system given that the food legal system is mainly aimed at issuing generic authorisations which bring benefits for all operators, and on the other hand, the potential impact of fees on the independence of EFSA. This consultation did not provide detailed figures on economic aspects which required further targeted consultations in order to gather the data.

1.2.2. Advisory Group on the Food Chain, and Animal and Plant Health and other Associations

During both phases of the work concerning the possible introduction of fees for EFSA, Stakeholders were consulted in the Advisory Group on the Food Chain, and Animal and Plant Health (hereafter Advisory Group), the competent advisory group for all issues concerning food and feed, animal health and welfare[2].

In May and June 2010, Stakeholders were in particular consulted in the Advisory Group on the Commission's draft report on the feasibility and advisability of presenting a legislative proposal enabling EFSA to receive fees for processing authorisation files. The minutes of these meetings are available on the internet at http://ec.europa.eu/food/committees/advisory/index_en.htm.

Feedback on the latest developments was provided to Stakeholders in the Advisory Group on 8 November 2010.

In November 2011, a targeted questionnaire was sent to the Members of the Advisory Group and to other interested stakeholder associations that are not members of the Advisory Group to gather socio-economic quantitative data on the sectors affected. The questionnaire was aimed, in particular, at gathering information about the size of the markets related to the 19 sectors interested in authorisation applications to EFSA, the number of jobs directly and indirectly linked to the sector and the structure of the markets with particular attention to the presence of SMEs in each sector (Annex II).

A Working Group of the Advisory Group, and other non-member Stakeholders took place on 2 December 2011 to discuss the baseline scenario, the problem definition and the policy objectives, as well as to gather points of view, input and data from the targeted groups that could be potentially affected by the initiative. Policy options were discussed on 4 May 2012 and written comments were received as a feedback to the meetings (Annex III).

[2] Commission decision n. 2004/613/EC, 6 August 2004 (OJ L275, 25 august 2004, p. 17).

1.2.3. Small and Medium Enterprises (SMEs) – European Enterprise Network

Following the recommendation to reduce the regulatory burden on very small companies as a core objective of the Smart Regulation Agenda, it was decided to consult SMEs via the Enterprise Europe Network. A background note and a questionnaire to gather data on the SMEs operating in the 19 sectors potentially affected by the introduction of fees for EFSA were sent through the Network in 2011. The tool enabled SMEs to be reached in a targeted way and to ensure a broad geographic coverage (results in Annex IV).

1.2.4. Member States (MS)

In 2006, DG SANCO sent a letter to all Member States asking them to contribute to the public consultation on fees and on 25 June 2007 the public consultation paper was also discussed in the framework of the Standing Committee on the Food Chain and Animal Health.

In June 2010, Member States were consulted on the Commission Report on the feasibility and advisability of presenting a legislative proposal enabling fees to be received for processing authorisation files. The minutes of the meeting are available at http://ec.europa.eu/food/committees/regulatory/scfcah/toxic/summary07062010_en.pdf.

On 17 December 2011 and 4 May 2012, a Working Group of Member States discussed the problem definition, the objectives and the policy options of the IA (Annex III).

1.2.5. European Parliament (EP), Council

A letter was sent to the European Parliament to ask for contributions on the public consultation. The Report on the feasibility and advisability of presenting a legislative proposal enabling fees to be received for processing authorisation files was sent to the EP and the Council in September 2010.

Both EP and Council were in favour of launching an IA on the possibility of establishing fees for EFSA. Intervening delegations in Council globally agreed with the principle but invited the Commission to remain vigilant, notably in terms of red tape and additional costs for SMEs[3]. Members of the European Parliament (MEPs) mentioned that fees would be justified when a service is provided to companies and if they did not destabilise EFSA's budget. They also stressed the need to be careful before deciding on this issue, because of the criticisms on EFSA[4].

1.2.6. European Food Safety Authority (EFSA)

EFSA was asked to contribute to the public consultation. While not expressing a position in favour of or against the establishment of fees, EFSA's Management Board stressed that it is for the decision-making bodies (Commission, European Parliament and Council) to construct the financial system allowing EFSA to function. The source of the funding may not be an issue provided that a certain number of conditions, particularly in relation to the independence and accountability of EFSA are covered by the legislators. Bilateral meetings were held in Brussels and Parma between the Commission and EFSA during May - July 2011 to gather quantitative data and to

[3] SG note SI (2010/332) Report on the 3050th meeting of the Council "Agriculture and Fisheries" 29 November 2010.

[4] SG note SP (2010) 7563 Meeting of the Committee on the Environment, Public health and Food Safety (ENVI) 27/28 October 2010.

discuss the analytical approach to EFSA's workload. EFSA participated, when appropriate, in the meetings of the Inter Service Steering Group and in all the meetings with stakeholders.

1.2.7. Impact Assessment Steering Group (IASG)

The Impact Assessment Steering Group (IASG) was set up in March 2011 consisting of the Secretariat General (SG), Directorate General (DG) Budget (BUDG), DG Environment (ENV), DG Agriculture and rural development (AGRI), DG Competition (COMP)[5], DG Enterprise and Industry (ENTR), DG Internal Market and Services (MARKT), Legal Service (LS) and DG Joint Research Centre (JRC). The IASG met four times. An internal working group in DG SANCO was set up in April 2011 in order to prepare a baseline study, representing a starting point for the analysis. All relevant units were consulted and contributed to the study.

1.3. Discarded section on work sharing in EFSA's Panels

The IA initially included an additional part concerning the functioning of EFSA's Committee and Panels (which currently both assess the applications and adopt EFSA's final scientific opinions). The options envisaged different types of work sharing for the assessment of authorisations depending on the complexity of the dossier. In particular, for routine applications (less complex), there would have been less or no involvement of EFSA's Scientific Panels and more involvement of EFSA's staff or the national bodies included in EFSA's "Article 36 network".

The consultation of Member States (MS) on 17 January 2012 showed that they were not in favour of the possibility of reducing EFSA's Scientific Panels' involvement or exclusion in the assessment of routine authorisations. They also considered that it would be extremely difficult to draw a clear distinction between routine and complex authorisations. Finally, in order to preserve EFSA's Panels specific scientific role, they reaffirmed the need for the Panels to continue to be responsible for the adoption of the opinions related to *all* authorisation applications.

In the light of those comments, the proposed options were re-examined and discarded.

1.4. Modifications following the opinion of the Impact Assessment Board

The IA report was submitted to the IA Board on 1 August 2012 and was formally presented on 19 September 2012. Following this meeting the Board issued an opinion on 21 September 2012 in which it was asked to:

- clarify the problem definition by spelling out the political and budgetary considerations underlying the decision to carry out the IA;
- improve the presentation of objectives and options and better clarify the reasons for discarding certain options;
- better explain the assessment and the comparison among options;
- better present stakeholders' views.

The Board's suggestions have been taken into account in the final version of the IA and sections 2 (paragraphs 1, 2 and 5), 3 (paragraphs 1, 2 and 3), 4 [adding one new option (para 4.1) and two new *sub options* (4.2.3, 4.2.5)], sections 5 and 6 were modified accordingly.

[5] Was not able to participate.

2. POLICY CONTEXT, PROBLEM DEFINITION AND SUBSIDIARITY TEST

2.1. Background

EFSA produces scientific opinions and advice which provide a sound foundation for European policies and legislation and support the EU co-legislators, the Commission and each individual MS in taking effective and timely risk management decisions.

EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. In all these fields, EFSA provides independent scientific advice and clear communication based on up-to-date scientific information and knowledge.

EFSA also provides the scientific assessment of regulated products/substances/claims/processes (hereafter "regulated products") marketed in the EU. The assessment represents the scientific basis for the marketing authorisation issued by the risk managers or for their decision to maintain such regulated products on the EU market.

Its main tasks are thus: 1) scientific opinions on general public health issues (e.g. contaminants and pathogens); 2) scientific opinions on authorisations applications; 3) data collection and analysis of all aspects related to the safety of the food chain; 4) identification of emerging risks and scientific support to Commission in case of emergency/crisis; 5) risk communication.

Regulation (EC) n° 178/2002 provides that the Authority should be financed by the Budget of the European Union. It foresees, however, the possibility to investigate the feasibility of introducing fees with regard to the processing of authorisation applications submitted by industry (recital 57).

Regulation (EC) n° 178/2002 clearly exempts Community Institutions and Member States, which are already contributing to EFSA's Budget through the General Budget of the European Union, from the payment of fees.

- *Requirements of Regulation (EC) n° 178/2002*

According to its founding Regulation (EC) n° 178/2002, EFSA shall be mainly financed by the European Union's General Budget.

More precisely, Article 43 of EFSA's founding Regulation provides that the revenues of the Authority shall consist of a contribution from the EU and from any State with which the EU has concluded an agreement. Regulation (EC) n° 178/2002 also foresees that the **possibility to introduce fees** with regard to the **processing of authorisation applications presented by industry** should be examined after the entry into force of the Regulation and in the light of the experience acquired (recital 57). More specifically, Article 45 provides for the publication of a report on the feasibility and advisability of the introduction of fees within three years following the entry into force of Regulation (EC) n°178/2002.

- *The Report on the advisability and feasibility of the introduction of fees*

On the basis of the request provided for in Article 45 of Regulation (EC) n° 178/2002, on the 23 September 2010 the Commission issued the Report on the feasibility and advisability of putting forward a legislative proposal which would enable the Authority to charge fees for services rendered[6]. The Report was prepared in the light of the comments made in the framework of the public consultation.

[6] COM(2010) 496 final (23.9.2010)

Four options were preliminarily explored:

1) Flat-rate fee for all applicants for authorisation;

2) Graduated fees for all applicants for authorisation;

3) Graduated fees for applicants who are authorisation holders;

4) Maintain the existing system without fees

In the Report the introduction of fees appeared, at first glance, to be a viable solution for the EU to best use public money and, on the basis of the preliminary analysis carried out, the Report suggested that the introduction of a fee system would not affect EFSA's work and independence. The introduction of fees was also considered to be a possible instrument to overcome some functional problems highlighted in the study, such as the poor quality of certain dossiers received by EFSA and the difficulties experienced by EFSA in dealing with peaks of applications.

Considering the incompleteness of the data available, the report stated, however, that it was not possible to draw any definitive conclusions and suggested to launch an impact assessment in order to perform a more in-depth analysis. More precisely, the following conclusions were drawn:

"In view of all the issues outlined in this report, in particular the complexity of establishing a fee-system in the area of EU food legislation, the Commission considers that more reflection is needed on the range of options to be considered and it is not possible to draw any definitive conclusions at this stage. This will be done in the course of an impact assessment. Without pre-empting the outcome of such an assessment, the option of graduated fees for applicants who are authorisation holders should in any cases be given further consideration. In this context, the issue of enhanced services for applicants will also have to be explored (….).

In order to develop the optimum approach, the Commission intends to launch an impact assessment which will take into account the results of the Member States', stakeholders' and EFSA's comments and the observations and remarks highlighted in this report. The assessment will also look at other EU policy areas as well as practices of other EU regulatory agencies.

Each potential candidate sector will have to be assessed in detail in order to identify the economic and budgetary impact of the various scenarios of fees on enterprises (including SMEs). This will allow an identification of the distributional impact of the different types of fees on the different sectors, the amount of fees that could be set up, the conditions to determine affordable fees for SMEs and their impact on innovation. It is also essential to assess the impact that a fee-system would have on EFSA's overall functioning and efficiency, in particular: the various options for providing a more professional service to applicants, the impact on the sharing of work with national agencies/bodies, the balance between the interests of a more efficient service and the preservation of general interest objectives, the perception of EFSA's independence, and the impact on the overall sustainability of EFSA's functioning."

2.2. Problem definition

The proposal to carry out an IA to verify the conclusions drawn by the report was welcomed by the European Parliament and Council, when consulted on the Commission report of 2010. They urged, in particular, the Commission to perform an IA in order to ensure that a reasoned decision on the issue was taken.

The current IA has been carried out to respond to these requests and is driven by the political will to explore the possibility of optimising the use of EU public funds.

EFSA is currently financed by the EU budget and receives adequate financial resources to carry out the tasks entrusted to it[7]. Some of its tasks (assessment of authorisation applications) include, however, services that could be considered as benefiting industry and could thus be financed by the applicants.

According to EU financial rules, the introduction of a fee system could reduce the EU contribution to EFSA's budget by the amount of fees collected. Only fees remunerating new tasks performed by EFSA would provide additional funds for the Agency's functioning.

The possibility to streamline the use of EU funds will thus be verified by analysing the practicability/workability of the introduction of a fee system for EFSA and the empirically validated beneficial effects on the actors concerned (EFSA and the applicants in the food and feed chain) and on the EU market, taking into consideration issues of competitiveness, innovation and SMEs.

To this end the IA takes into account the cost-benefit *ratio* of the introduction of fees on EFSA's functioning, EU budget (savings of public money) and on applicants.

The Commission Report of 2010 concluded, on the basis of the experience gained at that time by other agencies charging fees, that the introduction of fees would not affect EFSA's independence. Meanwhile the situation has changed, putting some Agencies in the spotlight on the issue of their independence. Criticisms on independence were given a large share of media attention in the particular case of EFSA because of the high sensitivity of public perception of food safety. The European Parliament also emphasised the sensitivity of EFSA's independence in the framework of recent debates (discharge procedures).

Such a context implies that the possible advantages of the introduction of a fee system have to be weighed against the reputational image of the agency.

The IA thus verifies whether the introduction of a fee system for EFSA will result in an optimisation of the EU contribution to EFSA's budget while preserving, at the same time, the good performance and efficiency of the current system, as well as its independence.

Since other EU regulatory agencies undertake scientific tasks that appear similar to those performed by EFSA and already charge fees, the investigation also analyses whether EFSA's system could be aligned with those agencies.

Finally, the IA takes the opportunity to explore the possibility of introducing additional services for applicants. Whilst EFSA is already providing some general services, as suggested during the consultation leading to the 2010 Report, there could be room for additional services which could facilitate the access of applicants - in particular SMEs - to the authorisation procedures.

The evaluation has to be performed within the following limits:

- *Two sets of interlinked legislation (general and sector based food law)*

General principles of food law are provided for in Regulation (EC) n° 178/2002, EFSA's founding Regulation. However, legal provisions related to authorisation procedures fall under approximately under 24 different Regulations and Directives and authorisations are delivered in 19 sectors, each of them submitted to one or more specific procedures for authorisations (39 workflows) and presenting different characteristics.

[7] EFSA 2009, 2010, 2011 Annual Reports include results of indicators on the delivery of its tasks (available under 2009, 2010, 2011 March MB meetings on http://www.efsa.europa.eu/en/mb/mbmeetings.htm)

The scope of the proposal on the possible introduction of fees for EFSA is **limited to the modification of Regulation (EC) n° 178/2002**. The amendment of other pieces of legislation (sector based legislation) is not considered as feasible both because of the high number concerned and the fact that, since most of them were recently adopted or significantly revised in accordance with the 2000 *White paper on Food safety*, they are still in the implementing period.

Due to the limited scope of the analysis, a global approach, able to cover a wide range of sectors and actors has to be used. While not entering into the specificities of each sector, the study has however to take into account the implications of this global approach on the different sectorial procedures.

- *Applying a cost recovery model*

The cost recovery approach chosen is in line with the approach taken by other similar EU agencies charging fees and is consistent with the recommendations of the Inter-institutional Working Group (IWG) on regulatory agencies, which confirm that in partially self-financed agencies the clients should pay for the full cost of the service[8].

As is the case for the European Medicines Agency (EMA), the calculation of the level of fees charged by the Agency is based on the service actually provided and is related to each specific product. The model also applies the principle of proportionality between the fees and the assessment related costs of each application.

More precisely, the amount of the fee is based on the average cost of the work performed by EFSA in relation to the assessment of a specific "regulated product"(see Annex XVII on costs of processing dossiers in each sector).

The costs taken into account for determining the costs of an application dossier are the fixed and flexible costs incurred by EFSA in relation to the assessment of authorisation dossiers. All fixed and flexible costs were taken into account except when there was a specific reason justifying the exclusion of a cost. In particular, as it is for other similar agencies, the costs linked to guidance were excluded since they were considered as linked to a public interest task. No further exclusion of cost from recovery was found justified, being noted that the need to reduce burdens for SMEs is typically solved via a different mechanism (reduction of fees) that has been considered in all options proposed.

Moreover, the cost recovery model adopted was conceived as covering the costs strictly linked to the services provided to the applicant. As a result, it was considered that the fee collection cost linked to the management of the fee system could be recovered but not the investment costs borne by EFSA to develop the fee collection system. Those investment costs were estimated at EUR 12 Million for the development of an electronic submission system of applications. The investments cost are, however, taken into account in the evaluation of the proposed options.

The following factors have also be taken into particular account in the analysis:

- *Predominant system of generic authorisations*

The legal framework within which authorisation procedures are provided for in the food area is mainly aimed at issuing generic authorisations for the benefit of all operators. It contains little protection of proprietary data and seldom offers exclusivity to the applicant. This predominant system of generic authorisations has been in place since the beginning of EU food legislation

[8] See IWG conclusions, *Joint statement and common approach*, 18 June 2012, p. 11

and is linked to the historical development of the food legislation (characterised by the inclusion of authorised products/substances in a so called "positive list").

- *International context*

Internationally, several important agencies (e.g. in the United States of America, Japan) in charge of the scientific assessment of regulated products in the food area do not charge fees for this task, except in the sector of plant protection products. In the case of the Australia/New Zealand common agency, fees are charged on a case-by-case basis when the applicant is considered as drawing an exclusive economic benefit from the authorisation.

2.3. Underlying drivers

Unlike other Regulatory Agencies such as EMA or the European Chemicals Agency (ECHA), EFSA has not been designed to integrate a cost–recovery approach.

The different approach adopted with economic operators and the misalignment *vis à vis* other agencies which have a cost recovery system in place may be explained by the specificity of the food and feed sector and the overall mission of EFSA.

EFSA was established as an agency aimed at safeguarding public health. Except its task on the scientific assessment of authorisation dossiers aiming at the protection of public health but where a service provided to industry can be identified, EFSA's tasks are globally focussed on the scientific advice and support to public authorities (the EU co-legislators, the Commission and each individual MS). Half of the EFSA' Scientific Committee/Panels do not assess authorisations applications or do it very marginally.

This approach is reflected in the design of the authorisation systems: industry does not submit authorisation applications directly to EFSA contrary to what is the case for EMA and ECHA but submits authorisation applications to Member States or the Commission, which in turn consult EFSA on the submitted dossier.

2.4. Who is affected, in what ways and to what extent?

The actors affected by the scientific assessment of regulated products activities are:

- EFSA, which performs the scientific evaluation and deploys a considerable amount of resources to provide its services;
- Producers, importers or manufacturers of the sectors along the food and feed chain, who have an interest in regulated products and invest resources to develop new products, substances for the market and to prepare documented applications for authorisation to be submitted to EFSA;
- EU Member States, who in some sectors perform a preliminary scientific assessment of regulated products subsequently peer-reviewed by EFSA;
- European Consumers, who are beneficiaries of an extensive availability of safe products on the European Market.

2.5. Baseline scenario (Annex V)

- *The authorisation application procedure*

The scientific assessment of regulated products is the procedure by which EFSA assesses the applications submitted by applicants who want to obtain an authorisation to put a regulated product on the market.

This process is in most cases specified in sectorial legislation and involves the following main steps:

(1) *reception* of the application dossier by EFSA (via a Member State or the European Commission);

(2) *completeness check* by EFSA's staff (verification that the dossier includes all necessary information and documentation as prescribed by legislation and EFSA's guidance documents);

(3) *scientific evaluation* by the competent Scientific Committee or Panel that the product/substance/claim meets the scientific requirements to be authorised;

(4) *adoption* of a scientific opinion by the competent Scientific Committee or Panel and publication of the opinion by EFSA.

- *Sectors interested by authorisation application*

The sectors interested by authorisation applications to EFSA are the following 19:

1. Plant Protection Products: active substances (PPP)
2. Maximum Residues Levels (MRL[9]) of PPP
3. Genetically Modified Organisms (GMO)
4. Flavourings
5. Smoke flavourings
6. Extraction solvents
7. Food enzymes
8. Food contact materials
9. Food additives
10. Nutrient sources
11. Feed additives
12. Transmissible Spongiform Encephalopathy (TSE) tests
13. Animal by-products
14. Antimicrobial treatments
15. Health claims
16. Novel foods
17. Infant formulae
19. Food allergies (exemption from labelling)

- *Actors involved*

The workflows for authorisations linked to the **19 sectors** are **heterogeneous** and involve different sharing of work and responsibilities among EFSA's staff, EFSA's Scientific Committee/Panels, Member States and the European Union Reference Laboratories (EURL).

- *Type of applications submitted*

[9] In accordance with Article 19(7) of the recently adopted Regulation concerning the making available on the market and use of biocidal products (still to be published in the OJ), EFSA will also be involved in the establishment of MRLs for active substances used in biocidal products.

EFSA can receive **three different types of applications** for scientific evaluation:

- **new applications**, concerning regulated products not yet available on the market;
- **applications for renewal**, concerning regulated products for which the authorisation has expired (mandatory renewal after 10 years only for GMO, Feed Additives, PPP and Smoke Flavourings) or concerning regulated products affected by changes in technology or development of new scientific knowledge, including extension of uses.
- **applications for review**, concerning regulated products already present on the market and evaluated following a legal or political decision. In particular, some reviews are provided for in sector-based legislation as a transitional measure in order to create an EU list of authorised products/substances/marketing statements. The transitional provisions take into account the fact that authorisations have already been issued at Member States level and provide for a consolidated EU list on the basis of the new criteria set out in the legislation. Assuming that the cost of the authorisation had already been paid at Member States' level, the procedure was foreseen as initiated by Member States or the Commission free of charge. Other reviews concern EU generic authorisations (issued for an unlimited period of time) of substances/products on which, at a certain point in time, the public authorities have public health concerns and decide to assess again their safety.

  Reviews are therefore performed in the public interest and are, though currently rather high in number[10], not a systematic and foreseeable activity carried out by EFSA, but can be considered a *"una tantum"* evaluation.

- *Types of authorisation granted*

After the scientific assessment of the regulated products has been completed, risk managers can grant **two different types of authorisations**:

- In 11 sectors, the sectorial legislation foresees the granting of a **generic authorisation**; all operators can use/produce/market the regulated product independently of who submitted the application;
- In the remaining 8 sectors[11], the legislation provides for an **individual authorisation** granted to an authorisation holder. This means that the applicant submitting the application is the only one who can produce/market the regulated product under the authorisation for which it applied. To be noted that in one sector (feed additives) the legislation foresees generic authorisations for most of the categories of feed additives, but individual authorisations for 3 categories of feed additives (zootechnics, coccidiostats and histomonostats, representing roughly 14,5% [12] of the applications/authorisations).

[10] Over the period 2003-2010, out of 9456 applications received, 4187 related to the review of claims and 1999 applications were related to the review of flavourings.

[11] It has not been possible to include health claims as a sector with individual authorisations in particular because the effect of the authorisation of the health claim is always generic even if the application for its authorisation is individual (i.e.: all operators may use a permitted health claim if they comply with its conditions of use). Because of the limited scope provided by Article 21 of Regulation 1924/2006, even in cases where the Commission grants protection of proprietary data for Article 13.5 claims, the effect is generic; the protection granted consists in allowing only to the applicant to refer to the protected data substantiating a health claim. Further, current experience shows that out of 19 authorisations of claims (out of 96 decisions); only one concerns an authorisation with protection of proprietary data.

[12] Historical SANCO data.

In conclusion, 58% of the sectors applying to EFSA for the scientific evaluation of regulated products receive a generic authorisation.

- *Identification of the applicants*

The rules related to the 19 sectors grant to a significant spectrum of actors the right to apply for authorisations, from Member States to *"any person established in the Community"* (detailed list in the baseline scenario Annex V). The variety of potential applicants and the case of generic authorisations where it is difficult to identify who exactly benefits from the granting of the authorisation since it is granted to all operators and there is no existing mechanism to identify whether one specific operator may enjoy intellectual proprietary rights for the approved substance, may represent a challenge for the legal identification of the fee payer.

Historical data show that in practice the majority of applicants are usually economic actors, with a smaller role for SMEs. The latter are estimated to represent around 20% of the applicants to EFSA in each sector, except for some sectors in which the percentage is different (50% for feed additives, 10% PPP, 15% MRLs, 25% for TSE, 25% for Smoke Flavourings).

- *EFSA's resources for the scientific assessment of regulated products*

Under the current regulatory framework, EFSA finances the scientific assessment of regulated products through public funds. According to EFSA's Activity Based Budget (ABB), the share of the budget attributed to handling applications for the scientific assessment of regulated products in 2012 represents 30,2% of EFSA's total budget, this means that for 2012 over a total budget of 78.76 Million EUR, 23.78 Million were allocated to the scientific assessment of regulated products.

The table below shows the evolution of the resources allocated to the activities linked to regulated products.

Year	EFSA's total budget (appropriations) EUR Million	Total budget allocated to regulated products[13] EUR Million	Percentage of total budget allocated to regulated products
2010 (executed)	74.1	21.39	28.9%
2011(executed)	76.13	19.87	26.1%
2012	78.76	23.78	30.2%
2013 (foreseen)	78.28	24.55	31.4%

Source: EFSA

- *Number of applications received by EFSA*

The number of authorisation applications received per year by EFSA depends very much on the sector concerned. Some sectors are more dynamic, whilst in other areas the number of requests is more modest. On average, over the period 2003-2010, the number of authorisation applications received by EFSA amounted to 1182 per year, covering all sectors and types of workflow. The important impact of reviews on EFSA's workload is evident. Concerning health claims, in 2008 alone, 4187 applications were received out of a total of 9456 applications received over the period 2003-2010. Considering that reviews are not a systematic or foreseeable activity, but are started on a case-by-case basis and performed over a limited time

[13] Includes tasks not considered as eligible for fees such as the guidelines on the content of applications.

frame, a calculation without reviews should be made in order to identify a more stable number of dossiers received by EFSA.

In this way (excluding reviews), over the period 2003-2010, EFSA received 1518 applications for authorisations, which on average meant 189 applications per year. The forecasted number of applications for 2012-2015 is 346 on average per year (see Annex XVI), out of which 158 will be for generic and 188 for individual authorisations (120 out of 188 being MRL, which are very simple applications).

- *Fees already in place*

For GMOs and feed additives, the legal framework establishes fees for the EURL[14]. The fee is paid in the framework of an application for authorisation for which EFSA performs a risk assessment but remunerates the EURL's activity in relation to analytical aspects: validation of the analytical method to be used for the control of the substance submitted for authorisation (task falling outside EFSA's remit). The legislation specifies the exact amount of fees that the relevant EURL can charge according to the type of tasks performed. For feed additives, the maximum amount that can be charged by the EURL is EUR 6 000 with descending tariffs for simpler applications and applications for extension of use. For GMOs, the EURL fees can be up to EUR 90 000 for each application. A flat-rate contribution of EUR 30 000 must be paid by the applicant to the EURL at the beginning of the process, while the remaining EUR 60 000 has to be paid subsequently.

There are also fees established at national level in the case of decentralised procedures where the competent authority of a Member State carries out a preliminary risk assessment that is peer-reviewed by EFSA. This is the case for plant protection products (active substances and MRLs) and for novel food[15].

The amount of fees charged by MS also varies significantly from one to another.

In the case of active substances for PPP for instance, the range of fees charged by the reporting MS varies from EUR 23 100 to EUR 450 000. In the case of MRL of PPP, the range of fees varies from EUR 200 to EUR 15 000.

Concerning novel food, some MS do not charge any fee. Where a fee is in place, it ranges from EUR 830 to EUR 25 000. The Novel Food Regulation foresees the possibility of a simplified procedure. In this case, the amount of fees requested ranges from EUR 900 to EUR 2 000.

Table: type of authorisation issued by sector and double fee regime by sector

SECTORS	GENERIC AUTH.	AUTH. HOLDER	FEE PAID TO MEMBER STATE	FEE PAID TO EURL
PPP		X	X	
MRL		X	X	
GMO		X		X
TSE		X		
Feed additives (partly 14.5%)		X		X

[14] The main objective of the EU-RLs is to contribute to a high quality and uniformity of analytical results obtained in the various official food and feed control laboratories throughout the European Union.

[15] In the case of novel food, the peer review by EFSA is performed only when a MS has comments on the assessment carried out at national level.

Smoke Flavourings		X		
Recycling Plastic Processes		X		
Novel Foods		X	X	
Flavourings	X			
Extraction Solvents	X			
Food Contact Materials	X			
Food additives	X			
Feed additives	X	X (partly 14.5%)[16]		X
Animal by products	X			
Antimicrobial treatments	X			
Health Claims	X			
Enzymes	X			
Nutrient sources	X			
Food Allergies (exemption from labelling)	X			

- *Issues related to the authorisation procedure*

The 2010 Report highlighted some critical aspects of the authorisation procedure (submission of empty dossiers and length of the authorisation procedure). On the basis of the preliminary information gathered during the drafting of the report, they appeared to be linked to the lack of economic resources.

A more in depth analysis has shown however that other factors are at the origin of the underlined problems.

In particular, the submission of incomplete/empty dossiers is a phenomenon limited to the review of substances/products authorised at national level which have to be integrated in an EU list. According to the relevant rules, the product under scrutiny is allowed to be maintained on the market only if a dossier for its approval has been submitted to EFSA. This creates an incentive for operators to submit artificial dossiers in order to keep their products on the market during the transition period. It is thus considered a temporary phenomenon with restricted impact on EFSA's workload and functioning.

As far as the length of the procedure is concerned, the facts gathered during the preparation of the IA showed that the delays on authorisations are not due to a lack of resources but are mostly linked to the distribution of work within the Agency. The Panels' structure was not conceived for managing a high number of dossiers arriving at the same time (as happened for the reviews on claims). For this reason, in the road map of the IA a re-organisation of the distribution of work of the Panels was initially proposed, ensuring that more routine work could be undertaken by EFSA staff or externalised. As explained above (para. 1.3), that section of the IA was however discarded.

Moreover, peaks of workload originated by reviews should be overcome in the next few years since the review processes involving the highest number of dossiers are coming to an

[16] Based on SANCO's historical data

end in most of the sectors (only three are still managing significant reviews) and, where not, work is spread out over the years to avoid unmanageable peaks.

2.6. Subsidiarity test

Regulation (EC) n° 178/2002 created EFSA as an independent EU agency and set up rules for its functioning and funding. The establishment of an EU agency implies a duty of the EU institutions to guarantee that it functions properly and that it is financed adequately. The EU thus has the right to act in order to ensure adequate funding for EFSA.

The envisaged revision of Regulation (EC) n° 178/2002 in the IA only foresees the possibility of introducing the payment of fees for services delivered by EFSA and does not affect or modify Member States' power to charge fees for services rendered by national competent authorities.

The subsidiarity principle is thus respected, since the policy objectives can only be achieved at EU level and Member States' competence is not infringed.

3. OBJECTIVES

The Objectives have been selected in order to tackle the issues described in the sections above. They have been discussed and approved by the Impact Assessment Steering Group, Member States and Stakeholders.

3.1. General

- Protection of Health and Consumers;
- Correct functioning of the Internal Market;
- Promotion of economic growth, competitiveness and innovation;
- Safeguard efficiency and efficacy of the European public system for food safety risk assessment;
- Ensure consumer trust.

3.2. Specific

- Optimise use of public money;
- Introduce fees which take into account the characteristics of the different sectors and types of authorisations;
- Ensure appropriate and stable resources for EFSA;
- Safeguard the perception of EFSA's independence.

3.3. Operational

- Identify appropriate savings for the EU Budget;
- Develop a manageable fee system;
- Develop a fee system providing a satisfactory income for EFSA (close to EFSA's current funding for regulated products);
- Guarantee a fair fee system for the applicants (equality of treatment);
- Ensure a clear correlation between the level of services provided and the fees paid;
- Ensure that the system adequately takes into account SMEs.

3.4. Consistency with horizontal objectives of the EU

Smart Regulation: the EU legal framework which will be fit for purpose will optimise the EU contribution to EFSA's budget while preserving the quality and efficiency of the process for the scientific assessment of regulated products.

The approach to regulation will promote the interests of citizens, and deliver on the full range of public policy objectives.

Growth and Jobs: the safeguard of an efficient system of scientific assessment of regulated products, ensuring and supporting the quality of the applications, together with the fact of enabling EFSA to be financially able to perform such tasks, will benefit the producers/manufacturers/importers in the food and feed sector through faster market access and competitive advantage.

Innovation: by safeguarding an efficient and value-for-money scientific assessment, the system will encourage producers and manufacturers to invest in research and innovation in the food and feed sector.

4. POLICY OPTIONS

With a view to meeting the objectives set out in the previous section, a wide range of policy options falling under three broad categories have been analysed:

1. No policy change;
2. Mandatory fees approach;
3. Alternative approaches.

A screening of the policy options against a set of selected criteria led to the identification of those policy options that are likely to best meet the objectives. They were further assessed regarding their potential impacts.

The core criteria to screen the options were:

- *legal feasibility* = the action proposed is allowed in the legal framework considered;
- *optimisation of EU contribution to EFSA's budget* = the proposed option will possibly entail savings for the EU budget;
- *financial and governance sustainability* = the proposed option will provide an appropriate stable funding of EFSA's activities and the system will be manageable and cost-effective;
- *fairness* = the proposed option is fair towards all the sectors and actors affected by it;
- *flexibility and adaptability* = the proposed option ensures a degree of flexibility and adaptability to the characteristics of the sectors and actors affected;
- *impact on perception of independence* = the proposed option is likely to impact on the perception of EFSA's independence.

APPROACH 1. NO POLICY CHANGE

APPROACH 2. MANDATORY FEES

In all the options below, the application fee is defined as a fee covering the costs of the dossiers, these costs being variable according to the sector. As a matter of fact, applications for

regulated products received and processed by EFSA are covered by a huge diversity of Regulatory frameworks (24) and workflows (39 workflows). Some applications are processed by EFSA's staff only and following a first phase of assessment performed by a Member State (e.g. PPP and MRL), while others are processed with the involvement of experts in working groups and adopted by Panels (all except PPP). For some applications the safety assessments are more complex, including a safety assessment and an efficacy risk assessment (e.g. feed additives). In the GMO sector, the evaluation process covers molecular characterisation, food and feed safety, nutritional risk assessment, environmental risk assessment and post market environmental monitoring.

2.1 Application fee for risk assessment for all applicants and for all types of applications (new, renewal, review);

2.2 Application fee for risk assessment only for applicants who are authorisation holders and for all types of applications (new, renewal, review);

2.3 Application fee for risk assessment for all applicants for new and renewal applications;

2.4 Application fee for risk assessment only for applicants who are authorisation holders for new and renewal applications.

APPROACH 3. OTHER ALTERNATIVES

3.1 Fees for additional services for all applicants and for new and renewal applications;

3.2 Flat rate fee (administrative fee identical for all sectors) for all applicants and for new and renewal applications

3.3 Harmonize EFSA's fee system with that used by EMA;

3.4 Harmonize EFSA's fee system with that used by ECHA;

3.5 Give EFSA the power to decide on a case-by-case basis which applications should be subject to fees.

4.1. Options discarded at an early stage

Following the screening of the options illustrated above, the following preliminary options were discarded after discussion in the IASG, and with Member States and Stakeholders:

- *Application fee for risk assessment for all applicants and for all types of applications (new, renewal, review); Application fee for risk assessment only for applicants who are authorisation holders and for all types of applications (new, renewal, review)*

- These two options have been discarded because they also cover applicants submitting applications for review. As already mentioned above, reviews concern regulated products already on the market that are re-assessed following a decision of the public authorities justified by public health concerns and/or by the need to establish an EU list of authorised products/substances based on consistent public health criteria. It would therefore be difficult to justify the charging of fees for procedures not initiated by private parties and performed in the public interest. The two options also do not have the required flexibility and adaptability to the characteristics of the sectors since fees are charged regardless of the type of dossier. Finally, reviews have been initiated in most of the sectors where needed in the last few years. It would not be legally feasible to retroactively apply fees in the sectors where the reviews are not yet finalised.

- *Flat rate fee (administrative fee identical for all sectors) for all applicants and for new and renewal applications*

- the approach would result in all applicants paying the same fee. This is not in line with the principle generally applied requesting that the level of the fees has to have a link with the cost of the service; under this option, the link with the costs would not be established because the costs for EFSA for assessing an application varies from EUR 6 800 for an MRL to EUR 135 000 for a GMO (table 8, page 59 of the baseline study). The approach is thus unfair since applicants for simple dossiers would pay the same fees of those applying for more complex ones and in fact the former would end up financing the latter. The system is also not flexible and not adapted to the characteristics of the sector since it does not take into account the differences of the sectors affected.

- *To harmonize EFSA's fee system with that of ECHA*

This option would put in place a fee system in which, as happens in the ECHA system, all manufacturers and importers producing or importing a regulated product/substance in a range will have to register this regulated product/substance and pay an application fee upon the registration of their substance/product (see Annex VIII for details).

This would entail the introduction of a registration system for food substances/products authorised or to be authorised.

The option has been discarded since putting in place a registration system would encounter the following obstacles:

- From a legal point of view, it would require the modification of the legislation of 19 sectors and this would go beyond the limits set for the current IA. In addition, a registration system replacing an authorisation system would not fulfil the objectives of public health protection legally required in the food sectors. The specific risk level linked to the ingestion of food implies a systematic pre-approval of all substances added to food or that can be present as residues in food and not a registration system;
- The costs of putting in place and managing a registration system are high both for public authorities and for industry as is shown by the study carried out for ECHA[17]; such costs would not be fair or adapted to the characteristics of the food sectors where the aim of the registration system (to know substances/products on the market) is already fulfilled through the pre-marketing authorisation;
- In addition, also in this case the number of applications subject to fees is very different (roughly 6.900 per year for ECHA and 189, without reviews, per year for EFSA). As is the case for the EMA option, this renders the ECHA fee regime not applicable;
- Finally, a registration mechanism implies tasks for the agency supporting the registration process that are different from the ones of an agency supporting an authorisation process. Within the ECHA system, except for a few cases (namely, substances of very high concern that are subject to specific risk management processes like restriction and authorisation), the Agency's tasks are focussed on checking the quality of the registration dossiers submitted, maximising the availability of high quality data to enable the safe manufacture and use of

[17] See, CSES, *Interim Evaluation: Functioning of the European chemical market after the introduction of REACH*, 30 March 2012, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-final-report_en.pdf.

chemicals and the efficient functioning of the internal market, and not on the carrying out of a risk assessment and the delivery of scientific opinions as is the case for EFSA. Since a system of fees is related to the tasks of the agency, the ECHA system of fees cannot be applied to EFSA.

- *To harmonize EFSA's fee system with that of EMA*

The option would align EFSA's system with that of EMA, where an annual flat rate fee is paid by all applicants for the maintenance of the marketing authorisation and specific fees are charged for each of the different activities carried out by the Agency in relation to industry applications (see Annex IX for details).

This option has been discarded because its scoring is negative in almost all the criteria considered.

- Concerning the legal feasibility criteria, the possibility to assimilate EFSA's fees system to EMA's system does not appear possible. The two Agencies have different missions and, contrary to the food sector, in the pharmaceutical one all centralised applications follow the same administrative procedure and authorisations issued are individual;
- In addition, EMA carries out a wide range of services to industry which are liable for fees (e.g. the assessment of variations provides the Agency with roughly 40% of the income coming from fees). Similar variety of services is not present or possible in EFSA's system;
- Also, the number of applications subject to fees is very different (roughly 5.500[18] per year for EMA and 189, without reviews, per year for EFSA). Since this factor significantly affects financial and governance sustainability, it is not possible to apply an identical fee regime when numbers are so different;
- Finally as the actors and markets related to the sectors concerned by authorisation applications differ significantly from those relating to EMA: the food sector is not dominated by large firms and the authorisations issued in the food sector do not provide for exclusive marketing rights. The option would entail thus problems of fairness and would not have the required flexibility and adaptability to the different sectors.

- *To give EFSA the power to decide on a case-by-case basis which applications should be subject to fees*

This option stems from the example given by the New Zealand system (Annex X), where fees are charged on a case-by-case basis where, according to some criteria, an economic benefit for the applicant can be detected. This option, which allows considerable flexibility, has been considered legally unfeasible for the following reasons:

- From the legal feasibility criteria, the proposed system is not a viable option. According to European Court of Justice (ECJ) case-law (*Meroni* case, 9/56, 1958), Agencies cannot exert power involving a wide margin of discretion. For this reason, none of the EU Agencies' fee systems in place provide for the delegation of the power to decide on the criteria on the basis of which to charge fees by the Agency;

[18] See Annex IX including reference given in foot note "EMA received in 2011, 5500 dossiers for medicinal product for human use. The number includes all applications subject to the payment of fees, such as new products first evaluation, variations and renewals".

- In addition, the option is potentially harmful to the perception of EFSA's independence because of the wide margin of discretion left to the Agency;
- Finally, such an option poses serious concerns from the governance and financial sustainability points of view. First, if fees are charged on a case-by-case basis it would not be possible to plan the financial resources provided by the fees and therefore the linked EU subsidy. Second, this would cause problems of budget fluctuation for EFSA.

4.2. Options selected for in-depth analysis

The selected options are those considered to be the most relevant in relation to the criteria used for the screening. The retained options are the following 4 and will be referred to, as mentioned below, in the following sections of the IA.
In order to comply with the Commission policy "*Minimizing regulatory burden for SMEs – Adapting EU regulation to the needs of micro enterprise*"[19] a fee reduction for SMEs has to be foreseen. On the basis of other agencies' experience, in order to avoid putting in place a complex system leading to additional management costs, it was decided to establish a sole level of reduction applicable to all SMEs. Taking into consideration the already burdensome system of authorisation for SMEs, a reduction of fees of 90% was chosen as an incentive for SMEs to apply (see para. 5.2 for a detailed explanation). The 90% reduction for SMEs will be included in all the calculations.

Option 1: No policy change;

Option 2: Application fee for all applicants for risk assessment of new and renewal applications;

Sub - option 2: Application fee for all applicants for risk assessment of new and renewal applications, excluding sectors where initial assessment is performed by MS;

Option 3: Application fee only for applicants who are authorisation holders for risk assessment of new and renewal applications;

Sub-option 3: Application fee only for applicants who are authorisation holders for risk assessment of new and renewal applications, excluding sectors where initial assessment is performed by MS;

Option 4: Fees for additional services for all applicants and for new and renewal applications.

4.2.1. Description of option 1: No policy change

Under Option 1, no changes will be introduced to the current framework concerning the scientific assessment of regulated products in the EU.

The scientific assessment will continue to be covered by the EU Budget, while leaving EFSA the possibility of asking for the payment of charges for supporting activities such as seminars, workshops and training, as foreseen by Article 43 of Regulation (EC) n° 178/2002.

Under this scenario, applicants willing to market a new regulated product will only have to bear the costs of preparing the application to be submitted, while the scientific assessment will continue to be performed free of charge, except in

[19] COM(2011)803.

cases where it is partly performed at national level and where fees are charged by Member States.

4.2.2. Description of option 2: Application fee for all applicants for risk assessment of new and renewal applications

Under Option 2, the application fee will follow a cost-recovery approach.

The amount of the fee will be equal to the cost for EFSA of assessing an application in each specific sector, with an additional cost of establishing and managing the fee system by EFSA.

The costs and relative fees are all sector-sensitive/sector-related.

In particular the fees are calculated as follows:
The cost of assessing an average dossier in each specific sector includes: EFSA staff, infrastructure (building, supplies etc.), meetings (experts), outsourcing (grants and procurement), operating support (missions of EFSA staff, IT, translations) and overheads representing 16% of the direct costs. The additional cost for the collection of fees is 8% of overheads for each dossier. The cost of producing guidelines has been excluded from the calculation as they are considered to be of public interest.
Under this option, the fee system will make **all applicants (except institutions), either receiving an individual or a generic authorisation** liable to pay fees**.**

Fees will be in place for all applications concerning new regulated products **prior** to their introduction on the market and for applications concerning renewals of: **a)** applications for which the **authorisation** has **expired** (after 10 years) or **b)** applications submitted following **changes in technology** or **development of new scientific knowledge** – this case also includes the applications regarding extension of uses[20]. In total 346 applications on average per year will be liable for the payment of fees. For SMEs, a 90% reduction in the amount of fees is foreseen and is included in the calculations (see Annex XI).

The option covers also sectors in which a prior assessment of the application is done at national level (namely, PPP, MRL and novel food) or by the EURL (namely, GMO and feed additives) and fees are charged for the performance of such an assessment. In this case, applicants will have thus to pay fees both to EFSA and to the MS's authority or the EURL (double fee regime).

4.2.3. Description of sub - option 2: Application fee for all applicants for risk assessment of new and renewal applications, excluding sectors where initial assessment is performed by MS.

Option 2 includes sectors where fees are already paid at national level or to the EURL. In order to avoid a double fee regime a sub option, excluding the sectors where EFSA only performs a peer-review of the initial assessment carried out by an MS, will also be assessed (see Annex XII). In this case, 182 applications on average per year will be liable for the payment of fees.

[20] In particular in the sector of feed additives, there are applications assessed by EFSA requesting that a feed additive authorised for one species be authorised for other species.

The possibility of excluding sectors where fees are already paid to the EURL (namely GMO and feed additives) will not be assessed since the activity carried out by the EURL is considered different from the EFSA one. The EURL does not perform any assessment of substances/products but checks the validity of the analytical method for detecting substances/products in food and feed proposed by applicants.

4.2.4. Description of option 3: Application fee only for applicants who are authorisation holders for risk assessment of new and renewal applications

This option follows the same approach as the previous one, but the target of the fee payer is different.

The fees are calculated as per option 2 (including the collection costs) and the types of applications concerned are the same as for option 2 (applications for new regulated products and for renewals as defined under option 2). The reduction for SMEs is also 90% and included in the calculations (see Annex XIII).

However, under this option, the fee system will **only** make **applicants who are authorisation holders** liable to pay fees. Thus only 8 sectors will be subject to fees, meaning 188 applications on average per year. The option covers also sectors in which a prior assessment is done at national level (namely PPP, MRL and novel food) or in which the EURL performs analytical work (namely GMO and feed additives).

4.2.5. Description of sub-option 3: Application fee only for applicants who are authorisation holders for risk assessment of new and renewal applications excluding sectors where initial assessment is performed by MS

Since option 3 includes sectors where fees are already paid at national level or to the EURL, a sub-option, excluding the sectors where EFSA only performs a peer-review of the initial assessment carried out by MSs, will also be assessed in order to avoid a double fee regime. In this case 24 applications on average per year will be liable for the payment of fees.

The possibility to exclude also sectors where fees are paid for the EURL assessment (namely GMO and feed additives) is not taken into consideration, not only for the same reason explained in sub-option 2, but also since only 3 sectors, representing 4 applications on average per year (see details in Annex XIV), would remain liable for the payment of fees (TSE, smoke flavourings and recycling plastics processes). This is not considered to be a valid base for establishing a fee system.

4.2.6. Description of option 4: Fees for additional services for all applicants and for new and renewal applications

The fee for additional services is intended as a compulsory fee to be paid to have access to a series of additional services which EFSA would provide. Under this option EFSA would have additional tasks to carry out which will not be covered by the annual budget set in agreement with EU budgetary authorities. For this reason, the amount of fees collected will be additional to the budget set in accordance with EU budgetary authorities.

EFSA will provide, in particular, services such as:

- *Help desk for applicants;*
- *General pre-submission services (annual meeting + workshop for each sector) and individual pre-submission services; administrative and scientific support; help desk for SMEs;*
- *Network of application desks (APDESK) in Member States; post-authorisation monitoring services for GMOs.*

Under this option, **all applicants (except institutions), regardless of whether they will receive a generic authorisation or if they are authorisation holders,** will have to pay a fee. The additional services will not cover the following sectors (PPP, MRLs of PPP and novel food) because the applications are submitted for the first step of the assessment to national authorities. This means that only around 182 on average per year of incoming applications for the period 2012-2015 would be subject to fees.

The fee will have to be paid in the case of submission of new regulated products **prior** to their introduction on the market and for applications concerning renewals defined as under option 2. The level of fees will depend on the complexity of the application, according to the categorisation elaborated by EFSA (Normal, Complex, and Highly Complex, with a special regime for GMO cultivation).

For SMEs, a 90% reduction in the amount of fees is foreseen and is included in the calculations (see Annex XV).

5. ANALYSIS OF IMPACTS

5.1. Economic Impact

Methodological note

The calculations concerning the monetary impacts are based on information and data obtained from EFSA and from Stakeholder Associations who responded to a questionnaire on socio-economic data.

The calculations aim at evaluating, in quantitative terms, the options selected for assessment. The calculations concern the impact of fees on EFSA and on the potential applicants in monetary terms.

The forecasting is based on a limited time frame (2012-2015, Annex XVI). It is not possible to forecast for a longer period as the underlying factors that might influence the variables that are being forecasted (number of applications/amount of income from fees) are not completely predictable.

In particular, to calculate the income expected from fees under option 2, *sub-option 2*, option 3 and *sub-option 3*, the number of applications expected per year (Annex XVI) in each sector concerned has been multiplied by the estimated fee in this sector (Annexes XI, XII, XIII, XIV), taking into account reduced fees for SMEs.

The method applied has therefore been a judgmental method incorporating judgments and probability estimates. All calculations are sector-sensitive/sector-related.

The principle of balancing budget

For partially fee-funded EU agencies the principle of balancing budget applies. At the beginning of each year (Y), the Agency budget and the EU contribution to that are adopted through the budgetary procedure.

If at the end of year the actual fee revenues are higher than foreseen, the EU contribution is decreased accordingly. The positive or negative outturn is recovered in the next year (Y+1) by the EU (namely, the Commission), but the EU will adapt its contribution to take into account the savings only the following year (Y+2).

If the outturn is negative, no amount is to be recovered by the EU and thus no adaptation of future contribution occurs. Assuming that losses should normally not be of a recurring nature, the EU will compensate this negative outturn situation with any future positive outturns.

Thus if fewer applications are received, resources would have to be re-allocated internally by the Agency.

Economic Impact on EFSA

Under *Option 1* – *No policy change* – EFSA will continue to allocate the financial resources to carry out its activities related to the scientific assessment of regulated products according to its multi-annual and annual management plan. For 2012, the actual expenditures for such activities amount to EUR 23.78 Million, accounting for 30,2% of EFSA's total budget (EUR 78.76 Million). The current system ensures that EFSA receives the necessary funding to cope with its workload related to the scientific assessment of regulated products.

Under *Option 2* - *Application fee for risk assessment for all applicants of new and renewal applications* - EFSA will receive from fees for the scientific assessment of regulated products each year on average EUR 11.5 Million, which would represent 48.3% of EFSA's current expenditure on regulated products. Of the forecasted EUR 11.5 Million, EUR 172 000 per year would be needed to cover the collection costs of the fees system.

The fee income will not cover EFSA's actual expenditure on the scientific assessment activities but only half of it. The fluctuation of the number of applications received each year, the fact that in some sectors there are sometimes no applications during several years, will not ensure a manageable system for EFSA. As demonstrated by studies made on other agencies' experience, in order to cover possible losses EFSA might need to transfer funds allocated to public interest tasks to authorisations' assessment tasks[21].

The exclusion of sectors where an assessment is already done at MS level provided for in *sub-option 2* would further shrink EFSA's income. EFSA would get roughly EUR 8 Million per year, covering only 34 % of EFSA's current expenditure on regulated products (EUR 23.78 Million). Out of EUR 8 Million, EUR 138 000 per year would be needed to cover the collection costs of the fees system.

Under *Option 3* - *Application fee for risk assessment only for applicants who are authorisation holders for new and renewal applications* - EFSA will receive from fees for the scientific assessment of regulated products each year on average EUR 5.4 Million, which represents 22.7% of EFSA's current expenditure on regulated products. Of the forecasted EUR 5.4 Million, EUR 95 000 per year would be needed to cover the collection costs of the fees system.

[21] This was the conclusion drawn by the United States Government Accountability Office (US GAO) where it was highlighted that a program of user fees on the approval of drugs had "*the unintended effect of reducing the share of funding and staffing for other activities*" (see US GAO, *Food and Drug Administration. Effect of user fees on drug approval times, withdrawals, and other agency activities*, September 2002).

In *sub-option 3* EFSA's income would be only EUR 1.8 Million per year, meaning only 8% of EFSA's current expenditure on regulated products. Of the forecasted EUR 1.8 Million, EUR 36 700 would be needed for managing the fees system.

Considering the low number of applications (on average 188 dossiers per year for option 3 and 24 for sub-option 3) both option 3 and *sub-option 3* would cause fewer problems in term of manageability of the system and budget fluctuations.

Under *Option 4* - *Fees for additional services for all applicants and for new and renewal applications* - EFSA will receive for additional services to the applicants each year on average EUR 3 Million, which represents 60 % of the estimated yearly costs for services (EUR 5 Million). This is because the number of applications eligible for fees for services is rather low (on average 182 per year) and some of the costs for the services proposed by EFSA could not be included in the calculation of the fee to be charged since they are provided in the public interest. Therefore, those services will have to be funded by the EU budget. In particular, the costs of establishing and running the SMEs desk and the correlated SME network in Member States will have to be financed by public money.

Despite being the only option for which the fees income might be considered additional to the EU subsidy, option 4 appears to be unsustainable as the analysis shows that the budgetary costs would be significant.

Finally, all the options should also be weighed against the investment costs (EUR 12 Million) borne by EFSA for putting in place the fee system, since at best EFSA will get EUR 11.5 Million per year (option 2). This could mean that in option 2 EFSA will start to have an income from fees only one year after the putting in place of the fee system, since the money collected the first year will have to be all deployed to cover the investment costs. In *sub-option 2* (EUR 8 Million per year) and option 3 (5.4. Million per year) EFSA will be able to cover the investment cost only after, respectively, 1 ½ years and two years. For *sub-option 3* (EUR 1.8 Million per year) and option 4 (EUR 3 Million per year) it would require more time to pay off the investment: roughly 10 years in the first case and 4 years in the second.

Economic Impact on the EU Budget

Under Option 1 *No policy change*, the EU Budget will continue to finance EFSA's activities according to the provisions of the Financial Regulation. The option does thus not entail any savings for the EU budget.

Under Option 2 *Application fee for risk assessment for all applicants of new and renewal applications* and 3 *Application fee for risk assessment of new and renewal applications only for applicants who are authorisation holders*, the EU contribution to EFSA's Budget will be compensatory to the fee income. The EU would thus save roughly EUR 11.5 Million under option 2 and EUR 5.4 Million under option 3.

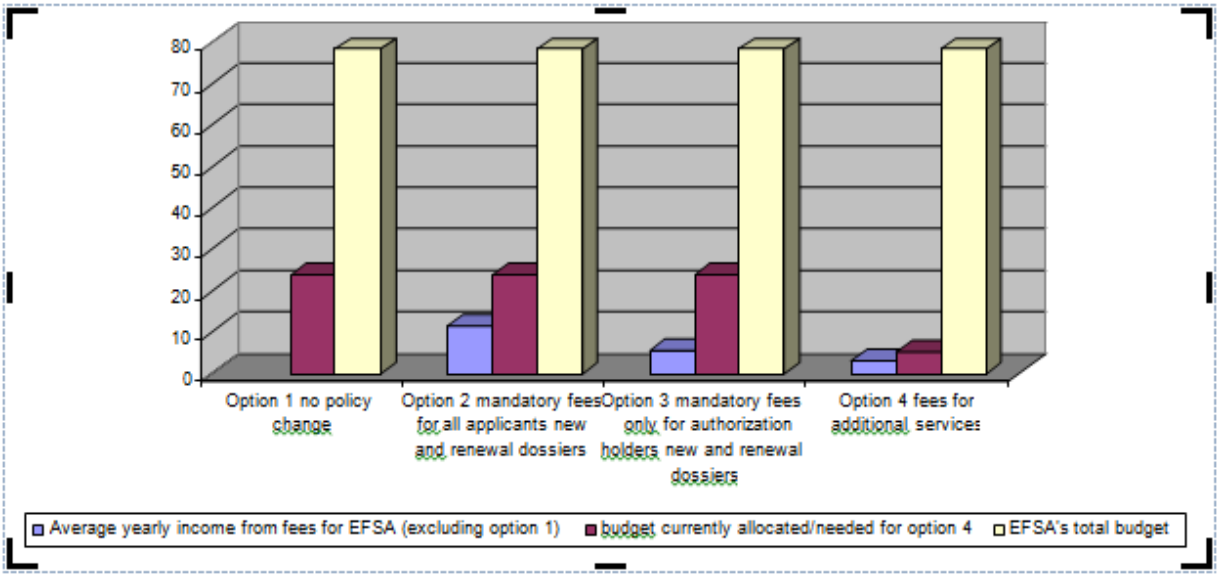
Over a budget of EUR 78.76 Million currently allocated to EFSA this would represent respectively only 15% (option 2) and 7% (option 3) of the funds at present allocated by the EU to EFSA. *Sub-option 2* and *sub-option 3* would provide lower savings, respectively 10% by ensuring an annual income of EUR 8 Million and 2% by ensuring an annual income of EUR 1.8 Million. Considering the fluctuation of the number of applications received each year, the contribution will be volatile from one year to the other. This could lead to uncertainties and additional administrative

costs in EFSA and in the Commission in establishing a mid-term financial plan for EFSA and in setting up a clear budgetary line in the EU Budget.

Under Option 4 *Fees for additional services for all applicants and for new and renewal applications*, considering that the services for which the fees are foreseen (Annex XV) will represent new activities for EFSA, the income envisaged could be additional financial resources in addition to the regular EU financing. No EU budgetary savings are thus foreseen under this option, but rather an increase of the EU contribution since, as mentioned above, it will not be possible to cover the expenses of some of the services proposed. In particular, the services related to SMEs, which will benefit from a reduction in fees and will imply that MS will have to be financed for the management of national SME help desks, will lead to a request for additional EU funding. Each year, the additional burden for the EU budget will amount to EUR 2 Million (since the expenses for the provision of the services will be EUR 5 Million and only EUR 3 Million will be covered by the payment of fees).

	Average yearly income from fees for EFSA (EUR Million)	**Budget currently allocated (expected budget needed for option 4) (EUR Million**
Option 1 no policy change	0	23.78
Option 2 application fees for all applicants new and renewal dossiers	11.5	23.78
***Sub - option 2* application fees for all applicants new and renewal dossiers, excluding sectors where initial assessment is performed by MS**	8	23.78
Option 3 application fees only for authorisation holders new and renewal dossiers	5.4	23.78
***Sub - option 3* application fees only for authorisation holders new and renewal dossiers, excluding sectors where initial assessment is performed by MS**	1.8	23.78
Option 4 fees for additional services	3	5

EFSA's income from fees, budget currently allocated for the scientific assessment of regulated products and EFSA's total budget for 2012



5.1.1. Economic Impact on applicants of the food and feed chain

Under Option 1 *No policy change*, applicants are not charged for the processing of the authorisation application by EFSA.

Under Option 2 *Application fee for risk assessment of new and renewal applications for all applicants*, the fees charged to applicants are variable according to the sectors to which they relate and the type of application submitted (new regulated product or a renewal) (see Annex XI). There will be a considerable difference in the amounts paid by applicants from one sector to another, irrespective of the size of their related markets and the type of authorisation granted.

This option also covers the sectors where fees are already in place at national level or for the analytical work of the EURL. This double fee regime will concern 5 of the 19 sectors. Stakeholders are of the opinion that the additional fee envisaged would represent a significant financial burden, which would be crucial to the decision to continue submitting new applications to EFSA.

The data obtained from the questionnaire show that each sector, according to the characteristics and requirements of its sectorial legislation, already faces costs linked to the requirements to be followed when submitting an application to EFSA (details in Annex II).

From the calculations performed it appears that in some cases, the fee envisaged to cover the scientific assessment of EFSA will be higher than the fee charged at Member State level where the preliminary assessment is performed.

SECTOR	TYPE OF DOSSIER	FEES OPTION 2	FEES ALREADY PAID BY THE APPLICANT
PPP	NEW	EUR 76 307	EUR 23 100 to 450 000 for MS
MRL	NEW	EUR 6 872	EUR 200 to 15 000 for MS
GMO	NEW	EUR 137 346	EUR 90 000 for EURL
Smoke Flavourings	NEW	EUR 38 261	
Flavourings	NEW	EUR 38 261	
Extraction solvents	NEW	EUR 38 261	

Food contact materials	NEW	EUR 38 261	
Recycling Plastics Processes	NEW	EUR 38 261	
Food additives	NEW	EUR 78 374	
Feed additives	NEW	EUR 56 242	EUR Max 6 000 for EURL
TSE	NEW	EUR 60 524	
Animal by-products	NEW	EUR 131 985	
Antimicrobial treatments	NEW	EUR 114 760	
Health claims	NEW	EUR 60 109	
Novel food	NEW	EUR 84 086	EUR 830 to 25 000 for MS
Infant formulae	NEW	EUR 84 086	
Food allergies	NEW	EUR 49 944	
Enzymes	NEW	EUR 75 211	
Nutrient sources	NEW	EUR 71 810	
GMO	RENEWAL	EUR 137 346	EUR 90 000 for EURL
Feed additives	RENEWAL	EUR 33 784	EUR Max 6 000 for EURL
PPP	RENEWAL	EUR 76 307	EUR 23 100 to 450 000 for MS
Smoke Flavourings	RENEWAL	EUR 38 261	

Covering all 19 sectors, this option will also result in fees for sectors where the authorisation granted is generic (11 out of the 19 sectors). Since for generic authorisations there will be one fee-payer for the submission of an application for authorisation but many beneficiaries of the authorisation who will not have paid a fee, economic actors may be encouraged to exploit the situation and wait for other companies to apply to EFSA ("free riding"). This distortion has been repeatedly indicated by Stakeholders as a major factor affecting the validity of Option 2. In fact, Stakeholders considered Option 2 to be unfair for putting at the same level applicants receiving a generic authorisation and those benefitting from the economic advantages of being authorisation holders.

Similar distortion would also occur under *sub-option 2* since for 11 out of the 16 sectors concerned by the payment of fees, applications issued are generic. However, this sub-option would avoid additional burdens created by a double system of fees and it would be perceived as fairer by Stakeholders, as sectors already paying fees at Member States level for the preliminary risk assessment of an application subsequently peer reviewed by EFSA (PPP and novel food) are excluded from the payment of fees.

Under Option 3 *Application fee for risk assessment of new and renewal applications only for applicants who are authorisation holders,* the fees are focused on a specific target: the authorisation holders operating in 8 of the 19 sectors concerned by authorisation applications.

Under this option, the criterion used to select the fee payer is the exclusive right to produce/market the regulated product submitted for authorisation.

The level of fees will be the same as under Option 2, therefore the difference in the amounts paid by the applicants is still significant and irrespective of the size of their related markets. Option 3 is considered by the Stakeholders as being fairer than Option 2 because it excludes from the payment of fees those sectors where there are generic authorisations. However, more than half of these sectors (5 out of the 8 sectors covered) are already paying a fee to the EURL

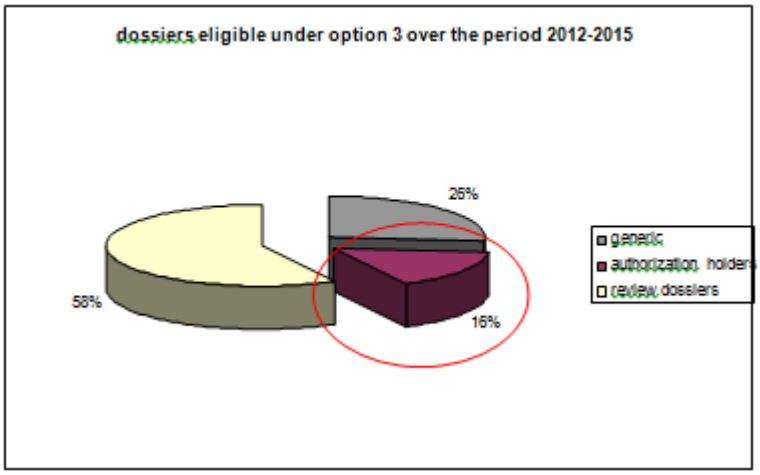
for analytical work or at Member State level where the preliminary scientific assessment has been performed and it would be burdensome to add an additional level of fees, in particular considering that there is only one fee paid to ECHA and EMA, even when these agencies share tasks with Member States in the framework of the risk assessment process. Moreover, as in option 2, in the majority of cases, EFSA's fee will be higher than the fee already paid.

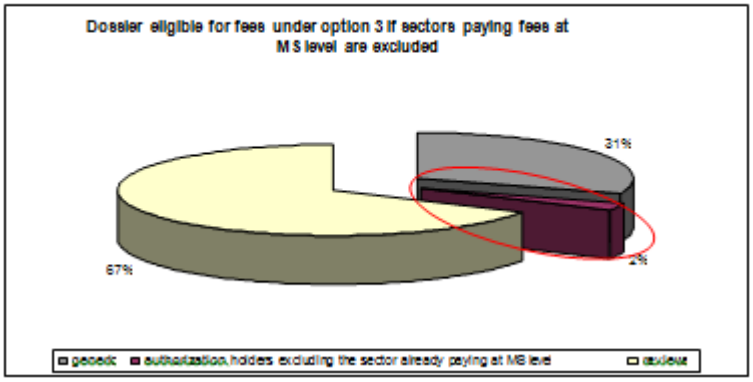
As reports on other agencies have highlighted[22], the system could also lead to a differentiation in the handling of regulated products, where the discriminatory fact will depend on the payment or exemption of the fee, leading *de facto* to a disparity between the sectors with generic authorisations and those with individual authorisations. In particular, due to the fact that they bring money to the agency and that the payment of fees creates applicants' expectations that their requests are treated as efficiently as possible, applications liable for fees could be given more importance in the management of dossiers received by EFSA.

Sectors with authorisation holder	type of dossier	fees option 3	fees already paid by the applicant
PPP	NEW	EUR 76 307	EUR 23 100 to 450 000 for MS
MRL	NEW	EUR 6 872	EUR 200 to 15 000 for MS
GMO	NEW	EUR 137 346	EUR 90 000 for EURL
TSE	NEW	EUR 60 524	
Feed additives Partly (14,5%)	NEW	EUR 56 242	EUR Max 6 000 for EURL
Smoke Flavourings	NEW	EUR 38 261	
Recycling Plastics Processes	NEW	EUR 38 261	
Novel Food	NEW	EUR 84 086	EUR 830 to 25 000 for MS
GMO	RENEWAL	EUR 137 346	EUR 90 000 for EURL
Feed additives 14,5%	RENEWAL	EUR 33 784	EUR Max 6 000 for EURL
PPP	RENEWAL	EUR 76 307	EUR 23 100 to 450 000 for MS
Smoke Flavourings	RENEWAL	EUR 38 261	

If the sectors already paying fees at Member States level for the preliminary risk assessment of an application subsequently peer reviewed by EFSA (PPP and novel food) were excluded from the payment of fees, 5 sectors (GMOs, TSE, feed additives with authorisation holders, smoke flavourings, and recycling plastics) (*sub-option 3*) out of the 8 sectors considered in option 2 would be concerned. The problem created by the coexistence of two fee systems (national and EU) (double fee regime) would be eliminated. However, from the forecasting for the next few years, it appears that the number of dossiers submitted to EFSA would be only 24 on average per year (see details in Annex XIV).

[22] See, for example, US GAO, *Food and Drug Administration. Effect of user fees on drug approval times, withdrawals, and other agency activities*, September 2002.





Under Option 4 *Fees for additional services for all applicants and for new and renewal applications*, fees would cover all sectors subject to an authorisation application, except Novel Food, PPP and MRL of PPP, all of which receive pre-submission services at national level and which are therefore not eligible for this option. The remaining 16 sectors would be charged respectively:

EUR 13 000 for Smoke Flavourings; Flavourings; Extraction Solvents; Recycling Plastics; Food Contact Materials; Food allergies; Feed additives (renewal);

EUR 25 000 for Food Additives; Feed Additives (new); TSE; Health Claims; Enzymes; Nutrient Sources;

EUR 40 000 GMO import and processing; Animal by Products; Antimicrobial treatments; Infant formulae;

EUR 90 000 + EUR 40 000 (yearly fee for post-market monitoring) for GMO cultivation (Annex XV).

Under this option, applicants for GMO and Feed Additives would still experience a double fee regime but for services rendered by EURL, which – as already highlighted – are considered different from those offered by EFSA.

Taking into consideration the list of services proposed by EFSA under Option 4, the benefits for applicants are at this stage not convincing.

From the Commission's analysis and from Stakeholders' feedback, it is evident that to represent a clear added value for applicants the additional services provided should be tailored to the specific needs of each sector. From Stakeholders' data gathering it emerged, in particular, that many applicants, in particular SMEs, often ask for assistance from specialized firms in order to be able to identify which piece of legislation, and what type of information should be present in

their applications. From the survey of SMEs it emerged that they are investing financial resources to have external consultancies prepare and submit the dossier to EFSA on their behalf. Those views are confirmed by the ex-post study performed on the ECHA system where it is pointed out that, despite the overall support offered by ECHA, the majority of companies (around 60%) rely on private consultancies to deal with the registration process[23]. To provide value for money for applicants services proposed have to be tailored to the specific needs of each sector and fees paid have to be cost–effective.

The list of services proposed by EFSA is rather general and does not ensure at this stage that the specific needs of each sector will be properly addressed. Some of the new services proposed (pre-submission scientific services) are considered by Stakeholders as being of potential added value, but their workability is not guaranteed since they would require the involvement of experts/members of the Panel, and such an involvement has not been precisely identified.

In addition, some of the services proposed can be considered as normal good administrative practice (help desk to provide clarifications, translations) and should thus be provided free of charge.

Finally, other services (training, workshops) are not new and can already be subject to the payment of charges to EFSA. Article 43 of Reg. (EC) n° 178/2002 enables EFSA to "*organize and charge for conferences, trainings and any other similar activities provided by the Authority*." This is, in fact, a fairer arrangement since only the participants who consider that they have a need for such services will pay.

The level of fees proposed does not, therefore, appear adequately linked to the type of services proposed.

5.2. Impact on SMEs (the SMEs Test)

SMEs are among the actors likely to be affected by the possible introduction of fees for the scientific evaluation of regulated products. Because of the number of sectors in the food and feed chain concerned by authorisation procedures, the structure of the market and the characteristics of the business are highly heterogeneous[24]. As a result, the identification and quantification in terms of number of SMEs has been hindered by the lack of data available and historical data has had to be used (see para 2.5 for more details).

According to the outcome of the SMEs Panel Survey (89 respondents), SMEs of the 19 sectors interested by authorisation applications are facing a series of difficulties regarding access to the market and competing in it (Annex IV).

In particular, those who replied to the questionnaire pointed out that the two major barriers to accessing the market of regulated products are the regulatory framework and the availability of capital. The availability of capital is the most relevant factor affecting their capacity to invest in research and innovation.

Empirical evidence collected demonstrates that already under the current situation, SMEs experience difficulties in finding the resources to invest in the development of new products. In addition, they cope with the dossier submission requirements by delegating, in many cases, the filing of applications to consulting companies (which have more resources and *know-how*), or by cooperating through *consortia* in order to share and reduce the costs of preparing

[23] See, CSES, *Interim Evaluation: Functioning of the European chemical market after the introduction of REACH*, 30 March 2012, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-final-report_en.pdf.

[24] To cover all products/substances/claims/processes subject to the scientific assessment of regulated products by EFSA, 40 NACE (European Classification of Economic Activities) have been used to investigate their economic characteristics.

applications for submission to EFSA. Therefore, if fees were introduced for authorisation applications, many SMEs might not be able to bear the additional costs.

According to the information gathered, the charging of fees to SMEs is expected to be felt disproportionately and will have an impact on their capacity to access and compete on the market. This opinion is confirmed by the study carried out in the ECHA system where it is highlighted that without the reduction of the fee to be paid to ECHA provided in that system, the burden of the registration system on SMEs would be clearly disproportionate[25].

For this reason, all the options envisaged have foreseen a reduction of 90% for SMEs as a mitigating measure.

According to historical data, micro enterprises are not applying to EFSA for the scientific assessment of regulated products. However, such micro enterprises are covered by the policy options proposed with the sole objective of preventing possible fraudulent behaviour of such enterprises presenting applications on behalf of bigger companies with the purpose of avoiding the fee payment.

Under Options 2 *Application fee for risk assessment of new and renewal applications for all applicants* and 3 *Application fee for risk assessment of new and renewal applications only for applicants who are authorisation holders* the fees for the SMEs would range up to EUR 13 735, with a double fee regime in the sectors where fees are already in place at Member States' level and for the EURL; under Option 4 *Fees for additional services for all applicants and for new and renewal applications* the fees for the SMEs will range from EUR 1 300 to EUR 4 000.

5.3. Impact on competitiveness and innovation

Quantitative data on the size and share of the market covered by the 19 sectors have been investigated through a data collection exercise. It was not possible to collect such information through the usual databases (such as Eurostat and available studies). In fact, the 19 sectors concern substances and products used in the processing of a high number of final products and their traceability is difficult. Data collection through a questionnaire sent to the Associations of the sectors demonstrated the same limits: no economic data are available at the disaggregated level needed (see Annex II).

The markets related to the 19 sectors interested by authorisation applications are heterogeneous. Some sectors, such as PPP, GMO and Enzymes, are dominated by very large companies. Among them there are, however, also sectors such as PPP, where besides markets dominated by multinationals, specialised markets exist, in which small and medium-size companies are successfully competing (e.g. microbial, semi-chemical and natural products-based PPP).

Experience gained within other EU systems shows that firms operating in competitive markets tend to absorb the fee costs by shrinking their profit margin since there is a limited capacity to transfer costs to consumers through price increases. In less competitive markets, some studies indicate that some companies may increase the prices[26].

In the food sector, within markets where large companies and multinationals are the main actors, such as PPP, GMO and Enzymes, or in *niche* product markets, the introduction of fees is neither expected to change the market structure in a significant way, nor to affect the number or size of the firms operating within it. Most of the sectors concerned by the introduction of

[25] See, for example, CSES, *Interim Evaluation: Functioning of the European chemical market after the introduction of REACH*, 30 March 2012, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-final-report_en.pdf.

[26] See, for example, CSES, *Interim Evaluation: Functioning of the European chemical market after the introduction of REACH*, 30 March 2012, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-final-report_en.pdf.

fees are, however, rather competitive. Low turnover firms operating within sectors like food and generic feed additives could be adversely affected by the introduction of fees because of the need to absorb the fee cost by shrinking their profit margin.

In particular, Options 2 *Application fee for risk assessment of new and renewal applications for all applicants* and 3 *Application fee for risk assessment of new and renewal applications only for applicants who are authorisation holders* are likely to have an impact on the competitiveness of the 19 sectors in the food and feed chain. More precisely, under Option 2, the inclusion of the sectors with generic authorisations represents a potential element of distortion. Applicants will pay a fee for the assessment of an authorisation dossier from which all other economic actors operating in the same sector can benefit without costs. This might cause a competitive disadvantage for the fee payer and lead to market distortions. Given that the situation described will interest 11 out of the 19 sectors along the food and feed chain, it is reasonable to assume that such an option could have a negative effect on competitiveness. *Sub-option 2* would have the same consequences since the sectors excluded in this option are characterised by the issuance of individual authorisations.

Such a situation is mitigated under Option 3, where the fee payer is an authorisation holder who benefits from the exclusive right to produce and market the authorised product/substance/claim/process. Fields included in this option are mainly characterised by the presence of big firms, operating in less competitive markets. The introduction of fees is not likely to affect them, notwithstanding the fact they are already paying fees either at Member State or EURL level. The double fee regime is, on the contrary, possibly going to affect the highly competitive market of feed additives, where the higher costs for business operators might result in a loss of competitiveness in the marketplace. *Sub-option 3* is likely to lead to similar consequences, but to a lesser extent since fewer sectors are covered, but firms (such as feed additives) already paying fees to the EURL are not excluded.

Option 4 *Fees for additional services for all applicants and for new and renewal applications* might have a milder effect on the competitiveness of the 19 business sectors, if the provision of services would represent a real added value for the fee payer and would ensure time to market. However, from the evaluation of the option on additional services it appears that parts of the services proposed do not address the specific needs of each sector and are unlikely to provide a concrete added value to the fee payer.

As far as **innovation** is concerned, according to Stakeholders the food ingredient industry spends between 3% and 8% of its turnover on Research and Development.

The experience of other agencies shows that the introduction of fees can *per se* directly and indirectly impact on the technological development and innovative activities of the industries/applicants in the food and feed sectors[27]. However, the sums at stake are much larger for the other agencies.

In the food sector, fees could represent a deterrent for innovation, especially in the case of *niche* products with minor commercial potential and for SMEs.

Additional obstacles to innovation may be envisaged under Option 2, where the interested sectors are mainly characterized by generic authorisations. Stakeholders pointed out that access to the capital needed to invest in the development of the new regulated products is far more difficult when the authorisation granted is generic since obtaining financial backing is usually easier when the economic return is ensured by exclusive marketing rights.

[27] See, for example, CSES, *Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry*, 14 June 2012, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/innovation-final-report_en.pdf.

Under Option 3, for an authorisation holder the negative impact of fees on innovation is estimated to be smaller than in the case of generic authorisations and, also, less for SMEs than under Option 2. This is because the granting of exclusive marketing rights and consequently the potential financial returns, represent an incentive to invest in research and innovation. The pre-existence of fees for some of the sectors covered by this category is a critical aspect but it could be mitigated by excluding those sectors (*sub-option 3*).

Under Option 4, the introduction of fees for additional services, specifically conceived to support the application process, could have a favourable impact. Supporting and advising applicants on the preparation of the dossier would represent an incentive to invest in new products since it would increase the chance of obtaining the authorisation.

The introduction of dedicated services for each specific sector could result in the speeding-up of the authorisation process, thereby providing quicker access to the market. This would bring an advantage to all applicants and, in particular, to SMEs. However, under the current definition of the additional services proposed it is not possible to identify clear incentives to innovation.

5.4. Impact on international competitiveness

As already mentioned, the international context is mainly characterised by authorisation systems in the food and feed sectors free of fees. As a consequence, the introduction of fees at EU level might negatively affect the global competitive position of EU firms and could result in cross-border investment flows.

This point of view was stressed in particular by industry and stakeholders. However, no data was provided to support these potential negative impacts.

The image of the EU as a region with a high regulatory burden could also make the EU market less attractive for non-EU firms which might prefer to produce in fees-free countries.

5.5. Social Impacts

5.5.1. Impact on the perception of EFSA's independence

Except for Option 1 *No policy change*, the other options (which foresee the possibility of a payment of fees to EFSA) have raised in the current context concerns about the impact on the perception of EFSA's independence from industry, consumers, NGOs and Member States during the consultation process.

The public perception on all issues linked to food safety and the role of EFSA in this matter is considered by all Stakeholders as currently highly sensitive in the EU. As a consequence, the introduction of fees is perceived as an element that could affect EFSA's credibility, in particular because it was initially created with a focus on public services.

The main arguments raised relate to a risk that fees would be considered as creating a financial dependence of EFSA on fees paid by industry to carry out its risk assessments.

The pre-submission services foreseen under option 4 are criticised in particular by consumers who consider that they could lead to a too close service-client relationship between EFSA and industry.

The above-mentioned problems of negative perceptions could impact on public confidence in EFSA's scientific expertise and on the credibility of the EU regulatory system in the area of food safety.

Mitigating measures were taken into consideration and, in particular, the alternative solution, suggested by stakeholders, to impose a levy on the business operators concerned, as it happens in some national systems. The revenue of the tax is in this case subsequently totally or partly transferred by the government to the agency. The agency does not receive direct financings from industry, thus avoiding any reputational damage to its independence. However, such a solution is not feasible within the current legal framework, since the EU does not have the power to impose taxes except under the conditions of Article 311 TFEU (which are not applicable in this case).

5.5.2. Impact on consumers

Except for Option 1 *No policy change*, the options considered during the IA may give rise to indirect impacts on end-consumers and households.

The introduction of fees provided under Options 2, 3, and 4 (as well as the *sub-options 2* and *3*) being an additional financial cost for applicants, could result in partial or total down streaming of these costs onto consumers.

The scale of the phenomenon could be rather broad in the food and feed sector considering the number and the size of the markets affected by the introduction of fees. However, most of the bigger food sectors are quite competitive and thus less likely to be affected by the raising of the price. In addition, the price of ingredients is only one small component out of many components constituting the price of the final products offered to consumers. Among the options proposing the introduction of fees, option 2 could be more problematic since it includes all the sectors. Notwithstanding the fact that option 3 includes the less competitive sectors (such, as PPP, GMO, TSE), it would probably be concerned by the price raising to a lesser extent as fewer sectors are included.

The safety of the products put on the market would not, however, be affected by the introduction of fees, since the procedures for delivering scientific opinions will remain as stringent as they are at present.

6. COMPARISONS OF THE OPTIONS

6.1. Cost-effectiveness analysis

To analyse and to compare the cost–effectiveness of the options, they have been evaluated considering the extent to which each option achieves its objectives (effectiveness); the extent to which objectives can be achieved at minimum cost (efficiency); their coherence with the overarching objectives and whether they are likely to limit trade-offs across the economic and social domain.

Symbols used in comparative assessment: = Strong disadvantage compared with status quo;

– Moderate disadvantage compared with status quo; 0 Status quo or no benefit/ disadvantage compared with status quo; + Moderate benefit compared with status quo; ++ Strong benefit compared with status quo.

Options / **Objectives**	**1. No Policy change**	**2. All applicants for new and renewal applications**	***Sub 2. All applicants for new and renewal applications except***	**3. Authorisation holders for new and renewal applications**	***Sub 3. Authorisation holders for new and renewal applications***	**4. Fees for additional services for all applicants and for new and renewal**

			sectors paying at MS		***except sectors paying at MS***	**applications**
GENERAL						
Protection of Health and Consumers	0	0	0	0	0	0
Correct functioning of the Internal Market	0	-	0	-	0	-
Promotion of economic growth, competitiveness and innovation	0	=	=	-	0	0
Safeguard efficiency and efficacy of the European public system for food safety risk assessment	0	=	-	-	0	+
Ensure consumer trust	0	=	-	-	-	=
SPECIFIC						
Optimise use of public money	0	+	+	+/-	+/-	=
Introduce fees which take into account the characteristics of the different sectors and types of authorisations	0	=	-	-	+	-
Ensure appropriate and stable resources for EFSA	0	+/-	+/-	-	=	-
Safeguard the perception of EFSA's independence	0	-	-	-	-	=
Options / **Objectives**	**1. No Policy change**	**2. All applicants for new and renewal applications**	***Sub 2. All applicants for new and renewal applications except sectors paying at MS***	**3. Authorisation holders for new and renewal applications**	***Sub 3. Authorisation holders for new and renewal applications except sectors paying at MS***	**4. Fees for additional services for all applicants and for new and renewal applications**
OPERATIONAL						
Identify appropriate savings for the EU Budget	0	+	+/-	-	-	=
Develop a Manageable fees system for EFSA	0	=	=	-	-	-
Develop a fee system providing a	0	+/-	-	-	-	=

satisfactory income for EFSA (close to EFSA's current funding for regulated products)						
Guarantee a fair fee system for the applicants (equality of treatment)	0	=	-	-	+	+
Ensure a clear correlation between the level of services provided and the fees paid	0	=	-	-	-	=
Ensure that the system adequately takes into account SMEs	0	+	+	+	+	+

OPTION 1: NO POLICY CHANGE

Under Option 1, EFSA's mission to ensure that safe products are put on the market is entirely funded by the EU Budget.

Under the current situation, EFSA's resources are established in accordance with the provisions of the financial regulation to ensure appropriate resources linked to the planned activities. In this way budget stability and an appropriate management of the different activities are guaranteed.
This option does not change the contribution the EU gives to EFSA and thus does not entail any savings for the EU budget. However, public financing prevents any possible negative impact on the perception of EFSA's independence and possible distortion of priorities.
EFSA’s applicants are not charged with additional financial burdens for the submission of an authorisation application other than the cost of preparing the application dossier, enabling them to invest resources in the research and development of new products for the benefit of economic growth, competitiveness and innovation.

OPTION 2: APPLICATION FEE FOR RISK ASSESSMENT OF NEW AND RENEWAL APPLICATIONS FOR ALL APPLICANTS

Under Option 2, the EU contribution to EFSA's budget would be reduced by 15%. However, the introduction of fees would cause fluctuation in EFSA's resources dedicated to the scientific assessment of regulated products. From the forecasts for the coming years, as the analysis showed, the expected fee income would be considerably lower than EFSA’s current expenditures for such activities and would cover the investment costs needed to put in place the fee system only after the first year.

Applicants would have to pay rather high fees for the scientific assessment of regulated products and some sectors will pay higher fees than others regardless of the size of their markets or turnover, regardless of whether they are already charged at Member State level or by the EURL, or of the type of authorisation they are granted. On this last aspect, there is also the risk of free riding.

By foreseeing the financing of the scientific assessment of all regulated products from payments by industry, Option 2 is, in the current context, expected to negatively affect the perception of the independence of EFSA's scientific opinions. In addition, the introduction of fees for only one activity of EFSA (scientific assessment of regulated products) could entail a distortion of priorities between the other activities, such as scientific opinions on general public

health issues (for example contaminants or animal health and welfare) paid by public money and activities paid by fees (scientific opinions on authorisation applications).

Compared to Option 1, the cost-effectiveness of Option 2 is negative, both for EFSA and the 19 business sectors covered by this option.

SUB-OPTION 2: APPLICATION FEE FOR RISK ASSESSMENT OF NEW AND RENEWAL APPLICATIONS FOR ALL APPLICANTS, EXCLUDING SECTORS WHERE INITIAL ASSESSMENT IS PERFORMED BY MS

Under *Sub-option 2* the savings of EU funds would be slightly lower than in option 2 but the system would be fairer since firms already paying at national level would be exempted. As in option 2, distortion deriving from the application of fees also to generic authorisations would still cause problems in terms of competitiveness and fairness of the system. Also in this case, the expected fee income would be considerably lower than EFSA's current expenditure for such activities and the investment costs would take a long time to be paid off.

Compared to Option 1, the cost-effectiveness of sub-option 2 is negative, both for EFSA and the 16 business sectors covered by this option.

OPTION 3: APPLICATION FEE FOR RISK ASSESSMENT OF NEW AND RENEWAL APPLICATIONS ONLY FOR APPLICANTS WHO ARE AUTHORISATION HOLDERS

Option 3 has the same limitations as Option 2:

- Negative impact on the management of EFSA's budget;
- No added value and rather high fees for the applicants;
- No consideration of the different characteristics of the sectors affected, except with regard to the type of authorisation;
- Potential negative impact on the perception of the independence of EFSA's scientific opinions.

Compared to Option 2, the income from fees for EFSA, and thus EU savings, will be substantially lower. In addition, the revenue from fees appears even more limited if the fee collection cost is fully taken into account (management and investment costs).

By charging a restricted number of sectors, the majority of which are already paying fees in the framework of the same authorisation procedure, Option 3 presents a higher risk of affecting the competitiveness of the food and feed market and entailing distortion of the market.

Finally, Option 3 could lead to the establishment of a different handling of the scientific assessment of regulated products in which the priority would be given to applications paying fees.

Compared to Option 1, the cost-effectiveness of Option 3 is negative, both for EFSA and the EU budget and the 8 sectors covered by this option.

SUB-OPTION 3: APPLICATION FEE FOR RISK ASSESSMENT OF NEW AND RENEWAL APPLICATIONS ONLY FOR APPLICANTS WHO ARE AUTHORISATION HOLDERS, EXCLUDING SECTORS WHERE INITIAL ASSESSMENT IS PERFORMED BY MS

Sub-option 3 appears to be the fairest one, since it applies only to authorisation holders who are not paying fees at national level and would have the minimum effect on competition. However, the fee income and EU budget savings would be very limited, especially if the fee collection cost is fully taken into account (management cost and investment costs).

Compared to Option 1, the cost-effectiveness of sub-option 3 is negative, particularly for EFSA and the EU budget.

OPTION 4: FEES FOR ADDITIONAL SERVICES FOR ALL APPLICANTS AND FOR NEW AND RENEWAL APPLICATIONS

The assessment demonstrated that Option 4, despite being aimed at providing a clear added value for the fee payers, to promote innovation and competitiveness, suffers from several limitations.

As currently proposed, the list of services is not tailored to the needs of the applicants of each specific sector, but are rather general.

The added value for the fee payer is therefore not straightforward as the list of services proposed by EFSA is not backed by data or evidence on the real needs of the applicants in terms of services and the particular needs/benefits of each specific sector.

In addition, some of the services proposed are to be considered as normal good administrative practice (help desk to provide clarifications, answers by phone, translations).

Finally, some of the services proposed can already be charged for by EFSA (trainings and workshops). As a matter of fact, Article 43 of Reg. 178/2002 enables EFSA to "*organize and charge for conferences, trainings and any other similar activities provided by the Authority*." This is a fairer arrangement since only participants who consider that they have a need for such services will have to pay.

Consequently, Option 4 does not present a clear correlation between the level of services provided and the fee requested.

As designed, the option would affect EFSA's budget manageability and will entail additional costs for the Authority.

As the assessment demonstrated, EFSA's income from fees for additional services is expected to be quite low and subject to considerable fluctuations over the years. In addition, the forecasted flows of applications to EFSA in the coming years will not ensure that the fee income will cover the costs of providing the services. The calculations clearly showed that, on average, each year EFSA can expect to receive from fees for services around EUR 3 Million, with costs estimated at around EUR 5 Million per year, thus requiring EUR 2 Million to be financed by the public budget.

In addition, as designed, these services could raise criticisms of lack of independence, in particular concerning the pre-submission services offered to industry on scientific aspects. EFSA could be perceived as being both adviser and judge in the same process (counselling on the scientific content of applications and assessing the validity and relevance of their scientific content).

The introduction of services for applicants will create expectations (about EFSA's performance and quality of the services) which, at the moment, cannot be guaranteed with sufficient certitude, nor can it be ensured that the option proposed will provide value for money for the applicants.

This option will also cover the sectors with generic authorisations and thus create a risk of "free riding" (one fee payer, many beneficiaries). This could raise criticisms on the fairness of the whole system.

Compared to the *status quo*, Option 4 does not provide a positive balance in terms of cost-effectiveness. In fact, this option would lead to additional costs for EFSA and would bring extra financial burden for the EU budget without a clear added value for applicants.

6.2. Views of industry, consumers and Non-Governmental Organisations (NGOs)

Industry

Only one association was clearly in favour of the options establishing of fees and in particular, option 4. It stressed that the services foreseen by the option would lead to an improved efficiency of the whole system since pre-submission meetings would reduce both the number of applications withdrawn and costs incurred by EFSA for assessing inadequate applications.

The vast majority of the Stakeholders from industry, however, clearly favour Option 1: No policy change.

General reasons for favouring option 1:

- Additional burden for all sectors that will be detrimental to innovation and competitiveness. The regulatory burden is already high in all sectors concerned and in addition, some of these sectors are already paying fees at national level or to EURL for the same applications.

- Additional risk of negative perception of EFSA's independence. Fees will be perceived by certain organisations as a barrier to EFSA's independence, which will impact on public confidence in its scientific review process.

- Absence of compatibility of a fee system with EFSA's legal structure and role. EFSA was established for public health purposes, and its role is to assess the safety of what industry intends to put on the market. It provides scientific services only to the Commission, Member States and the European Parliament, with no direct link to industry.

- Difficult to establish fees at horizontal level. This would be done more adequately in sectorial legislation, but would require costly subsequent adjustments.

- Fees should not be used as a substitute for the public financing of EFSA, which is justified by EFSA's role of protecting the health of consumers.

- There are better ways to find additional resources for the risk assessment process (better allocation of resources at national and EU level, better focus by EFSA on safety issues).

If option 1 is not followed, the views are:

Option 2 is strongly opposed. All Stakeholders consider it unfair to have fees for generic authorisations (one pays, all benefit). In addition, they argue that because of the already high regulatory burden and the small economic benefit derived from generic authorisations, there is a high risk of hampering innovation (this will discourage further submissions) and of industry moving to other countries. The level of fees is also considered inadequate.

Option 3 is considered to be a possible option by some Stakeholders since it is focussed on authorisations linked to exclusive rights of the applicant. However, concerns are raised on the extra burdens created by fees since the main sectors involved already pay fees for the same applications. The level of the fees is considered to be too high. Doubts are expressed on the concept that exclusive rights provide the same benefits in all sectors and further distortions of competition are signalled in some sectors.

Option 4 is considered as an option with added value by a number of Stakeholders since it could provide better services to applicants and result in additional funds for EFSA. However, there is significant concern that the scientific pre-submission services would damage the perception of EFSA's independence. The level of fees is considered to be too high and several Stakeholders consider that these services should be provided on a sector-specific, tailor made and voluntary basis (only those wanting these additional services should be required to pay for them).

Consumers

Consumers are concerned about EFSA's independence. The main association representing consumers was against all the presented options. Worries were raised on the possibility that the establishment of fees would further damage the Agency's image by the "perception of EFSA being bought by industry". Option 4 was considered unacceptable since fees should not lead to a service-client relationship, or induce EFSA to be more responsive to industry's needs. The only acceptable solution, if a fee system has to be put in place, would be for industry to pay fees to the Commission.

NGOs

The few comments received from Non-Governmental Organizations (NGOs) stressed the need to strengthen EFSA's independence.

One organisation argued that industry should bear the costs of risk assessment. The fees should, however, be paid to a publicly managed fund to avoid that industry's money would influence the risk assessment process. Fees should increase EFSA's overall budget in order that EFSA has a better capacity to finance independent risk assessment studies and independent experts.

Member States

The majority of MSs, including those charging fees at national level (in the pesticide sector), had reservations about the options introducing a fee system for EFSA. In particular:

Option 2 was not supported because applicants for generic authorisations, who do not get any exclusive benefit, would have to pay fees. The level of fees under option 2 was also considered to be disproportionate to what is paid by some sectors to MS.

Option 3 was considered fairer than option 2, given that the authorisation holder derives benefits from the authorisation, but the fees were considered too high.

Option 4 was considered as a workable option by some MS, but there were significant concerns on the perception of independence, the level of the fees and the fact that some services are of public interest. The financing of the support for SMEs was considered to be problematic since it could involve extra public money and necessitate adequate financing of the tasks foreseen at MS level under this option.

Six MS (DE, AT, FI, SE, NL, DK), five of which are charging fees at national level (for pesticides), expressed, in principle, support for the introduction of fees, on condition that the new system would provide an added value for Stakeholders while preserving EFSA's independent risk assessment. Options 3 and 4 were preferred among the available options. However, it was stressed that the first could be problematic since it includes sectors where fees are already paid at national level or to the EURL. Option 4 could raise issues on EFSA's independence, the added value of the services offered and the possibility that the costs of the services could exceed the amount of money collected from fees. For one of the six MS generally supporting the introduction of fees, none of the options was however satisfactory.

(See details of consultations in Annex III).

6.3. Preferred option: No Policy change

From the analysis it appears clear that none of the options proposing the introduction of fees presents evident benefits for EFSA, for the EU or for the applicants and consumers.

The IA shows that the workability and practicability of establishing a fee system for EFSA is difficult due to:

- Complexity of the legal framework, embracing 19 different pieces of legislation;
- Heterogeneity of the authorisation procedures with different sharing of work between EFSA's staff, EFSA's Panels, Member States and EURL;
- Limited number of dossiers, variable from one sector to another, received by EFSA for the scientific assessment of regulated products and an even smaller number of eligible dossiers for fees;
- Member States and EURL already charge fees in the framework of the same authorisation process in certain sectors;
- Different types of authorisation granted (generic and individual);
- EFSA was created as a provider of services mainly to the public authorities.

The elements mentioned above impact negatively on the suitability of the options proposed ("one size does not fit all") and the analysis shows that to establish "*a posteriori*" a fee system, taking into consideration these structural limitations is of very limited practicability/workability.

The analysis made of the impacts of the different options proposing fees, with regard to EFSA, the EU budget, applicants and consumers demonstrated, in particular, that the cost/benefit ratio was not in favour of the establishment of fees:

- None of the options proposing fees ensures a satisfactory income for EFSA, nor does it provide significant savings for the EU budget, considering the low number of dossiers eligible for fees and their variability. At best, EFSA would get 48% of the actual expenditure on regulated products (15% of EFSA's total budget);
- The introduction of a fee system would create fluctuations of EFSA's budget due to the variability in the number of dossiers per year and there is a risk, in particular in option 2, that in order to ensure appropriate resources for the scientific assessment of regulated products resources originally designated to public health tasks are re-allocated to the assessment of authorisations;
- The needs and characteristics of each of the 19 sectors and related markets are not adequately taken into consideration;
- The level of fees for applicants is considered burdensome and in some cases additional to other fees paid in the framework of the same authorisation procedure;
- The correlation between the fee level and the services proposed is not clearly ensured;
- The perception of EFSA's independence is in the current context likely to be negatively affected.

To sum up, from the cost/benefit perspective it appears that within the current context the introduction of fees would not bring any clear benefit, either for EFSA, the EU institutions, or for Stakeholders.

The conclusions drawn by the analysis carried out during the IA are supported by Stakeholders' views. Stakeholders' consultation clearly indicated that the majority of the actors potentially affected by the options envisaging the introduction of fees for the processing of authorisation dossiers for EFSA are opposed to the establishment of such fees. In particular, the concerns on the impact on competitiveness and innovation and on the perception of EFSA's independence have been considered by the Commission as key factors towards the selection of the preferred option, coherently with the horizontal objectives of the EU to foster growth and jobs and the need to ensure consumers' trust in the safety of the food chain.

As a result, the Commission has identified as the preferred option **No policy change**.

The scientific assessment of regulated products will continue to be covered by the EU Budget, while leaving EFSA the possibility of charging for supporting activities such as seminars, workshops and others, as foreseen by Article 43 of Regulation (EC) n° 178/2002.

On this last aspect the Commission will invite EFSA to respond to the request for an improved support to applicants, expressed by Stakeholders during the consultations for this Impact Assessment process. EFSA could, in particular, examine whether charging for conferences, seminars and training could help in offering these improved services.

7. MONITORING AND EVALUATION

A number of key indicators are provided for the monitoring of the efficiency of the risk assessment of regulated products in EFSA's management plan. With regard to the effective delivery of the work programme related to this activity, the indicator is the number of scientific outputs adopted. Concerning the effective use of the financial resources and effective execution of grants and procurement, the indicators are the proportion of the original budget for this activity committed/paid at year end and the proportion of original grants and procurements contributing to this activity committed/paid at year end.

EFSA also has in place indicators regarding the timeliness of its scientific advice: the proportion of scientific outputs adopted within deadline.

EUROPEAN
COMMISSION

Brussels, 11.2.2013
SWD(2013) 45 final

Part II/III

COMMISSION STAFF WORKING DOCUMENT

Impact Assessment on the Revision of Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety on the establishment of fees for EFSA

ANNEXES

TABLE OF CONTENTS

ANNEX I STAKEHOLDERS CONSULTATIONS TIMELINE 49

ANNEX II PROCESSED DATA FROM ASSOCIATION'S CONSULTATION – QUESTIONNAIRE 50

ANNEX III MINUTES AND SUMMARY RECORDS OF STAKEHOLDERS AND MEMBER STATES MEETINGS HELD DURING THE IA ON FEES FOR EFSA 52

ANNEX IV SMES PANEL CONSULTATION 88

ANNEX V BASELINE SCENARIO FOR THE IMPACT ASSESSMENT ON THE POSSIBILITY OF INTRODUCING FEES FOR EFSA TO PROCESS AUTHORISATION DOSSIERS PRESENTED BY INDUSTRY 100

ANNEX VI FIXED AND VARIABLE COSTS OF EFSA'S PANELS AND SUPPORTING UNITS ASSESSING APPLICATION DOSSIERS 122

ANNEX VII DIFFERENCES BETWEEN ECHA AND EFSA SYSTEMS 123

ANNEX VIII DIFFERENCES BETWEEN EMA AND EFSA SYSTEMS 126

ANNEX IX THE INTERNATIONAL CONTEXT 129

ANNEX X FEES REGIME UNDER OPTION 2 142

IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS OPTION 2 144

IMPACT ON EFSA'S BUDGET OF FEES FROM SMES OPTION 2 145

ANNEX XI FEES REGIME UNDER *SUB-OPTION 2* 149

IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS SUB-OPTION 2 150

IMPACT ON EFSA'S BUDGET OF FEES FROM SMES SUB-OPTION 2 150

ANNEX XII FEES REGIME UNDER OPTION 3 152

IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS OPTION 3 153

IMPACT ON EFSA'S BUDGET OF FEES FROM SMES OPTION 3 153

ANNEX XIII FEES REGIME UNDER *SUB-OPTION 3* 155

IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS SUB-OPTION 3 155

IMPACT ON EFSA'S BUDGET OF FEES FROM SMES SUB-OPTIONS 3 157

ANNEX XIV FEES REGIME UNDER OPTION 4 158

IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS OPTION 4 160

IMPACT ON EFSA'S BUDGET OF FEES FROM SMES OPTION 4 161

YEARLY EFSA'S INCOME OPTION 4 163

ESTIMATED ANNUAL COSTS FOR EFSA OPTION 4 163
ANNEX XV EXPECTED NUMBER OF APPLICATIONS SUBMITTED TO EFSA 2012-2015 166
ANNEX XVI COST OF PROCESSING THE APPLICATION DOSSIER IN EACH SECTOR FOR EFSA 168
ANNEX XVII MONITORING 169

8. ANNEX I STAKEHOLDERS CONSULTATIONS TIMELINE

Table: Stakeholders consultation timeline on the IA on the possible revision of Regulation EC n.178/2002

Nov 2011	Dec 2011	January 2012	February 2012	March 2012	May 2012
Plenary of the AG Information on the IA **Questionnaire to associations to gather socio-economic data**	**Working Group of the AG + additional associations on Baseline scenario, Policy problem and objectives**	**Working Group of MS on baseline scenario + policy problems + objectives + options**	**SMEs Panel Consultation**	**Plenary of the AG Information on the IA process**	**Working Group of the AG + additional associations on Policy Options and heir Impacts** **Working Group of MS on policy options and their impacts**

9. ANNEX II PROCESSED DATA FROM ASSOCIATION'S CONSULTATION –QUESTIONNAIRE

Substance/Product/claim	AVG cost for applicant (€)	value of the market (€)	number of SMES	Fees for MS (€)	Fees for the EURL (€)	Type of authorisation granted
(PPP) active substances	From 500 000 Up to 3.7million	7-8 billion for PPP 250 million for microbial, semio-chemical and natural products based PPP)	Mostly multinationals	23 100/ 450 000		Individual
(MRL) of PPP	200 000 per new MRL (less for extension of use)			200/15 000		Individual
(GMO)		Around 12 billion (world market)	few		90 000	Individual
Flavourings	354 000 up to 500 000	1.5 million				GENERIC
Smoke flavourings	350 000 385 000		50% worldwide			Individual
Extraction solvents	/	/	/	/	/	GENERIC
Enzymes	feed 300 000 food 450 000	/	On a sample of 28 Companies 68% small; 21% medium			GENERIC

Food contact materials	up to 2 million€	100 billion				GENERIC
Food additives NEW	250 000 up to 1.8 million					GENERIC
Food additives REVIEW						GENERIC
- Nutrient sources,	20 000/45 000	Around 8.6 billion	85%			GENERIC
- Health claims	8 000/200 000 up to 1 million					GENERIC
- Novel food	20 000/45 000			900/2 000		Individual
Feed additives					max 6 000 €	GENERIC
(TSE) TEST	/	/	/	/	/	Individual
Animal by-products	/	/	/	/	/	GENERIC
Decontamination treatments	/	/	/	/	/	GENERIC

10. ANNEX III MINUTES AND SUMMARY RECORDS OF STAKEHOLDERS AND MEMBER STATES MEETINGS HELD DURING THE IA ON FEES FOR EFSA

Summary of written comments received from Industry, Consumers, NGOs and MS

***MEETINGS*:**

14 November 2011 – Plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health

2 December 2011 - Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on the IA on fees for EFSA

17 January 2012 - Working Group of the Member States on the IA on fees for EFSA

16 March 2012 - 2nd Plenary meeting of the Advisory Group on the Food Chain and Animal and Plant Health

4 May 2012 - 2nd Working Group of the Member States on the IA on fees for EFSA

4 May 2012 - 2nd Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on the IA on fees for EFSA

SUMMARY OF WRITTEN COMMENTS

from Industry, Consumers, NGOs and MS.

Industry

The vast majority of the stakeholders clearly favoured option 1 (no fees).

General reasons for opposing fees:

- Additional burden for all sectors that will be detrimental for innovation and competitiveness. The regulatory burden is already high in all sectors concerned and in addition, some of these sectors are already paying fees at national level or to EU Reference Laboratories for the same applications.

- Additional risk of wrong perception of EFSA's independence. Fees will be perceived by certain organisations as a barrier to EFSA's independence, which will impact on public confidence in its scientific review process.

- Absence of compatibility of a fee system with EFSA's legal structure and role. EFSA was established for public health purposes, and its role is to assess the safety of what industry intends to put on the market. It provides scientific services only to the Commission, Member States and Parliament, with no direct link with industry. In particular, applications for authorisations are submitted to EFSA via the Commission or MS. The direct link for the payment of fees is missing.

- Difficult to establish fees at a global level. This would be done more adequately in sectorial legislation, but would require costly subsequent adjustments.

- Fees should not be used as a substitute for the public financing of EFSA, which is justified by EFSA's role of protection of the health of consumers.

- There are better ways to find additional resources for the risk assessment process (better allocation of resources at national and EU level, better focus by EFSA on safety issues).

If option 1 is not followed, the views are

Option 2 (fees for all applicants including generic) is totally rejected. All stakeholders considered it unfair to have fees for generic authorisations (one pays, all benefit). In addition, they argued that because of the already high regulatory burden and the small economic benefit derived from generic authorisations, there is a high risk of hampering innovation (this will

discourage further submissions) and of industry moving to other countries. The level of fees was also considered unacceptable.

Option 3 (fees only for authorisation holders) is considered to be a possible option by some stakeholders since it does not concern generic authorisations, but is focussed on authorisations that are linked to exclusive rights of the applicant. However, concerns have been raised on the extra burdens created by fees since the main sectors involved already pay fees at national level or to the EU reference laboratories for the same applications. The level of the fess is considered to be too high. Doubts have been expressed on the concept that exclusive rights provide the same benefits in all sectors and further distortions of competition are signalled in some sectors

Option 4 (fees for additional services) is considered as an option with added value by a number of stakeholders since it provides better services to applicants and additional funds for EFSA. However, there is significant concern that the scientific pre-submission services would damage the perception of EFSA's independence. The level of fees is considered to be too high and several stakeholders consider that these services should be provided on a voluntary basis (only those wanting these additional services should be required to pay for them).

Consumers

Oppose the establishment of fees since it will only further damage EFSA's actual and perceived independence, "perception of EFSA being bought by industry". Option 4 completely unacceptable since fees should not lead to a service-client relationship or induce EFSA to be more responsive to industry's needs. Still important that EFSA receives sufficient funding to cope with the increasing number of authorisation dossiers while having enough funds left to undertake independent scientific work to fill knowledge gaps.

NGOs

Generally support the strengthening of EFSA's independence.

It is argued by one organisation that industry should carry the burden of costs for risk assessment and therefore pay fees to EFSA. Such fees should be paid to a publicly managed fund so that industry's money has no influence on the risk assessment process. Fees should increase EFSA's overall budget in order that EFSA has a better capacity to finance independent risk assessment studies and independent experts. For these reasons, it opposes options 1 and 4.

MS

Generally, there is not a significant number of MS who express firm support for any of the options. 3 MS are in favour of no fees (option 1). 1 MS is in favour of option 1 or of option 4. Two MS expressed support for the principle of fees, but one considered that fees should be established only if stakeholders (consumers and industry) support them and the other MS has difficulties with all options (2 is unfeasible because unfair, 3 has the disadvantage that fees

are already applied in most sectors concerned, thereby creating additional costs; 4 should be applied only to those who need these services). One MS is, in principle, in favour of option 3 since those having a benefit should pay, but is concerned by the risks involved by the establishment of fees and the negative reactions of stakeholders.

More specifically, option 2 is not supported because applicants for generic authorisations who do not get any exclusive benefit would have to pay fees. Therefore the risk of "free riding" is considered high. The level of fees under option 2 was also considered as disproportionate to what is paid by some sectors to MS. Only one MS supported this option.

Option 3 was considered preferable to option 2 (supported by one MS and, in principle, by a second one) given that the authorisation holder derives benefits from the authorisation and that the risks identified are smaller (no risk of free riding, risk for independence would be the same as for option 2, less risk of down-streaming costs to final consumers, smaller amount of funding provided by fees, so less risk to the stability of EFSA's budget)

Option 4 was considered as a workable option by one MS, but there were significant concerns on the perception of independence (services perceived as a consultancy for industry), the level of the fees and the fact that some services are of public interest. The financing of the support for SMEs was considered to be problematic since it could involve extra public money and necessitate adequate financing of the tasks foreseen at MS level under this option. One MS considers that EFSA should already provide adequate services to applicants and that these fees should not be applied to those who have no need for such additional services.

Plenary meeting of the Advisory Group

on the

Food Chain and Animal and Plant Health

Summary Record

Brussels, 14 NOVEMBER 2011

1. Opening of the meeting and adoption of the Agenda

The Deputy Director-General of DG SANCO opened the meeting on behalf of COM and welcomed participants for the second time in the Group's extended format of 45 members. He stressed the importance of exchange of views on SANCO's overall work and the role of the Advisory Group in this respect. He asked for visible and open support of the Group to SANCO in making necessary and useful changes with added value in the legislation.

COMMENTS AND QUESTIONS RAISED

In response to FEFAC's request for SANCO's view on the action plan on food waste announced by DG ENV, COM confirmed that SANCO sees this as a priority in its work, as a horizontal issue where SANCO is undoubtedly one of the main partners.

The Agenda was approved, together with the minutes of the previous meeting of 14 March 2011.

[…….]

12. Impact assessment on the possibilities of establishing fees for EFSA to process authorisation dossiers

COM informed on the ongoing impact assessment on the possible establishment of fees for EFSA and related aspects. COM gave an overview on the impact assessment process, as well as on stakeholders' consultations planned and future steps. Stakeholders have received a questionnaire on socio-economic data gathering asking for their input by 30 November 2011.

WG of the Advisory Group on the Food Chain and Animal and Plant Health

on the Impact Assessment on the Revision of Regulation 178/2002 (laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety) on the establishment of fees for EFSA and related aspects (scientific assessment of applications for authorisations)

Minutes

Brussels, 2 DECEMBER 2011

Participants from the Commission: *Robert Vanhoorde, Jeannie Vergnettes, Rossella Chiodo* (SANCO Unit 03), *Orsi Nagy* (SANCO Unit 02)

Participants from EFSA: *Karine Lheureux*

COM opened the meeting and welcomed participants.

COM introduced the Impact Assessment on the possibility of introducing fees for EFSA to process authorisation dossiers presented by industry and related issues, and presented baseline study key findings including the background, sectors concerned, workflows of the processing authorisation applications, as well as main costs involved in the processing of application dossiers.

COM also presented the renewed roadmap, problem definition, general, specific and operational objectives and highlighted the next steps. COM explained that the IA now addressed two main issues: the establishment of fees and the suitability of the risk assessment system currently in place in EFSA's founding Regulation.

COM underlined that the main aim of this meeting was to check with the participants whether the problem definition and the objectives were adequately defined, coherent and consistent.

EFSA presented its new service – the application desk – as a central contact point for applicants aimed at providing flexible services related to all activities concerning applications. One of the possible services might be pre-submission support to applicants, dealing strictly with administrative and legal workflow, not pre-risk assessment, so no threat to EFSA's independence.

The main concerns expressed by stakeholders:

EUROPABIO, ESA, IBMA and CEFIC pointed out that fees exist at national level and it would be important to take them into account since the regulatory burden is already high. They requested a detailed breakdown of the costs for assessing dossiers in relation to activities. FEFANA stressed that there should be a link between costs and fees. ECPA pointed out that there are fees to be paid to MS as well. CEFIC underlined that fees should be considered only for authorisation holders

EUROPABIO expressed concerns that new fees would add an additional burden, especially to SMEs. It stressed that the high regulatory costs in its sector already prevented SMEs from submitting applications with the effect that some innovations are kept off the market. The specificities of SME's should be considered.

AESGB considered that pre-submission fees should be envisaged. EUROPABIO expressed concerns that this type of fees could be perceived as weakening EFSA's independence.

EUROPABIO also stated that fairness should be added as an objective and raised the problem of costs' recuperation (link between the cost of fees and the revenue deriving from an authorisation).

BEUC stressed that too many tasks transferred to EFSA's internal scientific staff might undermine EFSA's independence and weaken transparency. BEUC also expressed concern that the tasks remunerated by fees would become prioritised. It requested clarification on the possibility for EFSA to use revenue generated by fees to perform self- tasks.

IBMA considered that the objectives were not presented in the right order. IBMA and FEFANA considered that consistency with other legislation impacting on the sectors concerned is essential.

ELC underlined the importance of feasibility (currently no incentive to submit dossiers in case of review) and requested a clear identification of who should pay fees. It explained the specificity of the allergens procedure: benefits mostly consumers; does not constitute a sector.

EUROPABIO asked to clarify the notion of retroactivity and the definition of SMEs. It suggested that the IA should take into account products developed in third countries since in such cases there is no obligation to submit an application to EFSA.

ECPA recalled the specificity of the pesticides legislation (sharing of work is different; national competence different from other sectors) and questioned the relevance of additional EU fees in this sector.

ESA and EUROPABIO asked COM to explain what type of SME test would be performed.

PLASTIC EUROPE and FEFANA stressed the importance of independence.

COM clarified the following:

With regard to specific requests for clarification

COM explained that the current exercise is not focused on national fees, although the data on them will be considered in the IA to avoid excessive burdens and potential overlapping. COM clarified that the IA will take into account the costs for each sector, but that it was too early to discuss specific fees.

COM explained that the definition of SME is the one defined in EU rules. The questionnaire sent to SMEs will go through the new specific tool recently established by DG ENTR. This questionnaire will be along the same lines as that sent to the Advisory Group, but adapted to individual SME.

COM explained that pre-submission fees should be considered in the next steps of the IA. EFSA clarified that pre-submission service did not mean pre-assessment since this type of service should not impact on the independent risk assessment.

COM explained that in the case of the establishment of fees, the amount of EFSA's budget financed by fees will serve to pay the services remunerated by fees. It also explained that the EU subsidy was a balance subsidy and therefore covered the financing of EFSA tasks not

remunerated by fees. It noted that around 30-35% of EFSA's budget is currently allocated to the assessment of authorisation dossiers.

Compatibility with other EU legislation will be taken into account.

COM reassured that all comments, as well as a costs-benefit ratio, will be taken into account when assessing options.

COM pointed out that the cost recuperation approach was not valid since it would imply that industry could provide justified estimates of what could be the revenue deriving from authorisations.

With regard to problem definitions and objectives

The comments did not criticise the problem definitions, but several comments mentioned the objectives. COM therefore explained that the objectives of the IA covered the concerns expressed by the participants. It stressed in particular that:

- Preserving EFSA's independence is listed as an objective.

- The concerns about the need for a sectorial approach, fairness, the importance of considering specific and generic authorisations and SMEs were in particular covered by the objective "Develop a clear, sustainable and justified fee-system, adapted to the different sectorial authorisation procedures and the typology of authorisations granted taking into account SMEs"

- The identification of who should pay fees was also listed as an operational objective. In addition COM clarified that notwithstanding fees are already mentioned in the objectives, this does not imply any preliminary decision on the preferred option. The consideration of objectives related to fees is needed in order to have terms of comparison when the options will be screened and analysed.

COM presented the next steps and timing of the impact assessment process, informed stakeholders that the follow-up meeting to discuss options will be held most probably in February 2012, thanked participants for their valuable comments and closed the meeting.

WG of the Member States on the Impact Assessment on the Revision of Regulation 178/2002 on the establishment of fees for EFSA and related aspects

Minutes

Brussels, 17 JANUARY 2012

Participation from the Commission: *Robert Vanhoorde, Jeannie Vergnettes, Rossella Chiodo, Giulia Bertezzolo*

Particpation from EFSA: *Francois Monnard*

COM

Introduced the background and goals of the Impact Assessment (IA).

Clarified that the aim is not to have an auto-financed EFSA.

Presented the baseline scenario (PowerPoint presentation).

COMMENTS

MS asked for the following clarifications:

- if the IA is only considering the case of introducing fees for specific authorisations (authorisation holder) (*Sweden*);
- how the calculations presented have been done (*Belgium*);
- if COM has taken into consideration the position of SMEs (*Finland*);
- why novel food has not been included in the number of authorisations granted (slide n. 7) (*Netherlands*);
- how COM can predict the number of future applications (*Ireland*).

COM

- Clarified that COM is considering the 3 options presented and is open to other options;
- Said that for the IA public documents and data received from EFSA have been used, that the exercise has been done in collaboration with EFSA and that some simulations have been carried out;
- Stressed that building an equitable system is also one of COM's targets;
- Replied that the IA requires a specific analysis of SMEs, that a specific questionnaire for SMEs has been sent out and that COM is preparing a specific analysis through DG Enterprise. The data will be fully reported in the IA and COM will consider the possibility of introducing a specific regime or exceptions for SMEs;
- Replied that novel food has not been included because at the time when the IA started COM was not sure if there had been generic authorisations or not in this area (slide n. 7);
- Clarified that EFSA has a system to foresee the number of applications that there will be in the next 5 years and that the IA is based on those data. Also, clarified that some data provided by the industry and by stakeholders have been used.

MS raised the following concerns:

- there is a need to have an accurate picture of the costs of the authorisations in order to have an equitable system, which only covers EFSA's costs (*Belgium*);
- it would be useful to have an idea of the percentage of authorisations which would be affected by the introduction of fees (*Sweden* and *Netherlands*);
- different sectors and procedures need different resources (slide n.13) (*Netherlands*);
- the introduction of fees may influence EFSA's processing of requests. EFSA will probably speed up its work in some sectors in order to get more money (*Ireland*).

COM

- Confirmed that it is fully aware that different resources are needed depending on different sectors and procedures (slide n.13).
- Clarified that the introduction of fees should not lead to a system where EFSA works at two different speeds (dossiers where there are fees and dossiers where there are no fees).

* * *

COM

Gave a presentation on problem definition and policy objectives (PowerPoint presentation).

COMMENTS

MS raised the following concerns:

- if fees are going to be introduced special attention should be paid to the transparency of EFSA (*UK* and *Belgium*);
- since fees may have a considerable impact on the functioning of EFSA, it should be verified if EFSA's capacity to deal with its workload is adequate (*Belgium*);
- nothing should be done to the detriment of the quality and expertise of EFSA (*Belgium*).

* * *

COM

Gave a presentation on policy options and cost – benefit (CB) analysis on FEES (PowerPoint presentation).

Also explained that:

- the possibility of giving EFSA the power to decide on a case-by-case basis that a fee should be charged (slide n. 9) has been discarded because it is not possible to give an Agency this type of legal/political power.
- the possibility of harmonising the EFSA fees system with that of EMA's has been discarded because EMA's system is linked to different legal and economic backgrounds.

COMMENTS

MS asked for the following clarifications:

- why reviews of authorisations have not been included in the Cost-Benefit analysis (*UK*);
- more information on the potential special regime for SMEs, considering that creating two different systems (SMEs and non-SMEs) bring additional costs which have to be considered in the IA (*Denmark* and *Germany*);
- if it would be possible for the Commission (instead of EFSA) to collect the money paid for the fees (*UK*, *Belgium* and *France*);
- what type of applications is COM including in the scope of the introduction of fees? (*Belgium*);
- if the fees paid would be an extra budget for EFSA, in addition to COM's financial support (*Belgium*);
- Agreed with the rationale to exclude reviews from the scope and asked how the 3rd option (administrative fee) would work (*Netherlands*).

COM

- Replied that reviews are done *una tantum* and that it cannot be predicted when there will be another request for a review. For this reason, reviews cannot be included in the analysis, since this would bring an element of uncertainty to the system of fees;

- Clarified that COM understands that SMEs and large enterprises have different budgets, but does not want to put in place too complex a system, which would not be manageable (e.g. revision of EMA system because it is too complicated to run).
- Emphasised also that the number of SMEs in the food sector is much higher than those in the pharmaceutical one;
- Clarified that the possibility of COM collecting the money received for fees is not feasible because the fees paid would be considered as a tax and it would be a problem also for the EU budget;
- Explained in more detail that option 3 covers services to applicants to facilitate the submission process and clarified that options 2 and 3 can be combined.

MS raised the following concerns:

- considering that there are 18 different sectors, it should be verified that the introduction of a system of fees would not become a burden for EFSA's work (*Belgium*);
- consideration should be given to the fact that the introduction of fees could give the panellists the opportunity to ask to be paid (*Ireland*).

COM

- clarified that the objective is not to establish a full cost recovery system in EFSA in order to finance all its activities. Fees will be established only for activities linked to the assessment of authorisation dossiers and not for all dossiers.
- Acknowledged that the introduction of fees could lead to requests from experts for an increase in their indemnities.

Ireland and Belgium

Suggested that COM should verify if it is advisable to introduce fees, in particular in relation to:

- the impact that the introduction of fees could have on the independence of EFSA;
- the fact that the costs of processing the authorisations once a system of fees is in place could exceed the amount of money collected from the fees.

COM

Clarified that the impact on independence is taken into consideration in the IA. This issue was also explored during the consultation on the report on fees and the EP and the Council asked for an IA. COM explained, however, that the decision on whether or not a system of fees should be put in place has not yet been taken.

Sweden

Explained that it does not share the view of other countries on the impact that the introduction of fees may have on EFSA's independence. It stressed that it is very common for public authorities to get paid for providing some services. It is worried that fees would not sufficient

to cover all costs in some sectors. It asked in cases where work is shared between MS and EFSA:

1. if EFSA charges fees, whether those are redistributed to MS;
2. if EFSA does not charge any fee, whether MS will be free to charge fees.

COM clarified that:

1. current rules do not provide for a system of redistribution. At the moment we have a centralized system with the possibility to allow grants and to use Art. 36 (financial support).
2. MS can charge fees within the framework of current rules when they are responsible for performing part of the risk assessment (for pesticides in particular).

* * *

COM

Gave a presentation on policy options and cost – benefit (CB) analysis on Panels/work sharing (PowerPoint presentation).

COMMENTS

Sweden, UK, Germany, France and *Denmark*

Asked for a scrutiny reserve.

MS asked for the following clarifications:

- how the risk assessment could be carried out in option B (*Netherlands*);
- what is the connection between the introduction of fees and the re-organization of EFSA (*Sweden* and *Norway*);
- the introduction of fees and the re-organization of EFSA workflow would imply an amendment of Reg. 178/2002.

MS put forward the following comments:

- option A (Executive Director decides on the complexity of a dossier) would be unfeasible (*Ireland*);
- options A and B would imply an upgrade of EFSA's staff expertise since their new roles would require them to have an appropriate knowledge (*Netherlands* and *UK*);
- within the UK Authority, the staff do a prior assessment of dossiers, which is then peer reviewed by experts and the system is effective (*UK*);

- the introduction of fees would require an increase in the number of EFSA staff and a consequent increase in costs. Thus, the introduction of fees would make sense only if they really increase EFSA's resources (*Belgium*);
- to contemplate a re-organization of EFSA would be too much considering that the introduction of fees would affect only a limited part of EFSA's workload (*Denmark*)

COM

- Replied that the introduction of fees is an opportunity to look at the entire authorisation system and to address some weaknesses which have been detected.
- Explained that the introduction of fees and the re-organisation of EFSA imply a modification of Reg. 178/2002.
- Clarified that the 3 options mentioned are not the only ones which can be envisaged.
- Acknowledged that the options presented might pose problems of implementation, especially for Panels involved in complex sectors (e.g. GMOs).

After the meeting, two written comments were received:

- The Ministry of Agriculture and Forestry of *Finland* provided some comments concerning the work sharing in EFSA. In particular, it proposed a new option in which Panels would be responsible for peer reviewing the assessment made by EFSA staff on routine dossiers.
- The Sounding Board of the EFSA Focal Point for the *Netherlands* provided some comments concerning the introduction of fees and the change of work- sharing in EFSA. In particular, it proposed the development of a (tiered) fees system in two phases: 1) a registration or start fee, and 2) an assessment fee. Regarding work-sharing, it pointed out that EFSA staff should only assess the completeness of dossiers.

Plenary meeting of the Advisory Group

on the

Food Chain and Animal and Plant Health

Summary Record

Brussels, 16 MARCH 2012

1. Opening of the meeting and adoption of the Agenda

The Deputy Director-General of DG SANCO opened the meeting on behalf of COM and welcomed participants. He underlined the importance of the Advisory Group in the exchange

of relevant information on SANCO's work. He stressed the relevance of stakeholders' input in

the phase of impact assessments and confirmed that there is a strong political wish to improve collaboration even further. He presented the agenda which was then adopted.

[……..]

8. Impact assessment on the possibilities of establishing fees for EFSA to process authorisation dossiers – state of play

COM presented a short update of present actions concerning the impact assessment, in particular performing the evaluation of the selected options, evaluation of the impact of the possible introduction of fees and of the modification of work sharing on economic and monetary aspects, competitiveness, innovation, consumers, EFSA's independence, and the Member States. COM informed participants that it has launched a questionnaire to Small and Medium-sized Enterprises (SME) to perform the SME test on fees. COM also confirmed that the next stakeholder consultation will take place via a follow-up working group meeting to be organised in the coming months.

COMMENTS AND QUESTIONS RAISED

In response to FEDIAF's question on how the questionnaire for SME is organised, COM clarified that the questionnaire goes through the DG ENTR enterprise network to national antennas which distribute it further to the SMEs in each Member State.

WG of the Member States on the Impact Assessment on the Revision of Regulation 178/2002 on the establishment of fees for EFSA and related aspects

Minutes

Brussels, 4 MAY 2012

Participants Member States, EFTA and candidate countries: *Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Ireland, Latvia, Luxembourg, Poland, Portugal, Romania, Slovenia, Sweden, United Kingdom, Norway, Croatia*

Participants from the Commission: *R. Vanhoorde* (Chair), *J. Vergnettes, R. Chiodo, J. Houins-Roulet, S. Osaer, V. Volosinova.*

Participants from EFSA: *O. Ramsayer*

The problem definition and policy objectives having already been discussed in the meeting of 17 January 2012, the objective of the meeting was to consult the MS on the different options for the establishment of fees for EFSA:

Option 1: status quo (no fees);

Option 2: mandatory fees for all applicants (new and renewals), including generic authorisations (all 19 sectors);

Option 3: mandatory fees for authorisation holders only (8 out of 19 sectors);

Option 4: additional services for all applicants, including generic authorisations, with few exceptions in areas where the dossiers are submitted at Member State level.

It was further explained by COM that

- SMEs would benefit from 80 to 90% reduction in all options (2, 3 or 4).
- Micro-enterprises are considered as not liable for the payment of fees under all options.

MS were invited to comment and give their position on the options presented.

On the initial option on work sharing between Panels/EFSA staff/external bodies, UK asked for confirmation that this option is no longer being considered in the IA and hence it will not be included in a legislative proposal. COM confirmed that its intention was not to include it in the legislative proposal.

Most MS regretted the short time given for reflection; however, all MS appreciated the complexity of the fees systems and asked for further explanation on which basis the fees were calculated. The EFSA representative provided some background to how costs were calculated for the different options.

– MS were asked to comment/raise questions option by option:
–

Option 2: fees for all applicants (new and renewals)

Generally not supported by MS because applicants for generic authorisations who do not get any specific benefit would have to pay fees:

– UK:
  - only initial reaction.
  - Costs of fees seem high and disproportionate to what is paid already by some sectors to MS.
  - Asked what the basis was for establishing these fees.
  - Asked why renewals (being less complex) cost the same as new dossiers.

–
– COM explained that the basis for establishing the level of the fee was a cost recovery approach e.g.: the cost incurred on average by EFSA for assessing an application determines the level of the fee. The average cost for assessing an application includes meetings, infrastructure, staff and administrative overheads. COM is aware that the cost of renewals and therefore the level of the corresponding fee could be less since they are less complex dossiers. However, as the methodology used for the estimation of the cost of dossiers for EFSA is based on the current costs for EFSA, the results for renewal reflect this methodology. In the future, it is not excluded that these costs could be lower.

–
AT requested more information concerning micro-enterprises.

COM clarified that the new guidelines for IA automatically exclude micro-enterprises from new requirements unless their inclusion is justified by specific reasons such as protection of health, safety etc. It re-confirmed that micro-enterprises will not be considered as liable for the payment of fees to EFSA under all presented options.

Option 3:

This option was considered as preferable to option 2, given that the risks identified were smaller, but the establishment of a fee for MRL dossiers was considered to be problematic.

UK:

- Asked whether the fee will be variable according to the complexity of the dossier; i.e. differentiating between an excellent well-prepared dossier that requires less work vis-à-vis

a poor dossier demanding a lot of work for EFSA. Would it be foreseen to vary a fee according to such situation (this applies also for option 2)

- MRLs of pesticides have to be excluded from the scope since most tasks are performed at MS level.

Sweden:

- Option 3 is preferable since the risks of down streaming and the risk for the stability of the budget are smaller, the risk for the perception of independence being similar to option 2.

–

– COM confirmed that all risks are smaller for option 3 and that the cost for developing guidelines will be excluded from the fees.

–

– Norway asked why the novel food falls under option 3 despite the fact it becomes generic in revised legislation.

–

– COM explained that there was a need to consider the current situation.

Option 4:

In summary, as option 4 on additional services is an option that had not been discussed before (not included in the report on fees), there were numerous requests for clarifications. The added value for applicants, including the reduction for SMEs, was perceived as positive, but there were concerns on i) the mandatory status of the fee, ii) the financing of the SME desk was considered as problematic (especially if it required tasks from MS), iii) the need to assess the impact of this option on the potential reduction of costs of the risk assessment process, iv) the legal feasibility of this option, v) the inclusion of generic applications since this inclusion was considered as unfair under option 2 and finally vi) the higher risk for the actual and perceived independence of EFSA.

UK asked about the MS helpdesk and whether this would entail costs for MS. It questioned the different reductions (i.e. 80% or 90%) for SMEs and asked how the different sectors are grouped (normal/complex/highly complex) and how it will work in practice.

Norway asked whether these additional services could help in reducing the costs for the RA and whether these savings have been assessed.

COM replied that there was a need for clustering/grouping to keep the system manageable. It clarified that the payment of fees for these services is mandatory.

As for the 80 or 90% reduction for SMEs, 80% was found appropriate for discouraging SMEs from misusing the system. It was clarified that the cost for the already existing application-desk was not covered by this. COM further explained that for option 4, the income generated by fees could be an addition to EFSA's general budget, if the tasks listed are clearly new tasks for EFSA whereas for options 2 & 3, EFSA's budget would be proportionally reduced (principle of balancing subsidy).

EFSA clarified that the SME desk in MS would need to be negotiated with MS, but was considered to be a useful tool for overcoming the linguistic barrier, in particular useful for SMEs. It informed that the grouping by sectors was made on the basis of the complexity of

their assessment by EFSA. It explained that at this stage it was difficult to make estimations on the impact of these additional services on the reduction of costs of RA.

AT asked whether these services are optional or mandatory.

COM replied that fees in all options are mandatory.

SE stressed that it needed to further reflect on option 4, but agreed with the presented assessment of risks. It mentioned the need to draw a clear line between public services and private services. It stressed that the costs of each service should be made clear, as well as their impact on final costs for EFSA. Given that the inclusion of generics in option 2 was considered as unacceptable, what will be the reasoning to find it acceptable in option 4? Charging for specific services to applicants will lead to a higher expectation of a positive outcome so it creates a higher risk for independence.

COM recognised the risk of a negative perception of 'independence' for option 4. With regard to the question on costs, COM signalled that the assessment of impact on final costs for EFSA would constitute a second layer of 'assumptions' that could be questionable.

DE commented that the reduction for SMEs should also be 90%. It considered as positive the grouping of sectors according to complexity. It questioned the legal feasibility of option 4 and asked whether this option is additional to either option 2 or 3.

COM re-iterated that these are all separate options. Fees for additional services will need to be established by specific legal provisions.

BE asked how the separation between dossiers of general interest and services to applicants will be done. It pointed out that there could be a risk of creating a two-speed functioning of EFSA. It also asked what the impact on independence would be and whether all options are compatible with EFSA's new policy on independence.

COM replied that this risk of EFSA functioning at 2-speeds had already been considered in the general report on fees.

EFSA confirmed that all options considered are compatible with the Policy on Independence. On the 2-speed agency, the perception of EFSA is that fees would help as there would be strict timetables for regulated products.

General feedback on all options:

UK considered option 4 as the most workable option.

Perception of independence remains the critical issue: the more transparent the process, the better.

Impact on SMEs and competitiveness remains a difficult issue and they envisage problems with this. There might be a need to provide proof of being an SME.

DE supported fees in general; option 4 seemed the most interesting, but had a reserve on the setting up of a network of APDESKS in the MS.

For options 2 & 3, they would like to see feedback from the stakeholders.

AT generally supported fees for EFSA. Not 100% clear on how option 4 would work, whether EFSA would receive fees for answering the phone. Option 4 could be perceived as the backdoor for option 2.

EFSA explained that the triggering point for asking fees under option 4 would be at the moment of the submission of a dossier.

Norway insisted on no fees for generic authorisations.

While option 4 is interesting, they foresee problems with perception of independence as it would be perceived as a counselling/consultancy service to the food industry. Option 3 is the most acceptable.

BE asked about the overall timetable from now on.

COM explained the tight schedule with the IA Board taking place on 17 July 2012 and for this reason written feedback from MS was requested by 18 May.

– **In conclusion,** some MSs supported the general principle of fees. None supported fees for generic authorisations. One MS (+ one EEA State) had an interest in option 3 and a few others in seeing option 4 further developed, but with a request to consider it carefully given that this option presented a higher risk in terms of perception of independence.

– WRITTEN COMMENTS:

AT is in principle in favour of the establishment of fees for EFSA. However, the level of fees must be set in such a way that the authorisation procedure for companies, in particular for SMEs, is affordable.

Option 2, which provides that all applicants should pay a fee, is preferred. It could also be considered that all applicants pay a fee, but those who are authorisation holders and therefore derive increased advantages pay a higher fee.

CZ does not support the establishment of fees for EFSA (option 1). "The primary target of its establishment is not to decrease EFSA costs or influence positively EFSA´s budget". In CZ opinion the increased administrative burden for both applicants and EFSA itself, relating to the establishment of fees is not acceptable under these circumstances. This position is in line with the opinion of the Czech Association of Special Foods (association of dietary food supplements), representing sectors that would be directly affected by the introduction of fees.

If fees are established, CZ will be able to support an option leading to stimulation of innovations, bringing more predictable and more balanced requirements, especially for SMEs. Preference concerning options 2 – 4 cannot be given at this moment.

DK in principle supports the idea of EFSA fees, but a future system should be beneficial to the users, while ensuring that EFSA's role as a community provider of independent scientific risk assessments remains intact.

Concerns are: the fairness of average fees; free riding; instability of EFSA's budget; how to distinguish SMEs from subsidiaries in large industries.

Therefore, DK considers it essential that the stakeholders (industry and consumers) take ownership and support the establishment of a fee system.

FI is, in principle, in favour of the possibility for EFSA to collect fees for its services. However, at this stage FI has difficulties with all options currently under discussion. FI considers option 2 unfeasible from a fairness point of view. Option 3 has the disadvantage that fees are already applied in most of the sectors considered to be eligible for fee collection. Therefore, fees for EFSA would result in additional costs that would inevitably be reflected in the prices of the products, thus creating extra financial burden on consumers and affecting the competitiveness of the EU industry.

Regarding option 4, FI considers that EFSA should already provide these services to applicants, and that these fees should not be applied to those who have no need for such additional services.

FI stressed that future legislation should provide a legal basis for fee collection.

NL in principle supports option 3, following the logic that someone who benefits from obtaining an authorization should pay for it ("*het profijt beginsel*" (direct benefit principle)). At the same time, NL also recognizes that there are general risks associated with the establishment of fees (for option 3 and all other options).

NL also underlined that the few reactions they have received from stakeholders range from the very critical to negative with regard to the establishment of a fees system.

PL is in favour of option 1, i.e. maintaining the *status quo* (no fees for EFSA) or option 4 provided that SMEs fees will be reduced by 90%. Poland wants to protect SMEs against obstacles as they are the most vulnerable group of the putative payers.

RO supports option 1(no fees) since it is more in conformity with EFSA's mission and functioning.

SE considers option 3 as fairer than 2 and 4 since the applicants who pay the fees also derive a direct benefit from the application procedure.

SE supports reduced fees for SMEs, the exclusion of reviews from the scope of fees and a fee level sensitive to the sector concerned.

It considers that option 4 raises questions (in the light of the objective of improving EFSA's economic situation or its functioning):

- Option 4 will generate costs and it is not clear if these costs are completely covered by the fees since the reduction for SMEs has to be financed. These services could also create additional work initially but reduce EFSA's workload in a second phase;

- Option 4 raises questions on the perception of independence since when charging fees for services in a pre-application phase, applicants will expect these services to contribute to a favourable response in the application phase;

- Option 4 also raises questions of fairness since, as in option 2, generic authorisations will be subject to a fee;

- Option 4 proposes to establish a network of helpdesk in MS, but since this would be a new task for MS, how would the fees collected by EFSA for this service be redistributed to MS?

It suggests considering a combination of option 4 with option 3, in which the use of additional services would be optional instead of mandatory, and in which the mandatory fee for processing applications is reduced in cases where an enterprise has already paid a fee for additional services in the pre-application phase.

UK stresses that, even if the various pros and cons have been highlighted clearly, it is difficult to take a firm position since there are a number of factors to be considered (i.e. independence of EFSA, minimising burden for industry etc.). In general, UK is not convinced about the advisability and feasibility of introducing fees.

2nd Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on the Impact Assessment (IA) on the Revision of Regulation 178/2002 on the establishment of fees for EFSA and related aspects

Minutes

Brussels, 4 MAY 2012

The objective of the meeting was to consult the WG of the Advisory Group on the Commission's Impact Assessment on the different options for the establishment of fees for EFSA:

Option 1; status quo (no fees)

Option 2: mandatory fees for all applicants (new and renewals), including generic authorisations (all 19 sectors)

Option 3: mandatory fees for specific authorisation holders only (8 out of 19 sectors)

Option 4: additional services for all applicants including generic authorisations, with few exceptions in areas where fees are already paid at MS level or EURL.

The Commission further explained that:

- SMEs would benefit for 80 to 90% reduction in all options (2, 3 or 4).
- Micro-enterprises are not liable for the payment of fees under all options.

Stakeholders were invited to raise questions, comments and give their position overall and per option presented.

Option 1:

The vast majority of the stakeholders clearly favoured option 1 as being the preferred option and requested that it should be formally considered in the IA. In particular supported by FEFANA, EuropaBio, FoodDrinkEurope, FEFAC, AMFEP, ELC.

Option 2:

No stakeholder supported this option. All participants considered it unfair to have fees for generic authorisations (one pays, all benefit). In addition, they argued that because of the already high regulatory burden and the small economic benefit derived from generic authorisations, there was a high risk of hampering innovation (this will discourage further submissions) and of industry moving to other countries.

They expressed criticisms on its legal and practical feasibility (ELC, FEFANA in particular):

- The legal framework provides that only COM, EP and MS submit authorisation dossiers to EFSA for assessment and therefore does not provide for direct contact between EFSA and applicants.

- Establishment of fees via a general Regulation is incompatible with the specificities of the numerous Directives and Regulations setting up sectorial authorisations.

- Some of the dossiers submitted by industry are solely for the protection of public health (allergy).

The level of the fees (based on cost recovery) was considered to be too high and disproportionate since it did not take sufficiently into account the different level of complexity of the dossiers. There was also general criticism of the cost of renewals that should be lower than the cost of new substances and there were several requests for more appropriate costs to deal with specific cases (EuropaBio for stacks, IBMA for bio-based plant protection products, FEFANA for feed additives, ELC for extension of use of food additives). Clarifications were required on the calculation of costs.

Concerns were expressed about fees being used as a substitute for public financing. Fees should be set up only if they contribute to a better quality of EFSA outputs (AESGP, EuropaBio).

EFSA clarified the calculations of costs: actual average costs of dossiers during 2009-2010 (including costs for staff, experts, infrastructure, outsourcing, meetings; costs of guidance documents not included).

COM stressed that it was aware of the different levels of complexity of dossiers in some sectors, but that it was not possible at this stage in an exercise covering 19 sectors to address this issue in detail. More refined calculations taking account of specificities would be made if this option was chosen. It acknowledged the legal difficulty in dealing with 19 sectors covered by different legislation.

Option 3:

This option was considered to be fairer than option 2 since it did not concern generic authorisations, but focussed on authorisations that are linked to exclusive rights of the applicant.

Concerns were raised on the concept of exclusive rights since the benefit coming from such rights is not always straightforward and the introduction of fees could further create distortions of competition (EuropaBio, FEFANA).

The level of fees should be more realistic to take account of the impact on SMEs (IBMA) and of the difference in complexity of the dossiers (EuropaBio/stacks issue).

The reduction for SMEs is not always justified and could further distort competition. In addition, in some sectors, the size of the enterprise is not always relevant because the benefit is correlated to the size of the market (FEFANA: feed additives for minor species).

In some sectors, the fees for EFSA will be an additional burden and therefore a disincentive for innovation because fees are already perceived at national level for the same application (ELC).

Fees should be linked to an added value for the applicant (AESGP).

Option 4:

Generally stakeholders considered that this option had an added value since its aim was to improve the quality of the services to applicants, but there was a significant concern that the additional services subject to fees could be perceived as negatively impacting on EFSA's independence.

Stakeholders stressed that this option should contribute to a more efficient system for applicants. This should be the case if scientific pre-submission meetings with applicants are offered (IBMA, AESGP). AESGP advocated the organisation of direct pre-submission meetings with the members of EFSA Panels.

EuropaBio indicated that paying for such services should result in faster and more efficient processing of applications by EFSA, for example a decrease in the high number of "stop the clock". It emphasised the need for better predictability of EFSA's outcomes. It questioned if other incentives could not be included in the EFSA system to make it more efficient.

ELC asked for the possibility to make these services optional, for the combining of options and for the need to consider these types of services for novel food.

EFSA recognised that currently predictability for applicants is not optimal. Their intention is to design a kind of 'service-level agreement' that will clarify which services to expect and which not, the interactions at different stages in the process, and the transparency of the process in order to preserve independence.

On the use of the "stop the clock", the target could indeed be to reduce this and it could be regarded as an **indicator** to measure the benefit of these additional services. (e.g. by end of year 3, 50% reduction of "stop the clock" for new dossiers and 80% for renewal dossiers).

Some concerns were expressed about the legal feasibility: compatibility of the payment of fees by industry with the legal structure according to which only COM and MS submit authorisation applications to EFSA; possible need to make legal changes in 19 sectors (FEFANA, ELC).

The main concern was on the perception of EFSA's independence. AESGP and EuropaBio stressed that these services will help growth, innovation and competitiveness, but that they had to be weighed against public perception of the scientific outcomes. CEO indicated that a fee system would be acceptable if it provided additional funds to finance independent studies and only if there were no direct payments by industry to EFSA ("to build a firewall between EFSA and Industry").

Next steps:

All stakeholders were asked to further provide written feedback in 2 weeks' time. COM explained that it was foreseen to present the IA to the IA Board mid-July.

Summary of written comments received after the meeting

Consumers and NGOs

BEUC

Opposes the establishment of fees since it will only further damage EFSA's actual and perceived independence, "perception of EFSA being bought by industry". Option 4 completely unacceptable since fees should not lead to a service-client relationship or induce EFSA to be more responsive to industry's needs. Still important that EFSA receives sufficient funding to cope with the increasing number of authorisation dossiers while having enough funds left to undertake independent scientific work to fill knowledge gaps.

Cancer Prevention Society

Importance of strengthening the independence of EFSA.

CEO and Earth Open Source

Support the principle that industry should carry the burden of costs for risk assessment and therefore pay fees to EFSA. Such fees should be paid to a publicly managed fund in order that industry's money has no influence on the risk assessment process. The fees should increase EFSA's overall budget in order that EFSA has a better capacity to finance independent risk assessment studies and independent experts. For these reasons, they oppose options 1 and 4.

Industry

ELC

Option 1 is considered the most realistic one since there is no need for costly subsequent adjustment of vertical legislation and it does not create additional risk of wrong perception of EFSA's independence. It is also 100% fair for generic authorisations and has no financial impact on sectors, innovation and SMEs.

Opposes option 2 (no added value for applicants, unfair for generic authorisations, costs not appropriate, negative impact on innovation in a sector, the food ingredients industry, that invests 3% to 8% of its turnover in RTD and return on investment would be affected.

Option 3 could be acceptable if fees are lowered (3 000 to 9 000 Euro suggested) and if process is faster and more predictable.

Option 4 could be acceptable with lower fees and if no negative perception of independence.

EuropaBio

Opposes the introduction of fees for EFSA and therefore in favour of option 1 because: fees will add to the already high costs of submitting GM crops for regulatory review in the EU; fees will discourage SMEs and public research institutes from submitting applications as well

as SMEs located in third countries, thus increasing the risk of asymmetric authorisations with trading partners and trade disruption; fees will be perceived by certain organisations as a barrier to EFSA's independence, which will impact public confidence in its scientific review; submitting a GM product for review is not only in the interest of the applicants, it is also beneficial to the general public so using public funding is justified.

If fees are established, options 2 and 3 should be accompanied by better processing. Any fee system should be linked to timely delivery and an efficient process. Fees for stacks should be lower. Fees for GM monitoring are not acceptable since this is already covered by the fee for renewal. Option 4 would provide added value only if focussed on scientific pre-submission meetings involving the experts of the Panels.

FoodDrinkEurope

In favour of option 1 (no fees).

ERNA

Not against the principle of fees but following conditions would need to be met:

- lower level of fees than those presented;

- fees should be additional to EFSA's budget;

- fees should be service-driven;

- no fees for generic authorisations.

Option 1 should be given attention. Option 4 could be acceptable if it would improve the predictability of outcomes via pre-submission meetings and if services were optional or subject to lower fees.

EHPM

In favour of option 1 because fees are an additional burden for enterprises, especially for SMEs, that already face high regulatory costs.

If fees are introduced, they should be optional, proportionate (too high a level presented), not applicable to generic authorisations, additional to EFSA's current budget and should improve services to applicants and predictability of EFSA's opinions. The introduction of fees should also not damage the perception of independence.

If fees are introduced, option 4 would be the best, but applicants should choose on a voluntary basis to pay for these additional services.

AESGP

In favour of option 4 since it is the only option providing added value to the system. Scientific pre-submission meetings would reduce both the number of applications withdrawn and costs incurred by EFSA for assessing inadequate applications. It is a fair option for EFSA since it will provide additional funding and establish a clear link between the introduction of fees and

additional services leading to improved efficiency of the whole system. It considers the fees as affordable and that SMEs will benefit from the additional services.

AMFEP

Considers the establishment of fees to be disproportionate (additional barrier for SMEs; there are better ways to optimise national and EU resources allocated to risk assessment, in particular by avoiding duplications).

The enzymes sector could, in fact, evolve to a situation where there will be co-existence of generic and producer specific approval. Thus, the introduction of fees could bring additional risks of distortions.

The idea of personalised services such as pre-submission consultations and tailored support for SMEs is welcomed, but the costs of these services should be proportionate and reflect the real workload for EFSA.

FEFANA

Opposes the establishment of fees since they are detrimental to innovation and competitiveness.

It underlines that the establishment of fees is difficult at a global level and has to be done in sectorial legislation. In addition, the current sectorial legislation applicable to feed additives already provides for fees to EURL. These fees already represent a significant burden for industry (one million Euros paid to JRC for the re-authorisation process) and are criticised as being a tax.

It highlights that according to the current legal framework, EFSA is a service provider to the Commission, Member States and Parliament with no direct link with industry since applications for authorisations are submitted via the Commission or MS. In this context, fees should be paid to the Commission or MS, and they will be seen as a tax.

The aim of the authorisation systems in food legislation is the protection of public health and a tool to ensure that private business is controlled for the benefit of the public.

Fees for extension of use are unfair and contrary to the legislator's efforts to promote authorisations for minor species.

Fees (options 2 and 3) will bring additional distortions in a sector where there are already problems of biased competition. It will hamper innovation and push additive production outside Europe.

The reduction for SMEs foreseen in the options is not adequate for the feed additives sector since it is based on the size of the applicant, because the return for investment linked to an application is linked to volume and size of the margin. This will lead to orphaned categories of animals.

Option 4 will not bring substantial benefits to the risk assessment activities of EFSA unless this service is overcharged in order benefit other tasks. In addition, pre-submission services would only provide added value if carried out by experts assessing the file, which will be difficult to organise and might shed serious independency concerns about the work of EFSA.

There are more efficient ways to find resources for EFSA, in particular by reducing its workload linked to self-tasks and to non-safety tasks such as efficacy assessments.

Fees should not be a tool to substitute public authorities' responsibility to adequately fund EFSA, especially considering that industry already pays taxes in the EU.

FEFAC

Opposes the establishment of fees. It will be an additional cost that will jeopardize innovation in the animal nutrition sector and will damage the credibility of the food system by affecting the perception of EFSA's independence.

The EU livestock sector is already facing challenges (need for improved efficiency and lower impact on environment).

Additional costs would not be bearable because of the low market potential (minor animal species) and because some of the substances would have no exclusivity rights.

The cost of dossiers and, in particular, the cost for efficacy assessments is already a high enough regulatory burden.

List of participating organisations

Brussels, 4 MAY 2012

Members of Advisory Group

AESGP

Association of the European Self-Medication Industry

AVEC

Association of Poultry Processors and Poultry Import and Export Trade in the European Countries

BEUC

Bureau européen des unions de consommateurs

CEFIC

Conseil européen des fédérations de l'industrie chimique

COPA-COGECA

Comité des organisations professionnelles agricoles de l'Union européenne – Confédération générale des coopératives agricoles de l'Union européenne

ECPA

European Crop Protection Association

ECSLA

European Cold Storage and Logistics Association

EDA

European Dairy Association

EHPM

European Federation of Associations of Health Product Manufacturers

ESA

European Seeds Association

EUROCOOP

European Community of Consumer Cooperatives

EUROPABIO

European Association of Bioindustries

FEFANA

EU Association of Specialty Feed Ingredients and their Mixtures

FOODDRINK EUROPE

Confédération des industries agroalimentaires

IFAH-EUROPE

International Federation for Animal Health Europe

IFOAM-Europe Group

International Federation of Organic Agriculture Movements — European Union Regional Group

UECBV

Union européenne du commerce du bétail et de la viande

UGAL

Union des groupements de détaillants indépendants de l'Europe

Non members of Advisory Group

AJHconsulting

AMFEP

Association of Manufacturers and Formulators of Enzyme Products

CEO

Corporate Europe Observatory

EFFA

European Flavour Association

ELC

Federation of European Specialty Food Ingredients Industries

ERNA

European Responsible Nutrition Alliance

IBMA

International Biocontrol Manufacturers Association

PlasticsEurope

1. ANNEX IV SME's Panel Consultation

Response statistics for SME panel consultation related to the introduction of fees for authorisation applications to the European Food Safety Authority				
Meta Informations				
I. COMPANY DATA				
1) To which of the sectors listed below does your enterprise belong? (if your activities fall in more than one category, please fill in a questionnaire for each of them)				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(87)
1 Plant Protection Products: active substances (PPP)	12	13.48%	13.48%	13.79%
2 Maximum Residue Levels (MRL) of PPP	4	4.49%	4.49%	4.60%
3 Genetically Modified Organisms (GMO)	2	2.25%	2.25%	2.30%
4 Flavourings	10	11.24%	11.24%	11.49%
5 Smoke flavourings	1	1.12%	1.12%	1.15%
6 Extraction solvents	1	1.12%	1.12%	1.15%
7 Enzymes	1	1.12%	1.12%	1.15%
8 Food contact materials	12	13.48%	13.48%	13.79%
9 Food additives	8	8.99%	8.99%	9.20%
10 Nutrient sources	6	6.74%	6.74%	6.90%

11 Feed additives	2	2.25%	2.25%	2.30%
12 Transmissible Spongiform Encephalopathy (TSE) tests	0	0.00%	0.00%	0.00%
13 Treatments related to Animal by-products	1	1.12%	1.12%	1.15%
14 Antimicrobial treatments	3	3.37%	3.37%	3.45%
15 Health claims	9	10.11%	10.11%	10.34%
16 Novel foods	5	5.62%	5.62%	5.75%
17 Infant formulae	2	2.25%	2.25%	2.30%
18 Food allergens (exemption from labelling)	8	8.99%	8.99%	9.20%
N/A	-	-	2.25%	-
2) What is the size of your company?				
	Number of requested records	% Requested records(89)	% of total number records(89)	
medium-sized < 250	34	38.20%	38.20%	
small < 50	36	40.45%	40.45%	
micro < 10	19	21.35%	21.35%	
3) What is your annual turnover (in Euros)?				

	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(86)
≤ € 2 million	22	24.72%	24.72%	25.58%
≤ € 10 million	37	41.57%	41.57%	43.02%
≤ € 50 million	16	17.98%	17.98%	18.60%
More than 50 million	11	12.36%	12.36%	12.79%
N/A	-	-	3.37%	-
4) Is your company directly or indirectly controlled by another company?				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(79)
Yes	8	8.99%	8.99%	10.13%
No	71	79.78%	79.78%	89.87%
N/A	-	-	11.24%	-
5) Is your company affiliated with a person or entity which is subject to direct or indirect control of another entity?				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(78)
Yes	9	10.11%	10.11%	11.54%
No	69	77.53%	77.53%	88.46%

N/A	-	-	12.36%	-
6) By which of the following factors is your capacity to invest in research and development mainly affected? Please choose only one of them				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(85)
Cost of capital	49	55.06%	55.06%	57.65%
Cost of labour	18	20.22%	20.22%	21.18%
Cost of energy	18	20.22%	20.22%	21.18%
N/A	-	-	4.49%	-
7) What do you consider to be the major barrier to access to the market for the regulated products in which you operate?				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(68)
Availability of Capital	19	21.35%	21.35%	27.94%
Control of resources	3	3.37%	3.37%	4.41%
Economy of scale	9	10.11%	10.11%	13.24%
Research and development	6	6.74%	6.74%	8.82%
Regulation	28	31.46%	31.46%	41.18%
Other (please specify):	3	3.37%	3.37%	4.41%

N/A	-	-	23.60%	-
II. COST OF PREPARING AN APPLICATION TO BE SUBMITTED TO THE EUROPEAN FOOD SAFETY AUTHORITY				
8) How many authorisation dossiers have you launched in the last 12 months?				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(86)
0	76	85.39%	85.39%	88.37%
1	5	5.62%	5.62%	5.81%
3-5	2	2.25%	2.25%	2.33%
6-10	0	0.00%	0.00%	0.00%
More than 10	3	3.37%	3.37%	3.49%
N/A	-	-	3.37%	-
9) What is the cost of preparing a dossier for the submission of an authorisation application to the European Food Safety Authority? (Please indicate a number or a cost range in Euros)				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(38)
Less than € 1000	6	6.74%	6.74%	15.79%
Between € 1000 and € 5000	10	11.24%	11.24%	26.32%

Between € 5000 and € 10000	13	14.61%	14.61%	34.21%
Between € 10000 and € 20000	4	4.49%	4.49%	10.53%
Between € 20000 and € 30000	0	0.00%	0.00%	0.00%
Between € 30000 and € 40000	0	0.00%	0.00%	0.00%
Between € 40000 and € 50000	0	0.00%	0.00%	0.00%
Between € 50000 and € 60000	0	0.00%	0.00%	0.00%
Between € 60000 and € 70000	0	0.00%	0.00%	0.00%
Between € 70000 and € 80000	0	0.00%	0.00%	0.00%
Between € 80000 and € 90000	0	0.00%	0.00%	0.00%
Between € 90000 and € 100000	0	0.00%	0.00%	0.00%
Between € 100000 and € 110000	2	2.25%	2.25%	5.26%
Between € 110000 and € 120000	0	0.00%	0.00%	0.00%
Between € 120000 and € 130000	0	0.00%	0.00%	0.00%
Between € 130000 and € 140000	0	000%	0.00%	0.00%
Between € 140000 and € 150000	0	0.00%	0.00%	0.00%
Between € 150000 and € 160000	0	0.00%	0.00%	0.00%
Between € 160000 and € 170000	0	0.00%	0.00%	0.00%
Between € 170000 and € 180000	0	0.00%	0.00%	0.00%

Between € 180000 and € 190000	0	0.00%	0..00%	0.00%
Between € 190000 and € 200000	0	0.00%	0.00%	0.00%
Between € 200000 and € 210000	0	0.00%	0.00%	0.00%
Between € 210000 and € 220000	0	0.00%	0.00%	0.00%
Between € 220000 and € 230000	0	0.00%	0.00%	0.00%
Between € 230000 and € 240000	0	0.00%	0.00%	0.00%
Between € 240000 and € 250000	0	0.00%	0.00%	0.00%
Between € 250000 and € 260000	0	0.00%	0.00%	0.00%
Between € 260000 and € 270000	0	0.00%	0.00%	0.00%
Between € 270000 and € 280000	0	0.00%	0.00%	0.00%
Between € 280000 and € 290000	0	0.00%	0.00%	0.00%
Between € 290000 and € 300000	0	0.00%	0.00%	0.00%
Between € 300000 and € 310000	0	0.00%	0.00%	0.00%
Between € 310000 and € 320000	0	0.00%	0.00%	0.00%
Between € 320000 and € 330000	0	0.00%	0.00%	0.00%
Between € 330000 and € 340000	0	0.00%	0.00%	0.00%
Between € 340000 and € 350000	0	0.00%	0.00%	0.00%
Between € 350000 and € 360000	0	0.00%	0.00%	0.00%

Between € 360000 and € 370000	0	0.00%	0.00%	0.00%
Between € 370000 and € 380000	0	0.00%	0.00%	0.00%
Between € 380000 and € 390000	0	0.00%	0.00%	0.00%
Between € 390000 and € 400000	0	0.00%	0.00%	0.00%
Between € 400000 and € 410000	1	1.12%	1.12%	2.63%
Between € 410000 and € 420000	0	0.00%	0.00%	0.00%
Between € 420000 and € 430000	0	0.00%	0.00%	0.00%
Between € 430000 and € 440000	0	0.00%	0.00%	0.00%
Between € 440000 and € 450000	0	0.00%	0.00%	0.00%
Between € 450000 and € 460000	0	0.00%	0.00%	0.00%
Between € 460000 and € 470000	0	0.00%	0.00%	0.00%
Between € 470000 and € 480000	0	0.00%	0.00%	0.00%
Between € 480000 and € 490000	0	0.00%	0.00%	0.00%
Between € 490000 and € 500000	0	0.00%	0.00%	0.00%
More than € 500000	2	2.25%	2.25%	5.26%
N/A	-	-	57.30%	-
10) What is the average time needed to prepare a dossier for authorisation?				

	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(40)
Less than 6 months	20	22.47%	22.47%	50.00%
6 months	5	5.62%	5.62%	12.50%
12 months	8	8.99%	8.99%	20.00%
18 months	3	3.37%	3.37%	7.50%
24 months	3	3.37%	3.37%	7.50%
More than 2 years	1	1.12%	1.12%	2.50%
N/A	-	-	55.06%	-
11) Are you delegating the preparation of the dossier to be submitted to EFSA to consulting companies or others on your behalf?				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(53)
Yes	27	30.34%	30.34%	50.94%
No	26	29.21%	29.21%	49.06%
N/A	-	-	40.45%	-
12) Are you an authorisation holder?				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(86)

Yes	17	19.10%	19.10%	19.77%
No	60	67.42%	67.42%	69.77%
Partly, on some of on substances/products/claims/treatments/process	9	10.11%	10.11%	10.47%
N/A	-	-	3.37%	-

III. POSSIBLE IMPACT OF FEES				
13) Would the introduction of fees for EFSA's authorisation assessment prevent you from launching new product/substances/claims ?				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(84)
Yes	47	52.81%	52.81%	55.95%
Yes, if the fee is more than 30% of the total cost of preparing the dossier for submission to EFSA	11	12.36%	12.36%	13.10%
Yes, if the fee is more than € ..... (please indicate)	15	16.85%	16.85%	17.86%
No	11	12.36%	12.36%	13.10%
N/A	-	-	5.62%	-
14) Would the introduction of service from EFSA related to the submission of applications (E.G. assistance to pre-submission; electronic submission of dossier; IT navigation system; dedicated help desk etc.) change your decision to launch new product/substances/claims?				
	Number of requested records	% Requested records(89)	% of total number records(89)	% of total number records(69)
Yes	45	50.56%	50.56%	65.22%
No	18	20.22%	20.22%	26.09%
Do not know	6	6.74%	6.74%	8.70%

N/A	-	-	22.47%	-

11. ANNEX V BASELINE SCENARIO FOR THE IMPACT ASSESSMENT ON THE POSSIBILITY OF INTRODUCING FEES FOR EFSA TO PROCESS AUTHORISATION DOSSIERS PRESENTED BY INDUSTRY

EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Relations with agencies and advisory groups

Brussels, October 2011

SANCO 0.3/RC D(2011)

WORKING DOCUMENT

Baseline scenario for the

Impact Assessment on the possibility of introducing fees for EFSA to process authorisation dossiers presented by industry

SUMMARY

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: F101 3/74 - Tel. direct line +32 229-78630

rossella.chiodo@ext.ec.europa.eu

Introduction

The aim of this baseline study is to perform a screening of the current situation with regard to the processing of authorisation dossiers submitted to the European Food Safety Authority (EFSA) and emanating from industry.

The objective is to set up a strong factual basis which will be used to develop and compare the policy options later on in the Impact Assessment process.

All sectors have been considered in the screening.

This exercise includes:

- the analysis of the different types of authorisation procedures and of their specific characteristics, such as the category of authorisations granted (individual or generic);

- the identification of the actors involved in the authorisation processes;

- the identification of all other fees related to the authorisation applications already in place at Member State level and European level.

In quantitative terms, we have identified the number of applications received and processed by EFSA, the costs for the Authority and the ones for the applicants.

Main sources for the baseline study have been the 19 sectorial regulations and related implementing rules; the consultations of concerned SANCO Units and EFSA's Units.

State of play

According to Regulation 178/2002 the **European Food Safety Authority (EFSA) is mainly financed by the general budget of the European Union**.

More precisely, Article 43 of its founding Regulation provides that the revenues of the Authority shall consist of a contribution from the European Union (EU) and from any State with which the EU has concluded an agreement and of charges for publications, conferences, training and any other similar activities provided by the Authority.

Regulation 178/2002 also foresees that after its entry into force and in the light of experience acquired, **the possibility to introduce fees with regard to the processing of authorisation dossiers presented by industry should be examined** (recital 56).

1. EFSA's Responsibilities

EFSA has the following tasks: 1) delivering of scientific opinions for the Commission, the Member States and the European Parliament; 2) delivering of technical and scientific assistance to the Commission; 3) collection and analysis of data on the safety of the food

chain; 4) identification of emerging risks; 5) providing scientific support for the Commission in cases of emergency; and 6) communication to the public on risks.

Most of the above-mentioned tasks are of general interest. In particular, EFSA's scientific and technical support services enable public authorities to manage risks in a way ensuring the protection of consumer health while remaining proportionate to the extent of the risk at stake. With regard to regulated substances or products, it is EFSA's role to provide the safety assessments which will be the scientific base for the initial pre-market approval by the risk managers or for their decision to maintain these substances or products on the EU market.

Existing legislation makes EFSA responsible for processing authorisation applications in 19 food and feed sectors.

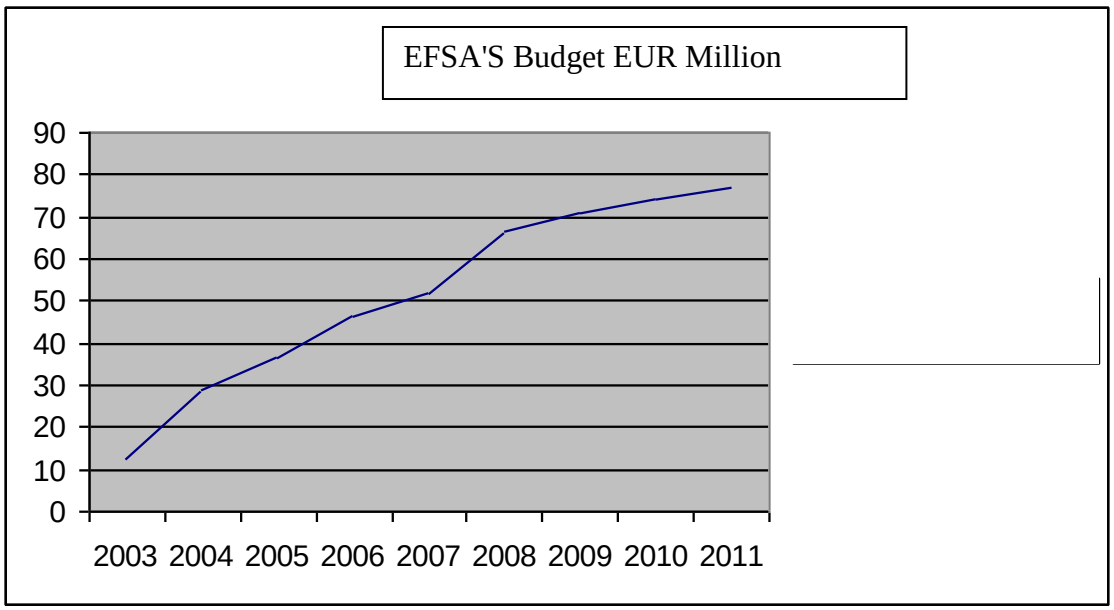
2. EFSA's Budget

From its establishment to now, the Budget of EFSA has grown in accordance with the foreseen financial planning that provided for a progressive setting up of the Authority. The last five years have shown that the Authority has now entered a phase of stabilisation, both in terms of budget and of staff.

Table 1.

	2003	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
BUDGET (EUR Million)	12.6	28.9	36.7	46.6	51.6	66.4	70.9	74.2	76.2

Graph1.



3. Scientific evaluation of Regulated Products

Processing authorisation applications is the procedure by which EFSA assesses the dossiers submitted by applicants who want to obtain an authorisation to put on the market a product, a substance, a claim or a process (hereinafter referred to as "regulated products") . This process is specified by sectorial legislation and involves the following steps:

- reception of the application dossier by EFSA (usually via a Member State or the European Commission);

- completeness check by EFSA's staff (verification that the dossier includes all necessary information and documentation as prescribed by legislation and EFSA's guidance);

- scientific evaluation by the competent Scientific Committee or Panel that the regulated product meets the scientific requirements for authorisation.

In addition to the evaluation of a **new regulated product** prior to its introduction on the market, the legislation spells out two other regulatory workflows : 1) the "**renewal"** of the authorised products due to the expiry of their authorisation, where the deadline to re-submit the products for re-evaluation is spelt out in the legislation (after ten years) or due to the subsequent changes in technology or to the development of new scientific knowledge, 2) the "**review"** of regulated products that although already on the market 1) have to be submitted to a first evaluation at EU level, as for Food enzymes; 2) have to re-evaluated since they were authorised a long time ago at the EU level as for food additives.

This last case is to be considered as a "*una tantum*" workflow. It is, in fact, a process decided and initiated by the public authority and involving the consistent receipt of dossiers to be processed by EFSA due to the pre-existence of such substances/products on the market.

Following EFSA's risk assessment, as expressed in a scientific opinion adopted by the competent EFSA Scientific Committee/Panel, a legal act granting an EU authorisation is prepared by the European Commission and adopted in accordance with the relevant procedures.

The authorisation granted can be classified as **generic**, when an EU authorisation is granted to all operators and the regulated product generically authorised can be used/produced/marketed by anyone, independently of who applied for the authorisation.

The authorisation can also be granted to an identifiable "holder" who is the only one who can use/market/produce the regulated products. In this case the authorisation can be classified as **individual.**

It should be noted that a number of simplified procedures are in place. These are for requests for notification of equivalence and extension of uses, where normally a simple notification or a simplified application dossier is requested.

This possibility is available for extraction solvents, food additives, feed additives, novel food, and food flavourings. However, the dossiers for extension of use represent a significant number of dossiers for EFSA, only in the sector of feed additives. In this last case, the extension of use to another species systematically requires a scientific assessment by EFSA while for food additives or flavourings; the extension of use is almost always dealt with by the risk managers. Novel food is an intermediate case with a limited number of dossiers for extension of use requiring a scientific assessment by EFSA.

With regard to the completeness check, specific sectorial legislation includes implementing rules on the content of dossiers and provides for guidance/guidelines drafted by the European Commission and EFSA to assist applicants in the preparation of dossiers.

Once the completeness check has been finalised, the scientific evaluation by the Scientific Committee/Panel starts. Specific deadlines are laid down in the sectorial legislation to structure the evaluation process. Additional information from the applicant can be requested by EFSA by putting the process on hold ("stop the clock" mechanism).

Depending on the sector, the scientific evaluation process foresees different sharing of work and responsibilities between EFSA's staff, EFSA's Panels, Member States and the EURL. A particular case is, for instance, Plant Protection Products where a "Member State Rapporteur" carries out a preliminary risk assessment and in a second stage EFSA carries out a peer review.

It is possible for an application to be withdrawn or terminated early. Specific rules may apply to withdrawal.

4. Sectors concerned

The relevant legislation which provides for authorisation in the area of safety of the food chain covers 19 sectors/areas.

EU legislation concerning the above mentioned sectors involves 35 pieces of legislation, including implementing rules.

Table 2

1. **Plant Protection Products: active substances (PPP)**
2. **Maximum Residues Levels (MRL) of PPP**
3. **GMOs including GM food/feed**
4. **Flavourings**
5. **Smoke flavourings**
6. **Extraction solvents**
7. **Food enzymes**
8. **Food contact materials**
9. **Food additives**
10. **Nutrient sources**
11. **Feed additives**
12. **Transmissible Spongiform Encephalopathy (TSE) tests**
13. **Animal by-products**
14. **Antimicrobial treatments**
15. **Health claims**
16. **Novel foods**
17. **Infant formulae**
18. **Food allergies**
19. **Recycling Plastics**

The vertical legislation related to these sectors foresees differentiated application procedures peculiar to each sector. The modalities differ substantially between sectors with different degrees of involvement of EFSA, Member States, European Commission and the EU Reference Laboratories.

In most cases, the legislation provides for a detailed authorisation procedure including the procedural steps related to the risk assessment. However, some legal acts provide for the principle of an authorisation after consultation of EFSA but without specific details on the procedural steps to be followed.

In certain cases applications have to be submitted to EFSA via a Member State; in other cases the application is sent to the European Commission which in some cases checks the compliance of the application with some requested standards and then forwards it to EFSA. In a limited number of sectors (plant protection products, current legislation on novel food), the procedure is decentralised and involves a preliminary scientific assessment by Member States. To a lesser degree, the GMO legislation also provides for some mandatory sharing of the scientific evaluation work with the Member States.

In certain cases the EURL is involved. The core task of the EURL is the validation of analytical methods. This point will be further developed in the document.

5. Type of authorisation granted

In the 11 sectors concerned by an authorisation procedure for the placing on the market of a regulated product the EU legislation foresees a generic authorisation.

There are 8 sectors in which the regulators grant the authorisation to market the regulated product to a specific holder. This is the case for GMOs (cultivation and GM food and feed); categories of feed additives issued to a specific holder; plant protection products; smoke flavourings, recycling plastics, novel food and TSE tests.

6. Actors involved in the scientific assessment of application dossiers for authorisation

The EU legal procedures related to authorisations in the food chain sector are in almost all cases centralised at EU level. They require the adoption of an EFSA scientific opinion that will be the scientific basis for the adoption of an EU authorisation.

This implies that in accordance with EFSA's founding Regulation, EFSA's Scientific Committee/Panels are sole responsible for the adoption of EFSA scientific opinions. The work of the Scientific Committee/Panels is supported by EFSA's staff. In addition, preparatory work on the scientific opinions can be externalised by EFSA to contractors in accordance with the procurement procedures or to the members of a specific scientific network of national scientific bodies set up by its founding Regulation (Article 36 network).

However, in one specific area (PPP), the authorisation procedure is partly decentralised and Member States play a major role in the preliminary scientific assessment of applications for authorisation.

Member States are also responsible for a preliminary risk assessment in the area of novel food and for the scientific environmental risk assessment of GMOs for cultivation. They may contribute to the safety risk assessment of genetically modified food and feed.

In the case of feed additives and GM food and feed, the relevant EURL is responsible for checking analytical issues.

7. Fees already in place

The legal framework of a number of authorisation procedures establishes the possibility to have fees for the EURL relation to analytical aspects.

The legislation specifies the exact amount of fees that the EURL can charge according to the type of tasks performed. For feed additives the maximum amount that can be charged by the EURL is EUR 6 000 with descending tariffs for simpler dossiers and applications for extension of use. For GMOs, the EURL fees can be up to EUR 90 000 for each application. A flat-rate contribution of EUR 30 000 must be paid by the applicant to the EURL at the beginning of the process, while the remaining EUR 60 000 have to be paid subsequently.

The legislation also foresees the possibility of fees for MS in two sectors (plant protection products and novel food) but does not specify the level of the fees.

The amount of fees charged by the Member States differs significantly from one to another. In the case of active substances for Plant Protection Products, the range of fees charged by the MS rapporteur varies from EUR 23 100 to EUR 450 000. In the case of maximum residues limits of Plant Protection Products, the range of fees varies from EUR 200 to EUR 15 000.

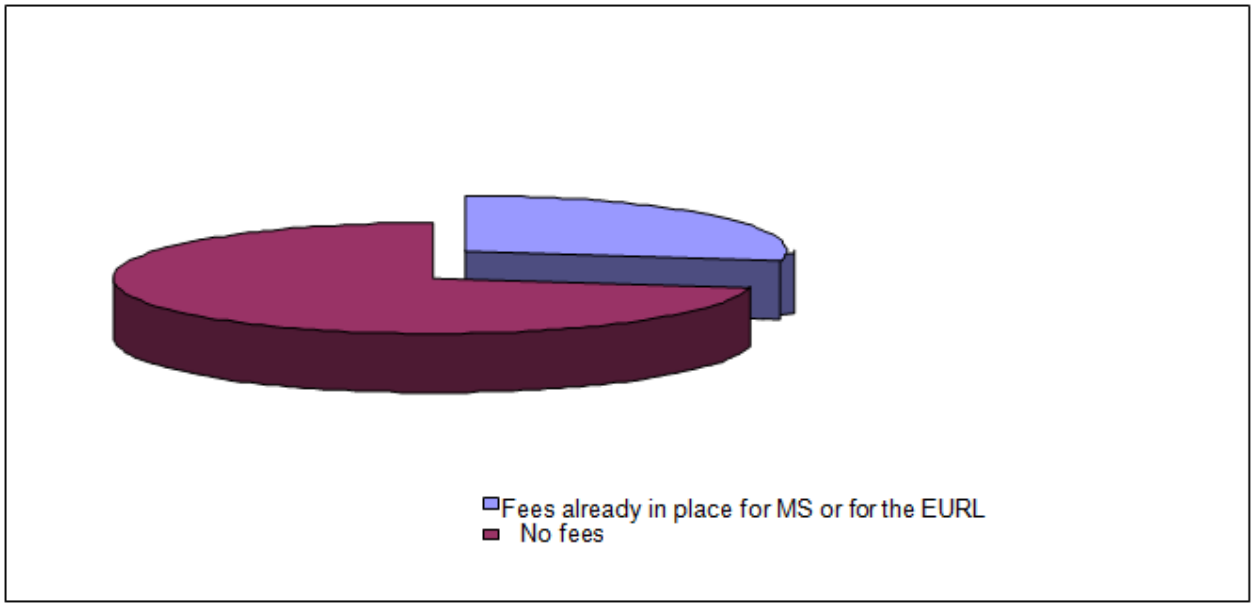
Concerning novel food, some Member States do not charge any fee. Where a fee is in place, it ranges from EUR 830 to EUR 25 000. Many Member States foresee a modulation of fees related to the complexity of the dossier and in certain cases the fee comprises an administrative fee and a scientific fee.
The novel food Regulation foresees the possibility of a simplified procedure. In this case the amount of fees requested ranges from EUR 900 to EUR 2 000. From the table it appears that fees are charged mainly in sectors where there is an authorisation holder. However, fees are charged in the sector of feed additives both for categories of feed additives issued to a specific authorisation holder and for categories of feed additives where the authorisation is generic.

Sector	**Authorisation Holder**	**Fees already in place - at national level or for the EURL-**
GMOs (including GM food/feed)	X	X
PPP	X	X
Smoke Flavourings	X	
Recycling material in contact with food	X	
MRL of PPP	X	X
TSE	X	
Novel Foods	X	X
Feed additives (3 categories)	X	X

Table 3

The chart that follows shows the extent of the sectors where fees are already in place at national level or for the EURL *vs* those where no fees are charged (considering all 19 sectors).

Graph 2.



Based on EFSA's data

8. The applicants

According to each sectorial legislation, different entities may submit an application for authorisation.

The table below shows that in the majority of cases the legal framework offers the possibility to apply to a significant spectrum of actors, from Member States to *"any person established in the Community"*. In addition, the European Commission and EFSA also have the possibility of initiating the process on their own initiative. It should be noted that in some cases the Regulation does not specify who submits the application for authorisation.

The table below states the identification of the possible applicants as mentioned in all 19 vertical legislations:

Table 4

Sectorial Legislation	Who may apply for an authorisation as defined in the sectorial Regulation
1 Food Contact Material	Anyone
2 MRL of PPPs	1. The party who requested from a MS the authorisation for the use of PPP 2. All parties demonstrating a legitimate interest in health 3. Manufacturers, growers, importers and producers 4. MS

3 Food Enzymes	1. MS 2. Interested parties a) Individually b) Collectively 3. COM may ask EFSA on its own initiative
4 Flavourings	1. MS 2. Interested parties a) Individually b) Collectively 3. COM may ask EFSA on its own initiative
5 Smoke Flavourings	Not specified
6 Extraction Solvents	Not specified
7 GMOs	Any person established in the Community
8 Food Additives	1. MS 2. Interested parties a) Collectively b) Individually 3 COM may ask EFSA on its own initiative
9 Health Claims	Food Operators
10 Feed Additives	Any person established in the Community
11 Nutrient Sources	Not specified
12 Animal by products	1. COM 2. MS (following an application) 3. Interested party which may represent several interested parties
13 PPP	1. The producer of an active substance 2. Jointly by an association of producers
14 TSE	1. Any natural or legal person, public or private body established within the EU 2. public or private body established within the EU
15 Infant Formula	Not specified

16 Food Allergies	Not specified
17 Novel Food	"The person responsible for placing the product on the EU market"
18 Antimicrobial treatments	Not specified
19 Recycling Plastics	Anyone

Despite the diversity of potential applicants, all applications are always submitted to the Commission or to a MS which in turn transmits the dossier to EFSA for the delivery of a scientific opinion.

Except in specific cases where Member States may act as the sole applicants (list of claims submitted by Member States in accordance with Article 13.1 of Regulation (EC) No 1924/2006), the applications for authorisations are in practice submitted by the economic operators specific to each sector. A number of sectorial legislations[28] require a precise identification of the applicant (name, address etc.) in the application dossier.

9. Structure and value of the related markets

An aspect related to the identification of the main actors who apply, is the structure and value of the related market.

The sectors involved represent fragmented markets with different characteristics. Some sectors are concentrated with few but large industries producing the regulated products subject to authorisations (e.g. GMOs, plant protection products, flavourings) but with a large number of SMEs or farmers using these products (e.g. PPP). Other sectors involve a larger number of SMEs submitting applications (feed additives). Further analysis and data gathering will be needed on the characteristics of the related markets.

Historical data collected in SANCO showed that the percentage of SMEs, submitting application dossiers for authorisation in the different concerned sectors were:

- 50% in the sector of feed additives

- 25% in the sector of smoke flavourings

- 15% in the sector of MRLs

- 10% in the sector of PPP.

[28] Article 15 (3 a) of Regulation 1929/2006 on claims, Article 7 (3a) of Regulation 2065/2003 (smoke flavourings), Article 5 (3a) of Regulation 1829/2003 (GM food and feed), Article 7 (3a) of Regulation 1831/2003 on feed additives, Article 3 (1) of Regulation 1331/2008 and Article 4 a) of Regulation 234/2011 (common authorisation procedure for food additives, food enzymes and flavourings).

With regard to the other sectors, the percentage of SMEs likely to submit dossiers to EFSA was estimated to be 20% on average.

10. Cost of a dossier for the applicant

A dossier submitted for an authorisation has to respect a set of requirements. Specific legal acts (usually implementing rules), completed by EFSA's guidance, indicate the type and quality of information required. The costs may differ significantly from sector to sector and by type of application. In some cases the cost of preparing an application for authorisation can cost a few hundred EUR, whereas in most cases the cost will be around EUR 350 000 with costs of EUR one Million for complex applications. The costs are linked in particular to the complexity of the scientific evidence required.

11. Number of authorisation applications

The number of authorisation applications received per year by EFSA depends very much on the sector concerned. Some sectors are more dynamic, whilst in other areas the level of requests from industry is rather modest. On average over the period 2003- 2010, the number of authorisation applications received by EFSA per year amounts to 1 182, covering all sectors and types of workflows. However, this data should be broken down to identify the contribution to the total amount of authorisation requests received from the ongoing reviews processes since these specific flows are transitional.

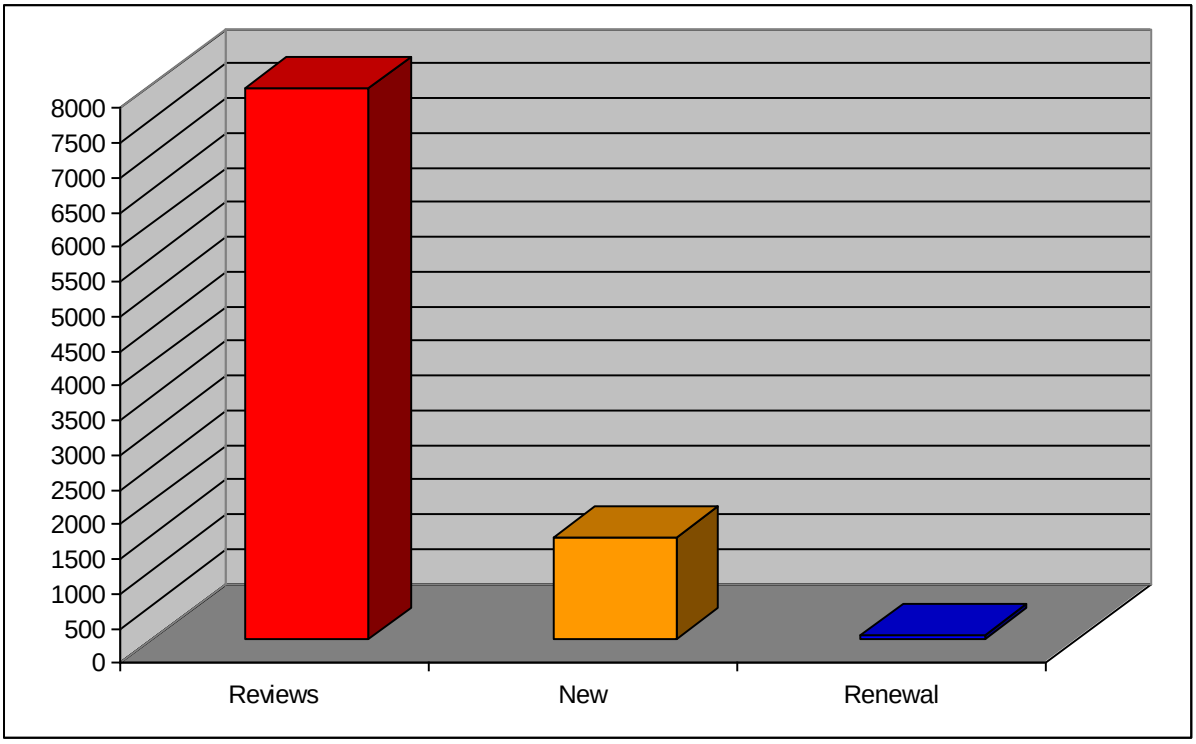
If the three main workflows (new dossiers received and processed by EFSA renewals, reviews of substances already authorised at national or EU level) are considered, the weight of each of them in the workload of EFSA can be identified. In particular, as the graph below shows, the major incidence on EFSA's workload over the period 2003- 2010 was the ongoing review processes of regulated products already on the market.

Number of applications received by EFSA

Regulated products	2003	2004	2005	2006	2007	2008	2009	2010	Total	Average
PPP REVIEW	24	27	33	16	55	37	22	63	277	34.625
PPP NEW	**1**	**2**	**7**	**7**	**7**	**26**	**2**	**4**	**56**	**7**
PPP RENEWAL							**6**	**2**	**8**	**1**
MRL REVIEW						410		1	411	51.375
MRL NEW						**41**	**106**	**108**	**255**	**31.875**
GMO RE VIEW			2		33			4	39	4.875
GMO NEW	**1**	**12**	**27**	**9**	**19**	**15**	**14**	**21**	**118**	**14.75**
GMO RENEWAL									**0**	
Flavourings REVIEW	400	38			253	653	571	84	1 999	249.875
Smoke flavourings REVIEW			16						16	2
Smoke flavourings RE NEWAL								**1**	**1**	
Extraction solvents NEW					**1**				**1**	**0.125**
Food enzymes REVIEW									0	
Food contact material NEW	**79**	**34**	**19**	**31**	**37**	**12**	**45**	**19**	**276**	**34.5**
Food contact material - Recycling processes REVIEW								62	62	7.75
Food additives NEW	**16**	**4**	**8**	**6**	**7**	**8**	**6**	**4**	**59**	**7.375**
Food additives REVIEW	41	1						2	44	5.5
Nutrient sources REVIEW	15	4	234	4	4	1	2	2	266	33.25
Feed additives RE VIEW					2	16	18	149	185	23.125
Feed additives NEW	**31**	**31**	**49**	**29**	**33**	**26**	**26**	**21**	**246**	**30.75**
Feed additives RE NEW		1	1	4	10	9	11	8	44	5.5
TSE NEW	**4**			**1**		**7**			**12**	**1.5**
Animal by-products NEW	**2**	**2**	**2**	**6**	**3**	**1**	**1**	**2**	**19**	**2.375**
Antimicrobial treatments NEW			**3**	**1**					**4**	**0.5**
Health claims RE VIEW						4 187		452	4 639	579.875

Health claims NEW					**5**	**243**	**37**	**27**	**312**	**39**
Novel food NEW	**2**	**8**	**5**	**4**	**7**	**8**	**7**	**4**	**45**	**5.625**
Infant formulae NEW	**3**		**1**		**1**				**5**	**0.625**
Food allergies NEW	**1**	**29**	**3**	**16**	**6**			**2**	**57**	**7.125**
TOTAL	**620**	**193**	**410**	**134**	**483**	**5 700**	**874**	**1 042**	**9 456**	**1 182**

Table 5



Graph 3. Source EFSA September 2011

In particular in the case of the health claims and flavourings review processes, the important incidence on EFSA's workload is evident. Concerning health claims, in 2008 alone, 4 187 dossiers were received for review out of a total of 9 456 dossiers received over the period 2003-2010. In comparison, over the same period, 1 999 dossiers were received for flavourings reviews.

Considering the exceptionality of the reviews, and in order to avoid distortion of the numbers involved, the calculation of the number of dossiers without reviews results over the period 2003-2010 in EFSA receiving 1 518 dossiers concerning authorisation applications, which on average means 189 dossiers per year.

It can be also useful to note that some of the important reviews mentioned (around 2 500 flavourings; around 4 000 claims) will be finalised by end 2012 (except the claims on botanicals that the Commission put on hold). After 2012, there will still be on-going reviews (around 250 food additives; around 220 applications for feed additives covering around 1 200

feed additives; around 400 MRLs) but they are less important, partly done (90 applications already processed for feed additives) and are more spread out over the years.

In addition, given that a series of reviews were linked to the re-structuration of the food safety legislation adopted in the framework of the White paper program on food safety[29], it is plausible that no new significant reviews will be launched in the next years.

[29] White paper on Food Safety 12 January 2000 COM (1999) 719 final

Table 6. **Number of authorisation applications received by EFSA per year excluding REVIEWS**

Regulated Products	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**Total**	**Average**
PPP NEW	**1**	**2**	**7**	**7**	**7**	**26**	**2**	**4**	**56**	**7**
PPP RENEWAL							**6**	**2**	**8**	**1**
MRL NEW						**41**	**106**	**108**	**255**	**31.875**
GMO NEW	**1**	**12**	**27**	**9**	**19**	**15**	**14**	**21**	**118**	**14.75**
GMO RENEWAL									**0**	
Smoke flavourings RE NEWAL								**1**	**1**	
Extraction solvents NEW					**1**				**1**	**0.125**
Food contact material NEW	**79**	**34**	**19**	**31**	**37**	**12**	**45**	**19**	**276**	**34.5**
Food additives NEW	**16**	**4**	**8**	**6**	**7**	**8**	**6**	**4**	**59**	**7.375**
Feed additives NEW	**31**	**31**	**49**	**29**	**33**	**26**	**26**	**21**	**246**	**30.75**
Feed additives RE NEW		**1**	**1**	**4**	**10**	**9**	**11**	**8**	**44**	**5.5**
TSE NEW	**4**			**1**		**7**			**12**	**1.5**
Animal by-products NEW	**2**	**2**	**2**	**6**	**3**	**1**	**1**	**2**	**19**	**2.375**
Antimicrobial treatments NEW			**3**	**1**					**4**	**0.5**
Health claims NEW					**5**	**243**	**37**	**27**	**312**	**39**
Novel food NEW	**2**	**8**	**5**	**4**	**7**	**8**	**7**	**4**	**45**	**5.625**
Infant formulae NEW	**3**		**1**		**1**				**5**	**0.625**
Food allergies NEW	**1**	**29**	**3**	**16**	**6**			**2**	**57**	**7.125**
Total	**140**	**123**	**125**	**114**	**136**	**396**	**261**	**223**	**1 518**	**189.30**

Calculation based on EFSA's data

Table 7. **Number of authorisation applications related to authorisation holders received by EFSA per year**

Regulated Products	2003	2004	2005	2006	2007	2008	2009	2010	Total	AVG
PPP NEW	1	2	7	7	7	26	2	4	56	7
PPP RENEWAL	0	0	0	0	0	0	6	2	8	1
MRL NEW	0	0	0	0	0	41	106	108	255	31.88
GMO NEW	1	12	27	9	19	15	14	21	118	14.75
GMO RENEWAL	0	0	0	0	0	0	0	0	0	0
Smoke flavourings RE NEWAL	0	0	0	0	0	0	0	1	1	0
TSE NEW	4	0	0	1	0	7	0	0	12	1,5
Feed additives NEW	26.2	26.2	41.41	24.51	27.89	21.7	21.7	21	210.61	26.33
Feed additives RENEWAL		1	1	4	10	9	11	8	44	5.5
Novel food NEW	2	8	5	4	7	8	7	4	45	5,63
Total	34.2	49.2	81.41	49.51	70.89	127.7	167.7	169	749.61	93.75

calculation based on EFSA's data

It should be noted that, out of the 1 474 dossiers received over the period 2003-2010, 749 were related to authorisation holders.

Concerning the scientific **output** produced by EFSA, table 8 shows that on average 716 dossiers and dossier-related documents are issued by the Agency. This number includes the relevant impact of health claims and flavourings as mentioned above.

If the review of health claims and flavourings is excluded the average number of outputs would be 202 per year.

Table 8. Number of applications dossiers processed (including reviews and dossiers withdrawn by applicants before delivery of the EFSA's scientific opinion) by EFSA

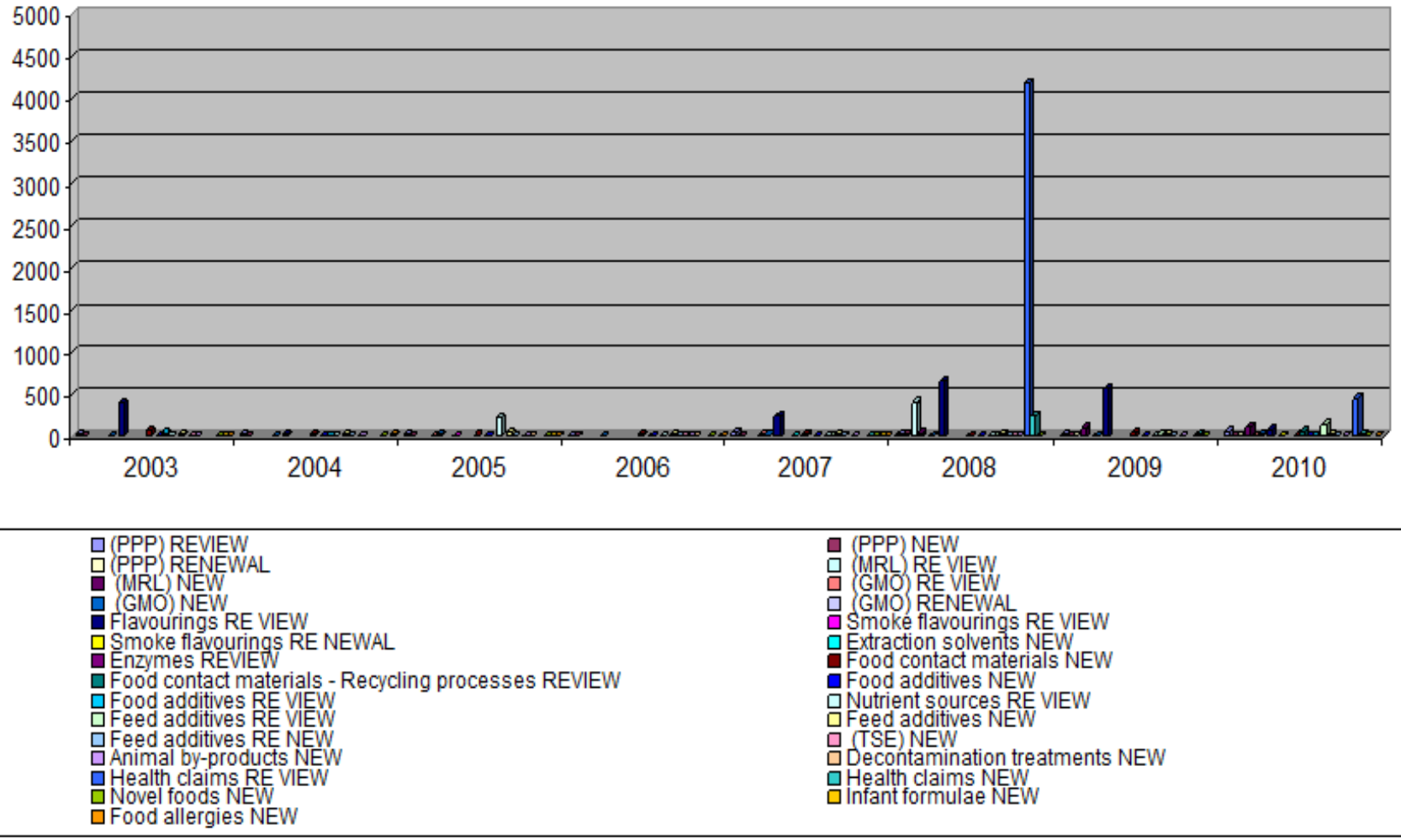
Regulated Products	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**Total**
Active substances (PPP) REVIEW		1	18	29	12	62	21	65	**208**

Active substances (PPP) NEW			2	1	8		9	1	**21**
Active substances (PPP) RENEWAL								7	**7**
MRL REVIEW							5	4	**9**
MRL NEW					3	23	87	81	**194**
GMO REVIEW					2	1	17	8	**28**
GMO NEW		2	10	7	5	10	17	15	**66**
GMO RENEWAL									**0**
Flavourings REVIEW		8	28	51	466	519	728	92	**1 892**
Smoke flavourings REVIEW			1		1	1	11		**14**
Smoke flavourings RENEWAL									**0**
Extraction solvents NEW							1		**1**
Food enzymes REVIEW									**0**
Food contact materials NEW	3	56	31	20	24	17	31	15	**197**
Recycling processes REVIEW									**0**
Food additives NEW		6	4	7	5	3	8	17	**50**
Food additives REVIEW						2	6	11	**19**
Nutrient sources REVIEW	4	6	3	8	20	72	147	4	**264**
Feed additives REVIEW							4	13	**17**
Feed additives NEW	6	32	31	32	32	24	27	15	**199**
Feed additives RENEWAL			1	3	7	7	9	13	**40**
TSE NEW		1	3	1		1	4		**10**
Animal by-products NEW	1	2	1	2		2	2	2	**12**
Antimicrobial treatments NEW			1	3					**4**
Health claims REVIEW							1 059	1 130	**2 189**

Health claims NEW						65	56	65	**186**
Novel foods NEW	2	1	8	3	3	11	5	7	**40**
Infant formulae NEW		3	1			1			**5**
Food allergies NEW		22	10	1	22				**55**
TOTAL	**16**	**140**	**153**	**168**	**610**	**821**	**2 254**	**1 565**	**5 727**

Source EFSA JUNE 2011

Graph 4. Dossiers received by EFSA per sector



12. Costs of evaluating application dossiers for EFSA

Given the number and the heterogeneity of sectors covered by EFSA, it is logic that the evaluation of the cost of applications for EFSA has to be done sector by sector.

It is necessary to break down all the activities required to assess the applications, to identify the time required for each activity, and to quantify the costs. It is important to identify how costs that are linked to general services, such as the development of guidelines, should be attributed or shared. The cost of the services rendered, together with the relationship between the costs per dossier, its complexity and the quality should also be taken into consideration, together with the impact on resources, time etc.

According to EFSA, the main costs involved in the processing of application dossiers are: EFSA staff, infrastructure (building, supplies etc.), meetings (experts), outsourcing (grants and procurement), operating support (missions of EFSA staff, IT, translations).

For each sector EFSA was asked to provide data on the cost (on average) of processing a typical dossier in order to identify the resources needed. A separate calculation of the cost of preparing the guidelines has been requested in order to differentiate this activity from the processing of dossiers.

Table 9.

Substance/Product/claim+ procedure	**Average cost of a dossier EUR**	**Average cost of guidelines EUR**
PPP REVIEW	75 500	31 000
PPP NEW	75 000	31 000
PPP RENEWAL	/	/
MRL RE VIEW	6 800	/
MRL NEW	6 800	/
GMO RE VIEW	135 000	76 600
GMO NEW	135 000	76 000
GMO RENEWAL	/	/
Flavourings RE VIEW	37 800	4 000
Smoke flavourings RE VIEW	37 800	/
Smoke flavourings RE NEWAL	37 800	/
Extraction solvents NEW	/	/
Food enzymes REVIEW	/	/
Food contact materials NEW	37 800	4 000

Food contact materials - Recycling processes REVIEW	37 800	
Food additives NEW	77 500	1 600
Food additives RE VIEW	120 000	1 600
Nutrient sources RE VIEW	71 000	1 600
Feed additives RE VIEW	55 600	2 300
Feed additives NEW	55 600	2 300
Feed additives RE NEW	33 400	1 400
TSE NEW	/	/
Animal by-products NEW	130 500	4 000
Antimicrobial treatments NEW	113 400	10 000
Health claims RE VIEW	59 300	13 700
Health claims NEW	59 300	13 700
Novel food NEW	83 100	5 900
Infant formulae NEW	83 100	/
Food allergies NEW	49 400	/
GMO application for cultivation	283 600	160 000

12. ANNEX VI FIXED AND VARIABLE COSTS OF EFSA'S PANELS AND SUPPORTING UNITS ASSESSING APPLICATION DOSSIERS*

	PRAS (active substance + MRL)	BIOHAZ	FIP-CEF	FIP-ANS	FEED	GMO	NUTRI
Fixed costs							
EFSA staff	53%	51%	44%	40%	38%	25%	43%
Infrastructure	14%	10%	10%	10%	9%	6%	14%
Operating support	3%	7%	4%	6%	5%	5%	3%
Overheads	12%	13%	12%	14%	13%	9%	13%
Out of which collection costs (excluding IT systems dev/maint)	0.9%	1.0%	0.9%	1.0%	1.0%	0.7%	1.0%
TOTAL FIXED	**82%**	**81%**	**70%**	**70%**	**65%**	**45%**	**73%**
Variable costs							
Meetings	3%	13%	14%	28%	19%	13%	19%
Outsourcing	-	1%	7%	-	11%	6%	-
Guidance	15%	5%	9%	2%	5%	36%	8%
TOTAL VARIABLE	**18%**	**19%**	**30%**	**30%**	**35%**	**55%**	**27%**
Grand Total	100%	100%	100%	100%	100%	100%	100%

* PRAS = EFSA's structure dealing with applications related to PPP and MRL of PPP (including peer review process)

BIOHAZ = Panel on Biological Hazards and and corresponding EFSA's Unit dealing with applications related to TSE test, animal-by-product and antimicrobial treatments.

FIP-CEF = Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and corresponding EFSA's Unit (FIP) dealing with applications related to flavourings, smoke flavourings, extraction solvents, food enzymes and food contact materials (including recycling plastic processes).

FIP-ANS = Panel on Food Additives and Nutrient Sources Added to Food (ANS) and corresponding EFSA's Unit (FIP) dealing with applications related to food additives and nutrient sources.

FEED = Panel on Additives and Products or Substances used in Animal Feed and corresponding EFSA's Unit dealing with applications related to feed additives.

GMO = Panel on GMO and corresponding EFSA's Unit dealing with applications related to genetically modified organisms and genetically modified food and feed.

NUTRI = Panel on Dietetic Products, Nutrition and Allergies and corresponding EFSA's Unit dealing with applications related to health claims, novel food, infant formulae and food allergies.

13. ANNEX VII DIFFERENCES BETWEEN ECHA AND EFSA SYSTEMS

As it happens for substances/products authorised within the EFSA system, chemical substances/products are used in many different end products. The EU chemicals industry has a key position in the value chain. A series of operators (biocides, plastics, pesticides for example) are also concerned by the two legislative frameworks governing chemical safety and food safety.

The chemical and food legislative framework on safety are however based on **completely different premises**.

The ECHA system relies on the principle that chemical substances might contain hazardous **properties but, if managed properly, can be safely used**. The distinction between hazard and risk is, therefore, key to the safe management of chemicals. Chemicals are mainly used by industry and only a limited range of products are sold to final consumers.

The approach adopted within the ECHA system is that industry itself is best placed to ensure that the chemicals it manufactures and puts on the EU market do not adversely affect human health and environment. To this end, industry has to have sufficient knowledge of the properties and characteristics of chemical substances to be able to manage their potential risks properly.

The EU chemical sector is therefore based on the principle "no data, no access to the market" and a registration system was established to put in a concrete form this principle. The registration of chemical substances aims at providing data on all chemical substances produced and imported in the EU in a tonnage per year exceeding 1 tonne. The registration and other tools linked to it (i.e. classification and labelling, safety data sheets) ensure that sufficient knowledge on substances is given to the relevant actors of the chemical chain in order to adequately manage the risks.

Only substances of very high concern are submitted to restrictions and authorisation. Where there is an unacceptable risk to health or the environment, restrictions at the EU level concerning the manufacture, placing on the market or use or prohibition of any of these activities may also be imposed. Proposals for restrictions may be prepared by a Member State or by the Agency on behalf of the Commission in the form of a structured dossier that shall demonstrate that there is a risk to human health or the environment that needs to be addressed at EU level and to identify the most appropriate set of risk reduction measures. ECHA manages several tools and support the whole system.

The food legislative system on safety and the tools used in that field are based on different principles due to the specificity of risks linked to food. The risk of exposure always exists in that sector since food is consumed every day by final consumers. In addition, consumers cannot take any risk management measures on substances foodstuffs contain. For this reason all food legislations are based on the principle that **only safe food can be put on the market**. This principle implies that all substances added to food or that can be present as residues in food are subject to an authorisation before being put on the market (pre-market approval). Such pre-market approvals exist since the beginning of the EU (the harmonisation of national systems is in place since the beginning of the XX century) and they now cover all safety issues linked to the addition of substances in food. Since substances ingested by animals can be found in food pre-market approvals cover also feed.

The use of a registration system instead of a pre-market approval would not guarantee an adequate protection to consumers. Even if the latter knew the characteristics of substances

contained in food or sold as a food (e.g. sweeteners) they could not take any measure at their level to avoid the risk or limit it, except by not consuming it. Labelling and information are not sufficient to protect them.

As a consequence, it is not possible to align the chemical safety system and the food one because each one is tailored to the specificity of the risks in its own area.

Also, from a **legal point of view**, the putting in place of a registration system for EFSA would require the modification of the legislation regulating the 19 sectors falling under EFSA's mandate. In addition, historically the REACH system required the registration of all chemical substances because 99% of the substances on the market were unknown. This involved a rather high cost for industry (€2.1 billion for the first registration period[30]). A similar need for registration of substances used in the food sector does not exist because they have been subject to a pre-market approval since a long time and they are thus known.

As far as the fee system is concerned, the **number of applications** received by the two agencies is significantly different. ECHA received roughly 6 900 applications per year from 2008 to 2011, while EFSA from 2003 to 2010 received on average 189 (without reviews) applications per year. This has a great impact on the income the Agency can get from fees. However, in the food legislative framework, it is not possible to identify a larger series of operators as fee-payers than applicants for generic and individual authorisation. It would also not be justified to create a system requiring a large number of operators to register because the safety of substances/products added to food have already been assessed and authorised since a long time.

Moreover, tasks of ECHA mostly relate to the registration of chemicals substances. This is reflected in its system of fees that provide for the payment of a fee in the following cases:

- *Submission of a registration;*
- *Request (in a registration submission) that certain information is kept confidential;*
- *Update of a registration submission that refers to a change in the tonnage range;*
- *Update of a registration submission that relates to a change in the identity of the legal personality of the registrant;*
- *Update of a registration submission that relates to a change in the access granted contained in the registration submission;*
- *Notification to the Agency of product and process orientated research and development activities, with a view to obtain an exemption from the obligation to register;*
- *Application for an authorisation under Article 62 of the REACH Regulation;*
- *Appeals to the Board of Appeals of the Agency against decisions of the Agency listed in Article 91(1) of the REACH Regulation.*

On the contrary, the tasks of EFSA relate to the risk assessment process linked to the authorisation of substances/products added to food or that can be present as residues in food (residues of pesticides for example).

If a registration system was not to be put in place for EFSA, only ECHA authorisation tasks and the correlated fee could be considered as a relevant example for EFSA. However, the procedure for authorisation foreseen in the ECHA system is rather peculiar since it is aimed at ensuring that the risk is properly controlled and favouring substitutes.

[30] See, CSES, *Interim Evaluation: Functioning of the European chemical market after the introduction of REACH*, 30 March 2012, available at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/market-final-report_en.pdf.

Manufacturers, importers or downstream users need to apply for an authorisation for every use of the substance and applications have *inter alia* to include an analysis of possible substitutes (substitution plan). However, in cases where the risk cannot be completely eliminated, an authorisation can still be given for a particular use if the socio-economic benefits of such use are superior to the risk. The authorisation is given to a specific company and is not applicable to any other. The company has thus a direct benefit from the authorisation application and the corresponding fee paid has a direct link to the work performed by ECHA.

Given the specificities of these types of application, it is not possible to compare it with an EFSA application dossier for authorisation. In addition, until now no authorisation dossier has yet been submitted to ECHA from industry, so no practical experience on this type of dossier has been gained by the Agency.

14.

ANNEX VIII DIFFERENCES BETWEEN EMA AND EFSA SYSTEMS

Some figures related to EMA need to be considered in order to understand why the EMA system is not applicable to EFSA. As a matter of fact, the EFSA system differs in many aspects from EMA's one. First of all, the two **markets** (pharmaceutical and food) in which the agencies operate are rather different. The majority of actors operating within the pharmaceutical sector are big firms, while the food sector is largely composed of smaller enterprises. Moreover, profits that pharmaceutical companies can make by putting in the market authorised products are much higher than those of firms operating in the food sector.

Secondly, from a **legal point of view** two main differences can be detected. According to pharmaceutical legislation all applications for a centralised authorisation follows the same administrative procedure, while in the food sector sector-based legislations provide for a number of different authorisation procedures (i.e. 19). Also, authorisations issued by EMA are individual (only the applicants can benefit from it). On the contrary, a large number of authorisations issued by EFSA are generic (any firm can commercialize the authorised product or substance).

Finally, the **type and quantity of work** related to the authorisation procedure that the two Agencies carry out is not comparable.

The number of applications received each year differs significantly for **EMA** (roughly **5500 per year**) [31] and **EFSA** (roughly **180 per year**). Fee revenue of EMA has increased by nearly four-fold between 2000 and 2009 largely due to an increase in the number of procedures. However the relative contribution of the main procedure types to the revenue is relatively stable with on average 10% derived from scientific advice, scientific services and maximum residue limits, 19% from marketing authorisation assessment, 42% from post-authorisation assessment, 24% from annual fees, 2% from inspections, and 4% from administrative activities, namely parallel distribution and certificates (see, figure 6 and 7, EMA, *Report to the European Commission on the implementation of Council Regulation (EC) No 297/95 of 10 February 195 on fees payable to the European Medicines Agency*, 2010).

Most of the fees received by EMA are linked to the specificity of the medicinal products area and cannot be applied to EFSA.

In particular, EMA has introduced the payment of different fees for a **variety of different services** provided by the Agency (for example, new applications, variations, post-monitoring etc.)

[31] EMA received in 2011 5500 dossiers for medicinal product for human use. The number includes all applications subject to the payment of fees, such as new products first evaluation, variations and renewals (see, EMA, *Monthly statistics report: January 2012*, available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000256.jsp&mid=WC0b01ac0580099fbb).

The number of EFSA activities is less varied. The only services provided by EFSA according to the Founding regulation (Reg. CE n. 178/2002) are the **assessment of authorisation dossiers** and, in certain cases (GMOs, feed additives and pesticides), the assessment of **authorisation dossiers linked to the renewal** of an authorisation. In some cases, the legislation provides for a review of old substances (but it is an *ad hoc* procedure limited to a specific time period). Contrary to EMA, EFSA has no control/vigilance activity since these activities in the food sector are performed by MS control authorities.

Given that fees have to be linked to a service provided by EFSA, the different categories of EMA fees (related to different services provided by the Agency) are considered below to check whether it would be possible to apply these fees for EFSA.

- **post authorisation assessments**. They represent the highest amount of fees for EMA. These post authorisation assessments are linked to the need to assess and to authorise each new strength/potency, each new pharmaceutical form and each new presentation of a medicinal product.

Except in the case of feed additive where in order to protect animal health and public health there is a need to assess dossiers on **extension of use of an additive to other species,** these post authorisation procedures do not exist in the food sector or are managed at risk management level (case of extension of use to other categories of foodstuffs of a food additive). The post authorisation EMA dossiers also relate to specific legislative provisions that do not exist in the food area, such as the assessment of generic medicinal products after the expiration of the data exclusivity period or the possibility of granting a conditional authorisation subject to the submission of additional studies.

- **the annual fees**. EMA annual fees are linked to the following tasks: the recording of the actual marketing of medicinal products authorised in accordance with Community procedures, the maintenance of marketing authorisation dossiers and of the various databases managed by the Agency, as well as the continuous follow-up of the risk-benefit balance of authorised medicinal products. These types of activities are necessary in the medicinal products area since the cost/benefit ratio needs to be confirmed or infirmed by post monitoring/pharmacovigilance. It is also made feasible by the requirement to have an authorisation holder responsible for monitoring the product and by the fact that a medicinal product is administered by medical doctors. Also, it has to be stressed that while medicinal products monitoring is justifiable by the fact that a medicinal product may have side effects on health, food products or substances are authorised only if they are considered to be safe. In the food sector post monitoring activities are not foreseen because in most cases, there is no authorisation holder responsible for monitoring the authorised substance/product and it is almost impossible to keep track of possible adverse effects that substances included as an ingredient in thousands of different foodstuffs or feedstuff may have. **The only case where there would be a possibility to ask for some kind of post monitoring fee for EFSA** is the GMO sector since the specific legislation provides for the submission of an annual monitoring report by the authorisation holder to EFSA. However, such a fee could also be considered as

duplicating the fee for renewal of GMOs since the renewal procedure includes, inter alia, the assessment of these post monitoring reports.

It is also important to note that it does not seem feasible to ask fees for the production by EFSA of reports on residues of pesticides and on medicinal veterinary drugs since the link with the applicant for the authorisation of such substances is in EMA for veterinary drugs and at Member State level for plant protection products. In addition, the most expensive part of the monitoring work is linked to the collation of data and is performed by MSs' control authorities (sampling and analysis + synthesis of national data before transmission to EFSA). EFSA is only producing a synthesis of the national data. It could also be argued that these reports are made for public health purposes and are not linked to any applicant's specific benefit.

Finally, since most of the food sectors are under the regime of a generic authorisation, it would not be justifiable to have an annual fee paid by an applicant for the monitoring of a substance that can be produced, imported and used by all firms.

- **inspections fees and certificates fees** are linked to the fact that EMA is not only a risk assessor but has also a competence for control and pharmacovigilance. These competences do not exist for EFSA.

- **the parallel distribution issue** is linked to the differences that exists among national legislation on medicinal products (i.e. different levels of reimbursement) and does not exist in the food area.

Conclusions

Among the current services provided by EFSA, only the assessment of new dossiers, the assessment of renewal dossiers and the assessment of requests for extension of use in the feed additives sector can generate fees.

The considerations above also demonstrate why there is a structurally limited number of dossiers eligible for fees in EFSA. It has also to be noted that in the area of pesticides, the fact that only the active substances are assessed at EU level significantly reduces the number of dossiers submitted to EFSA (around 500 active substances authorised at EU level but more than 10 000 preparations authorised at national level)

It is for the reasons mentioned above that it is not possible to apply the EMA system to EFSA. The only possibility to create new fees would be to revise completely all the **sectorial procedures. Even in these cases, however, most of the fees provided for in the EMA system would not be possible to be introduced.**

15. ANNEX IX THE INTERNATIONAL CONTEXT

Table 1. Comparative table

	Type of application	***Fees***	***Type of fees***	***Reductions or exclusions from fees***	***Public authority responsible***
U.S.A.					
Food and feed	Generic	NO	-	-	FDA *Food and Drug Administration*
		Except for: - specific services (i.e. a*nalytical certificates for colours*)	—		
Pesticides	Authorization holder	YES	- registration fee - annual fee	- Small business (up to 75%) - withdrawal of application	EPA *Environmental Protection Agency*
Australia - New Zealand					
Food and feed	Generic	NO	-	-	FSANZ *Food Standards Australia New Zealand*
		Except for: - exclusive commercial benefit (*authorization holder*) - expedite procedure (*upon applicant request*)	- application fee	- withdrawal of application - rejection of application	
Pesticides	Authorization holder	YES	- registration fee - annual fee		APVMA (Australia) EPA (New Zealand)
Japan					
Food and feed	Generic	NO	_		FSC *Food Safety Committee*
Pesticides	Generic	NO	_	_	FSC *Food Safety Committee*

FEES IN THE U.S. FOOD AND FEED SYSTEM

- **PESTICIDES AND CHEMICALS**

PUBLIC AUTHORITY RESPONSIBLE: **United States Environmental Protection Agency (EPA)**

Premises:

- all pesticides must be registered (except for some cases) (see, *sec. 3, FIFRA, May 22, 2008*, p. 16);
- the registration allows for a period of exclusivity of 15 years for the data submitted by the applicant: the data provided cannot be used for other application unless the new applicant offer a compensation to the original data submitter (see, *sec. 3, FIFRA, May 22, 2008*, p. 18);

Two main types of fees are provided for by the legislation:

1) Registration service fee (see, *sec. 33, FIFRA, May 22, 2008*, p. 98);

2) Maintenance fee (see, *sec. 4(i) (5), FIFRA, May 22, 2008*, p. 51 ss).

In order to align the current system with the previous one, FIFRA provide also for the payment of a cumulative fee by registrants of pesticide containing any active ingredient contained in any pesticide first registered before Nov. 1984 (see, sec. *sec. 4(i)(1)(2)(3)(4), FIFRA, May 22, 2008*, p. 36 ss).

* *

1) Registration service fee (see, *sec. 33, FIFRA, May 22, 2008*, p. 97 ss)

A registration service fee is due upon submission of the application (see, *sec. 33, FIFRA, May 22, 2008*, p. 98)

Actions that require a payment of a fee:

- New Active Ingredient
- New Use (As Defined in 40 CFR 152.3)
- Experimental Use Permit (As defined in 40 CFR 172.2)

Amount of fees

The fee prescribed by the following table must be submitted with each application for registration, amended registration or experimental use permit. Fees will be adjusted annually in accordance with §152 410. The Agency may waive or refund fees in accordance with §152 412.

Table—Registration Fees

Type of review	**Fee**
New chemical	$ 184 500
New biochemical or microbial	$ 64 000
New use pattern	$ 33 800
Experimental use permit	$ 4 500
Old chemical	$ 4 000
Amendment	$ 700

[53 FR 19114, May 26, 1988, as amended at 58 FR 34203, June 23, 1993]

Relevant reductions:

- SMALL BUSINESS: reduction from 50% up to 75% (see, *sec. 33, FIFRA, May 22, 2008*, p. 100);
- WITHDRAWAL: - within 60 days after submission (75% refund)
  - after 60 days after submission (up to 75% refund proportionate to the work done)

In any case 25% of fee is not refundable (maximum of refund, credit or reduction is 75%) (see, *sec. 33, FIFRA, May 22, 2008*, p. 98)

Relevant exemptions:

- REVIEW of confirmatory data submitted in support of an already-issued registration;
- AGENCY-INITIATED AMENDMENTS (e.g., label amendments to comply with a registration eligibility decision);
- RESUBMISSION: resubmission for the same pesticide by the same person (or a licensee, assignee, or successor of the person) of an application which has previously not been approved or withdrawn is exempted from the payment of fees for the resubmission (see, *sec. 33, FIFRA, May 22, 2008*, p. 99);

Use of money collected for fees: cover costs associated with the review and decision-making (see, *sec. 33, FIFRA, May 22, 2008*, p. 102)

2) Maintenance fees (see, *sec. 4(i)(5), FIFRA, May 22, 2008*, p. 51 ss)

All products which have to be registered (*sec. 3 and section 24(c) of FIPRA*, respectively p. 16 ss and p. 88-89) are subject to an annual maintenance fee which varies from year to year depending on the authorizing legislation.

There is a possibility of waiver for minor agricultural use products and public health pesticides (maintenance fees may not be waived due to the small business status of the applicant)

Maximum amount of fees:

GENERAL:

- registrant with less than 50 registered pesticide: $ 71 000
- registrant with more than 50 registered pesticide: $ 123 000

SMALL BUSINESS:

- registrant with less than 50 registered pesticide: $ 50 000
- registrant with more than 50 registered pesticide: $ 86 000

- **FOOD**

PUBLIC AUTHORITY RESPONSIBLE: **United States Food and Drug Administration (FDA)**

Premises:

- Under US food law FDA food-related activities are mainly funded through the public budget;
- Fees are provided only for specific services and the money collected are used to cover the cost of the services.

Under the current system the following types of fees are envisaged:

1) Certification fees

- **Colour additives** (see, *Code of Federal Regulations, Title 21, Part 80*)
- **Export certification for food and animal feed** (see, *sec. 801(e)(4)(B) of the Federal Food Drug and Cosmetic Act*)

2) Non compliance inspection fees (re-inspection and food-recall activities) (see *sec. 107, Food Safety Modernization Act, Jan. 4, 2011*)

3) Voluntary qualified importer program (see, *sec. 302, Food Safety Modernization Act, Jan. 4, 2011*)

* *

1) <u>Certification fees</u>

- **Colour additives** (see, *Code of Federal Regulations, Title 21, Part 80*)

According to law anybody can ask for a certification that a particular colour additive complies with the relevant rules.

In order for the certificate to be issued the applicant should pay a fee. The amount of the fee to be paid varies according to the quantity of the pounds of the batch covered by the requests (minimum fee $ 224).

- **FDA-regulated products exported** (see, *sec. 801(e)(4)(B) of the Federal Food Drug and Cosmetic Act*)

The Federal Food, Drug, and Cosmetic Act (FD&C Act) provide for the issuance of export certificate upon request of the exporters. Certificates state that the product meets certain requirements of law and the purpose of the certificates is to promote the export of products made in the United States.

The issuance of the certificate is subject to the payment of a fee up to $175 per certificate. Fees shall be collected and available solely for the costs of the Food and Drug Administration associated with issuing such certifications

2) <u>Non compliance inspection fees (re-inspection and food-recall activities)</u> (see *sec. 107, Food Safety Modernization Act, Jan. 4, 2011*)

The Food Safety Modernization Act has entrusted the FDA with the power to charge fees on stakeholder for the follow up activities related to the infringement of food law. Costs of re-inspection or food-recall related activities are thus paid by the inspected in order to ensure that facilities that fail to comply with health and safety standards bear the cost of their unlawful acts.

In 2010 the amount of money which was foreseen to be collected for re-inspection was $25 848 000.

SMALL BUSINESS: no fee reduction

The financial year 2012 budget does not contain any reduced fee rate for small business. However, during the financial year 2012 FDA will consider waiving in limited cases and is studying the possibility to introduce fee reductions for SB.

3) <u>Voluntary qualified importer program</u> (see, *sec. 302, Food Safety Modernization Act, Jan. 4, 2011*)

The program, introduced by the *Food Safety Modernization Act* of 2011, gives the possibility to importers who (on a voluntary basis) ask the FDA to be admitted to this program for a certain fiscal year, to obtain the expedited review and importation of designated foods.

Fees are collected to cover the administrative costs of such program for each year.

FEES IN THE AUSTRALIA NEW ZEALAND

FOOD AND FEED SYSTEM

- **PESTICIDES AND CHEMICALS**

PUBLIC AUTHORITY RESPONSIBLE (AUSTRALIA): **Australian Pesticides and Veterinary Medicines Authority (APVMA)**

Premise:

- all pesticides must be registered;

Two main types of fees are provided for by the legislation:

1) **Application fee** (see, *Agricultural and Veterinary Chemicals Code Act, 1994*);
2) **Annual fee** (see, *Agricultural and Veterinary Chemicals Code Act, 1994*)**.**

- **Levies**

The Australian system has introduced also the obligation for the authorisation holder to pay levies on the sales of products which contain registered substances.

A levy is payable on all sales for each product greater than $5 000. The amount to be paid depends on the dollar value of sales on an annual basis.

* * *

1) Application fee (see, *Agricultural and Veterinary Chemicals Code Act, 1994*)

Is due upon submission of the application

Actions that require a payment of a fee:

- New products or active constituents / labels
- Variations of products or active constituents / labels

Amount of fees:

The amount of fees varies according to the different categories. Also, for some categories they are fixed (from $545 up to $53 745), while for others they are modular and the total amount is calculated by adding the cost of different steps of the procedure (i.e. screening $505, finalisation $2 230).

Relevant reductions or exemptions:

No reductions or exemptions are provided for.

However, when an applicant voluntarily WITHDRAWS an application during screening, or the APVMA treats the application as having been withdrawn during screening, the APVMA will refund the application fee apart from the screening component.

Also, if the APVMA REJECTS an application at screening, it will refund the application fee apart from the screening component.

2) Annual fee: (see, *Agricultural and Veterinary Chemicals Code Act, 1994*)

An annual fee is due by the application holder to maintain product registration for the next financial year.

Amount of fees:

The amount of the annual fee is: $430.

* * *

PUBLIC AUTHORITY RESPONSIBLE (NEW ZEALAND): **Environmental Protection Authority (EPA)**

Premise:

- pesticides must be assessed only if they are hazardous;

One main type of fee is provided for by the legislation:

1) Application fee: is due upon submission of the application

Amount of fees:

The application fees vary depending on the complexity of the application and the length of time it takes to process. Some fees are negotiable.

- Rapid assessment application (low or reduced hazard, similar to substances already approved): the fee is NZ$57 500
- Full release application (all other files): fee depends on the complexity of the application and it's up to NZ$1 725 000

Relevant reductions or exemptions:

No reductions or exemptions are provided for but for special applications fees may be negotiated.

- **FOOD**

PUBLIC AUTHORITY RESPONSIBLE: **Food Standards Australia New Zealand (FSANZ)**

Premises:

- the FSANZ is a regulatory Agency which issue standards concerning food related issues;
- standards are listed in a Code (*Australia New Zealand Food Standards Code*) which may be amended upon request of any interested party;
- successful applications to vary a standard in the *Code* lead to a modification of the relevant part of the code;
- as a consequence, everybody may benefit of the amendment for which it has been submitted the successful application (there are no application holders)
- Under Australia New Zealand food law FSANZ food-related activities are mainly funded through the public budget;
- Fees are envisaged under special circumstances.

Under the current system the following types of fees are provided for:

1) Exclusive capturable commercial benefit fee (see, *sec. 8, Food Standards Australia New Zealand Act*, 1991, p.8);

If the applicant can be considered the only person or body who will economically benefit from the coming into effect of the draft standard for which the application is being submitted, the applicant has to pay the full cost of processing the application.

The fee is due upon the receipt by the applicant of the notice that the application has been accepted

2) Expedited procedure fee (see, *sec. 27, Food Standards Australia New Zealand Act*, 1991, p. 25)

The fees have to be paid if the applicant asks for the procedure of assessment to be started immediately.

The fee is due upon the receipt by the applicant of the notice that the application has been accepted

<u>Amount of fees</u>:

The amount of fees to be paid depends on the type of procedure which the Agency decide that should be applied and are due in order to cover the costs of processing the application.

Procedure	Hours	Hourly Charge	Admin Charge	Total Fees $AUD	Indicative Total Fees $NZ[1]
Minor Procedure	Maximum of 100 hours	11,500	10,000	21,500	26,875
General Procedure	Maximum of 350 hours	40,250	10,000	50,250	62,815
	Maximum of 650 hours	74,750	10,000	84,750	105,940
	Maximum of 1000 hours	115,000	10,000	125,000	156,250
	More than 1000 hours	115,000+**	10,000	125,000+**	156,250+
Major Procedure	1200 hours or more	138,000***	10,000	148,000+***	185,000+

* The figures above are therefore only indicative, calculated on an exchange rate of $AUD1 = $NZ1.25.
** If FSANZ determines, under the FSANZ Regulations, that the application consideration process is likely to require more than 1000 hours, a surcharge of $AUD115 per hour will apply for each completed hour.
*** If FSANZ determines, under the FSANZ Regulations, that the application consideration process is likely to require more than 1200 hours, a surcharge of $AUD115 per hour will apply for each completed hour.

Reductions or exemptions:

No reductions or exemptions are provided for by the rules.

However, if the application is a paid application and is withdrawn or rejected (under certain circumstances), fees may be partially refundable, in accordance with the FSANZ Regulations.

FEES IN THE JAPANESE FOOD AND FEED SYSTEM

The Food Safety Commission (FSC) is entirely funded by public budget and it does not charge any fee to applicants. FSC is an independent risk assessment body and not directly receive any dossiers from applicants concerned, but through risk management bodies (i.e. Ministry of Agriculture, Forestry and Fisheries (MAFF), Ministry of Health, Labor and Welfare (MHLW)).

MAFF, when receiving dossiers, charges application fees to those who wish authorization or approvals for marketing of pesticides, veterinary drugs, fertilizers or feeds. Those items are strictly regulated by respective laws or requirements under the authorization of MAFF. Prior to MAFF's authorization for their use or marketing, MAFF seeks FSC for risk assessments, which will be used in its decision making process for market approval. The fees charged by MAFF covers only relevant administration costs of MAFF, but not include any cost of FSC's work on risk assessments.

As for MHLW, applicants are not required to pay any fees for the use of food additives or marketing of GM foods because the authorization of MHLW is generic and benefits public in consumption of foods concerned.

16. ANNEX X FEES REGIME UNDER OPTION 2

Fees for Industry/ Applicant under Option 2

The amount of the fee in each sector is 1) the cost of assessing an average dossier in each specific sector which includes: direct costs (EFSA Staff, Infrastructure (building, supplies etc.), Meetings (experts), Outsourcing (grants and procurement), and Operating support (Missions of EFSA staff, IT, translations) + 2) overheads (16% of direct costs)

+ 3) Collection cost of fees (8% of overheads)

Option 2			

Costs of guidelines have been excluded from the calculation as they are considered public service.

Sector	type of dossier	FEES FOR SMES	FEES FOR REGULAR APPLICANTS
PPP	NEW	€ 7 630	€ 76 307
MRL	NEW	€ 687	€ 6 872
GMO	NEW	€ 13 734	€ 137 346
Smoke Flavouring	NEW	€ 3 826	€ 38 261
Flavouring	NEW	€ 3 826	€ 38 261
Extraction solvents	NEW	€ 3 826	€ 38 261
Food contact material	NEW	€ 3 826	€ 38 261
Recycling Plastics Processes	NEW	€ 3 826	€ 38 261
Food additives	NEW	€ 7 837	€ 78 374
Feed additives	NEW	€ 5 624	€ 56 242
TSE	NEW	€ 6 052	€ 60 524
Animal by-products	NEW	€ 13 198	€ 131 985
Antimicrobial treatments	NEW	€ 11 476	€ 114 760
Food allergies	NEW	€ 4 994	€ 49 944
Health claims	NEW	€ 6 010	€ 60 109
Novel food	NEW	€ 8 408	€ 84 086
Infant formulae	NEW	€ 8 408	€ 84 086
Enzymes	NEW	€ 7 521	€ 75 211
Nutrient sources	NEW	€ 7 181	€ 71 810
GMO	RENEWAL	€ 13 734	€ 137 346
Feed additives	RENEWAL	€ 3 378	€ 33 784
PPP	RENEWAL	€ 7 630	€ 76 307
Smoke Flavourings	RENEWAL	€ 3 826	€ 38 261

17. IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS OPTION 2

EFSA FEES INCOME OPTION 2 FROM REGULAR APPLICANTS[32]		2012	2013	2014	2015	TOT	AVG
PPP	NEW	534 149 €[33]	839 377 €	915 684 €	915 684 €	3 204 894 €	801 224 €
MRL	NEW	639 096 €	639 096 €	776 536 €	776 536 €	2 831 264 €	707 816 €
GMO	NEW	1 373 460 €	1 373 460 €	1 373 460 €	1 373 460 €	5 493 840 €	1 373 460 €
Smoke Flavouring	NEW	0 €	0 €	0 €	0 €	0 €	0 000 €
Flavouring	NEW	765 220 €	765 220 €	765 220 €	765 220 €	3 060 880 €	765 220 €
Extraction solvents	NEW	19 131 €	19 131 €	19 131 €	19 131 €	76 522 €	19 131 €
Food contact material	NEW	1 300 874 €	1 300 874 €	1 760 006 €	1 760 006 €	6 121 760 €	1 530 440 €
Recycling Plastics Processes	NEW	153 044 €	153 044 €	38 261 €	38 261 €	382 610 €	95 653 €
Food additives	NEW	626 992 €	626 992 €	626 992 €	626 992 €	2 507 968 €	626 992 €
Feed additives	NEW	1 068 598 €	1 068 598 €	1 068 598 €	1 068 598 €	4 274 392 €	1 068 598 €
TSE	NEW	30 262 €	0 €	0 €	0 €	30 262 €	7 566 €
Animal by-products	NEW	131 985 €	131 985 €	131 985 €	131 985 €	527 940 €	131 985 €

[32] The percentage of regular applicants is on average 80% of the number of dossiers except (based on historical data) for PPP (90%), MRL (85%), Smoke flavourings (75%), Feed additives (50%) and TSE (75%). The numbers issued from percentage were rounded, except in case of small number of dossier per year. When only one dossier per year, half of the fee was taken into account.

[33] The euro symbol is automatically put after the number by excel

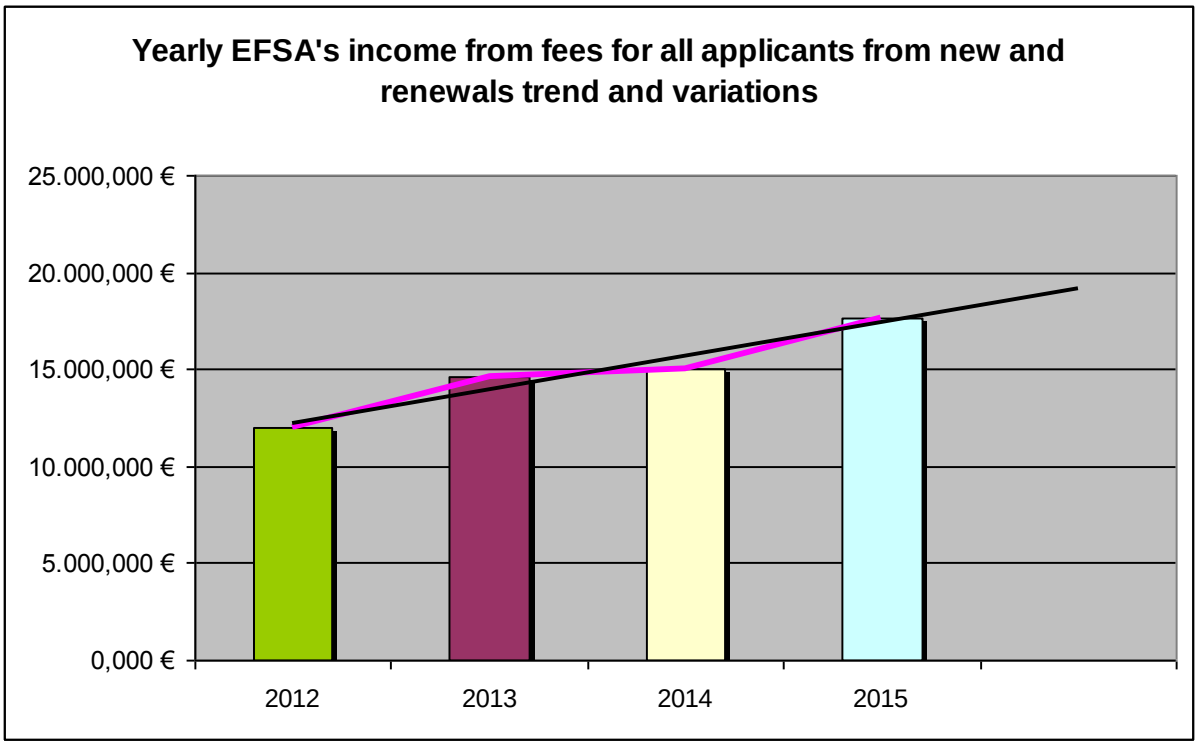
Antimicrobial treatments	NEW	229 520 €	229 520 €	229 520 €	229520 €	918 080 €	229 520 €
Health claims	NEW	1 202 180 €	1 202 180 €	1 202, 80 €	1 202 180 €	4 808 720 €	1 202 180 €
Novel food	NEW	336 344 €	336 344 €	1 009 032 €	1 009 032 €	2 690 752 €	672 688 €
Infant formulae	NEW	4 204 €	42 043 €	42 043 €	42 043 €	130 333 €	32 583 €
Food allergies	NEW	0€	24 972 €	24 972 €	24 972 €	74 916 €	18 729 €
Enzymes	NEW	0 €	0 €	0 €	0 €	0 €	0 €
Nutrient sources	NEW	287 240 €	359 050 €	430 860 €	574 480 €	1 651 630 €	412 908 €
GMO	RENEWAL	0 €	0 €	0 €	137 346 €	137 346 €	34 337 €
Feed additives	RENEWAL	0 €	0 €	135 136 €	168 920 €	304 056 €	76 014 €
PPP	RENEWAL	152 614 €	1 907 675 €	763 070 €	2 594 438 €	5 417 797 €	1 354 449 €
Smoke Flavourings	RENEWAL	0 €	0 €	0 €	0 €	0 €	0 €
TOT		**8 854 913 €**	**11 019 561 €**	**11 312 686 €**	**13 458 804 €**	**44 645 962 €**	**11 161 491 €**

18. IMPACT ON EFSA'S BUDGET OF FEES FROM SMES OPTION 2

Sector[34]	type of dossier	2012	2013	2014	2015	tot	avg
PPP	NEW	6 105 €	9 157 €	9 920 €	9 920 €	35 101 €	8 775 €
MRL	NEW	11 339 €	11 339 €	13 400 €	13 400 €	49 478 €	12 370 €
GMO	NEW	35 710 €	35 710 €	35 710 €	35 710 €	142 840 €	35 710 €
Smoke Flavouring	NEW	0 €	0 €	0 €	0 €	0 €	0 €
Flavouring	NEW	19 131 €	19 131 €	19 131 €	19 131 €	76 522 €	19 131 €
Extraction solvents	NEW	765 €	765 €	765 €	765 €	3 061 €	765 €
Food contact material	NEW	32 139 €	32 139 €	44 383 €	44 383 €	153 044 €	38 261 €
Recycling Plastics Processes	NEW	3 826 €	3 826 €	1 530 €	1 530 €	10 713 €	2 678 €
Food additives	NEW	15 675 €	15 675 €	15 675 €	15 675 €	62 699 €	15 675 €
Feed additives	NEW	106 860 €	106 860 €	106 860 €	106 860 €	427 439 €	106 860 €
TSE	NEW	1 513 €	0 €	0 €	0 €	1 513 €	378 €
Animal by-products	NEW	5 279 €	5 279 €	5 279 €	5 279 €	21 118 €	5 279 €
Antimicrobial treatments	NEW	4 590 €	4 590 €	4 590 €	4 590 €	18 362 €	4 590 €
Health claims	NEW	30 055 €	30 055 €	31 257 €	30 055 €	121 420 €	30 355 €
Novel food	NEW	8 409 €	8 409 €	25 226 €	25 226 €	67 269 €	16 817 €

[34] The percentage of SME applicants is on average 20% of the number of dossiers except (based on historical data) for PPP (10%), MRL (15%), Smoke flavourings (25%), Feed additives (50%) and TSE (25%). The numbers issued from percentage were rounded, except in case of small number of dossier per year. When only one dossier per year, half of the fee was taken into account.

Infant formulae	NEW	1 682 €	1 682 €	1 682 €	1 682 €	6 727 €	1 682 €
Food allergies	NEW	0 €	999 €	999 €	999 €	2 997 €	749 €
Enzymes	NEW	0 €	0 €	0 €	0 €	0 €	0 €
Nutrient sources	NEW	7 181 €	8 617 €	11 490 €	14 362 €	41 650 €	10 412 €
GMO	RENEWAL	0 €	0 €	0 €	2 747 €	2 747 €	687 €
Feed additives	RENEWAL	0 €	0 €	3 378 €	4 054 €	7 432 €	1 858 €
PPP	RENEWAL	4 578 €	48 836 €	19 840 €	65 624 €	138 879 €	34 720 €
Smoke Flavourings	RENEWAL	0 €	0 €	0 €	0 €	0 €	0 €
Tot		**294 836 €**	**343 068 €**	**351 114 €**	**401 992 €**	**1 391 011 €**	**347 753 €**


Yearly EFSA's income from fees for all applicants from new and renewals trend and variations
25.000,000 €
20.000,000 €
15.000,000 €
10.000,000 €
5.000,000 €
0,000 €
2012
2013
2014
2015

19. ANNEX XI FEES REGIME UNDER *SUB-OPTION 2*

Sub - option 2			
Sector	**type of dossier**	**FEES FOR SMES**	**FEES FOR REGULAR APPLICANTS**
GMO	NEW	€ 13 734	€ 137 346
Smoke Flavouring	NEW	€ 3 826	€ 38 261
Flavouring	NEW	€ 3 826	€ 38 261
Extraction solvents	NEW	€ 3 826	€ 38 261
Food contact material	NEW	€ 3 826	€ 38 261
Recycling Plastics Processes	NEW	€ 3 826	€ 38 261
Food additives	NEW	€ 7 837	€ 78 374
Feed additives	NEW	€ 5 624	€ 56 242
TSE	NEW	€ 6 052	€ 60 524
Animal by-products	NEW	€ 13 198	€ 131 985
Antimicrobial treatments	NEW	€ 11 476	€ 114 760
Food allergies	NEW	€ 4 994	€ 49 944
Health claims	NEW	€ 6 010	€ 60 109
Infant formulae	NEW	€ 8 408	€ 84 086
Enzymes	NEW	€ 7 521	€ 75 211
Nutrient sources	NEW	€ 7 181	€ 71 810
GMO	RENEWAL	€ 13 734	€ 137 346
Feed additives	RENEWAL	€ 3 378	€ 33 784
PPP	RENEWAL	€ 7 630	€ 76 307
Smoke Flavourings	RENEWAL	€ 3 826	€ 38 261

20.

IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS SUB-OPTION 2[35]

EFSA FEES INCOME OPTION 2 FROM REGULAR APPLICANTS		2012	2013	2014	2015	TOT
GMO	NEW	€ 1 373 460	€ 1 373 460	€ 1 373 460	€ 1 373 460	€ 5 493
Smoke Flavouring	NEW	€ -	€ -	€ -	€ -	€
Flavouring	NEW	€ 765 220	€ 765 220	€ 765 220	€ 765 220	€ 3 060
Extraction solvents	NEW	€ 19 131	€ 19 131	€ 19 131	€ 19 131	€ 76
Food contact material	NEW	€ 1 300 874	€ 1 300 874	€ 1 760 006	€ 1 760 006	€ 6 121
Recycling Plastics Processes	NEW	€ 153 044	€ 153 044	€ 38 261	€ 38 261	€ 382
Food additives	NEW	€ 626 992	€ 626 992	€ 626 992	€ 626 992	€ 2 507
Feed additives	NEW	€ 1 068 598	€ 1 068 598	€ 1 068 598	€ 1 068 598	€ 4 274
TSE	NEW	€ 30 262	€ -	€ -	€ -	€ 30
Animal by-products	NEW	€ 131 985	€ 131 985	€ 131 985	€ 131 985	€ 527
Antimicrobial treatments	NEW	€ 229 520	€ 229 520	€ 229 520	€ 229 520	€ 918
Health claims	NEW	€ 1 202 180	€ 1 202 180	€ 1 202 180	€ 1 202 180	€ 4 808
Infant formulae	NEW	€ 4 204	€ 42 043	€ 42 043	€ 42 043	€ 130
Food allergies	NEW	€ -	€ 24 972	€ 24 972	€ 24 972	€ 74
Enzymes	NEW	€ -	€ -	€ -	€ -	€
Nutrient sources	NEW	€ 287 240	€ 359 050	€ 430 860	€ 574 480	€ 1 651
GMO	RENEWAL	€ -	€ -	€ -	€ 137 346	€ 137
Feed additives	RENEWAL	€ -	€ -	€ 135 136	€ 168 920	€ 304
Smoke Flavourings	RENEWAL	€ -	€ -	€ -	€ -	€
TOT		**€ 7 192 710**	**€ 7 297 069**	**€ 7 848 364**	**€ 8 163 114**	**€ 30 501**

IMPACT ON EFSA'S BUDGET OF FEES FROM SMES SUB-OPTION 2[36]

[35] For calculations, modalities mentioned in footnote 5 of Annex XI were used.

[36] For calculations, modalities mentioned in footnote 7 of Annex XI were used.

SECTOR	type of dossier	2012	2013	2014	2015
GMO	NEW	€ 35 710	€ 35 710	€ 35 710	€ 35 710
Smoke Flavouring	NEW	€ -	€ -	€ -	€ -
Flavouring	NEW	€ 19 131	€ 19 131	€ 19 131	€ 19 131
Extraction solvents	NEW	€ 765	€ 765	€ 765	€ 765
Food contact material	NEW	€ 32 139	€ 32 139	€ 44 383	€ 44 383
Recycling Plastics Processes	NEW	€ 3 826	€ 3 826	€ 1 530	€ 1 530
Food additives	NEW	€ 15 675	€ 15 675	€ 15 675	€ 15 675
Feed additives	NEW	€ 106 860	€ 106 860	€ 106 860	€ 106 860
TSE	NEW	€ 1 513	€ -	€ -	€ -
Animal by-products	NEW	€ 5 279	€ 5 279	€ 5 279	€ 5 279
Antimicrobial treatments	NEW	€ 4 590	€ 4 590	€ 4 590	€ 4 590
Health claims	NEW	€ 30 055	€ 30 055	€ 31 257	€ 30 055
Infant formulae	NEW	€ 1 682	€ 1 682	€ 1 682	€ 1 682
Food allergies	NEW	€ -	€ 999	€ 999	€ 999
Enzymes	NEW	€ -	€ -	€ -	€ -
Nutrient sources	NEW	€ 7 181	€ 8 617	€ 11 490	€ 14 362
GMO	RENEWAL	€ -	€ -	€ -	€ 2 747
Feed additives	RENEWAL	€ -	€ -	€ 3 378	€ 4 054
Smoke Flavourings	RENEWAL	€ -	€ -	€ -	€ -
Tot		**€ 264 406**	**€ 265 328**	**€ 282 729**	**€ 287 822**

21. ANNEX XII FEES REGIME UNDER OPTION 3

The amount of the fee in each sector is 1) the cost of assessing an average dossier in each specific sector which includes: direct costs (EFSA Staff, Infrastructure (building, supplies etc.), Meetings (experts), Outsourcing (grants and procurement), Operating support (Missions of EFSA staff, IT, translations) + 2) overheads (16% of direct costs)

+ 3) collection cost of fees (8% of overheads)

Costs of guidelines have been excluded from the calculation as they are considered public service.

Option 3			
Sector	**type of dossier**	**FEES FOR SMES**	**FEES FOR REGULAR APPLICANTS**
PPP	NEW	7 630€	76 307 €
MRL	NEW	687€	6 872 €
GMO	NEW	13 734€	137 346 €
Feed additives	NEW	5 624€	56 242 €
TSE	NEW	6 052€	60 524 €
Smoke Flavouring	NEW	3 826€	38 261 €
Recycling Plastics Processes	NEW	3 826€	38 261 €
Novel food	NEW	8 408€	84 086 €
GMO	RENEWAL	13 734€	137 346 €
Feed additives	RENEWAL	3 378€	33 784 €
PPP	RENEWAL	7 630€	76 307 €
Smoke Flavourings	RENEWAL	3 826€	38 261 €

22. IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS OPTION 3

Sector with authorisation holder[37]	type of dossier	2012	2013	2014	2015	TOT	AVG
PPP	NEW	534 149 €	839 377 €	915 684 €	915 684 €	3 204 894 €	801 224 €
MRL	NEW	639 096 €	639 096 €	776 536 €	776 536 €	2 831 264 €	707 816 €
GMO	NEW	1 373 460 €	1 373 460 €	1 373 460 €	1 373 460 €	5 493 840 €	1 373 460 €
Feed additives (14,5%)	NEW	154 947 €	154 947 €	154 947 €	154 947 €	619 787 €	154 947 €
TSE	NEW	30 262 €	0 €	0 €	0 €	30 262 €	7 566 €
Smoke Flavouring	NEW	0 €	0 €	0 €	0 €	0 €	0 €
Recycling Plastics Processes	NEW	153 044 €	153 044 €	38 261 €	38 261 €	382 610 €	95 653 €
Novel food	NEW	336 344 €	336 344 €	1 009 032 €	1 009 032 €	2 690 752 €	672 688 €
GMO	RENEWAL	0 €	0 €	0 €	137 346 €	137 346 €	34 337 €
Feed additives	RENEWAL	0 €	0 €	135 136 €	168 920 €	304 056 €	76 014 €
PPP	RENEWAL	152 614 €	1 907 675 €	763 070 €	2 594 438 €	5 417 797 €	1 354 449 €
Smoke Flavourings	RENEWAL	0 €	0 €	0 €	0 €	0 €	0 €
TOT		**3 373 916 €**	**5 403 943 €**	**5 166 126 €**	**7 168 624 €**	**21 112 608 €**	**5 278 152 €**

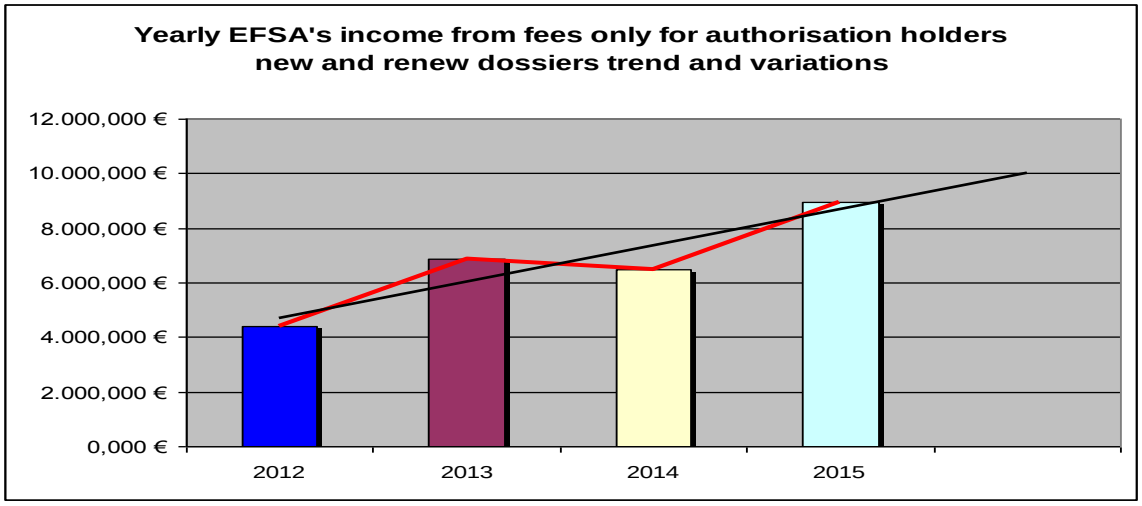
23. IMPACT ON EFSA'S BUDGET OF FEES FROM SMES OPTION 3

Sectors with authorisation holder[38]	type of dossier	2012	2013	2014	2015	TOT	AVG
PPP	NEW	6 105 €	9 157 €	9 920 €	9 920 €	35 101 €	8 775 €

[37] For calculations, modalities mentioned in footnotes 5 of Annex XI were used.

[38] For calculations, modalities mentioned in footnotes 7 of Annex XI were used

MRL	NEW	11 339 €	11 339 €	13 400 €	13 400 €	49 478 €	12 370 €
GMO	NEW	35 710 €	35 710 €	35 710 €	35 710 €	142 840 €	35 710 €
TSE	NEW	1 513 €	0 €	0 €	0 €	1 513 €	378 €
Feed additives Partly (14,5%)	NEW	15 190 €	15 190 €	15 190 €	15 190 €	60 760 €	15 190 €
Smoke Flavourings	NEW	0 €	0 €	0 €	0 €	0 €	0 €
Recycling Plastics Processes	NEW	3 826 €	3 826 €	1 530 €	1 530 €	10 713 €	2 678 €
Novel Food	NEW	8 409 €	8 409 €	25 226 €	25 226 €	67 269 €	16 817 €
GMO	RENEWAL	0 €	0 €	0 €	2 747 €	2 747 €	687 €
Feed additives 14,5%	RENEWAL	0 €	0 €	3 378 €	4 054 €	7 432 €	1 858 €
PPP	RENEWAL	4 578 €	48 836 €	19 840 €	65 624 €	138 879 €	34 720 €
Smoke Flavourings	RENEWAL	0 €	0 €	0 €	0 €	0 €	0 €
TOT		**86 670 €**	**132 467 €**	**124 195 €**	**173 402 €**	**516 733 €**	**129 183 €**



24. ANNEX XIII FEES REGIME UNDER *SUB-OPTION 3*

25.

Sub - option 3			
Sector	**type of dossier**	**FEES FOR SMES**	**FEES FOR REGULAR APPLICANTS**
GMO	NEW	13 734 €	137 346 €
Feed additives	NEW	5 624 €	56 242 €
TSE	NEW	6 052 €	60 524 €
Smoke Flavouring	NEW	3 826 €	38 261 €
Recycling Plastics Processes	NEW	3 826 €	38 261 €
GMO	RENEWAL	13 734 €	137 346 €
Feed additives	RENEWAL	3 378 €	33 784 €
PPP	RENEWAL	7 630 €	76 307 €
Smoke Flavourings	RENEWAL	3 826 €	38 261 €

26.

27. IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS SUB-OPTION 3[39]

Sectors with authorisation holder and fully evaluated by EFSA	type of dossier	2012	2013	2014	2015	TOT	AVG
GMO	NEW	1 373 460 €	1 373 460 €	1 373 460 €	1 373 460 €	5 493 840 €	1 373 46 €
Feed additives	NEW	15 495 €	15 495 €	15 495 €	15 495 €	61 979 €	15 495 €
TSE	NEW	3 026 €	0 €	0 €	0 €	3 026 €	757 €
Smoke Flavouring	NEW	0 €	0 €	0 €	0 €	0 €	0 €
Recycling Plastics Processes	NEW	15 304 €	153 €	3 826 €	3 826 €	38 261 €	9 565 €
GMO	RENEWAL	0 €	0 €	0 €	13 735 €	13 735 €	3 434 €
Feed additives	RENEWAL	0 €	0 €	13 514 €	16 892 €	30 406 €	7 601 €
Smoke Flavourings	RENEWAL	0 €	0 €	0 €	0 €	0 €	0 €

[39] For calculations, modalities mentioned in footnotes 5 of Annex XI were used.

TOT		171 171 €	168 145 €	170 180 €	18 7293 €	696 790 €	174 198 €

28. IMPACT ON EFSA'S BUDGET OF FEES FROM SMES SUB-OPTIONS 3[40]

Sectors with authorisation holder	type of dossier	2012	2013	2014	2015	TOT	AVG
GMO	NEW	3 571 €	3 571 €	3 571 €	3 571 €	14 284 €	3 571 €
TSE	NEW	151 €	0 €	0 €	0 €	151 €	38 €
Feed additives Partly (14,5%)	NEW	1 519 €	1 519 €	1 519 €	1 519 €	6 076 €	1 519 €
Smoke Flavourings	NEW	0 €	0 €	0 €	0 €	0 €	0 €
Recycling Plastics Processes	NEW	383 €	383 €	153 €	153 €	1 071 €	268 €
GMO	RENEWAL	0 €	0 €	0 €	275 €	275 €	69 €
Feed additives 14,5%	RENEWAL	0 €	0 €	338 €	405 €	743 €	186 €
Smoke Flavourings	RENEWAL	0 €	0 €	0 €	0 €	0 €	0 €
TOT		5 624 €	5 473 €	5 581 €	5 923 €	22 600 €	5 650 €

[40] For calculations, modalities mentioned in footnote 7 of Annex XI were used.

29. ANNEX XIV FEES REGIME UNDER OPTION 4

30.

Option 4			
FORECASTING			
Sector	**type of dossier**	**FOR REGULAR APPLICANTS**	**FEES FOR SMES**

PPP	NEW	**NA**	
MRL	NEW	NA	
GMO	NEW	40 000/90 000€	4 000€
Smoke Flavouring	NEW	13 000 €	1 300 €
Flavouring	NEW	13 000 €	1 300 €
Extraction solvents	NEW	13 000 €	1 300 €
Food contact material	NEW	13 000 €	1 300 €
Recycling Plastics Processes	NEW	13 000 €	2 500 €
Food additives	NEW	25 000 €	2 500 €
Feed additives	NEW	25 000 €	2 500 €
TSE	NEW	25 000 €	2 500 €
Animal by-products	NEW	40 000 €	4 000 €
Antimicrobial treatments	NEW	40 000 €	4 000 €
Health claims	NEW	25 000 €	2 500 €
Novel food	NEW	NA	
Infant formulae	NEW	40 000 €	
Food allergies	NEW	13 000 €	1 300 €
Enzymes	NEW	25 000 €	2 500 €
Nutrient sources	NEW	25 000 €	2 500 €
Feed additives	RENEWAL	13 000 €	1 300 €

31. IMPACT ON EFSA'S BUDGET OF FEES FROM REGULAR APPLICANTS OPTION 4

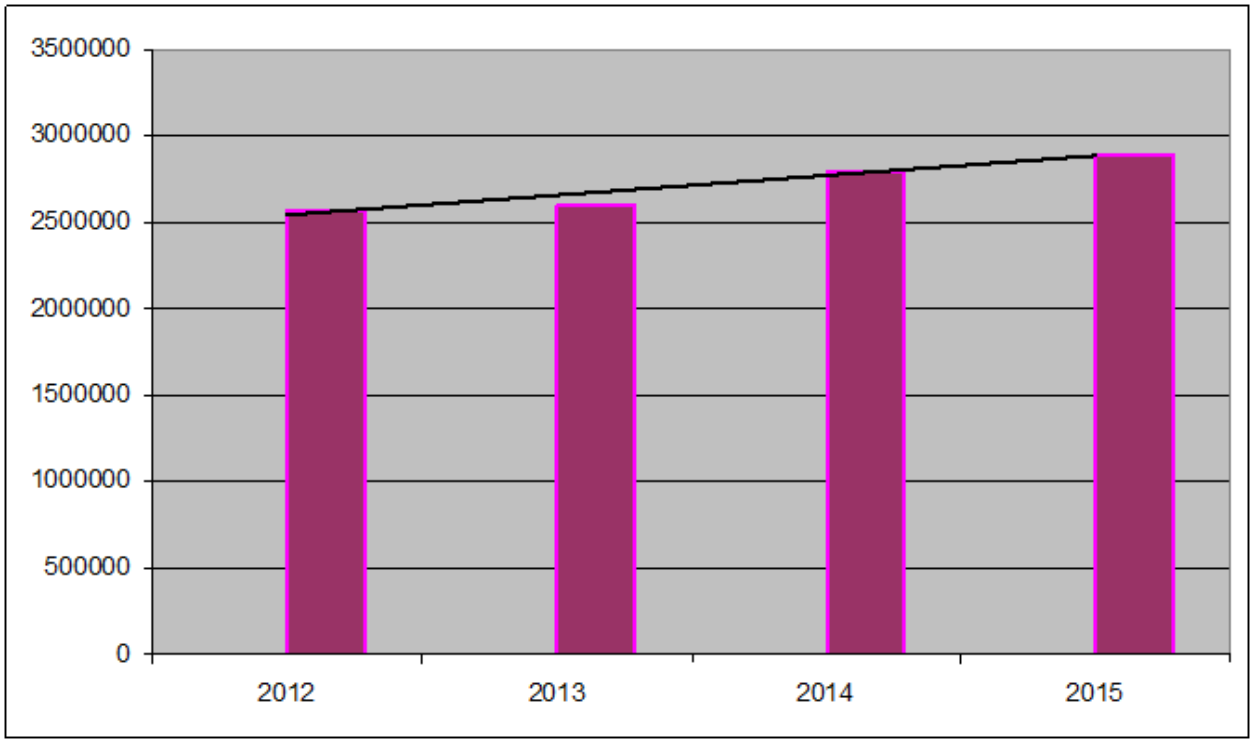
Sector	**type of dossier**	**2012**	**2013**	**2014**	**2015**	**tot**	**avg**
PPP	NEW	NA					
MRL	NEW	NA					
GMO	NEW	400 000 €	400 000 €	400 000 €	400 000 €	1 600 000 €	400 00
Smoke Flavouring	NEW	0 €	0 €	0 €	0 €	0 €	
Flavouring	NEW	260 000 €	260 000 €	260 000 €	260 000 €	1 040 000 €	260 00
Extraction solvents	NEW	6 500 €	6 500 €	6 500 €	6 500 €	26 000 €	6 50
Food contact material	NEW	442 000 €	442 000 €	598 000 €	598 000 €	2 080 000 €	520 00
Recycling Plastics Processes	NEW	52 000 €	52 000 €	13 000 €	13 000 €	130 000 €	32 50
Food additives	NEW	200 000 €	200 000 €	200 000 €	200 000 €	800 000 €	200 00
Feed additives	NEW	475 000 €	475 000 €	475 000 €	475 000 €	1 900 000 €	475 00
TSE	NEW	12 500 €	0 €	0 €	0 €	12 500 €	3 12
Animal by-products	NEW	40 000 €	40 000 €	40 000 €	40 000 €	160 000 €	40 00
Antimicrobial treatments	NEW	80 000 €	80 000 €	80 000 €	80 000 €	320 000 €	80 00
Health claims	NEW	500 000 €	500 000 €	500 000 €	500 000 €	2 000 000 €	500 00
Novel food	NEW		0 €	0 €	0 €	0 €	
		0 €	0 €	0 €	0 €	0 €	
Infant formulae	NEW	0 €	20 000 €	20 000 €	20 000 €	60 000 €	15 00
Food allergies	NEW	0 €	0 €	0 €	0 €	0 €	
Enzymes	NEW	100 000 €	125 000 €	150 000 €	200 000 €	575 000 €	143 75
Nutrient sources	NEW	0 €	0 €	0 €	25 000 €	25 000 €	6 25
Feed additives	RENEWAL	0 €	0 €	52 000 €	65 000 €	117 000 €	29 25
		2 568 000 €	2 600 500 €	2 794 500 €	2 882 500 €	10 845 500 €	**2 711 37**

32. IMPACT ON EFSA'S BUDGET OF FEES FROM SMES OPTION 4

Sector	type of dossier	2012	2013	2014	2015	tot	avg
GMO	NEW	52 000 €	52 000 €	52 000 €	52 000 €	208 000 €	52 000 €
Smoke Flavouring	NEW	- €	- €	- €	- €	- €	- €
Flavouring	NEW	32 500 €	32 500 €	32 500 €	32 500 €	130 000 €	32 500 €
Extraction solvents	NEW	1 300 €	1 300 €	1 300 €	1 300 €	5 200 €	1 300 €
Food contact material	NEW	54 600 €	54 600 €	75 400 €	75 400 €	260 000 €	65 000 €
Recycling Plastics Processes	NEW	12 500 €	12 500 €	50 000 €	5 000 €	35 000 €	8 750 €
Food additives	NEW	25 000 €	25 000 €	25 000 €	25 000 €	100 000 €	25 000 €
Feed additives	NEW	95 000 €	95 000 €	95 000 €	95 000 €	380 000 €	95 000 €
TSE	NEW	2 500 €	0 €	0 €	0 €	2 500 €	625 €
Animal by-products	NEW	8 000 €	8 000 €	80 000 €	80 000 €	32 000 €	8 000 €
Antimicrobial treatments	NEW	8 000 €	0 €	0 €	0 €	8 000 €	2 000 €
Health claims	NEW	62 500 €	0 €	0 €	65 000 €	127 500 €	31 875 €
Food allergies	NEW	- €	13 000 €	13 000 €	13 000 €	3 900 €	975 €
Enzymes	NEW	- €	- €	- €	- €	- €	- €

Nutrient sources	NEW	12 500 €	1 500 €	20 000 €	25 000 €	72 500 €	18 125 €
Feed additives	RENEW AL	0 €	0 €	6 500 €	7 800 €	14 300 €	3 575 €
		3 664 000 €	2 972 000 €	3 220 000 €	3 933 000 €	1 378 900 €	**344 725 €**

33. YEARLY EFSA'S INCOME OPTION 4



34. ESTIMATED ANNUAL COSTS FOR EFSA OPTION 4

TABLE 2 list of additional services and their estimated annual costs

Services proposed by EFSA	Estimated annual costs (Euro)
Pre-submission and post adoption assistance to applicants	
Annual meetings with applicants for each area of REPRO (+BIOHAZ)	**400 000**
Workshops within each area / training on administrative aspects	**190 000**
Workshops within each area / training on scientific aspects	**300 000**
Individual applicant pre-submission meetings (administrative)	**220 000**
Individual applicant pre-submission meetings (scientific)	**400 000**
Individual applicant post-adoption meetings (scientific)	**190 000**
Total	**1 700 000**
Service Desk for extended and closer contacts with applicants	
Help desk	**100 000**
Phone helpdesk	**130 000**
Total	**230 000**

SMEs	
Operate an APDESK SME team in Parma	**200 000**
Operate an APDESK SMEs web space on EFSA webpage	**50 000**
Operate a network of APDESK in MSs, in particular for SMEs	**660 000**
Organise regular visit to Member States as “extended focal point” and meets the SMEs	**150 000**
Total	**1 000 000**

Guidance	
Develop sector specific tailor-made guidance targeted to applicants need	**400 000**
Total	**400 000**

IT	
Annual maintenance of the Electronic submission of applications system	**1 500 000**
Total	**4 500 000**

Post-market monitoring	
Post market authorisation meetings	**160 000**
Operate a EFSA Post Market monitoring team	**40 000**
Workshop / training administrative and scientific aspects	**40 000**
Total	**250 000**

Total	**5 000 000**

35. ANNEX XV EXPECTED NUMBER OF APPLICATIONS SUBMITTED TO EFSA 2012-2015

Sector	Type of dossier	2012	2013	2014	201
PPP	NEW	8	12	13	1
MRL	NEW	110	110	130	13
GMO	NEW	13	13	13	1
Smoke Flavourings	NEW	0	0	0	
Flavourings	NEW	25	25	25	2
Extraction solvents	NEW	1	1	1	
Food contact materials	NEW	42	42	58	5
Recycling Plastics Processes	NEW	5	5	2	
Food additives	NEW	10	10	10	1
Feed additives	NEW	38	38	38	3
TSE	NEW	1	0	0	
Animal by-products	NEW	2	2	2	
Antimicrobial treatments	NEW	2	2	2	
Health claims	NEW	25	25	26	2
Novel foods	NEW	5	5	15	1
Infant formulae	NEW	1	1	1	
Food allergies	NEW	0	1	1	
Enzymes	NEW	0	0	0	
Nutrient sources	NEW	5	6	8	1
GMO	RENEWAL	0	0	0	
Feed additives	RENEWAL	0	0	5	
PPP	RENEWAL	3	32	13	4
Smoke Flavourings	RENEWAL	0	0	0	
Total		296	330	363	39

36. ANNEX XVI COST OF PROCESSING THE APPLICATION DOSSIER IN EACH SECTOR FOR EFSA

Sector	type of dossier	cost of dossier (Euro)
PPP	NEW	75 000
MRL	NEW	6 800
GMO	NEW	135 000
Smoke Flavouring	NEW	37 800
Flavouring	NEW	37 800
Extraction solvents	NEW	37 800
Food contact material	NEW	37 800
Recycling Plastics Processes	NEW	37 800
Food additives	NEW	77 500
Feed additives	NEW	55 600
TSE	NEW	59 694
Animal by-products	NEW	130 500
Antimicrobial treatments	NEW	113 400
Health claims	NEW	59 300
Novel food	NEW	83 100
Infant formulae	NEW	83 100
Food allergies	NEW	49 400
Enzymes	NEW	74 350
Nutrient sources	NEW	71 000
GMO	RENEWAL	135 000
Feed additives	RENEWAL	33 400
PPP	RENEWAL	75 000
Smoke Flavourings	RENEWAL	37 800

37. ANNEX XVII MONITORING

Objective	Indicator	Achieved 2010	Achieved 2011	Target 2012
Effective delivery of work programme	Number of scientific outputs adopted	331	384	351
Effective use of financial resources	Proportion of original budget for Activity 2 committed/paid at year end	99%/93%	99%/90%	100%/92%
Effective execution of grants & procurements	Proportion of original grants and procurements budget for Activity 2 committed/paid at year end	94%/79%	47%/99%	100%/97%

Objective	Indicator	Achieved 2010	Achieved 2011	Target 2012
Timeliness of scientific advice	Proportion of scientific outputs adopted within deadline	85%	85%	90%
Compliance with declaration of interests (DoI) policy	Proportion of experts with approved annual DoI before first meeting invitation Proportion of experts with approved specific DoI	99%	98%	100%

	before participation in EFSA meeting	99%	99%	100%

Source EFSA 2012 Management Plan