ROADMAP			
Title of the initiative	**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)**		
Type of initiative	x CWP • Non-CWP • Implementing act/Delegated act		
Lead DG – responsible unit	DG SANCO – Unit 03 Relations with Agencies and Advisory Groups		
Expected date of adoption	Month/Year: 3rd quarter 2012 (provisional)		
Version of Roadmap	No: 4.1	Last modification:	Month/Year: October 2011

This indicative roadmap is provided for information purposes only and is subject to change.
It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.

A. Context, problem definition

(i) What is the political context of the initiative?
(ii) How does it relate to past and possible future initiatives, and to other EU policies?
(iii) What ex-post analysis of the existing policy has been carried out and what results are relevant for this initiative?

(i) what is the political context of the initiative?

Article 45 of Regulation 178/2002/EC requires the European Commission to publish a report on the advisability and feasibility of presenting a proposal establishing fees for EFSA three years after its creation.

Regulation 178/2002 specifies that the Authority should be financed by the general budget of the European Union but that the possibility of fees should be investigated, in particular regarding the processing of authorisation dossiers presented by industry.
Following the consultation of Stakeholders, Member States and EFSA, the European Commission report was adopted on the 23 September 2010.
The European Parliament and the Council welcomed the Report and asked for an Impact Assessment on the possibility of introducing fees for EFSA, taking into account the authorisation system and the diversity of the sectors involved.

As an Agency of the European Union, the European Food Safety Authority is also concerned by the broader ongoing discussion of the European Parliament, the Council of the European Union and the European Commission concerning the governance of the European Agencies. An Inter-institutional Working Group has been set up with a view to assessing the existing situation, the operation, coherence, effectiveness, accountability and transparency of these Agencies.

While assessing the opportunity to introduce a fee system for the Agency, issues closely related with it will be analysed and taken into account, in particular with regard to the efficiency of the processing of authorisations and the safeguarding of the independence of the Agency.

In this respect, it should be noted that some aspects of the governance of EFSA (composition of the Management Board) are outside the scope of the Impact assessment. Changing the composition of the Management Board is not a decision with an economic impact but a purely political decision to bring it in line with the recommendations of the Inter-Institutional Working Group on agencies.

What are the main problems which this initiative will address?

1. Under the current authorisation application system, public money is employed both for public interest services and for private interests. The possibility to explore the option to introduce fees for authorisation applications submitted by industry is also foreseen by Regulation 178/2002.

Whilst most of the tasks performed by EFSA are of general interest, such as the scientific opinions requested by the Commission, Member States and European Parliament on food safety issues of general interest, some other tasks, and in particular the assessment of authorisation dossiers submitted by industry, may also bring direct profit to natural or legal persons.
The legal framework imposing authorisation procedures for foods, substances or claims used in the food chain is mainly aimed at granting general approvals for the benefit of all operators. The applicant bears the cost of preparation of a dossier, which varies very much based on the characteristics of the application and the sector it relates to.
The system contains little protection of proprietary data and seldom offers exclusivity to the applicant. However, in certain cases, the authorisation is not generic but granted to specific authorisation holders that derive specific economic advantages from the authorisation system.
EFSA has to process applications that fall under different pieces of legislation requiring scientific assessment and/or reassessment through mechanisms which, unlike the pharmaceutical or chemical sector, have not been designed to integrate a requirement of a cost-recovery system.

2. Experience shows that the risk assessment system in place within EFSA that is used both for assessing risks linked to general food safety issues (for example BSE) and for assessing authorisation dossiers is not suited to certain constraints linked to authorisation procedures (tight deadlines, irregular flows of applications).
The system based on scientific opinions issued by a Panel composed of high level independent experts was conceived to regularly deliver a rather high number of scientific opinions. However, the members of the Panel are external experts employed by national bodies and not internal staff of EFSA. Therefore the time they are able to devote to the EFSA scientific work is necessarily subject to time limits and constraints. This limited availability of the independent scientific experts is partly reduced in the current system by the support provided by EFSA's internal staff and by the national scientific bodies that are members of a specific network for cooperation with EFSA (Article 36 list).
In addition, even though the capacity of the system to mobilise expertise is limited part of the expertise is used for routine work that could be standardised and does not need to be carried out by high level experts.

In fact, the workload linked to the assessment of applications has been coped with up to now by prioritising these assessments over other parts of EFSA's mandates, by limiting to a minimum the services the applicants could have expected and by spreading the workload over rather long periods.

In addition, under the current EFSA model, on top of managing the normal flow of applications for authorisations, EFSA has to carry out reviews on nationally authorised substances/claims or on "old authorisations", which form an important part of the increased workload (e.g. health claims, "old" pesticides, flavourings, “old” additives).
Constraints/limitations affecting the service/assessment capacity available increase the misalignment of expectations of service/assessment from the economic operators concerned. The longer processing periods risk having an impact primarily on delaying the ‘time to market’, with negative impacts on perception of the public policy/regulatory policy concerned and potentially in some cases on innovation.

Who will be affected by it?

The European Food Safety Authority,
Enterprises considered to be liable to pay fees
Member States

(i) Is EU action justified on grounds of subsidiarity?
(ii) Why can Member States not achieve the objectives of the proposed action sufficiently by themselves? (Necessity Test)
(iii) Can the EU achieve the objectives better? (Test of EU Value Added)

EFSA is a European Agency created under Regulation 178/2002/EC and therefore its functioning and funding should be regulated at European level.
EFSA provides scientific advice and support on issues that are already implemented in EU legislation and are important to all Member States to facilitate trade and to ensure the same level of public safety across the EU.

B. Objectives of the initiative

What are the main policy objectives?

A. General

- Protection of Health and Consumers
- Correct functioning of the Internal Market
- Promotion of economic growth, competitiveness and innovation
- Ensure efficiency, efficacy and independence of the European public system for risk assessment and trust of consumers

B. Specific

- Introduction of a fair fee system for EFSA's private interests-related services with regard to the processing of authorisation dossiers

- Ensure High quality services delivered by EFSA to the applicants in terms of quality and timing
- Optimal and sustainable use of a limited capacity of expertise in the EU
- Guarantee and safeguard EFSA's independence
- Ensure best use of EU public resources for the general public interests.

C. Operational

- Develop a clear, sustainable and justified fees system adapted to the different sectorial authorisation procedures and the typology of authorisation granted taking into account SMEs specific needs.
- Identify who will should be liable to pay fees
- Set up an appropriate level of fees with particular attention to SMEs
- Introduce more flexibility and reduce backlogs and delays in EFSA's processing of authorisation applications
- Introduce a more efficient distribution of tasks allowing Panels to focus on complex tasks while ensuring high quality and independent outcomes

Do the objectives imply developing EU policy in new areas?

No

C. Options

(i) What are the policy options being considered?
(ii) What legislative or 'soft law' instruments could be considered?
(iii) How do the options respect the proportionality principle?

(i,) Options

A. <u>On fees</u>

1. No EU action – Continue to finance EFSA's activities for the processing of authorisation dossiers presented by industries with a private economic benefit through EFSA's general budget

2. Introduction of fees to be paid by all applicants submitting authorisation applications
   Sub-option 1
   Flat rate fee to be paid by all applicants submitting authorisation applications for new substances/ products/claims
   Sub-option 2
   Differentiated fee to be paid by all applicants submitting authorisation applications for new substances/ products/claims
   Sub-option 3
   Flat rate fee to be paid by all applicants submitting authorisation applications for new substances/ products/claims; for renewal of authorisation; extension of use and re-evaluation of authorisation dossiers
   Sub-option 4
   Differentiated fee to be paid by all applicants submitting authorisation applications for new substances/ products/claims; for renewal of authorisations; extension of use and re-evaluation of authorisation dossiers

3. Introduction of fees only for applicants in certain sectors where there is an authorisation holder

   Sub-option 1
   Flat rate fee to be paid by authorisation holders for new substances/ products/claims
   Sub-option 2
   Differentiated fee to be paid by authorisation holders for new substances/ products/claims
   Sub option 3
   Flat rate fee to be paid by authorisation holders for new substances/ products/claims, renewal, extension of use and re-evaluation of authorisation dossiers
   Sub option 4
   Differentiated fee to be paid by authorisation holders for new substances/ products/claims, renewal, extension of use and re-evaluation of authorisation dossiers

Note: For each of the options a SMEs test will be carried out and total or partial exemption will be foreseen

B. On EFSA's organisation related to the processing of authorisation applications

1. No EU action – no intervention in the legal rules governing the organisation of EFSA's scientific work on risk assessment (scientific opinions).

2. The Scientific Committee and Scientific Panels remain responsible for complex issues related to the processing of authorisation applications and the adoption of the related scientific opinions, while the routine assessments, including adoption of scientific opinions, are handled by EFSA (staff and Executive Director).

3. The Scientific Committee and Scientific Panels remain responsible for complex issues related to the processing of authorisation applications and the adoption of the related scientific opinions, while the routine assessments, including the drafting of scientific opinions, are externalised to the national scientific bodies who are members of EFSA's scientific network.
   The "routine opinions" are adopted by the Executive Director.

4. The Scientific Committee and Scientific Panels remain responsible for complex issues related to the processing of authorisation applications and the adoption of related scientific opinions, while EFSA's Executive Director may decide, after consultation of the competent Panel, to allocate the routine assessment of authorisation dossiers, including the drafting of the opinion, to EFSA' staff or to a rapporteur and a co-rapporteur from the Article 36 list of national scientific bodies. The "routine opinions" are adopted by the Executive Director.

(ii) The nature of the problem is likely to lead to a legislative option being selected.

D. Initial assessment of impacts

What are the benefits and costs of each of the policy options?

A. For fees

1. Do not change EFSA's system and functioning of the Panels, do not introduce fees (no EU action).
   If the current EU approach was to continue, public money will continue to be spent for private interests. EFSA's budget will be stable and ensured by the general budget of the European Union.

2. Introduction of fees to be paid by all applicants submitting authorisation applications
   All applicants will have to pay fees, but the characteristics of the different sectors will not be adequately taken into consideration. This could be avoided by introducing a differentiated system as in sub-options 2 and 4. In addition, the existence of fees at national level or for JRC will be an additional cost for the applicant. This might create obstacles to innovation. The system of fees will be simpler since it globally covers all applications. If the sub-option related to a more detailed variety of tasks is retained, EFSA would receive fees better linked to each different sectorial authorisation procedure and type of authorisation granted but this could lead to the establishment a more complex system of fees.

3. Introduction of fees only for applicants in certain sectors where there is an authorisation holder
   The fees will concern a smaller group of applicants and only certain sectors. These fees will in most cases add to fees already in place at national level or to the fees to be paid to the JRC. EFSA will receive fees for services granting economic benefit to private actors and will be remunerated for the work carried out.
   The sub-option of differentiated fees will particularly take into account the specificity of each sector. There is a possibility that the identified beneficiaries of the EFSA's services will be very limited in number and the introduction of a fee system would not be sustainable for EFSA.
   If the sub-option related to a more detailed variety of tasks is retained, EFSA would receive fees in accordance with each sectorial authorisation procedure and type of authorisation granted which could result in a more complex system of fees.

B. For EFSA's organisation related to the processing of authorisation applications

1. No EU action – no intervention in the legal rules governing the organisation of EFSA's scientific work on risk assessment (scientific opinions).
   If no initiative is taken the problems underlined will persist and the backlogs in the processing of authorisation dossiers will remain.

2. The Scientific Committee and Scientific Panels remain responsible for complex issues related to the processing of authorisation applications and the adoption of related scientific opinions, while routine work, including adoption of the "routine scientific opinions", is handled by EFSA (staff and Executive Director).

   The Scientific Committee and Scientific Panels are focussed on complex scientific work which is in line with their role. EFSA might not always have the internal capacity to handle this routine work. The implication of MS via the multi-national composition of the Scientific

Committee and Scientific Panels is diminished.

3. The Scientific Committee and Scientific Panels remain responsible for complex issues related to the processing of authorisation applications and the adoption of related scientific opinions, while routine work, including the drafting of scientific opinions, is externalised to the national scientific bodies that are members of EFSA's scientific network. The "routine opinions" are adopted by the Executive Director.
   The Scientific Committee and Scientific Panels are focussed on complex scientific work which is in line with their membership and initial concept. The national capacities of scientific expertise are involved in this scientific process and should provide large and diverse capacity of expertise. Member States are involved and should have an improved sense of ownership towards the results of the scientific assessments. EFSA remains dependent on external capacities of expertise that might not always be available when needed, in particular if these extra tasks for Member States are not financially compensated.

4. The Scientific Committee and Scientific Panels remain responsible for complex issues related to the processing of authorisation applications and the adoption of related scientific opinions while EFSA's Executive Director may decide, after consultation of the competent Panel, to allocate routine work for assessing authorisation dossiers, including the drafting of the scientific opinion, to EFSA's staff or to a rapporteur and a co-rapporteur from the Article 36 list of national scientific bodies. The "routine opinions" are adopted by the Executive Director.
   Same advantages as 2 and 3. In addition, the cooperation with the Scientific Committee and Scientific Panels is provided for. There is additional flexibility to promote efficiency since according to the different situations, the Executive Director might choose to have EFSA's staff performing the routine work or to have it externalised to MS bodies. It could be difficult to find a rapporteur and a co-rapporteur in some areas of expertise.

Could any or all of the options have significant impacts on (i) simplification, (ii) administrative burden and (iii) on relations with other countries, (iv) implementation arrangements? And (v) could any be difficult to transpose for certain Member States?

(i) simplification: no
(ii) Administrative burden: unlikely, because the information obligations are unlikely to change and testing costs are not normally considered as administrative costs.
(iii) On relations with other countries: unlikely, as even though applicants can be importers it is unlikely that introducing fair fees would raise major problems for third countries.
(iv) Implementation arrangements? Not applicable.
And **(v) could any be difficult to transpose for certain Member States?** No. Should it be decided to use a legislative proposal, it will be a Regulation that will immediately apply.

(i) Will an IA be carried out for this initiative and/or possible follow-up initiatives? (ii) When will the IA work start? (iii) When will you set up the IA Steering Group and how often will it meet? (iv) What DGs will be invited?

(i) Will an IA be carried out for this initiative and/or possible follow-up initiatives?
The Commission report on presenting a legislative proposal enabling EFSA to receive fees concludes

that more reflection is needed on the range of options to be considered and that it is not possible to

draw any definitive conclusions at this stage. This will be done in the course of an impact assessment.
(ii) When will the IA work start?
The IA work started in the first quarter of 2011.
(iii) When will you set up the IA Steering Group and how often will it meet?
The IA Steering Group was set up in the first quarter of 2011. It will meet at least three times, more if considered necessary.
(iv) Which DGs will be invited?
ENV/AGRI/ENTR/ LS/SG/BUDG/JRC/ TRADE/COMP

(i)Are any of options likely to have impacts on the EU budget above €5m?
(ii) If so, will this IA serve also as an ex-ante evaluation, as required by the Financial Regulation? If not, provide information about the timing of the ex-ante evaluation.

(i) No increase of the EU contribution is foreseen.
(ii) Not applicable.

E. Evidence base, planning of further work and consultation

(i) What information and data are already available? Will existing impact assessment and evaluation work be used?
(ii) What further information needs to be gathered, how will this be done (e.g. internally or by an external contractor), and by when?
(iii) What is the timing for the procurement process & the contract for any external contracts that you are planning (e.g. for analytical studies, information gathering, etc.)?
(iv) Is any particular communication or information activity foreseen? If so, what, and by when?

(i) What information and data are already available? Will existing impact assessment and evaluation work be used?
EFSA has provided SANCO with a preliminary analysis of the number and costs of applications' assessments.
There is an ongoing evaluation of the EFSA planned to be finalised 1st Q 2012, and an effort will be made to take any relevant findings into account for this proposal.
(ii) What further information needs to be gathered, how will this be done (e.g. internally or by an external contractor), and by when?
Further analysis:
the costs of applications in each sector;
direct and indirect costs for each actor;
the level of fees that could be envisaged;
the potential impact on competitiveness, innovation and SMEs;
impact on EFSA's overall functioning and efficiency.

The impact assessment will be carried out internally by Unit 03. It might involve commissioning advice from an external contractor or buying studies/data (to be decided).

(iii) What is the timing for the procurement process & the contract for any external contracts that you are planning (e.g. for analytical studies, information gathering, etc.)?
If a contractor is considered to be necessary, we are planning 6 months for the information gathering and analytical studies.

(iv) Is any particular communication or information activity foreseen? If so, what, and by

when?

Stakeholders and Member States will be regularly informed of the progress of the IA in the Advisory Group on the Food Chain, Animal and Plant Health. It is not foreseen to have communication activities all along the IA process, but it might be considered when the final IA report will be adopted.

Which stakeholders & experts have been or will be consulted, how, and at what stage?

In 2006 DG SANCO prepared a working paper on the feasibility and advisability of presenting a legislative proposal enabling EFSA to receive fees for processing authorisation files. The same year, the Commission launched a public consultation of stakeholders on fees for EFSA on the SANCO website and letters were also sent to all Member States, the European Parliament and EFSA.

In 2007, the Commission launched a web consultation and organised meetings with Member States in the Standing Committee on the Food Chain and Animal Health and with stakeholders in the Advisory Group on the Food Chain, and Animal and Plant Health.

A detailed summary of all the written comments received in 2007 is available on the Commission's website at http://ec.europa.eu/food/consultations/sum_cons_efsa_fees_en.pdf

In May and June 2010, the Commission consulted Member States and stakeholders on the Commission's draft report. The minutes of these meetings are available on the internet[1].

A feedback of the latest developments was provided to stakeholders in the Advisory Group on the Food Chain, Animal and Plant Health on 8 November 2010.

Further consultation will take place on follow-up initiatives.

[1] http://ec.europa.eu/food/committees/advisory/summary_20052010_efsa_en.pdf and http://ec.europa.eu/food/committees/regulatory/scfcah/toxic/index_en.htm