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2007/0102 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending Council Directive 96/22/EC concerning the prohibition on the use in
stockfarming of certain substances having a hormonal or thyreostatic action
and of beta-agonists**

{SEC(2007)733}

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **General context**

1. Prohibition of the use of certain substances for non food producing species (pet animals)

Article 2 (a) of Council Directive 96/22/EC specifically prohibits the placing on the market of substances listed in Annex II for administering to animals of "all species". The motive behind the prohibition of substances for all species is that misuse would be more difficult if no product authorised for whatever species were on the market.

Comparison of the prices and presentations of products with e.g. thyreostatic action intended for use in pet animals, however, shows that it is economically unattractive to use pet products e.g. in cattle. Reports of the Member States related to the implementation of the national residue plans to be established according to Directive 96/23/EC¹ show that illegal use can rather be linked to illegal production or import of substances. This is emphasised by the growing importance of the Internet and the increasing international trade. The same reports show that no illegal uses of stilbenes, stilbene derivates, their salts and esters could be discovered in more than five years past.

Several Member States and the veterinary pharmaceutical industry complained to the Commission services that marketing authorisations cannot be granted for products containing substances to treat hyperthyroidism in pet animals due to the restrictions of Directive 96/22/EC. They appealed to the Commission to mitigate the situation.

2. Oestradiol 17 β and its ester like derivates

In 1981 (with Directive 81/602/EEC), the EU prohibited the use of substances having a hormonal action for growth promotion in farm animals. These prohibitions apply to Member States and imports from third countries alike. One of these substances is oestradiol 17 β . The legal instrument in force is Directive 96/22/EC as amended by Directive 2003/74/EC. The legislative proposal that preceded Directive 2003/74/EC² intended the prohibition of oestradiol 17 β and its ester like derivates for all purposes (growth promotion, zootechnical purposes and treatment applications). In

¹ OJ L 125, 23.5.1996, p. 10.

² OJ C 337, 28.11.2000, p. 163.

the adoption procedure it was, however, amended to only reduce the circumstances under which oestradiol 17 β may be administered for purposes other than growth promotion. Only three uses remained permissible on a transitional basis and under strict veterinary control: treatment of foetus maceration/mummification, pyometra in cattle (for animal welfare reasons) and oestrus induction in cattle, horses, sheep and goats (Article 5a). The latter use has to be phased out by until 14 October 2006 and for the rest of the uses the Commission was to present a report in October 2005. The report was presented on 11 October 2005 to Council and Parliament. It comes to the conclusion that the use of the alternative substances such as prostaglandins is already common. Veterinarians predict an insignificant impact of future unavailability of oestradiol 17 β and its ester like derivatives on farmers and on animal welfare. It was moreover observed that the unavailability of oestradiol and its ester like derivatives would have minimal economic effect. This is because the incidence of fetal mummification and fetal maceration is low, and although the incidence of pyometra is higher, methods of prevention not involving use of oestradiol do exist and would be preferable.

vcz

- **Existing provisions in the area of the proposal**

Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β -agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, 29 April 1996, as amended by Directive 2003/74/EC. This proposal intends to modify the above directive.

- **Consistency with the other policies and objectives of the Union**

The proposal is consistent with the marketing authorisation provisions in Directive 2001/82/EC³ (Veterinary Medicinal Products Code) and Regulation (EC) n°726/2004 of the European Parliament and of the Council of 31 March 2004⁴.

Oestradiol 17 β is currently classified in Annex II of Regulation (EEC) No 2377/90⁵ with restrictions of use. This entry will have to be modified if the proposal is adopted because it identifies oestradiol 17 β as a substance that can be used in food producing animals.

Further specified exemptions for pet animals would make this already complex legislation even more complex. It will therefore be in line with

³ OJ L 311, 28.11.2001, p. 1.

⁴ OJ L 136, 30.4.2004, p. 1.

⁵ OJ L 224, 18.8.1990, p. 1.

the Communities goal to simplify legislation if pet animals are deleted from the scope of this legislation.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Member States and the veterinary pharmaceutical industry have provided their opinion on thyrostatic substances. The Member States have also confirmed in a Council meeting on 11 October 2005 in July 2006⁶ that if oestradiol 17β and its ester like derivates were to be prohibited for food producing animals, the substance should remain available for pet animals.

Moreover, pet animals affected by hyperthyroidism suffer due the continuous unavailability of appropriate treatment. In can therefore be taken for granted that a proposal allowing such treatment is supported by veterinarians and pet owners.

The changes proposed in relation to oestradiol 17β are the direct result of the activities required by Article 11a of Directive 2003/74/EC. Council discussed the report presented on 11 October 2005 in July 2006.

- **Collection and use of expertise**

Scientific/expertise domains concerned

Veterinary medicine, endocrinology

Methodology used

Study

Main organisations/experts consulted

University of Liverpool, Department of Veterinary Clinical Science, Prof Hilary Dobson

Summary of advice received and used

The existence of potentially serious risks with irreversible consequences has not been mentioned.

The advice asserts that in the majority of cases, prostaglandin is the main currently available alternative for oestradiol 17β and its ester like derivates and that the use of this alternative by practising veterinarians is already common. It concludes that the non-availability of oestradiol 17β and its ester like derivates would have minimal effect on farm industry

⁶ Council Document 11303/06 AGRILEG 122 of 05/07/2006.

economics, veterinarians and farmer's decisions, and animal health and welfare.

Means used to make the expert advice publicly available

The report was sent to Council and Parliament and made available on the homepage of Directorate General Health and Consumer Protection at http://ec.europa.eu/food/animal/resources/publications_en.htm under the heading "Prevention and Control of Animal Diseases".

- **Impact assessment**

Information campaigns, financial incentives, self regulation or co-regulation are not an option where the authorisation of an appropriate treatment of pet animals is barred by a legal prohibition to place on the market certain substances for all animal species. It can moreover not be expected that Member States withdraw their marketing authorisations for oestradiol 17 β for food producing animals if the existing legislation still allows its use for certain purposes.

On the other hand, lack of action would mean ignoring the needs of animal welfare and the advice provided by the Scientific Committee on Veterinary Measures relating to Public Health (concluding that there is a substantial body of recent evidence suggesting that oestradiol 17 β has to be considered as a complete carcinogen) as well as the advice provided by the expert report on the necessity of the use of oestradiol 17 β in animal production.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

1. Take pet animals out of the scope of the legislation.
2. Prohibit the use of oestradiol 17 β in food producing animals entirely.

- **Legal basis**

Treaty Article 152(4)(b)

- **Subsidiarity principle**

The subject of the proposal falls under the exclusive competence of the Community since 1981. There is a long standing consensus that the subject is to be regulated at Community level. The subsidiarity principle therefore does not apply.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s).

Only very limited changes are introduced necessary in order to avoid further suffering of pet animals due to the unavailability of an appropriate treatment and in order to take scientific and expert advice concerning oestradiol 17 β into account.

Animal owners, practicing veterinarians, the veterinary pharmaceutical industry and Member States authorisation agencies will be affected by this proposal.

As concerns thyrostatic substances this proposal allows the pharmaceutical industry to successfully apply for the authorisation of products containing thyrostatic substances for use in pet animals. It also keeps products containing oestradiol 17 β intended for pet animals on the market. It would allow the authorisation of veterinary medicinal products containing of stilbenes, stilbene derivates, their salts and esters. New authorisation have, however to consider potential misuse. Presentations that are likely to be misused can therefore be rejected.

Products for pet animals are a growing market because the numbers of pet animals kept is raising and the animals are kept until old age. Hyperthyroidism is more frequent in old animals. Thus a proposal to allow the authorisation of veterinary medicinal products containing thyrostatic substances for pet animals will have positive effect for their owners, practicing veterinarians and the veterinary pharmaceutical industry.

The withdrawal of products containing oestradiol 17 β will have no or only a negligible negative effect on farmers practicing veterinarians and the veterinary pharmaceutical industry. Some veterinarians and farmers will have to accustom themselves to new veterinary medicinal products for the treatment of reproductive disorders. Member States agencies responsible for the authorisation of veterinary medicinal products will have to withdraw respective marketing authorisations. This falls under the routine activities of these agencies. Nevertheless, as confirmed in the expert report, the withdrawal of products containing oestradiol 17 β and its ester-like derivatives will have no or only a negligible negative effect on the veterinary pharmaceutical industry. They will, however, contribute to achieving a high level of human health protection. The proposal has no particular geographical focus nor has it a particular effect for small industries.

Considering the above, it is unlikely that the proposal will have measurable effects on employment, on investment and the creation of new businesses or on the competitiveness of businesses. If at all measurable the effect will most likely be positive due to the increased business with pet animals. Accordingly the proposal does not have to contain measures to take account of the specific situation of small and medium-sized firms.

- **Choice of instruments**

Proposed instruments: directive.

Other means would not be adequate for the following reason(s):

This proposal is an amendment of an existing Directive and therefore to maintain formal parallelism should take a form of a Directive. The only other option would be to revoke and replace the existing Directive by another instrument. Considering the limited changes proposed to the current Directive this seems unnecessary and disproportionate.

4. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5. ADDITIONAL INFORMATION

- **European Economic Area**

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyreostatic action and of beta-agonists

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission⁷,

Having regard to the opinion of the Economic and Social Committee⁸,

Having regard to the opinion of the Committee of the Regions⁹,

Acting in accordance with the procedure laid down in Article 251 of the Treaty

Whereas:

- (1) Article 2 of Council Directive 96/22/EC¹⁰ prohibits inter alia the placing on the market of thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters for administering to animals of all species.
- (2) The reason for that absolute prohibition was that potential abuse or misuse would be more difficult if there was on the market no product authorised for any animal species whatsoever.
- (3) However, experience gained in particular with national residue plans submitted under Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC¹¹ has shown that the misuse of product presentations intended for pet animals does not play a role as a source of abuse or misuse. That is partly because it is economically

⁷ OJ C ...

⁸ OJ C ...

⁹ OJ C ...

¹⁰ OJ L 125, 23.5.1996, p. 3. Directive as amended by Directive 2003/74/EC of the European Parliament and of the Council (OJ L 262, 14.10.2003, p. 17).

¹¹ OJ L 125, 23.5.1996, p. 10. Directive as last amended by Regulation (EC) No 882/2004 of the European Parliament and of the Council (OJ L 165, 30.4.2004, p. 1).

unattractive to use presentations for pet animals for growth promotion in food producing animals.

- (4) Moreover, the prohibition of thyrostatic substances has harmful consequences for the welfare of pet animals (dogs and cats) due to the lack of an alternative treatment for hyperthyroidism in those animals.
- (5) The Protocol on protection and welfare of animals annexed to the Treaty establishing the European Community provides that the Community and the Member States are to pay full regard to the welfare requirements of animals in the implementation of Community policies, in particular with regard to the internal market.
- (6) It is therefore appropriate to limit the scope of this Directive only to food producing animals and withdraw the prohibition for pet animals.
- (7) The Opinion of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) of 30 April 1999 on potential adverse effects to human health from hormone residues in bovine meat and meat products (which was reviewed on 3 May 2000 and confirmed on 10 April 2002) concluded that there is a substantial body of recent evidence suggesting that oestradiol 17 β has to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects, and that the data currently available do not make it possible to give a quantitative estimate of the risk to human health. As a result, Directive 96/22/EC was amended by Directive 2003/74/EC which inter alia prohibited permanently the use of oestradiol 17 β as a growth promoter and reduced substantively all other circumstances in which it can be administered to all farm animals for therapeutic or zootechnical purposes pending further examination of the factual and scientific situation and the veterinary practices in the Member States.
- (8) Article 11a of Directive 96/22/EC called for the presentation of a report on the necessity of the use of the hormone oestradiol 17 β in animals (food producing animals) for therapeutic purposes by 14 October 2005. The European Commission has sought expert advice and established the relevant scientific report, which has been forwarded to the European Parliament and the Council on 11 October 2005¹². That Report concludes that oestradiol 17 β is not essential in food animal production, because the use of the available alternatives (especially prostaglandins) by practising veterinarians is already quite common in the Member States and that the complete prohibition of the use of oestradiol 17 β for food-producing animals would have no or only a negligible impact on farming and animal welfare.
- (9) A temporary exemption was provided for the use of oestradiol 17 β for oestrus induction in cattle, horses, sheep or goats until 14 October 2006. Since effective alternative products exist and are already used and in order to ensure the high level of health protection chosen in the Community, that exemption should not be renewed.

Directive 96/22/EC should therefore be amended accordingly,

¹² See the "Report concerning the availability of alternative veterinary medicinal products to those containing oestradiol 17 β or its ester-like derivatives for the treatment of fetal maceration or mummification in cattle, and for the treatment of pyometra", available at: http://ec.europa.eu/food/animal/resources/comm_staff_work_doc11102005_en.pdf

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/22/EC is hereby amended as follows:

- (1) Article 2 is replaced by the following:

"Article 2

Member States shall prohibit the placing on the market of the substances listed in Annex II for administering to any animals, the meat and products of which are intended for human consumption, for purposes other than those provided for in point 2 of Article 4."

- (2) Article 5a is deleted.
- (3) In Articles 3, 6, 7, 8, 11 and 14 a, the references to Article 5a are deleted.
- (4) In Article 11, paragraph 1 is replaced by the following:

"1. Third countries whose legislation authorizes the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to all species of animals the meat and products of which are intended for human consumption may not appear on any of the lists of countries provided for under Community legislation from which Member States are authorized to import farm or aquaculture animals or meat or products obtained from such animals. "

- (5) Article 11a is replaced by the following:

"Article 11a

With regard to the substances listed in Annex III, the Commission shall seek additional information, taking into account recent scientific data from all possible sources, and keep the measures applied under regular review with a view to timely presentation to the European Parliament and to the Council of any necessary proposals."

- (6) Annex II is replaced by the text in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [1 July 2007] at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

“ANNEX II

List of prohibited substances:

List A:

- Thyrostatic substances,
- Stilbenes, stilbene derivatives, their salts and esters,
- Oestradiol 17 η and its ester-like derivatives.

List B:

- Beta-agonists”

LEGISLATIVE FINANCIAL STATEMENT

This document is intended to accompany and complement the Explanatory Memorandum. As such, when completing this Legislative Financial Statement, and without prejudice to its legibility, an attempt should be made to avoid repeating information contained in the Explanatory Memorandum. Before filling in this template, please refer to the specific Guidelines that have been drafted to provide guidance and clarification for the items below.

1. NAME OF THE PROPOSAL :

Directive of the European Parliament and of the Council amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyreostatic action and of beta-agonists

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned and associated Activity/Activities: Food safety, veterinary medicinal products

3. BUDGET LINES

- 3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings :
No financial implications
- 3.2. Duration of the action and of the financial impact: not applicable (n.a.)
Until modified or revoked

3.3. Budgetary characteristics (*add rows if necessary*) :

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
	Comp/ Non-comp	Diff ¹³ / Non-diff ¹⁴				
	Comp/ Non-comp	Diff ¹³ / Non-diff ¹⁴	YES/ NO	YES/NO	YES/NO	No [n.a.]
	Comp/ Non-comp	Diff/ Non-diff	YES/ NO	YES/NO	YES/NO	No [n.a.]

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
			a	n.a.	n.a.	n.a.	n.a.	
Operational expenditure¹⁵								
Commitment Appropriations (CA)	8.1	a	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Payment Appropriations (PA)		b	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

¹³ Differentiated appropriations.

¹⁴ Non-differentiated appropriations hereafter referred to as NDA.

¹⁵ Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

Administrative expenditure within reference amount¹⁶

Technical & administrative assistance (NDA)	8.2.4	c	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
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TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Payment Appropriations		b+c	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Administrative expenditure not included in reference amount¹⁷

Human resources and associated expenditure (NDA)	8.2.5	d	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6	e	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Total indicative financial cost of intervention

TOTAL CA including cost of Human Resources		a+c +d+ e	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
TOTAL PA including cost of Human Resources		b+c +d+ e	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

¹⁶

Expenditure within article xx 01 04 of Title xx.

¹⁷

Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

Co-financing details

If the proposal involves co-financing by Member States, or other bodies (please specify which), an estimate of the level of this co-financing should be indicated in the table below (additional lines may be added if different bodies are foreseen for the provision of the co-financing): not applicable

EUR million (to 3 decimal places)

Co-financing body	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
.....	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
TOTAL CA including co-financing	a+c +d+ e+f	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

4.1.2. Compatibility with Financial Programming

- 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 Agreement¹⁸ (i.e. flexibility instrument or revision of the financial perspective).

¹⁸ See points 19 and 24 of the Interinstitutional agreement.

4.1.3. Financial impact on Revenue

- Proposal has no financial implications on revenue
- Proposal has financial impact – the effect on revenue is as follows:

NB: All details and observations relating to the method of calculating the effect on revenue should be shown in a separate annex.

EUR million (to one decimal place)

Budget line	Revenue	Prior to action [Year n-1]	Situation following action					
			[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5] 19
a) Revenue in absolute terms			n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
b) Change in revenue	÷		n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

(Please specify each revenue budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line.)

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later
Total number of human resources	0.2	0.2	0.2	0.2	0.2	0.2

¹⁹ Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years.

5. CHARACTERISTICS AND OBJECTIVES

Details of the context of the proposal are required in the Explanatory Memorandum. This section of the Legislative Financial Statement should include the following specific complementary information:

5.1. Need to be met in the short or long term

Availability of veterinary medicinal products containing thyrostatic substances in order to treat hyperthyroidism in dogs and cats, non use of oestradiol 17 η in animal production in order prevent long term increased exposure to oestradiol 17 and associated possible increased related cancer rates.

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy: Not applicable

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

Financial objectives are not applicable

5.4. Method of Implementation (indicative)

Show below the method(s)²⁰ chosen for the implementation of the action.

²⁰

If more than one method is indicated please provide additional details in the "Relevant comments" section of this point.

- Centralised Management**
- Directly by the Commission
- Indirectly by delegation to:
 - Executive Agencies
 - Bodies set up by the Communities as referred to in art. 185 of the Financial Regulation
 - National public-sector bodies/bodies with public-service mission

Shared or decentralised management

- X With Member States
- X With third countries

Joint management with international organisations (please specify)

Relevant comments: Marketing authorisations for thyrostatic substances and oestradiol 17η will have to be modified by Member States. Control of non use of oestradiol 17η is the task of Member States. Third countries will have to ensure that animals or animal products imported into the Community will not have been treated with oestradiol 17η.

6. MONITORING AND EVALUATION

6.1. Monitoring system

Not foreseen

6.2. Evaluation

6.2.1. Ex-ante evaluation

Not foreseen

6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

Not foreseen

6.2.3. Terms and frequency of future evaluation

Not foreseen

7. ANTI-FRAUD MEASURES

Not applicable

8.

DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost: Not applicable

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year n		Year n+1		Year n+2		Year n+3		Year n+4		Year n+5 and later		TOTAL		
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs
OPERATIONAL OBJECTIVE No.1 ²¹																	
Action 1 thyrostatic subst.																	
- Output 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
- Output 2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Action 2 Oestradiol																	
- Output 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sub-total Objective 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
OPERATIONAL OBJECTIVE No.2 ¹																	
Action 1.....																	
- Output 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Sub-total Objective 2	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
OPERATIONAL OBJECTIVE No.n ¹																	
Sub-total Objective n	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
TOTAL COST	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

²¹

As described under Section 5.3.

8.2. Administrative Expenditure

8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the action using existing and/or additional resources (number of posts/FTEs)					
		Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5
Officials or temporary staff ²² (XX 01 01)	A*/AD	0.1	0.1	0.1	0.1	0.1	0.1
	B*, C*/AST	0.1	0.1	0.1	0.1	0.1	0.1
Staff financed ²³ by art. XX 01 02		n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Other staff ²⁴ financed by art. XX 01 04/05		n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
TOTAL		0.2	0.2	0.2	0.2	0.2	0.2

8.2.2. Description of tasks deriving from the action

Interpretation and explanation of instrument in presentations, letters, meeting also with respect to World Trade Organisation Panels

8.2.3. Sources of human resources (statutory)

(When more than one source is stated, please indicate the number of posts originating from each of the sources)

- Posts currently allocated to the management of the programme to be replaced or extended
- Posts pre-allocated within the APS/PDB exercise for year n
- Posts to be requested in the next APS/PDB procedure
- Posts to be redeployed using existing resources within the managing service (internal redeployment) Instrument is a modification of existing legislation.
- Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

²² Cost of which is NOT covered by the reference amount.

²³ Cost of which is NOT covered by the reference amount.

²⁴ Cost of which is included within the reference amount.

8.2.4. Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)

EUR million (to 3 decimal places)

Budget line (number and heading)	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
1. Technical and administrative assistance (including related staff costs)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Executive agencies ²⁵	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Other technical and administrative assistance	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– <i>intra muros</i>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
– <i>extra muros</i>	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total Technical and administrative assistance	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

8.2.5. Financial cost of human resources and associated costs not included in the reference amount

EUR million (to 3 decimal places)

Type of human resources	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later
Officials and temporary staff (XX 01 01)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total cost of Human Resources and associated costs (NOT in reference amount)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Calculation – **Officials and Temporary agents**

Reference should be made to Point 8.2.1, if applicable

Not applicable

²⁵

Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.

Calculation– **Staff financed under art. XX 01 02**

Reference should be made to Point 8.2.1, if applicable

Not applicable

8.2.6 Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
XX 01 02 11 01 – Missions	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
XX 01 02 11 02 – Meetings & Conferences	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
XX 01 02 11 03 – Committees ²⁶ (Standing Committee for the Food Chain and Animal Health)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
XX 01 02 11 04 – Studies & consultations	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
XX 01 02 11 05 - Information systems	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
2. Total Other Management Expenditure (XX 01 02 11)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
3. Other expenditure of an administrative nature (specify including reference to budget line)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

Calculation - *Other administrative expenditure not included in reference amount*

Not applicable

²⁶

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