EXPLANATORY DOCUMENT

CONSULTATION PAPER ON THE FEASIBILITY AND ADVISABILITY OF PRESENTING A LEGISLATIVE PROPOSAL ENABLING THE EUROPEAN FOOD SAFETY AUTHORITY (EFSA) TO RECEIVE FEES FOR PROCESSING AUTHORISATION FILES

COMMISSION STAFF WORKING PAPER

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INTRODUCTION

The purpose of this consultation paper is to carry out the consultation laid down in Article 45 of Regulation (EC) No 178/2002[1] on the feasibility and advisability of legislation on fees received by EFSA.

The consultation and the report are in line with the good management practised by the Commission before using its power of legislative initiative, above all in complex and/or sensitive areas.

The consultation takes place at a key time for the Authority. The conclusions of the evaluation of EFSA and the recommendations of its MB have been made public. EFSA is still a young organisation (3 years of functioning) but is starting to develop into a more mature organisation. In this context, the Commission Services consider that the establishment of fees could be an important tool for EFSA.

This paper does not bind the Commission, but it lays the foundations for consulting the Member States, EFSA and the interested parties specified in Article 45 and for structuring that consultation.

It will serve for discussion in the Advisory Group on the Food Chain and Animal and Plant Health. It will also form the basis for detailed discussions with EFSA and the Member States.

This paper has been published on the DG Health and Consumer Protection (DG SANCO) website http://ec.europa.eu/food/consultations/index_en.htm and any interested party is welcome to send comments
by mail to: SANCO-EFSA-fees@ec.europa.eu
or: by post to the following address:

European Commission
Health and Consumer Protection Directorate General
Unit 03 Science and Stakeholder Relations
Mr R. Vanhoorde
Office F101, 04/168
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by 15 February 2007.

General comments may be made, but it is important for contributions to adhere to the structure of the paper and to respond to the questions raised under 4.3 and 5.3. Each contributor should identify himself: name and address of the person or the organisation and brief description of the sector of activity and/or interests he/it represents.

The responses or a summary of the responses will be published on the DG SANCO website at the following address:

http://ec.europa.eu/food/consultations/index_en.htm

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[1] JO L030 du 03.02.2005.

Comments on this paper will be used in drawing up the Commission report laid down in Article 45 mentioned above.

1. TASKS RENDERED BY EFSA FOR WHICH FEES COULD BE MADE PAYABLE

Given the wording of Article 45, a decision is needed on the nature of the system applicable to tasks performed by EFSA other than those for which EFSA can already charge fees, the latter as listed in Article 43 of Regulation 178/2002: publications, conferences, training and similar activities.

The tasks performed by EFSA are essentially as follows:

– scientific opinions given for the Commission, the Member States and the European Parliament;

– technical and scientific assistance to the Commission;

– collection and analysis of data on the safety of the food chain;

– identification of emerging risks;

– scientific support for the Commission in an emergency;

– communication to the public on risks.

Most of the above-mentioned tasks are of general usefulness and interest to the public authorities responsible for risk management and to local and national government as a whole. EFSA's scientific and technical support services enable public authorities to manage risks more effectively for the sake of consumer health protection and in a manner which is more appropriate and better suited to the size of the risk concerned. Lastly, EFSA's communications help provide consumers with objective and comprehensible information on risks.

Some EFSA tasks may also bring direct profits to individual natural or legal persons (in practice, firms applying for marketing authorisations for products or substances).

These are usually cases in which EFSA assesses authorisation files under centralised Community procedures culminating in the granting of a marketing authorisation for a product or substance. In these authorisation procedures EFSA assesses the file submitted by the applicant, checks that the information and documentation it contains comply with Community legislation, and assesses the risks to determine whether the product or substance concerned meets the health criteria laid down in Community law.

In such cases, public money is used partly for private interests, and a legislative system for charging fees can be justified. Such a system has certain limitations, however:

– payment for a task by the user (receipt of a fee) implies that the activity concerned applies to services able to be supplied separately to clearly differentiated users — in other words, its products can be regarded as divisible. These are known as private consumption items ("public versus private goods").

– the fee is charged in order to cover the costs of a certain public service; the services rendered are its direct counterpart. The amount of the fee must be linked to the cost of the service rendered.

The authorisation domains linked to health protection, where fees are most commonly incurred in the Member States, are as follows:

– processing of authorisation files for medicinal products for human use;

– processing of authorisation files for veterinary medicinal products;

– processing of authorisation files for pesticides.

In the health field, fees may also be charged for inspection activities. Since EFSA has no inspection activities, however, this aspect is not within the scope of the fees which may be established.

Lastly it should be noted that, in cases other than authorisation files submitted by industry, in which the authorisation procedures already in place provide for automatic transmission of the files to EFSA via either the Commission or the Member States, EFSA carries out scientific work only at the request of the Commission, the European Parliament and the Member States. These Community institutions and indirectly the Member States, are already funding this service via the Community budget contribution to EFSA, and cannot therefore be made liable for a second payment in the form of a fee.

2. SCOPE OF THIS CONSULTATION

Section 1 makes it clear that not all services rendered by EFSA can be subject to fees. This paper therefore concerns only the feasibility and advisability of establishing fees for EFSA's processing of authorisation files.

It is provisional and restricts itself to information items relevant to the possible advantages and disadvantages of establishing fees payable to EFSA in the field of authorisation files. The findings of this consultation will form the basis for the Commission's recommendation in the final report on whether or not it appears feasible and advisable to provide for fees.

If the report recommends fees, it will also specify the sectors in which there are authorisations which will be affected by the payment of fees and the arrangements proposed. Only on this basis will impact studies yielding more detailed economic data be possible. These data depend in part on, for example, the economic structure of the sectors concerned and the arrangements proposed.

3. SITUATION AT COMMUNITY LEVEL

3.1. European Medicines Agency

The relevant example to bear in mind when drawing up the report laid down in Article 45 is that of the European Medicines Agency (EMEA), which receives fees paid by applicants (in practice, pharmaceutical companies) for

the assessment of authorisation files on medicines for human or veterinary use.

The fees system is centralised at EMEA level. The companies concerned pay the fees to EMEA. In accordance with the distribution rules laid down by its management board, EMEA then redistributes part of these fees to the national agencies for the tasks they carry out (rapporteur and co-rapporteur agencies for an authorisation file, inspection and pharmacovigilance tasks).

The fees are as follows, in order of magnitude:

– €232 000 for a complete assessment concerning a medicinal product for human use;

– €90 000 or €150 000 for a simplified assessment concerning a medicinal product for human use;

– €116 000 for a complete assessment concerning a veterinary medicinal product;

– €58 000 or €98 000 for a simplified assessment concerning a veterinary medicinal product;

– €58 000 for an assessment of maximum residue limits of a veterinary medicinal product.

Administrative fees are also charged if a file is rejected as invalid, depending on the cost of processing the file (€5800 for a complete assessment concerning a medicinal product for human use; €2900 for a complete assessment concerning a veterinary medicinal product; €1740 for maximum residue limits).

EMEA fees are more detailed than is shown above in simplified form. The EMEA site www.emea.eu.int gives further information. New arrangements allow discounts for small and medium-sized businesses (SMEs) or even exemptions from fees in some cases.

The main measures for SMEs are as follows:

- 90% reduction of certain fees payable to EMEA, particularly for scientific advice, inspections and scientific services;

- exemption from fees for administrative services;

- exemption from fees for scientific advice on orphan medicinal products;

- postponement of fees for applications for marketing authorisations to the end of the assessment procedure;

- conditional exemptions from fees if scientific advice has been sought and applied;

- a system of assistance with the translation of the documents required for the granting of the marketing authorisation;

- establishment at EMEA of an SME Window offering administrative help, assisting with communications and answering questions.

As is clear from certain reports by the Court of Auditors on EMEA's financial statements on medicine assessments, the level of fees charged by the agency must be based on the cost of the service rendered.

The Court calls *inter alia* for analytical instruments enabling the actual costs to be measured. EMEA has therefore introduced an analytical accounting system and a time management system, the aim being to identify personnel costs and the costs of its various activities. Lastly, the Court points out that the competent national authorities should also document their costs in order to justify the sums paid to them by EMEA.

It should be noted that EMEA also receives fees for its inspection and pharmacovigilance tasks.

3.2. Fees for assessing authorisation files in the food sector

Where EFSA does not currently receive fees for authorisation files, the only fees received for processing such files go to national bodies under "decentralised" Community authorisation procedures, which make national bodies responsible for global or initial assessments of authorisation files. Fees are also proposed as compensation for certain analytical activities linked to authorisation files.

3.2.1. Plant protection products

Council Directive 91/414/EEC[2] provides for an authorisation system for active substances, the authorisation of plant protection products remaining at national level.

Authorisation of active substances used as a basis for plant protection products

The list of active substances is drawn up on the basis of Directive 91/414/EEC. The procedure followed in processing authorisation files implies a rapporteur Member State to assess the file. The application of the Directive also provides for a four-stage reassessment programme. Chapter 4 ("Fees") of Commission Regulation (EC) No 451/2000 (second and third stages) provides for Member States to "establish a regime obliging the notifiers to pay a fee for the administrative treatment and the evaluation of notifications as well as the dossiers related thereto". The amount of this fee is not harmonised, but must correspond to the real cost of the assessment and the administrative processing of a notification and a file. Member States may, however, provide for a scale of fixed charges based on average costs

[2] JO L170 du 25.06.1992.

for the calculation of the total fee. Similar principles are set up by Article 29 of Commission Regulation CE 2229/2004[3] for the implementation of the fourth stage of the re-evaluation programme.

The forthcoming modification of Directive 91/414/EEC should not change the current situation since the principle of a Member State rapporteur will be maintained as well as the possibility for this Member State to charge fees for the assessment performed as rapporteur.

To summarise, the fees charged by the Member States for assessing a file on an active substance (other than a microorganism) as a rapporteur range from €100 000/€150 000 to €300 000. A Member State charges more than €300 000, but calculates the exact costs and refunds the overpayment. Fees may be lower for reassessments of active substances already on the market.

EFSA plays a major role in assessing active substances without receiving fees. It receives the initial assessment by the Member State, coordinates the peer review of the initial assessment involving the 25 Member States, and sends a final report to the Commission for use in drawing up the legislation.

Maximum limits for pesticide residues

Regulation (EC) No 396/2005[4] on maximum residue levels of pesticides in or on food and feed of plant and animal origin requires Member States to which an application for maximum residue levels (MRLs) is submitted to draw up an evaluation report on the application. The application and the evaluation report are then sent to EFSA, which assesses them and issues an opinion. Under Article 42 of the Regulation, Member States may recover the costs of work associated with setting, modifying or deleting MRLs, or with any other work arising from obligations under the Regulation, by means of a fee or charge. Member States shall ensure that the fee or charge is established in a transparent manner and corresponds to the actual cost of the work involved. It may include a scale of fixed charges based on average costs for the work. On the other hand, the Regulation does not provide for the possibility that EFSA charges fees for its own assessment work.

3.2.2. *Feed additives*

Where feed additives are concerned, Directive 70/524/EEC[5], recently repealed by Regulation (EC) No 1831/2003[6], provided for a decentralised authorisation procedure, thus enabling Member States to receive a fee when acting as rapporteur Member State for the examination of an authorisation file. In practice, some Member States made use of this possibility (e.g. a fee of €6 200 in Belgium) while others did not.

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3 JO L379 of 24.12.2004

4 J0 L070 du 16.03.2005

5 OJ L 270, 14.12.1970.

6 OJ L 268, 18.10.2003.

The new Regulation provides for a centralised authorisation procedure for additives for use in animal nutrition. EFSA is now responsible for assessing authorisation files, but no fee is laid down for its processing of these files.

Article 21 of the new Regulation does, however, require applicants for the authorisation of additives to contribute to supporting the cost of the tasks of the Community reference laboratory concerning authorisation-file assessments (usually the assessment or validation of detection methods). On this basis, implementation Regulation EC No 378/2005[7] provides for the Community Reference Laboratory to receive a fee of €3 000 for each file. This fee takes the form of a flat-rate payment, the amount of which can be revised in the light of experience acquired. .

3.2.3. Novel foods and novel food ingredients; assessments of genetically modified organisms

Regulation (EC) n° 258/97[8] and Directive 2001/18/EC[9] are largely decentralised at the level of the Member States conducting initial assessments. The texts do not include provisions for fees, but some Member States have laid down fees for these assessments. Roughly speaking, the fees laid down range from €1 000 to €5 000 for simplified assessments (substantial equivalence) and from €2 000/3 000 to €10 000/€15 000 for assessments.

Regulation (EC) No 1829/2003[10] is based on a centralised authorisation procedure. EFSA is thus responsible for assessing the authorisation files, but no fee is laid down for its processing of those files. It should also be noted that, where the cultivation of GMOs is concerned, EFSA has to delegate the environmental risk assessment to a competent national authority.

As with feed additives, however, Article 32 of the new Regulation does require applicants for the authorisation of genetically modified products to contribute to supporting the cost of the tasks of the Community reference laboratory concerning authorisation-file assessments (usually the validation of detection methods).

EFSA does not receive fees for any complementary assessments which may be required by the Commission in implementation of the legislation in force.

3.2.4. Residual national competence

The competence of Member States to charge fees for authorisation files in the food sector is now essentially residual, since most food related

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7 OJ L 59, 05.03.2005.

8 OJ L 43, 14.02.1997.

9 OJ L 106, 17.04.2001.

10 OJ L 268, 18.10.2003.

authorisation procedures have been harmonised and centralised by Community legislation.

The national fee systems can therefore cover only limited areas. In practice, this means sectors where the authorisation system has been harmonised but remains partly decentralised as explained above in 3.2.

It is to be noted that the assessment of nutritional and health claims is still a national competence and therefore national fees could apply. However, the forthcoming Regulation on nutritional and health claims establishes a centralised authorisation procedure (assessment by EFSA) and does not provide for fees.

4. OPTIONS FOR IDENTIFYING THOSE LIABLE TO PAY FEES

Two options for determining who might be liable for fees should be examined:

4.1. Option 1

All applicants for an authorisation must pay a fee

The simplest approach would be to regard all applicants for an authorisation as submitting an authorisation file, since they have an interest in this. Given the high cost of compiling most authorisation files, it can be assumed that those who submit such files do so only when they expect to profit economically from the authorisation.

This approach has already been adopted in the context of the fees charged to support the cost of the tasks of the Community reference laboratory concerning certain authorisation-file assessments (such as the assessment or validation of detection methods). The fees charged for the analytical parts of authorisation files relating to additives for use in animal nutrition concern all applicants for authorisations, not only those who are the authorisation holders. The amount of these fees is fairly low (€3 000).

There are several advantages to this approach. Specific beneficiaries do not have to be identified. Moreover, since all applicants are automatically liable for fees, they can make a fair contribution to covering EFTA's costs in processing all authorisation files. All applicants are treated equally. Lastly, as with the EMEA, SMEs can be given special status.

The potential disadvantage of this approach would be to add to the costs of obtaining an authorisation and therefore possibly to discourage applicants who have little economic interest in meeting the cost of an authorisation file. This might be the case when, for example, an authorisation could also benefit other operators. Nevertheless, interested operators in this situation could pool their resources in order to submit an authorisation file.

4.2. Option 2

Only applicants with profits specifically vested in the authorisation must pay fees

This option should be considered if a distinction can be made between two types of authorisation procedure:

– those in which the marketing authorisation is granted to a specific person who is the authorisation holder. In these cases the instrument of the individual decision issued to the holder is essentially used to grant the authorisation, and it can be assumed that the holder gains a particular benefit;

– those in which a substance or product would be authorised generically (placed on a positive list). Here there is essentially no holder of the authorisation, and legislation with general scope is used to authorise the substance or product. Once the conditions for the marketing and use of the authorised substance or product have been set up, it can be marketed and/or used by anyone provided that it appears on the positive list and the conditions of use laid down in law are complied with. In such a situation, since the authorisation is general, there would seem to be no clearly identified individual beneficiary and the applicant could be one of several who might profit from the authorisation.

Nevertheless, the distinction between the two procedures is often not entirely obvious. Some legislative texts (smoke flavourings, additives for use in animal nutrition etc.) provide for positive lists but also include the concept of an authorisation holder. Under such legislation, the authorisation holder alone is entitled to apply for the authorisation to be modified and/or renewed. The holder also has special responsibilities in terms of safety monitoring of the product concerned, but the concept of the holder does not confer exclusive marketing rights. Only Regulation (EC) No 1831/2003 on additives for use in animal nutrition specifies that for certain categories of additives, only the holder of the authorisation is entitled to place the product on the market for the first time[11].

Lastly it should be borne in mind that, even in the case of generic authorisations, there may in fact be a particular beneficiary as a result of the existence of intellectual property rights. If a patented substance is authorised, even generically, the holder of the patent (who will in practice also be the applicant for authorisation) has special rights enabling him or her to prevent other operators from marketing the substance.

The advantage of this option would be to make applicants gaining special advantages protected by legislation liable to pay fees.

This, however, would mean either identifying each beneficiary individually, which seems impracticable and hardly conducive to legal certainty, or to have one approach per sector, which looks more manageable and closer to

[11] The Regulation defines the first placing on the market as follows:: "first placing on the market" means the initial placing on the market of an additive after its manufacture, the import of an additive, or, where an additive has been incorporated into feed without being placed on the market, the first placing on the market of that feed

the approach followed in the various countries having established fees for authorisation files.

4.3. Questions

Are the factors listed above the most important ones for identifying the advantages and disadvantages of the two options? If not, indicate other essential factors.

Which option do you prefer, and why?

5. OPTIONS - ADVANTAGES AND DISADVANTAGES OF CHARGING FEES

5.1. Option 1

EFSA is not entitled to charge fees for processing authorisation files

5.1.1. Advantages

– No cost to industry, therefore no real risk of undermining competition.

– No public perception of a risk of "diminished" independence of EFSA.

– Homogeneous management of the various EFSA activities maintained, since public funding applies to all EFSA activities.

5.1.2. Disadvantages

– The public budget continues to fund activities conferring special benefits on certain firms, whereas these public funds, restricted by definition, could more usefully be devoted to activities of general interest.

– EFSA regards the public funding allocated for 2007-2013 as well below what is required under its current terms of reference, whereas the introduction of fees would bring in an additional volume of resources which would also help cope with the increase in the number of applications addressed to EFSA (182 in 2004, 266 in 2005).

– The lack of fees makes the concept of individualised service less obvious and may not be conducive to bringing in more efficient and more modern methods of managing authorisation files.

– The absence of costs for applicants may in some cases culminate in files submitted by industry which are not adequately supported by proper scientific studies. If EFSA's assessment procedure is entirely free of charge, there is no financial risk to an applicant who submits an invalid file. If EFSA cannot charge fees, it cannot retain file-processing fees either. This state of affairs means unjustifiable costs and wasted time, to the detriment of other public-interest tasks. National fees, even fairly small ones, introduced for the processing of files on items such as novel foods and ingredients have the added advantage of limiting the submission of frivolous applications.

– There is a disparity in the treatment of the various tasks contributing to the assessment of authorisation files. The tasks of the Community reference laboratory concerning analytical methods are given financial compensation, whereas the beneficiaries are not asked to contribute to the costs of EFSA's risk-assessment tasks.

– There is a risk of loss of national expertise potential and synergy between EFSA and the national bodies, particularly in certain sectors.

- In the "additives for use in animal nutrition" sector, for instance, many Member States used to charge for the assessment of authorisation files. During the recent reform of the authorisation system in this sector, responsibility for assessments was centralised and transferred to EFSA, but without any provision for fees to pay for this activity. Under the collaboration procedures proposed between EFSA and national bodies, (Article 36 of Regulation (EC) No 178/2002), EFSA can nevertheless ask them to contribute to the preparation of these assessments. The funds allocated (subsidies mechanism) to the compensation of the national bodies when they work for EFSA are limited, however. The collaboration between EFSA and the national bodies could be more effectively supported by charging fees under a system similar to that of EMEA. In this type of system, some of the fees are reallocated to the national agencies in the form of subsidies when they contribute to scientific assessment.

- In the field of genetically modified food and feed, the new assessment procedure (Articles 6 and 18 of Regulation (EC) No 1829/2003[12]) entrusts EFSA with the task of assessing authorisation files and specifically provides for cooperation and sharing of assessment tasks with national organisations.

5.2. Option 2

EFSA is entitled to charge fees for processing authorisation files

5.2.1. Advantages

– Greater financing equity. The beneficiaries of an authorisation finance the activities necessary for obtaining it. Public funding can concentrate on EFSA's general-interest activities.

– An additional source of finance for EFSA. The introduction of fees provides a guarantee of more appropriate funding for complex and costly scientific assessments. Moreover, given the budget prospects for 2007-2013, this source of funding would mitigate the risk of endangering the legislative deadlines for assessments and avoid general-interest opinions (public health, BSE type) being delayed for the sake of authorisation files for which legal deadlines for opinions are proposed.

– Fees usually result in highly professional quality criteria for services rendered. Such criteria may provide a strong and permanent incentive to

[12] OJ L 268, 18.10.2003.

scientific excellence. There may therefore be better and faster assessment of innovative products, in many cases offering a higher standard of health and environmental protection.

– Charging of centralised fees for processing and assessing authorisation files offers enhanced opportunities for cooperation and synergy between EFSA and the national agencies/institutes. The reallocation of part of the centralised fee to the national agencies should enable their collaborative work with EFSA to be better compensated and recognised.

– Fee financing would be more in line with the new authorisation systems put in place in the food sector. These new systems provide for short deadlines (around six months) for scientific assessments of files. Meeting these deadlines means new working methods (enhanced support for EFSA scientists in the Committee and scientific working parties and/or more work-sharing with the national agencies) which must be financed.

– Disappearance of the processing gap created by the possibility of fee financing for scientific assessments carried out by bodies in the Member States and the technical work of the Community laboratories supported by their national networks, while EFSA assessments are unpaid.

– Fees would also help prevent submissions of ill-prepared files and minimise the loss of time and money involved in this type of file (since the fee is paid on submission of the file even if the file is rejected, processing fees are deducted from the reimbursement of the initial sum).

5.2.2. Disadvantages

– Risk of a perceived reduction in the independence of EFSA's scientific opinions. EFSA could more easily be exposed to charges of lack of independence if it is partially funded by industry.

However, guarantees already exist or can be reinforced to ensure the independence and transparency of the institution charging the fees:

- On the one hand, the existing rules in the EFSA founding Regulation, which ensure the independence of its expert opinions, must continue to be applied very rigorously. These include: the appointment of experts by the EFSA management board on the basis of a selection procedure consisting of a call for expressions of interest setting objective competence criteria; collective responsibility for the expert opinion (only a committee of experts set up as a Permanent Scientific Panel or Scientific Committee can adopt EFSA's scientific opinions); declarations of interest on an annual basis and also at each meeting of the scientific panel or committee). Transparency rules are also already being implemented. These consist mainly of the compulsory publication of scientific opinions, including the minority opinions expressed, and the public meetings of the EFSA management board.

- On the other hand, in reality, the assessment of authorisation dossiers accounts for only part of EFSA's activities. Public funding should

therefore remain the major component. The principle of majority public funding could also be laid down, so as to guarantee EFSA's independence and the stability of its budget.

- Finally, the benefits for the public of an efficient authorisation system could be better identified. In the medicinal field, for instance, the public sees advantages in a faster authorisation mechanism culminating in the marketing of innovative medicines treating priority diseases such as AIDS. Similarly, a more efficient system of processing authorisations in the food domain also confers advantages in that new products can bring side benefits in terms of sustainable production, for example.

– Companies applying for authorisations incur additional costs, i.e. the payment of the fee, before being able to place their products on the market, which may undermine their competitiveness.

However this should be assessed in the light of the following:

- The size of the European market reduces the economic impact of the fee. Firms granted a centralised authorisation giving them access to the market of 25 Member States have a major advantage which makes the fee more acceptable.

- The costs of fees are often marginal compared with other costs linked to the marketing of a product or substance. Fees may also be tax deductible.

- The economic impact of the fee should be looked at in the light of the arrangements generally adopted at Community level in this field. Fees laid down in Community legislation are flat-rate fees, the rate being adapted to the types of assessment concerned and the estimated workload. Moreover, measures taking into account the specific situation of small and medium-sized businesses should be taken (exemption or reduction systems).

- Fee charging is a factor contributing to more efficient management of the whole authorisation process. Thus, fees may encourage businesses to submit better-prepared applications and result in a more effective service from the public bodies.

- The introduction of Community fees should avoid duplication with national fees in order to rationalise bureaucratic burdens and costs. This implies a thorough examination of cases where the Community legislation provides for decentralised systems in which the Member States undertake the preliminary evaluation and can perceive fees, EFSA acting only at a second stage. The aim should be to develop a non bureaucratic system without risking the loss of scientific expertise in the Member States.

- Since certain EFSA activities would be financed by fees while others of equal or greater priority in terms of public health protection would not be so financed, there could be inequalities of means and resources. In addition, experience shows that, when fees are introduced, the person

paying them legitimately expects a suitable service in return. For example, petitioners ask for more meetings with the scientific organisations assessing their files, and there may be more pressure to shorten assessment times.

However appropriate mechanisms should be put in place to prevent distortions of priority and to ensure an appropriate balance between the interests of a more efficient service and the preservation of general-interest objectives.

The introduction of any fee system comes at a cost (heavy administrative fee-collection structures, monitoring of companies paying fees, need for analytical compatibility to justify costs, etc.). But, as the EMEA experience has shown, these costs are relatively low (two additional members of administrative staff).

– The introduction of fee charging for every file assessed may not always guarantee a stable annual EFSA budget, since the number of files for assessment may vary unpredictably from year to year. In addition, fee charging may provide grounds for reducing public funding even though such contributions are necessary for stable and efficient management of all of EFSA's scientific activities of general interest.

Since the Community subsidy for EFSA's budget has a balancing effect, this risk may be limited. In particular, a number of fixed costs should be able to be guaranteed by public funding in order to stabilise EFSA's budget.

5.3. Questions

Which option do you prefer, and why?

If option 1 is chosen, what factors could, in your opinion, mitigate against the loss of this potential source of finance?

If option 2 is chosen, what factors would be most appropriate, in your opinion, to mitigate the disadvantages of this option? In your response, please refer to factors already mentioned under 5.2.2 and any other mitigating factors that you may consider to be relevant.