COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 29.10.2004
COM(2004) 737 final

2004/0258 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

(presented by the Commission)

{SEC(2004) 1348}

EXPLANATORY MEMORANDUM

1. BACKGROUND

This proposal aims to implement at Community level the WTO General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Declaration on the TRIPs Agreement and Public Health (WT/L/540 of 2 September 2003).

By waiving WTO Members' obligations under Article 31(f) of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement), this Decision allows WTO Members to grant compulsory licences for the production and sale of patented pharmaceutical products intended for export to third countries with insufficient or no manufacturing capacity in the pharmaceutical sector. It includes substantial safeguards against trade diversion and rules to ensure transparency, and provides for future replacement of the Decision by an amendment to the TRIPs Agreement.

2. NEED FOR A COMMUNITY INTERVENTION

Given the active role played by the European Communities and their Member States in the adoption of the Decision, their commitment made at the WTO to fully contribute to the implementation of the Decision and their appeal to all WTO Members to ensure that the right conditions are put in place to allow the system set up by the Decision to operate efficiently, it is important for the Community to contribute to the system set up by the Decision through implementation in the Community legal order.

Within the Community uniform implementation of the Decision is needed to ensure that the conditions for the granting of compulsory licences for export are the same in all EU Member States, to avoid distortion of competition for operators in the EU single market and to apply uniform rules to prevent re-importation into the territory of the European Union of pharmaceutical products manufactured under compulsory licences.

In view also of the very specific nature of the provisions of the Decision, the fact that national arrangements for compulsory licensing already exist, and the need for urgent action to allow for the export of medicines to countries with public health problems, the Commission proposes implementation by way of a Regulation based on Articles 95 and 133 of the Treaty.

3. PROPOSED PROVISIONS

Article 1

The Regulation sets out a procedure and conditions for the grant of compulsory licences in line with the Decision. While supplementary protection certificates are not mentioned in the Decision, within the EU they entail the same effects as patents and so are included.

Article 2

The definition of the term "pharmaceutical product" is taken from the Decision, with text to reflect the definition of medicinal product in Directive 2001/83/EC.

Article 3

The competent authorities for granting compulsory licences pursuant to the Regulation will be those notified by the Member States.

Article 4

Eligibility is based on notifications and declarations to the WTO.

Article 5

This includes key elements of information required under the Decision and the TRIPs Agreement. The requirement to provide evidence of a specific request to the applicant by the importing country or from its authorised representatives should help ensure effective control of the amount of product supplied under compulsory licences**.**

Article 6

Competent authorities should verify whether basic conditions to trigger the system set out in the Decision have been met.

Article 7

Paragraph 1 reflects Article 31(b) of the TRIPs Agreement. While the TRIPs Agreement allows this requirement to be waived in the case of a national emergency or other circumstances of extreme urgency, here it is retained (paragraph 2) in view of the speed of modern communications and the desirability of voluntary agreements.

Article 8

This provision takes over the conditions set out in paragraph 2(b) of the Decision. In addition it reflects conditions usually found in licensing agreements.

Article 9

This specifies under which conditions a competent authority can refuse an application.

Article 10

Paragraph 2(c) of the Decision requires the exporting Member to notify the WTO Council for TRIPS about the grant of any licence. As the Commission is the usual interlocutor before the WTO for matters falling under the Common Commercial Policy, such notifications should be made via the Commission.

Articles 11 – 13

These are based on equivalent provisions in Council Regulation (EC) No 953/2003 on trade diversion.

Article 14

Termination of the licence is provided for if (a) the licence conditions are not respected, or (b) the circumstances which led to grant of the licence cease to exist (Article 31(g) of the TRIPs Agreement).

Article 15

Article 31(i) and 31(j)) of the TRIPs Agreement require provision to be made for review of decisions.

Article 16

As the licensee will not necessarily hold a medicinal products marketing authorisation within the EU for the product manufactured under a compulsory licence for export, the Regulation provides for licensees to ask for a scientific opinion from the European or national regulatory authorities if they should need this for export to the country concerned. Derogations from data protection and caducity rules are provided.

Article 17

This provides for review three years after entry into force of the Regulation.

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

Whereas:

(1) On 14 November 2001 the Fourth Ministerial Conference of the World Trade Organisation (WTO) adopted the Doha Declaration on the TRIPS Agreement and Public Health. The Declaration recognises that each WTO Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. It also recognises that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing.

(2) On 30 August 2003 the General Council of the WTO adopted the Decision on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, hereinafter "the Decision". Subject to conditions, the Decision waives certain obligations concerning the issue of compulsory licences set out in the TRIPS Agreement, to address the needs of WTO Members with insufficient manufacturing capacity.

(3) Given the Community's active role in the adoption of the Decision, its commitment made at the WTO to fully contribute to the implementation of the Decision and its appeal to all WTO Members to ensure that conditions are put in place which will allow the system set up by the Decision to operate efficiently, it is important for the Community to implement the Decision in its legal order.

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1 OJ C […] […], p.[…]
2 OJ C […] […], p.[…]
3 OJ C […] […], p.[…]

(4) Uniform implementation of the Decision is needed to ensure that the conditions for the granting of compulsory licences for export are the same in all Member States and to avoid distortion of competition for operators in the single market. Uniform rules should also be applied to prevent re-importation into the territory of the Community of pharmaceutical products manufactured pursuant to this Regulation.

(5) This Regulation is intended to be part of the wider European and international action to address public health problems faced by least developed countries and other developing countries, and in particular to improve access to affordable medicines.

(6) As the compulsory licensing system set up by this Regulation is intended to address public health problems, it should be used in good faith. It should not be used with the primary purpose of addressing other objectives, and in particular objectives of a purely commercial nature.

(7) Products manufactured pursuant to this Regulation should reach those who need them and should not be diverted from those for whom they were intended. Compulsory licences issued under this Regulation should therefore impose clear conditions upon the licensee as regards the acts covered by the licence, the identification of the pharmaceutical products manufactured under the licence and the countries to which these products will be exported.

(8) Provision should be made for customs action at external borders to deal with products manufactured and sold for export under a compulsory licence and which a person attempts to re-import into the territory of the Community.

(9) To avoid facilitating overproduction and possible diversion of products, competent authorities should take into account existing compulsory licences for the same products and countries, as well as parallel applications indicated by the applicant,

(10) Since the objectives of the action to be taken, in particular the establishment of harmonised procedures for the granting of compulsory licences which contribute to the effective implementation of the system set up by the Decision, cannot be sufficiently achieved by the Member States because of the options available to exporting countries under the Decision and can therefore, by reason of the potential effects on operators in the internal market, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS REGULATION:

Article 1

This Regulation establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible WTO members affected by public health problems.

Member States shall grant a compulsory licence to any person making an application in accordance with Article 5 and subject to the conditions set out in Articles 5 – 8.

Article 2

For the purposes of this Regulation, the following definitions shall apply:

(1) "pharmaceutical product" means any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council[4], active ingredients and diagnostic kits;

(2) "right holder" means the holder of any patent or SPC in relation to which a compulsory licence has been applied for under this Regulation; in cases where more than one right holder is involved, for the purposes of this Regulation the singular term should be read as plural;

(3) "importing WTO member" means the name of the WTO member to which the pharmaceutical product is to be exported;

Article 3

The competent authorities in the Member States for granting compulsory licences under this Regulation shall be those which have competence for the granting of compulsory licences under national patent law, unless the Member State concerned determines otherwise.

Member States shall notify the Commission of the competent authorities designated for the purposes of this Regulation.

Notifications shall be published in the *Official Journal of the European Union*.

Article 4

The following are eligible importing WTO members:

(a) any least-developed country member of WTO

(b) any other member of WTO that has made a notification to the Council for TRIPs of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

However, any WTO member that has made a declaration to the WTO that it will not use the system as an importing WTO member is not an eligible importing WTO member.

[4] OJ L 311, 28.11.2001, p. 67

Article 5

1. Any person may submit an application for a compulsory licence under this Regulation to a competent authority in the Member State or States where patents or supplementary protection certificates have effect and cover his intended activities of manufacture and sale for export.

2. If the person applying for a compulsory licence is submitting applications to competent authorities in more than one Member State for the same product, he shall indicate that in each application, together with details of the quantities and importing WTO members concerned.

3. The application pursuant to paragraph 1 shall set out the following:

   (a) the name and contact details of the applicant and of any agent or representative the applicant has appointed to act for him before the competent authority;

   (b) the name of the pharmaceutical product or products the applicant intends to manufacture and sell for export under the compulsory licence, including any additional information needed to ensure the precise identification of the product or products in question;

   (c) identification of the patent(s) and/or supplementary protection certificate(s) in respect of which a compulsory licence is sought;

   (d) the amount of pharmaceutical product which the applicant seeks to produce under the compulsory licence;

   (e) the importing WTO member or members;

   (f) evidence of prior negotiation with the right holder pursuant to Article 7;

   (g) evidence of a specific request to the applicant from authorised representatives of the importing WTO member and indicating quantity of product required.

4. The competent authority may prescribe additional formal or administrative requirements for efficient processing of the application.

Article 6

1. The competent authority shall verify that each importing WTO member cited in the application has made a notification to the WTO pursuant to the Decision of 30 August 2003 of the General Council of the WTO on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, hereinafter "the Decision" in respect of each of the products covered by the application that:

   (a) specifies the names and expected quantities of the product(s) needed;

   (b) unless the importing WTO member is a least-developed country, confirms that the importing WTO member has established that it either has no manufacturing capacities in the pharmaceutical sector or has examined its manufacturing

capacity in that sector and found that, excluding any capacity owned or controlled by the right holder, it is currently insufficient for meeting its needs;

(c) confirms that where a pharmaceutical product is patented in the territory of the importing WTO member, that WTO member has granted or intends to grant a compulsory licence for import of the product concerned in accordance with Article 31 of the TRIPS Agreement and the provisions of the Decision.

2. The competent authority shall verify that the quantity of product cited in the application does not exceed that notified to the WTO by the importing WTO member(s), and that, taking into account other compulsory licences ordered in the Community, the total amount of product authorised to be produced for any importing WTO member does not significantly exceed the amount notified to the WTO by that member.

Article 7

The applicant shall provide evidence to satisfy the competent authority that he has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

The determination of a reasonable period of time shall take into account whether the importing WTO member has declared a situation of national emergency or other circumstances of extreme urgency.

Article 8

1. The licence granted shall be non-exclusive and non-assignable. It shall contain the specific conditions set out in paragraphs 2 to 8 to be fulfilled by the licensee.

2. The amount of patented product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing WTO member or members cited in the application.

3. The licence shall be strictly limited to the acts of manufacturing the product in question and selling for export to the WTO member or members cited in the application. No product made under the compulsory licence shall be offered for sale or put on the market in any country other than the WTO member(s) cited in the application.

4. Products made under the licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to this Regulation. The products shall be distinguished from those made by the right holder through special packaging. The packaging and any associated literature shall bear an indication that the product is subject of a compulsory licence under this Regulation, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and sale in the importing WTO member or members concerned. Unless the applicant proves that such distinction is not feasible or has a significant impact on price, special colouring or shaping of the products themselves shall also be required.

5. Before shipment to the importing WTO member or members cited in the application, the licensee shall post on a website the following information:

   (a) the quantities being supplied under the licence and the WTO members to which they are supplied

   (b) the distinguishing features of the product or products concerned.

   The website address shall be communicated to the competent authority.

6. If the product(s) covered by the compulsory licence are patented in the importing WTO members cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import and sale of the products.

7. The licensee shall keep complete and accurate books and records of all quantities of product manufactured and of all dealings therein. The licensee shall make these books and records available on request to an independent person agreed by the parties, or otherwise appointed by the competent authority, for the sole purpose of checking whether the terms of the licence, and in particular those relating to the final destination of the products, have been met.

8. The licensee shall be required to provide proof of exportation of the product, through a declaration of exportation certified by the customs authority concerned, and proof of importation or putting on the market certified by an authority of the importing WTO member, and shall retain such records for at least three years. Upon request these proofs must be supplied to the competent authority.

9. The licensee shall be responsible for the payment of adequate remuneration to the right holder as determined by the competent authority taking into account the economic value of the use that has been authorised under the licence to the importing WTO member(s) concerned.

Article 9

The competent authority shall refuse an application if any of the conditions set out in Article 5 (3) and (4) and Articles 6, 7 and 8 is not met. Before refusing an application, the competent authority shall give the applicant an opportunity to rectify the situation and to be heard.

Article 10

1. When a compulsory licence has been granted the competent authority shall notify the Commission of the grant of the licence, and of the specific conditions attached to it.

   The information provided shall include the following details of the licence:

   (a) the name and address of the licensee;

   (b) the product or products concerned;

   (c) the quantity to be supplied;

(d) the country or countries to which the product or products are to be exported;

(e) the duration of the licence;

(f) the address of the website referred to in Article 8 (5).

2. The Commission shall forward the information referred to in paragraph 1 to the Council for TRIPS.

Article 11

1. It is prohibited to import into the Community products subject of a compulsory licence under this Regulation for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse.

2. Paragraph 1 shall not apply in the case of re-export to the importing WTO member cited in the application and identified in the packaging and documentation associated with the product, or placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purpose of re-export to that importing WTO member.

Article 12

1. Where there is reason to suspect that, contrary to Article 11(1), products subject of a compulsory licence under this Regulation are being imported into the Community, customs authorities shall suspend the release of, or detain, the products concerned for the time necessary to obtain a decision of the relevant national authority on the character of the merchandise. The period of suspension or detention shall not exceed 10 working days unless special circumstances apply, in which case the period may be extended by a maximum of 10 working days. Upon expiry of that period, the products shall be released, provided that all customs formalities have been complied with.

2. The relevant national authority and the manufacturer or exporter of the products concerned shall be informed without delay of the suspended release or detention of the products and shall receive all information available with respect to the products concerned. Due account shall be taken of national provisions on the protection of personal data, commercial and industrial secrecy and professional and administrative confidentiality. The importer, and where appropriate, the exporter, shall be given ample opportunity to supply the relevant national authority with the information which it deems appropriate regarding the products.

3. The procedure of suspension or detention of the goods is carried out at the expense of the importer. If it is not possible to recover those expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.

4. If the relevant national authority finds that products suspended for release or detained by customs authorities were intended for import into the Community contrary to the

prohibition in Article 11 (1), that authority shall ensure that these products are seized and disposed of in accordance with national legislation. These procedures are carried out at the expense of the importer. If it is not possible to recover these expenses from the importer, they may, in accordance with national legislation, be recovered from any other person responsible for the attempted illicit importation.

5. Where products suspended for release or detained by customs authorities subsequent to further control by the relevant national authority are found not to violate the prohibition in Article 11(1), the customs authority shall release the products to the consignee, provided that all customs formalities have been complied with.

6. The relevant national authority shall inform the Commission of any decisions on seizure or destruction which are adopted pursuant to this Regulation.

Article 13

Articles 11 and 12 shall not apply to goods of a non-commercial nature contained in travellers' personal luggage for personal use within the limits laid down in respect of relief from customs duty.

Article 14

1. Subject to adequate protection of the legitimate interests of the licensee, a compulsory licence granted pursuant to this Regulation may be terminated by a decision of the competent authority or by one of the bodies referred to under Article 16 in either of the following cases:

   (a) if the conditions of the licence are not respected by the licensee;

   (b) if and when the circumstances which led to the grant of the licence cease to exist and are unlikely to recur.

   The competent authority shall have the authority to review, on its own initiative or upon reasoned request by the right holder or the licensee, whether either of those situations applies.

(2) Termination of a licence granted under this Regulation shall be notified to the Commission who shall inform the WTO.

(3) Within a reasonable time following termination of the licence the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to countries in need or otherwise as prescribed by the competent authority in consultation with the right holder.

Article 15

Appeals against any decision of the competent authority, and disputes concerning compliance with the conditions of the licence, shall be heard by the appropriate body responsible under national law.

Article 16

1. Where the application for a compulsory licence concerns a medicinal product authorised in accordance with Article 6 of Directive 2001/83/EC, the provisions of Article 24(4) and (5) and of Article 14(4) and (5) of Regulation (EC) No 726/2004 of the European Parliament and the Council[5] shall not apply.

   For the purpose of the application of this paragraph, and by way of derogation from Article 10(1) of Directive 2001/83/EC, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the product concerned is a generic of a reference medicinal product which is or has been authorised under Article 6 of that Directive or under Article 3 of Regulation (EC) No 726/2004.

2. Where the application for a compulsory licence concerns a medicinal product and the applicant for the compulsory licence is not the holder of a marketing authorisation valid within the Community for the product concerned, he may avail himself of the scientific opinion procedure provided for under Article 58 of Regulation (EC) No 726/2004 or any similar procedure provided under national law.

3. For the purposes of obtaining a scientific opinion under paragraph (2) and by way of derogation from Article 10(1) of Directive 2001/83/EC, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the product concerned is a generic of a reference medicinal product which is or has been authorised under Article 6 of that Directive or Article 3 of Regulation (EC) No 726/2004.

Article 17

Three years after the entry into force of this Regulation, the Commission shall present a report to the European Parliament, the Council, and the European Economic and Social Committee on the operation of this Regulation and the contribution it has made to the implementation of the system established by the Decision.

Article 18

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[5] OJ L 136, 30.4.2004, p. 1.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

Policy area(s): Internal Market for Goods and Services

Activit(y/ies): Formulate community law in the area of biotechnology, plant protection and pharmaceuticals

TITLE OF ACTION: PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON COMPULSORY LICENSING OF PATENTS RELATING TO THE MANUFACTURE OF PHARMACEUTICAL PRODUCTS FOR EXPORT TO COUNTRIES WITH PUBLIC HEALTH PROBLEMS

1. BUDGET LINE(S) + HEADING(S)

2. OVERALL FIGURES

2.1. Total allocation for action (Part B): € million for commitment

Not applicable

2.2. Period of application:

(start and expiry years)

Start: Date of entry into force

Expiry: Indefinite

2.3. Overall multiannual estimate of expenditure:

(a) Schedule of commitment appropriations/payment appropriations (financial intervention) *(see point 6.1.1)*

None

(b) Technical and administrative assistance and support expenditure *(see point 6.1.2)*

None

(c) Overall financial impact of human resources and other administrative expenditure *(see points 7.2 and 7.3)*

	2005	2006	2007	2008	2009	2010	Total
Commitments/ payments	0.108	0.108	0.108	0.108	0.108	0.108	0.648

TOTAL a+b+c							
Commitments	0.108	0.108	0.108	0.108	0.108	0.108	0.648
Payments	0.108	0.108	0.108	0.108	0.108	0.108	0.648

2.4. Compatibility with financial programming and financial perspective

[x] Proposal is compatible with existing financial programming.

[…] Proposal will entail reprogramming of the relevant heading in the financial perspective.

[…] Proposal may require application of the provisions of the Interinstitutional Agreement.

2.5. Financial impact on revenue:[6]

[x] Proposal has no financial implications (involves technical aspects regarding implementation of a measure)

OR

[…] Proposal has financial impact – the effect on revenue is as follows:

Not applicable

3. BUDGET CHARACTERISTICS

Type of expenditure		New	EFTA contribution	Contributions form applicant countries	Heading in financial perspective
Non-comp	Diff/	NO	NO	NO	**5**

4. LEGAL BASIS

Articles 95 and 133 of the EC Treaty.

[6] For further information, see separate explanatory note.

5. DESCRIPTION AND GROUNDS

5.1. Need for Community intervention [7]

5.1.1. Objectives pursued

The proposal implements at EU level the WTO General Council Decision of 30 August 2003 which sets out a mechanism in national patent law to allow the manufacture and export of pharmaceutical products to countries in need without the authorisation of the patent holder. At present exports without such authorisation may not take place. The aim of this mechanism is to facilitate access to affordable medicines for people in developing countries which do not have sufficient manufacturing capacity themselves. Intervention at Community level is required in view of the Community's involvement in external negotiations and the need to avoid differences in application and distortions of competition affecting operators within the Internal Market.

5.1.2. Measures taken in connection with ex ante *evaluation*

The WTO General Council Decision is the result of several years' negotiation on the basis of EU positions coordinated in the Article 133 Committee.

5.1.3. Measures taken following ex post evaluation

Not applicable

5.2. Action envisaged and budget intervention arrangements

The proposed mechanism is a voluntary one both for the countries in need who seek to obtain affordable medicines and the companies who intend to supply them. Once the legislation comes into force, compulsory licences will be granted by national authorities on the basis of applications from companies and notifications by developing countries that they require particular pharmaceutical products. No financial assistance is involved.

5.3. Methods of implementation

After adoption of the draft legislation by the Council and European Parliament, it will be MS national authorities who grant compulsory licences.

6. FINANCIAL IMPACT

6.1. Total financial impact on Part B - (over the entire programming period)

Not applicable

[7] For further information, see separate explanatory note.

6.2. Calculation of costs by measure envisaged in Part B (over the entire programming period)[8]

Not applicable

7. IMPACT ON STAFF AND ADMINISTRATIVE EXPENDITURE

Human and administrative resource requirements will be covered from within the budget allocated to the managing DG in the framework of the annual allocation procedure.

7.1. Impact on human resources

Types of post		Staff to be assigned to management of the action using existing resources		Total	Description of tasks deriving from the action
		Number of permanent posts	Number of temporary posts		
Officials or temporary staff	A B C	1 A		1 A	*If necessary, a fuller description of the tasks may be annexed.* Preparing for and attending meetings of Council and Parliament to negotiate the proposal through to adoption. Monitoring application and impact of system set up by this legislation, in liaison with stakeholders including EU MS, companies, third countries and international organisations.
Other human resources		0	0	0	
Total		1	0	1	

7.2. Overall financial impact of human resources

Type of human resources	Amount (€)	Method of calculation *
Officials Temporary staff	108.000	Annual costs per official: 108.000 €
Other human resources (specify budget line)		
Total	108.000 €	

The amounts are total expenditure for twelve months.

7.3. Other administrative expenditure deriving from the action

Not applicable

[8] For further information, see separate explanatory note.

The amounts are total expenditure for twelve months.

[1] Specify the type of committee and the group to which it belongs.

I.	Annual total (7.2 + 7.3)	108.000 €
II.	Duration of action	2005 - 2010
III.	Total cost of action (I x II)	€648.000

8. FOLLOW-UP AND EVALUATION

8.1. Follow-up arrangements

8.2. Arrangements and schedule for the planned evaluation

Use of the mechanism envisaged by the proposal is optional for business; on-going evaluation will be possible through analysis of the notifications made to the WTO and the Commission for every compulsory licence granted under the Regulation. Report and review is proposed in the Regulation itself five years after entry into force.

9. ANTI-FRAUD MEASURES

No financial assistance is involved.