EUROPEAN COMMISSION

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2009/0076 (COD)

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT pursuant to Article 294(6) of the Treaty on the Functioning of the European Union concerning the

position of the Council on the adoption of a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products

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1. BACKGROUND

Please note that this Communication refers to the title of the Regulation and the numbers of articles as they were presented in the text of the political agreement (17474/10).

Date of transmission of the proposal to the European Parliament and to the Council (document COM(2009) 267 final – 2009/0076 COD):	12 June 2009
Date of the opinion of the European Economic and Social Committee:	17 February 2010
Date of the opinion of the European Parliament, first reading:	22 September 2010
Date of adoption of the position of the Council:	21 June 2011

2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The objective of the proposal is to improve the functioning of the internal market through further harmonisation of the rules on the authorisation and mutual recognition of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment.

3. COMMENTS ON THE POSITION OF THE COUNCIL

3.1. General comments

The European Parliament gave its opinion at first reading on 22 September 2010. The Commission accepted in full, in part or in principle 193 of the 309 amendments adopted by the European Parliament in its first reading. Around half of these 193 amendments are already reflected, at least in part, in the common position. The position of the Commission on the amendments adopted by the European Parliament in its first reading is set out in document SP(2010)7193.

The Commission accepted amendments, either fully or in principle or in part, which would clarify the context of the proposal or further improve it. These include, in particular, modifications to the definition of biocidal products, the scope of derogations under exclusion criteria, the extension of the scope of the Union authorisation, the criteria for low-risk biocidal products and the provisions on treated articles.

The Commission rejected amendments which would alter the nature of the proposal, such as amendments which lower the level of environmental and human health protection or undermine the internal market in biocidal products. It also rejected amendments that are practically or technically not feasible or pose an unnecessary burden for the industry and the competent authorities.

The Commission considers that the common position does not alter the key objectives of the proposal and can thus support it. Nevertheless, the Commission considers that certain aspects of the text should be improved and would be happy to work with the other institutions in order to make such improvements. In particular, with regard to the procedures foreseen for the establishment of Maximum Residue Levels, the wording of the common position is not compatible with Regulation (EC) No 470/2009 and this inconsistency should be addressed as a priority.

3.2. Detailed comments

3.2.1. Parliamentary amendments accepted in full, in part or in principle by the Commission and incorporated in full, in part or in principle in the common position

Amendments 1, 4-7, 9-10, 13, 21-23, 25, 27, 30-35, 37-39, 43-44, 49, 53, 55, 56, 58, 62-63, 70, 75, 79, 80, 82-83, 85-91, 93-96, 112, 115, 116, 123-125, 137, 139, 142-144, 160-161, 165, 167-172, 178-181, 183-187, 189-190, 194, 199, 206-215, 218-220, 225-232, 234-235, 239, 241-242, 247-249, 255-257, 266-267, 269, 272, 275-277, 279, 292-296, 299-303, 308, 310-312, 316, 319-320, 323-329, 331-332, 341, 346-347, 354, 359/rev and 360-361 were accepted in full, in part or in principle by the Commission and incorporated in full, in part or in principle in the Council's position.

3.2.2. Parliamentary amendments rejected by the Commission but incorporated in full, in part or in principle in the common position

Amendments 2, 3, 17, 20, 52, 54, 69, 71, 126, 156 and 349 were rejected by the Commission but incorporated in the Council's position in full, in part or in principle. These amendments mainly concern reduced time limits for the inclusion and renewal of inclusion of candidates for substitution as well as other active substances and shorter deadlines for certain tasks to be carried out by the European Chemicals Agency (further 'the Agency'). While the Commission rejected them on grounds that they would increase the administrative and regulatory burden by adding to the workload of the Agency, Member States and economic operators without clear benefits in terms of improved levels of protection, the Council considered them acceptable.

3.2.3. Parliamentary amendments accepted in full, in part or in principle by the Commission but not incorporated in the common position

Amendments 11, 16, 24, 36, 48, 58-59, 62, 65-66, 72-74, 77-78, 99, 101, 106, 118, 120-121, 157, 162, 166, 175, 178, 191, 193, 196, 200, 203-204, 221-223, 236, 332, 358 and 361 were accepted in full, in part or in principle by the Commission but not incorporated in the Council's position. The most common reasons for the rejection of the amendments by the Council are inconsistency with other changes introduced by the Council, placing of undue administrative burden on industry, competent authorities or the Agency and no clear added value of the amendments.

3.2.4. Parliamentary amendments rejected by the Commission and the Council and not incorporated in the common position

Amendments 12, 14-15, 19, 26, 28, 40-42, 45-47, 50-51, 57, 64, 81, 84, 92, 97-98, 100, 102-105, 107-111, 117, 119, 122, 127-136, 138, 140-141, 145-147, 150, 158-159, 163-164, 173-174, 176, 182, 188, 192, 195, 197-198, 201, 205, 216-217, 224, 233, 237-238, 240, 246, 250-253, 258-259, 262-265, 270-271, 274, 280-288, 291, 297, 306-307, 309, 318, 321-322, 330, 342-343, 350 and 353 were rejected by both the Commission and the Council.

3.2.5. Changes made by the Council to the Proposal

The Council proposed the following main changes to the Commission proposal:

Inclusion of active substances: the Council has changed the procedure for the approval of inclusions of active substances. The list of approved active substances would not be included as an Annex to the Regulation but would be established as a free standing measure through implementing measures and regularly updated. The Commission considers that the approval of active substances should be undertaken by using an Annex to the Regulation. Consequently, any additions or amendments to the annex listing approved active substances would constitute changes to non-essential elements of the Regulation and would be adopted through delegated acts based on Article 290 TFEU. However, in order to allow the legislative procedure to continue, it will not oppose the changes introduced by the Council. The Commission has made a declaration on this matter at the time of the political agreement (see Annex 1).

Simplified authorisation procedure: the Council replaced the concept of 'low-risk biocidal products' with products subject to a simplified authorisation procedure. The criteria proposed for these products would be more focused on the properties of the substances contained in the product rather than on a case by case risk assessment of the product itself as was the case in the Commission's proposal. These products would no longer be subject to a Union level authorisation procedure as foreseen in the Commission's proposal but would instead be submitted for authorisation in one Member State. Once an authorisation is granted in one Member State, the product could then, subject to the submission of a notification, be marketed in each of the other Member States. The Commission considers that the Council's approach will encourage the development and marketing of biocidal products that present a lower risk to man and the environment and can therefore accept the Council's position on this issue.

The scope of the Union authorisation: According to the Council's position, the Union authorisation would, as of 2013, be open for biocidal products falling within product types 6, 7, 9, 10, 12, 13 and 22 and, as of 2020, for biocidal products falling within product types 14, 15, 17, 21 and 23, provided that the products concerned have similar conditions of use across the Union. At the latest by 2017, the Commission would carry out a review and accompany it, if appropriate, with legislative proposals; e.g. to postpone the opening of the Union authorisation for some or all product types listed. While the Commission initially proposed a Union authorisation system with much more limited scope, it can, in principle, accept the Council's position provided the extension is implemented gradually and that adequate resources are provided to the Agency and the Commission. The Commission has made a declaration underlining the resource implications and calling on the Member States to take the consequent steps to ensure the provision of adequate resources under the new financial perspectives (see Annex 2).

Treated articles: In line with the approach taken by the European Parliament, the Council introduced the 'primary biocidal function' as the criterion for differentiating between biocidal products and treated articles. Furthermore, it shifted the focus of control from biocidal products to active substances. The Council decided to impose stricter requirements for treated articles where the active substances are intended to be released ('external effect') than for treated articles where the active substances are not intended to be released ('internal effect'). Further rules may be adopted by the Commission, including the possibility of a notification scheme. The Commission can support these changes concerning treated articles as they are in line with the objectives of the Regulation.

Nature and composition of the Biocidal Products Committee: the Commission initially proposed the Committee to be composed of independent scientific experts who would be nominated by the Member States but appointed by the Management Board of the Agency. The Council opted for an approach according to which the members of the Committee would be directly appointed by the Member States and there would be close links between the Committee and Member States' competent authorities. Given that the responsibility for the detailed implementation of the Regulation will fall on the competent authorities in the Member States it is coherent that these same authorities should be closely involved in the work of the Biocidal Products Committee. The Commission can, therefore, accept the Council's position.

Fees: the Commission initially proposed a system whereby the fee for a Union authorisation would be paid to the Agency which would then reimburse the Member State for the work as an evaluating competent authority. The Council's position is based on a system where for the procedures carried out at the Union level, one fee is paid to the Agency for its work and another is paid to the competent authority which carries out the role of the evaluating competent authority. This is acceptable to the Commission. Further, the Commission's proposal foresaw that the amount of fees payable to the Agency as well as the harmonised structure (including issues such as reimbursements, reductions/waiving) of fees applicable to both the Agency and the Member States would be adopted by means of delegated acts. However, the Council's position foresees that the level of fees payable to the Agency and the rules defining conditions of payment and possible reductions should be adopted by means of implementing acts. With regard to the establishment of a harmonised structure of fees for the Agency and the Member States, Council has provided that the Commission may address these questions through guidance documents. Whilst the Commission regrets the approach taken by the Council, it can accept it in order to allow for the legislative procedure to continue. The Commission made a declaration set out in Annex 1 with respect to the Council's position on the use of delegated acts for setting the fees payable to the Agency.

To take account of the resource implications resulting from the changes introduced by the Council and the Parliament in the first reading, including the need to adjust the fee system as a way to reduce the impact on the Union budget, the Commission has prepared a revised financial statement which is attached as Annex 3 to this Communication.

4. CONCLUSION

The changes introduced by the Council are acceptable to the Commission as they are consistent with the objectives of the Commission's proposal and further build upon it. Therefore the Commission can accept the Council's position.

The Commission already outlined its concerns over the increased resource implications resulting for the Agency and the Commission in the declaration set out in Annex 2. In light of the additional tasks allocated to the Agency and the time needed to prepare all aspects of its future work as well as the fact that the legislative process is taking longer than initially anticipated, the Commission considers it necessary to postpone the date of applicability of the proposed Regulation to 1 September 2013 with the exception of provisions which allow the Commission and the Agency to take preparatory steps (e.g. delegated/implementing acts,guidance documents).

Annex 1

Declaration on comitology

In a spirit of compromise, the Commission will not stand against a qualified majority vote in favour of the Presidency text. However, the Commission would underline that it does not share the views of the Council that the measures for the approval of active substances (Article 8a) and for rules on fees payable to the European Chemicals Agency (Article 70(1)) are of an implementing nature and thus fall under Article 291 TFEU. As regards both these matters, the Commission is of the view Article 290 is the appropriate procedure given that they entail measures of general application which would modify or supplement the non-essential elements of the Regulation.

Annex 2

Declaration on resource implications

The extension of the scope of the Union authorisation together with additional tasks allocated to the European Chemicals Agency, the shorter deadlines and the increased frequency of renewals for active substances will necessarily result in a significant increase in the workload of the Agency and the Commission. At the same time, the workload for national authorities will accordingly be reduced as a result of a wider scope of Union authorisation. In light of the increased workload, the Agency and the Commission will need additional financial and human resources to ensure effective implementation of the Regulation. In view of this, the Commission calls on the Council to address these requirements under the new financial perspectives. The Commission is prepared to work with the Council on a suitable solution.

Annex 3

LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

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LEGISLATIVE FINANCIAL STATEMENT FOR PROPOSALS

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products.

1.2. Policy area(s) concerned in the ABM/ABB structure[1]

Policy area: 07 Environment

Activity Code 07 03: Implementation of Union environmental policy and legislation

1.3. Nature of the proposal/initiative

X The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[2]

☐ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objectives

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

Development of New Policy Initiatives (ABB code 07 05) – 2008 AMP

To prepare and propose environment policies, measures and initiatives, based on comprehensive and precise data on the state of the environment and pressures on it, consulting widely with interested parties, implementing the 6th EC Environment Action Programme. To prepare policy responses that may be necessary in the light of new evidence of threats to the environment, or to human health from the environment.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No.1c

To develop new policy initiatives to contribute to the objectives of the 6th EAP priority area of environment and health. Contribute to a high level of quality of life and social well being for citizens by providing an environment where the level of pollution does not give rise to harmful effects on human health and the environment and by encouraging a sustainable urban development.

ABM/ABB activity(ies) concerned ABB code 07 05

[1] ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

[2] As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The objectives of the proposal are to ensure a high level of protection of public health and the environment as well as the harmonisation of the internal market for biocidal products, while enhancing competitiveness and innovation.

To achieve these objectives it is necessary that the hazards and risks from active substances and biocidal products are fully known before they are placed on the market.

To ensure the efficient implementation of the proposal it is appropriate to rely on the existing European Chemicals Agency, which will receive and deliver opinions on data submitted by industry, for example, for the evaluation of active substances or certain biocidal products, and will be the focal point for providing scientific advice and assistance to the Commission, to Member State competent authorities, to enterprises, especially SMEs, and for making relevant information available to the public.

The harmonisation of the internal market for biocidal products and the enhancement of competitiveness and innovation will be strengthened by having a coherent approach to the treatment of applications submitted by industry, by simplifying procedures for the authorisation of products, and by encouraging the development of 'new' substances and products having a better public health or environmental profile, so as to enable the European Union to compete better with its international competitors, and bring about the greater availability of substances or products with lower risks.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

The objectives and indicators identified to date are as follows:

Objectives	**Indicators for the policy**
Assessment of new active substances in view of their approval	Number of opinions delivered. Time from reception of a valid application to transmission of opinion to the Commission.
Renewal of approval of active substances	Number of opinions delivered. Time from reception of a valid application to transmission of opinion to the Commission.
Establishment of technical equivalence between active substances	Number of opinions delivered. Time from reception of a valid application to transmission of opinion to the Commission.
Authorisations of products	Number of opinions delivered. Time from reception of a valid application to transmission of opinion to the Commission.

Opinion in case of disagreement during mutual recognition procedures	Number of opinions delivered. Time from reception of a Commission request to transmission of opinion to the Commission.
Tasks related to data sharing and confidentiality	Number of searches in the database. Number of request for information for non-confidential data.
Development of general and specific guidance documents	Number of guidance documents developed.
Maintenance of Union register on biocidal products	Number of searches in the database
Completion of the review programme of existing substances	Number of opinions delivered. Time from reception of a draft Competent authority report to finalisation of Competent authority report.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

Before any active substance can be authorised for use in a biocidal product, it must be assessed whether its use poses any unacceptable risk for the environment or public health. This assessment is done by Member State competent authorities followed by a peer review organised at the Union level, before a decision is taken by the Commission.

In addition, to improve the authorisation process of biocidal products, it is proposed that certain products will be authorised directly at the Union level at the choice of the applicant. Other categories of biocidal products will continue being authorised at Member State level.

Also, for biocidal products to be authorised by the Member States, through the mutual recognition procedure, divergence of opinions between Member States will need to be addressed through an ad hoc conflict resolution procedure. Most of these divergences of opinions are expected to be of a scientific or a technical nature.

Processes aimed at facilitating data sharing between prospective applicants, at establishing technical equivalence of substances manufactured from different sources, at disseminating information, at identifying active substance manufacturers entitled to place their active substance on the Union market will also have to be improved and or developed.

Last, genuine scientific and technical support, including the development and maintenance of IT tools, for the implementation of the Regulation will need to be provided.

All these tasks are described in further details in Appendix II.

1.5.2. Added value of EU involvement

Until today the Commission Joint Research Centre provides a significant input to the review programme of existing active substances[3]. However, with the downsizing of its activities in the field of chemical substances due to the transfer of many of these activities to ECHA, the Commission JRC already announced that it would also stop its activities in the field of biocidal products at the end of 2013 and would then concentrate on other priorities.

As the Commission services will then no longer have the expertise and resources to address issues of scientific or technical nature linked to the evaluation of active substances and the authorisation of biocidal products, it was considered most appropriate to seek advice and support from an external body.

Relying on an external body to carry out the risk assessment is also in line with the approach adopted in other sectors such as medicinal products, plant protection products, food, where there is a clear separation between risk assessment (carried out by scientific bodies) and risk management (carried out by the Commission).

Having excluded the possibility of establishing a specific body to be in charge of the risk assessment of active substances and biocidal products, three existing bodies were considered as possible candidates to provide this scientific and technical support in the field of biocides:

- The European Agency for the Evaluation of Medicinal Products (EMEA), because the proposal to authorise certain biocidal products at the Union level is modelled upon the lines and principles of what already exist since 1995 for medicinal products for veterinary and human use;

- The European Food Safety Authority (EFSA), because Directive 98/8/EC is often referred to as the sister Directive of Directive 91/414/EEC regulating the placing on the market of plant protection products and where EFSA is the official scientific body in charge of preparing opinions for the Commission; and

- The European Chemicals Agency (ECHA).

Limited synergies can however be expected from the first two options. On the other hand, the choice of ECHA is expected to create significant synergies, on the basis of the following considerations:

[3] The current Directive 98/8/EC provides for the systematic evaluation of active substances, which were already on the market on 14 May 2000, when that Directive came into force. This evaluation is carried out by Member States, which have all been allocated a number of substances for which they have to produce assessment reports. These assessment reports are then peer reviewed by the other Member States and discussed at different meetings organised by the Commission JRC for the scientific and technical issues and then by DG Environment for the final discussions before the final steps of the decision-making process are taken (Comitology procedure). The scientific and technical discussions and the associated preparatory work (reading the reports and analysing the different issues) require significant resources, which are currently provided by the Commission JRC and financed under the LIFE + programme under budget line 07 03 07.

- First and foremost, the evaluation of active substances used in biocidal products follows many of the methodologies and principles that also apply to chemical substances regulated under the REACH Regulation. Data requirements are similar and the risk assessment of these substances, notably when they have certain hazardous properties, is even of the direct competence of ECHA.

- In addition, the proposal includes rules concerning data sharing for biocidal products, which have now been aligned on those of REACH and makes the sharing of data involving testing on vertebrate animals mandatory. Only REACH and ECHA have already set up the mechanisms and the databases to make such sharing possible.

- Another important element of choice is that many of the ECHA scientific staff is already familiar with biocidal products, through previous work at the Commission JRC, in Member States Competent Authorities as well as in industry.

- Last but not least, producers, downstream users of biocidal products and even the Commission already have a number of obligations under REACH. Notably, the data held by the Commission JRC relating to active substances under evaluation in the review programme shall be made available to ECHA, in accordance with the provision of Article 16 of the REACH Regulation.

For these reasons, it is felt that the ECHA, amongst the other options at hand - a new agency, the Commission JRC, the EMEA or EFSA - is the most effective one in terms of possible synergies .

In addition, with the phasing out of the Commission JRC support concerning the review programme of existing active substances announced for the end of 2013, ECHA is expected to take over that role from 2014 onwards.

The legislative proposal therefore relies on the assumption that a number of tasks of a scientific and technical nature related to the assessment of active substances used in biocidal products and of certain biocidal products will be given to ECHA.

To this end, financial resources are needed to ensure that ECHA has the appropriate level of staff and is able to convene as many meetings as necessary to deliver its opinions to the Commission.

1.5.3. Lessons learned from similar experiences in the past

The proposal is based on the conclusions of a study carried out in 2007 to analyse the deficiencies of the current Directive. The results of this study (available at http://ec.europa.eu/environment/biocides/study.htm) were incorporated in the Commission report on the impacts of the implementation of Directive 98/8/EC (available at http://ec.europa.eu/environment/biocides/impl_report.htm).

The Impact Assessment carried out by the Commission addresses five policy issues that require action: the extension of the scope of the Regulation to include articles and materials treated with biocidal products; the improvement of procedures for product authorisation with the possibility to authorise certain products at the Union level; the introduction of mandatory data-sharing at product authorisation and active substance approval stage along the principles of the REACH Regulation; a clarification on data requirements with a combination of data waiving with the use of existing information and a new approach for low-risk biocidal products; a partial harmonisation of fee structure to encourage the development of more new active substances and the retention of more existing active substances.

1.5.4. Coherence and possible synergy with other relevant instruments

See 1.5.2.

1.6. Duration and financial impact

☐ Proposal/initiative of **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

X Proposal/initiative of **unlimited duration**[4]

1.7. Management mode(s) envisaged[5]

X **Centralised direct management** by the Commission

X **Centralised indirect management** with the delegation of implementation tasks to:

– ☐ executive agencies

[4] The duration of the action is not limited in time as the proposal establishes the rules applicable to the placing on the market of biocidal products. The financial impact is, however, expected to be limited to supporting the European Chemicals Agency (ECHA) in taking up the additional tasks related to the assessment of active substances used in biocidal products and of certain biocidal products. ECHA will indeed receive from industry specific fees for certain of these activities as well as an annual fee for products authorised by the Union. It is expected that ECHA will be taking steps to prepare for these tasks from the year 2011. As 2013 is the last year of the current financial programming, estimates of the commitment and payment appropriations have been limited to that of 2012 and 2013 in this financial statement.
A detailed analysis of the ECHA budget for these additional tasks is provided in appendixes to this revised financial statement for the years 2012 and 2013 as well as for the next 8 following years (i.e. until 2021), in order to match the timetable attached to the REACH revised legislative Financial Statement (SEC(2006)924).

[5] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

– X bodies set up by the Communities[6]

– ☐ national public-sector bodies/bodies with public-service mission

– ☐ persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

☐ **Shared management** with the Member States

☐ **Decentralised management** with third countries

☐ **Joint management** with international organisations ***(to be specified)***

If more than one management mode is indicated, please provide details in the "Comments" section.

Comments

The overall responsibility for the implementation and enforcement of the proposed legislation will rest with the Commission services. However, the scientific and technical support will be provided by the European Chemicals Agency. ECHA will in particular have to provide opinions on the level of risk presented by active substances used in biocidal products as well as on the authorisations of certain biocidal products. ECHA will provide opinions on the basis of which the Commission will take decisions.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

In order to evaluate the progress of implementation and effects of the new policy, the indicators as set out in 1.4.4 will be gathered and monitored at regular intervals. For the most part, this will be done as part of the normal activity of ECHA on an annual basis.

In addition to this, Member States shall submit to the Commission every three years a report on enforcement and control measures and results of these measures. The Commission shall also draw up a report on the implementation of the Regulation and in particular on the functioning of the Union authorisation procedure and on the implementation of the provisions concerning treated articles.

2.2. Management and control system

2.2.1. Risk(s) identified

As the Council text would significantly increase the workload for ECHA and the Commission, increased resources would need to be provided to cover the additional tasks to be carried out.

[6] As referred to in Article 185 of the Financial Regulation.

Increased resources are provided through this revised financial statement. However, it will need to be monitored over time whether these resources correspond correctly with these additional tasks.

2.2.2. Control method(s) envisaged

As indicated in Section 2.1, ECHA will report annually on the progress of implementation and on the effects of the new policy. Member States will also report every three years on enforcement and control measures. This information will be used by the Commission in order to prepare the report on the implementation of the Regulation.

Also, in view of the number of assumptions and the degree of uncertainties with the different calculations underlying this financial statement, ECHA staff levels will have to be reviewed on an annual basis taking into account the real volume of activities.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

The European Chemicals Agency has specific budgetary control mechanisms and procedures which are based on Regulation (EC, Euratom) No 2343/2002.

The Management Board of ECHA, which comprises representatives of the Member States, the Commission and the European Parliament (Article 79(1) of the REACH Regulation), produces an estimate of the revenue and expenditure of ECHA (Article 96(5)) and adopts the final budget (Article 96(9)). Each year, the provisional and final accounts are sent to the European Court of Auditors (paragraphs 4 and 7 of Article 97). The European Parliament gives a discharge to the Executive Director of ECHA regarding the implementation of the budget (Article 97(10)).

In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF) apply without restrictions to ECHA, in accordance with Article 98(1) of Regulation (EC) No 1907/2006.

In accordance with Article 98(2), ECHA is also bound by the Inter-institutional Agreement of May 25, 1999 concerning internal investigations by the European Anti-Fraud Office (OLAF).

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description……...…….]	Diff./non-diff (7)	from EFTA[8] countries	from candidate countries[9]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
2	07 03 60 01 European Chemicals Agency - Activities in the field of biocides legislation - Contribution to Titles 1 and 2 from Heading 2	Diff.	YES	NO	NO	NO
2	07 03 60 02 European Chemicals Agency -Activities in the field of biocides legislation - Contribution to Title 3 from Heading 2	Diff.	YES	NO	NO	NO

These budget lines will cover ECHA's staff and administrative expenditure (titles 1 and 2) and ECHA's operating expenditure (title 3) for the activities to be carried out in the field of biocidal products in accordance with this Regulation, as part of the annual subsidy to the European Chemicals Agency (ECHA) from the Union budget (in addition to any appropriations granted under budget items 02 03 03 01 and 02 03 03 02 to finance the activities of the REACH Regulation (EC) No 1907/2006 and CLP Regulation (EC) No 1272/2008).

- No new budget lines are requested

7 Diff. = Differentiated appropriations

8 EFTA: European Free Trade Association.

9 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places)

Heading of multiannual financial framework:	**2**	**Conservation and management of natural resources (including market expenditure and direct payments)**

DG: ENV			2012[10]	2013	Estimates of the operational appropriations are limited to the current financial programming running until 2013.	**TOTAL**
• Operational appropriations						
Number of budget line: 07 03 60 01	Commitments	(1)	1,507	4,050		5,557
	Payments	(2)	1,507	4,050		5,557
Number of budget line: 07 03 60 02	Commitments	(1a)	1,249	2,302		3,551
	Payments	(2a)	1,249	2,302		3,551
Appropriations of an administrative nature financed from the envelope for specific programmes[11]						
Number of budget line		(3)				
TOTAL appropriations for DG ENV	Commitments	=1+1a +3	2,756	6,352		9,108
	Payments	=2+2a	2,756	6,352		9,108

[10] Expenditure for 2012 are based on the subsidy to ECHA from the date of adoption onwards. Some preparatory measures are also financed in 2011 and 2012 under the LIFE Programme (budget line 07 03 07) for an estimated amount of 1,500 M€.

[11] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

		+3						

• TOTAL operational appropriations	Commitments	(4)	2,756	6,352				9,108
	Payments	(5)	2,756	6,352				9,108
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)						
TOTAL appropriations under HEADING 2 of the multiannual financial framework	Commitments	=4+ 6	2,756	6,352				9,108
	Payments	=5+ 6	2,756	6,352				9,108

Heading of multiannual financial framework:	**5**	Administrative expenditure

EUR million (to 3 decimal places)

		2012	2013	Estimates of the administrative appropriations are limited to the current financial programming running until 2013.	**TOTAL**
DG: ENV					
• Human resources					
• Other administrative expenditure		0,204	0,204		0,408
TOTAL DG ENV	Appropriations	0,204	0,204		0,408

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	0,204	0,204		0,408

EUR million (to 3 decimal places)

		2012	2013	Estimates of the total appropriations are limited to the current financial programming running until 2013.	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	2,960	6,556		9,516
	Payments	2,960	6,556		9,516

3.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– X The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs			2012		2013		Estimates of the operational appropriations are limited to the current financial programming running until 2013.										**TOTAL**	
	OUTPUTS																	
⇩	Type of output [12]	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE No 1: ECHA scientific and technical support			**Please refer to Appendix 1 for a detailed breakdown of ECHA's costs and to Appendix 2 for the main underlying assumptions.**															
TOTAL COST				2,756		6,352												9,108

[12] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of administrative appropriations

– X The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to 3 decimal places)

	2012	2013	Estimates of the administrative appropriations are limited to the current financial programming running until 2013.	**TOTAL**
HEADING 5 of the multiannual financial framework				
Human resources				
07 01 02 11 01 – Missions	0,024[13]	0,024		
07 01 02 11 03 – Committees	0,180[14]	0,180		
Other administrative expenditure				
Subtotal HEADING 5 of the multiannual financial framework	0,204	0,204		0,408

Additional resources will be required to cover participation in meetings held in ECHA and for the organisation of an increased number of meetings of the Standing Committee on Biocidal Products.

TOTAL	0,204	0,204		0,408

[13] 20 2-day missions to Agency per year at 1,200 EUR per mission

[14] Standing Committee on Biocidal Products: 6 one-day meetings per year at 30,000 EUR/meeting

3.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources

– X The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

		2012	2013	Estimates of human resources are limited to the current financial programming running until 2013
• Establishment plan posts (officials and temporary agents)				
07 01 01 01 (Headquarters and Commission's Representation Offices)		0	3	
XX 01 01 02 (Delegations)				
XX 01 05 01 (Indirect research)				
10 01 05 01 (Direct research)				
• External personnel (in Full Time Equivalent unit: FTE)[15]				
XX 01 02 01 (CA, INT, SNE from the "global envelope")				
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)				
XX 01 04 ***yy*** [16]	- at Headquarters[17]			
	- in delegations			
XX 01 05 02 (CA, INT, SNE - Indirect research)				
10 01 05 02 (CA, INT, SNE - Direct research)				
Other budget lines (specify)				
TOTAL		0	3	

No additional staff will be necessary in 2012. Three additional posts will be required in 2013. These posts will be provided through internal re-deployment. See Appendix IV for a detailed breakdown.

Description of tasks to be carried out:

Officials and temporary agents	Additional staff is required to process the opinions received from ECHA and to turn these opinions into Commission decisions through delegated and implementing acts.
External personnel	

15 CA= Contract Agent; INT= agency staff ("*Intérimaire")*; JED= "*Jeune Expert en Délégation"* (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert;

16 Under the ceiling for external personnel from operational appropriations (former "BA" lines).

17 Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

3.2.4. Compatibility with the current multiannual financial framework

– ☐ Proposal/initiative is compatible the current multiannual financial framework.

– X Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. 2,960 M€ in 2012 (1,507 M€ for budget line 07 03 60 01 and 1,249 M€ for budget line 07 03 60 02) 6,556 M€ in 2013 (4,050 M€ for budget line 07 03 60 01 and 2,302 M€ for budget line 07 03 60 02)

– ☐ Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[18].

3.2.5. Third-party contributions

– The proposal/initiative does not provide for co-financing by third parties.

[18] See points 19 and 24 of the Interinstitutional Agreement.

3.3. Estimated impact on revenue

– X Proposal/initiative has no financial impact on revenue.

– ☐ Proposal/initiative has the following financial impact:

  – ☐ on own resources

  – ☐ on miscellaneous revenue

There is no impact on the revenue side of the Union budget. ECHA's budget foresees its own revenues consisting of the fees paid by industry, which ECHA is authorised to collect by virtue of the tasks entrusted to it under this Regulation and a balancing subsidy from the Union budget.

The proposal foresees that ECHA would charge fees (see Appendix II), in particular for the approval and renewal of approval of active substances, for the evaluation of application for the authorisation, modification of authorisation and renewal of authorisation of certain biocidal products at the Union level, as well as an annual fee to be paid by holders of Union authorisations and a submission fee to be paid by all applicants for a first national authorisation of a product.

Although the activities relating to approval of active substances and authorisation of biocidal products are expected to be self-financed after a few years, a balancing subsidy from the Union budget could still be necessary, if the fee structure does not cover the expenses.

The present financial fiche has been established with the hypothesis that some tasks would not be covered by the fees:

– Preparation of opinions on questions referred to ECHA by virtue of Article 30 of the proposal, in case of disagreement between Member States during a mutual recognition procedure

– Tasks related to data sharing and confidentiality

– Development of general and specific guidance documents

– Completion of Review Programme for existing substances

– Reductions for SMEs (as proposed in point (a) of Article 70(2))

– Other tasks of Union interest not covered by fees

Also, the proposal requires a clear separation of ECHA's budget between activities to be carried out in accordance with the provisions of the REACH Regulation and the new and additional tasks derived from this proposal. As a consequence, expenditures and revenues under these additional tasks have to be clearly identified by the accounting system of the Agency.

Appendix I

Draft Budget for the European Chemicals Agency (in Euros)

Tasks related to biocidal products

Expenditure	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Title1										
Salaries & allowances	1.014.600	4.109.400	6.388.100	6.568.500	6.708.000	7.565.300	8.168.600	9.786.900	12.530.100	13.774.200
Other personnel costs*	157.300	637.000	990.200	1.018.100	1.039.700	1.172.600	1.266.100	1.517.000	1.942.200	2.135.000
Total Title 1	**1.171.900**	**4.746.400**	**7.378.300**	**7.586.600**	**7.747.700**	**8.737.900**	**9.434.700**	**11.303.900**	**14.472.300**	**15.909.200**
Title 2*										
20 Rental of building and associated costs	173.600	703.100	1.093.000	1.123.900	1.147.800	1.294.500	1.397.700	1.674.600	2.144.000	2.356.800
21 Information & communication technology	115.100	466.100	724.500	745.000	760.800	858.100	926.500	1.110.000	1.421.200	1.562.300
22 Movable property and associated costs	24.000	97.300	151.300	155.500	158.800	179.100	193.400	231.700	296.700	326.100
23 Current administrative expenditure	21.900	88.800	138.100	142.000	145.000	163.500	176.600	211.500	270.800	297.700
25 Meetings expenditure	400	1.700	2.700	2.800	2.800	3.200	3.500	4.100	5.300	5.800
Total Title 2	**335.000**	**1.357.000**	**2.109.600**	**2.169.200**	**2.215.200**	**2.498.400**	**2.697.700**	**3.231.900**	**4.138.000**	**4.548.700**
Title 3*										
3003-3006 Substances, products and technical equivalence	7.400	15.900	24.200	24.700	25.300	28.200	30.600	35.300	45.100	49.800
3007 Assistance and guidance through helpdesk	50.000	59.500	90.800	92.400	94.600	105.400	114.500	132.200	169.000	186.500
3008 Scientific IT tools**	1.000.000	1.700.000	400.000	400.000	400.000	400.000	400.000	400.000	400.000	400.000
3009 Scientific and technical advice to EU institutions and bodies	8.300	17.900	27.300	27.800	28.400	31.700	34.400	39.700	50.800	56.000
3011 Biocidal product committee	0	1.131.200	1.171.200	1.086.900	1.197.800	1.235.800	1.287.000	1.345.000	1.302.800	1.480.600
3011 Fees paid to rapporteurs	0	56.000	111.000	271.000	275.000	444.800	452.600	474.000	874.000	880.000
3012 Board of appeal	0	22.400	34.200	34.900	35.700	39.800	43.200	49.900	63.800	70.300
3013 Communication including translations	100.000	300.000	200.000	200.000	200.000	200.000	200.000	200.000	200.000	200.000
3022 Management Board and management of the Agency	44.300	95.500	145.600	148.300	151.800	169.200	183.700	212.100	271.200	299.200
3030 Missions	25.000	25.800	39.300	40.000	41.000	45.700	49.600	57.200	73.200	80.800
3031 External training	3.700	8.000	12.300	12.500	12.800	14.200	15.500	17.900	22.800	25.200
38 International activities	10.900	46.900	71.500	72.800	74.500	83.000	90.200	104.100	133.100	146.900
Total Title 3	**1.249.600**	**3.479.100**	**2.327.400**	**2.411.300**	**2.536.900**	**2.797.800**	**2.901.300**	**3.067.400**	**3.605.800**	**3.875.300**
Total	**2.756.500**	**9.582.500**	**11.815.300**	**12.167.100**	**12.499.800**	**14.034.100**	**15.033.700**	**17.603.200**	**22.216.100**	**24.333.200**
Revenues										
Union subvention	2.756.500	6.351.800	4.936.800	3.151.800	3.053.000	1.842.200	1.974.600	2.954.300	-322.800	-1.386.400
Fee income of agency	0	3.230.700	6.878.500	9.015.300	9.446.800	12.191.900	13.059.100	14.648.900	22.538.900	25.719.600
Over income to next year	0	0	0	0	0	0	0	0	0	0
Total	**2.756.500**	**9.582.500**	**11.815.300**	**12.167.100**	**12.499.800**	**14.034.100**	**15.033.700**	**17.603.200**	**22.216.100**	**24.333.200**

*Relative to staff costs (based on ECHA 2011budget)

**Between 2014 and 2021, annual maintenance costs fixed at 20% of the initial development costs

Appendix II

Applied methodology and main underlying assumptions for the financial model of the European Chemicals Agency for activities relating to biocides

At the time of the political agreement, the Commission made a statement pointing out that the Council text would significantly increase the workload for ECHA and the Commission and that increased resources would need to be provided to cover the additional tasks to be carried out.

Concerning the role of ECHA, the Council's political agreement has introduced some important changes as compared to the Commission's initial proposal:

- the scope of the EU centralised procedure for product authorisation has been widened significantly which will mean that the Agency – but also the Commission - will have to process considerably more applications than initially foreseen;

- ECHA will have a greater involvement in data sharing in order to avoid duplicate testing on vertebrates and will also be called upon to take decisions regarding the "technical equivalence" of similar active substances;

- ECHA is now explicitly identified as providing the secretariat for the co-ordinating group overseeing mutual recognition;

- ECHA will be responsible for maintenance of the Register for Biocidal Product which will also include information important in view of data sharing;

- Finally, ECHA will only receive the fees necessary for its work including the functioning of the Biocidal Product Committee. Member States will charge their own fees directly including when they are acting as an evaluating Member State for an application at EU Level.

This revised financial fiche takes account of the additional workload both for ECHA and for the Commission.

This revised financial fiche also takes into account the revised timing for the adoption of the Regulation. As the regulation is now expected to be adopted around mid-2012, the 2012 staff levels and resources have been adjusted accordingly.

19 staff will be needed in 2012 rising rapidly to 59 in 2013 to eventually reach 110 by 2021(further details are provided in Appendix III).

The majority of ECHA's additional resource costs will be covered by the additional revenues derived from fees. However, there will need to be an EU subsidy for the early years to bridge the gap until the fee revenues achieve a sufficient level. ECHA will also face significant investment costs in the IT system necessary to manage the information flow linking applicants, Agency, Member States, the Commission and the general public.

While recognizing that the Union is in a period of severe financial constraints, it is nevertheless unrealistic to load further tasks on ECHA and the Commission without allocating the resources necessary to carry out these additional tasks.

Title 1 costs (staff costs)

Due to the fact that the Commission JRC in Ispra currently has a major role in operating the review programme of active substances used in biocidal products established by Directive 98/8/EC, significant experience exists with regard to how long certain tasks take and what kind of resources are needed in order to carry them out (differentiation between different categories of staff).

Based on this experience and on the model developed for the operation of REACH, a staff model has been developed for the operation of the activities related to biocides. The output of this staff model is how many staff (by grade) are required in a given year to fulfil the tasks of ECHA (operational tasks of the biocides legislation).

To these staff numbers additional resource requirements have been added for the management and training of these resources, taking into account economies of scale that can be achieved in particular in support tasks and staff from existing arrangements set up for the implementation of the REACH Regulation (e.g. for international relations, for external communication, helpdesk services, the Legal Department, Audit and Internal Control, Human Resources (HR), Finance, Information Technology (IT) Building Management). Based on the current ECHA staff ratio, these additional resources amount to 30% of those required for the operational tasks related to the biocidal legislation.

For the scientific staff, the ratio in % of AD and AST grades is in compliance with the REACH staff model. As is the case for staff carrying out REACH related tasks, a higher number of AD than AST staff is justified because of the complexity of the scientific tasks.

For 2012, it is proposed that ECHA should be able to recruit staff to prepare the ground before the date when ECHA tasks relating to biocidal products come into operation.

From 2013, ECHA would then be responsible for the different tasks set out in the proposal.

From 2014, the responsibility of coordinating the review programme of existing substances would be transferred from the Commission JRC to ECHA. ECHA would therefore need extra resources to carry out this additional task. Based on the current assumptions, ECHA would require 5 additional scientific officers to carry that task (who could already be recruited in second semester of 2013 to prepare the activities and ensure a smooth hand-over). It has also been taken into account that, based on the current pace of less than 30 dossiers being finalised every year by Member States, the Review Programme would last until 2024, assuming that the pace of evaluation would speed up to 50 dossiers being finalised every year as certain dossiers could be grouped for substances supported in several product-types.

Appendix III sets out the proposed establishment plan related to this proposal. The budget set out in Appendix I takes into account permanent / temporary staff (i.e. that appears in establishment plan) and contract agents (count for staff costs but do not appear in establishment plan).

All the resources computed have been multiplied by the average annual cost by grade and that has led to the total staff costs. In addition, the weighting factor for Helsinki (121.3% – cost of living adjustment applicable to all staff) and an annual indexation of 2% have been applied.

The other personnel costs in Title 1 have been assumed to represent 15.5% of salary costs of permanent / temporary staff - based on the current ratio between Articles 110, 111, 119 and the other Articles of Title 1 of the 2011 Agency budget.

Applied average costs for permanent/temporary staff by grade per annum (source ECHA)

Grade	Salary
AD 13	**243.156**
AD 12	**195.900**
AD 5-11	**120.288**
AST 7-11	**104.778**
AST 1-6	**66.872**

Applied average costs for contract agents by function group per annum (source ECHA)

Grade	Salary
FG IV	**55.632**
FG III	**54.648**
FG II	**34.992**

For the purpose of the computation of the staff required it has been assumed that per year the following resources would be needed:

– a desk officer per 8 applications for product authorisation;

– a desk officer per 8 applications for new active substance evaluation;

– a desk officer per 20 applications for the establishment of technical equivalence;

– a desk officer per 30 applications to amend an existing product authorisation;

– a desk officer per 20 opinions requested in case of disagreement during Mutual Recognition.

Title 2 costs (building, equipment and miscellaneous operating expenditure)

All building, equipment, furniture, IT and other administrative expenditure are directly proportional to the number of required staff and have been assumed to represent - based on the current ratio between Title 1 and Title 2 of the 2011 Agency budget - 28.6% of the total of Title 1.

Title 3 costs (Operating expenditure)

The major cost driver for the general operating expenditure is the expenditure for the Committee for Biocidal Products. The current average cost of a three day meeting of the ECHA Member State Committee is 70.000 EUR.

For the Committee for Biocidal Products and its experts groups, the costs include the reimbursement of travel, hotel, daily allowances according to currently applicable Commission rates.

The number of meeting-days/year of the Biocidal Products Committee has been set to 17 in 2013. Thereafter the number of meetings will increase to reflect the proportional increase in the number of opinions to be delivered.

The costs of sub-groups meetings has also been taken into account, assuming that there would be 4 sub-groups that would each meet 7 times a year on average during 2 days with 15 experts present in 2013 and 2014. Thereafter the number of meetings will also increase to reflect the proportional increase in the number of opinions to be delivered.

There is no coverage for the meetings of the Coordination Group, as these meetings are planned to be organised in ECHA back-to-back to the meetings of the Biocidal Products Committee.

Awareness rising to alert companies to their responsibilities will need to take place in the early years of the coming into force of the Regulation – a specific campaign will need to be planned and executed. While the staff needs for this activity is covered by the horizontal and support staff the work will also require a budget to cover the cost of at least one event (100.000 EUR); the production and translation (into 22 languages) of Guidance, an IT manual, simple publications explaining the legislation and its implications (400.000 EUR); webinars for companies (10.000 EUR); advertising and PR support (80.000 EUR); and a benchmarking survey at the start of the campaign for evaluation purposes (10.000 EUR). The costs of these activities are covered by the Communication budget for 2012, 2013 and 2014.

Mission costs reflect the many activities (support to Commission services, IT development, monitoring of the current review programme, awareness raising) which will require intensive contacts with the Commission services, Member States competent authorities, industry and other stakeholders.

The IT costs reflect the future needs. 1 million EUR and 1.7 million EUR will be necessary in respectively 2012 and 2013 due to the complexity of the transactions, number of active users, and new elements. This would also bring future amounts to a level of 400,000 EUR per year since maintenance should be calculated as 20% of the initial investment. This level of maintenance is justified especially as it is not realistic to assume a stable system after the initial investment without considerable evolving elements.

It has also been assumed for the purpose of the computation of ECHA expenses that 12.5% of the fee paid to ECHA would be paid back to the Rapporteur in charge of coordinating the peer-review of the scientific evaluation carried out by the evaluating Competent Authority.

Computation of expected fee income:

It is assumed that ECHA will have a very simple fee structure for tasks related to biocidal products.

For the purpose of the computation of the expected fee income it has been assumed that:

– Fees for approval of an active substance amount to EUR 80,000

– Fees for renewal of an approval amount to EUR 20,000 when a thorough evaluation is required but can be reduced to 5,000 when this is not the case.

– Fees for amendments to product authorisation range from EUR 5.000 to EUR 20.000 depending on the nature of the amendment and the extent to which data need to be re-assessed.

– Fees for the establishment of technical equivalence amount to EUR 20,000

– Fees for product authorisation amount to EUR 80,000 but can be increased to 120.000, when there will be a need to perform a comparative risk assessment.

– Annual fees amount to EUR 20,000

– Submission fees for a first national authorisation of a product amount to EUR 4,000

The specific needs of SMEs will be taken into account, as appropriate.

The amounts of fees above were calculated to ensure that the Agency would function on the basis of full-costs recovery and become self-financed by 2021.

It should be born in mind that a fee will also be charged by the evaluating Member State. For a product authorisation issued at Union level, applicants will thus have to pay EUR 80.000 to ECHA and another fee to the evaluating Member State. If one compares these fees with what would need to be paid in the case of mutual recognition (an evaluating fee to the Reference Member State and processing fees to the Concerned Member State), it is assumed that the fees charged for the centralised procedure will be of the same order of magnitude as those charged for a Mutual Recognition procedure involving 18, and possibly less, Member States, as one should also take into account all the support costs associated with the submission of applications in different Member States that will be saved for companies opting for the centralised procedure.

The submission fee, to be paid by all applicants for a first national authorisation of a product, is intended to cover the costs of ECHA support to national authorisation and mutual recognition of these authorisations. ECHA will indeed provide the secretariat to the coordination group overseeing mutual recognition and an IT platform, which should be used by applicants for the submission of their applications and the dissemination of their application to Member States.

One of the other underlying assumptions for the computation of the expected fee income is the number of products for which applications for a Union authorisation will be submitted.

The computation is rather complex and includes several parameters or assumptions:

- the number of products on the market today (20.000);
- the proportion of products to be eventually supported and authorised in accordance with the proposed Regulation (2/3);
- the application of the new concept of biocidal product family, which will facilitate the authorisation of very similar products through one application and decision (it was assumed that biocidal product families would contain 6 products on average for PT 1 to 5);
- the timing of decisions to be taken regarding the approval of active substances in the context of the Review programme for existing active substances;
- the obligation that products containing existing active substances should be authorised in accordance with the proposed Regulation within two years of the approval of active substances;
- the product-types included in the scope and the timelines for these product-types to be eligible for the centralised procedure as proposed by the Council;
- 30% of companies will opt for the centralised procedure when they will be in the position to do so.

All this taken into account, it is expected that the number of applications will raise from 10 in 2014 to 140 in 2021, as indicated in the table below:

	2013	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
Applications/year	0	10	40	50	70	70	70	140	140

Similarly, the number of expected applications for the establishment of technical equivalence has been set to 50 per year in the early years of the coming into force of the Regulation, and to 20 afterwards, as one would expect a peak of requests during these years, as companies will be expected to seek the establishment of the technical equivalence of their active substance with the one supported under the Review programme for existing active substances before starting to negotiate data sharing agreements.

	2013	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
Applications/year	50	50	50	20	20	20	20	20	20

Last but not least, in view of the number of assumptions and the degree of uncertainties with the different calculations, the staff levels will have to be reviewed on an annual basis taking into account the real volume of activities.

As an indication, a revenue increase from fees of 200.000 EUR would allow a 1 FTE increase to the staff level and a EUR 40.000-addition to Title 3. Conversely, if fees do not materialize as expected, then staff and Title 3 costs should be also adjusted accordingly.

Appendix III

Staff requirements in full time equivalent (FTE)

		2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Completion of review programme	AD		5,0	5,0	5,0	5,0	5,0	5,0	5,0	5,0	5,0
	AST			1,3	1,3	1,3	1,3	1,3	1,3	1,3	1,3
Approval of new active substances	AD		0,6	0,6	0,6	0,6	0,6	0,6	0,6	0,6	0,6
	AST		0,2	0,2	0,2	0,2	0,2	0,2	0,2	0,2	0,2
Renewal of active substance approvals	AD		0,3	0,3			0,2	0,4	4,0	6,0	6,0
	AST								1,4	2,1	2,1
Technical equivalence	AD	2,0	2,5	2,5	2,5	1,0	1,0	1,0	1,0	1,0	1,0
	AST		0,9	0,9	0,9	0,4	0,4	0,4	0,4	0,4	0,4
Authorisation of biocidal products	AD		1,0	1,3	5,0	5,0	8,8	8,8	8,8	17,5	17,5
	AST			0,4	1,8	1,8	3,1	3,1	3,1	6,1	6,1
Amendments of Union authorisations	AD				0,2	0,8	1,5	2,7	3,8	5,0	6,0
	AST				0,1	0,3	0,5	0,9	1,3	1,8	2,1
Mutual Recognition disagreements	AD		2,0	2,0	2,0	2,0	2,0	2,0	2,0	2,0	2,0
	AST		0,7	0,7	0,7	0,7	0,7	0,7	0,7	0,7	0,7
Data sharing and confidentiality	AD		3,0	3,0	2,0	2,0	2,0	2,0	2,0	2,0	2,0
	AST		0,8	0,8	0,5	0,5	0,5	0,5	0,5	0,5	0,5
Communication and guidance	AD	5,0	8,0	5,0	5,0	5,0	5,0	5,0	5,0	5,0	5,0
	AST		2,0	2,8	2,8	2,8	2,8	2,8	2,8	2,8	2,8
Committees and board of appeal	AD	1,0	4,1	4,2	4,1	4,2	4,2	4,3	4,3	4,3	4,5
	AST		0,8	0,8	0,7	0,8	0,8	0,8	0,9	0,9	0,9
IT development and maintenance	AD	4,0	4,0	4,0	3,0	3,0	3,0	3,0	3,0	3,0	3,0
	AST	2,0	2,0	2,0	1,0	1,0	1,0	1,0	1,0	1,0	1,0
Support staff	AD	3,0	10,0	9,0	10,0	9,0	11,0	11,0	14,0	18,0	17,0
	AST	1,0	2,0	3,0	2,0	3,0	4,0	4,0	6,0	7,0	7,0
Overall Management	AD	1,0	5,3	5,2	5,3	5,2	5,5	5,6	10,2	11,0	11,1
	AST		2,0	3,0	3,0	3,0	3,0	3,0	5,0	5,0	5,0
Total staff	**AD**	**16**	**47**	**43**	**45**	**44**	**50**	**52**	**63**	**81**	**81**
	AST	**3**	**12**	**16**	**14**	**15**	**19**	**20**	**28**	**29**	**29**
	TA	**11**	**47**	**50**	**50**	**50**	**60**	**60**	**80**	**100**	**100**
	CA	**8**	**12**	**9**	**9**	**9**	**9**	**12**	**9**	**10**	**10**
	Overall	**19**	**59**	**59**	**59**	**59**	**69**	**72**	**87**	**110**	**110**

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2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
11	**47**	**50**	**50**	**50**	**60**	**60**	**80**	**100**	**100**

Appendix IV

Commission resources

The number of opinions to be delivered by the Agency is expected to rise from 85 in 2013 to more than 400 in 2021 (see table below).

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Approval of new active substances		5	5	5	5	5	5	5	5	5
Approval of existing active substances		50	50	50	50	50	50	50	50	50
Renewal of active substance approvals		0	0	3	3	0	0	2	4	40
Authorisation of biocidal products		0	0	10	40	40	70	70	70	140
Amendments of Union authorisations		0	0	0	5	25	45	80	115	150
Opinion in case of disagreement during Mutual Recognition		30	30	30	30	30	30	30	30	30
Total		**85**	**85**	**98**	**133**	**150**	**200**	**237**	**274**	**415**

These opinions will have to be turned into Commission decisions through delegated and implementing acts.

This will represent a significant increase to the current workload, for which additional resources will need to be provided.

On the basis of the current practice and of the experience of other Commission services, it is estimated that one AST will be required for every 40 opinions. AD posts will also be needed to manage and coordinate the team of AST.

The number of additional posts would thus rise from 2 in 2013 to 12 in 2021.

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
AD		1	1	1	1	1	1	1	1	2
AST		1	1	1	3	3	5	6	7	10
Total		**2**	**2**	**2**	**4**	**4**	**6**	**7**	**8**	**12**

The additional posts of 2013 will be provided through internal re-deployment. The evolution of the needs will be assessed in the annual exercice of allocation of ressources.