

ROADMAP

Title of the initiative: **Revision of Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.**

Type of initiative: CWP

Lead DG: SANCO-E5

Expected date of adoption of the initiative (month/year): December 2011

Date of modification: 12.3.2010

Version No: 2

Initial IA screening & planning of further work

A. Context and problem definition

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

The introduction of the existing EU legislative framework on pharmacologically active substances in animals and animal products in the 90s greatly increased consumer protection. Directive 96/23/EC whose main objective was the fight against the use of growth promoters in livestock needs to be updated and aligned with the provisions of Regulation (EC) No 882/2004 "Official Food and Feed Control Regulation (OFFC)" to allow the use of or risk assessment principles prescribed in the Food Law (Regulation 178/2002). The ultimate goal is to ensure a consistent approach for the control of residues of veterinary medicines in food produced or imported to the EU.

The review of the inspection fees could potentially impact on how controls across the food chain are financed, including the area of residues of veterinary medicines. Also, The New Animal Health Strategy for the EU (2007-2013) includes an objective to improve border bio-security by way of developing and delivering a better risk based approach to Bio-security and to target illegal trade.

What are the main problems identified?

- Lack of consistency of Directive 96/23/EC with Reg. EC No 882/2004 on official controls;
- Lack of flexibility not permitting risk based changes to frequency and method of controls.
- Overlapping of legislation with legislation governing official controls of contaminants and pesticides in food;
- These problems result in public authorities being required to carry out controls using fixed frequencies which are less efficient than risk based controls to achieve equal compliance levels]

Who is affected?

- Authorities involved in official controls in the MS
- Farmers and establishments handling all food producing animals including aquaculture and bees and/or food of animal origin (including imports)
- Consumers are affected indirectly as the cost of the controls could be more efficiently used if based on risk.

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

EU action in the form of Regulation is justified to ensure products available in the single market reach comparable standards, and options are being considered that increase MS autonomy. The

options range from full subsidiarity (Member States deciding themselves) to a system including some obligation to all MS to carry out a minimum number of samples (% of their production) to ensure the control of certain groups of substances whose non-compliant use would represent a particularly serious violation such illegal substances (growth promoters) or antibiotics.

What are the main policy objectives?

- Significant simplification of existing rules, to align them with and ensure consistency with Regulation (EC) No 882/2004
- Increase flexibility on official controls for residues to ensure that are carried out with appropriate frequency on a risk basis.

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

No

C. Options

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered? (iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

(i) What are the policy options?

1. Improve current system by introduction of minor changes to the Directive
2. Risk based national planning- (repeal all regulation at EU level)
3. Align Directive 96/23/EC to general rules in 882/2004 combined with some implementing measures (e.g. to detail minimum requirements of national control programmes if that option is retained or criteria to assess the equivalence of Third Countries control systems)

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

None in particular but the necessary coordination with the other DGs will be ensured with the Inter-Service steering group which will support DG SANCO along the process.

Explain how the options respect the proportionality principle

The proportionality principle will be considered in the analysis of each option The principles to be set at EU level will go only as far as this brings added value to the system as a whole.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

These issues will be explored during the on-going impact assessment process. Given the objectives, there are likely to be impacts on costs for regulated businesses, costs for public authorities, and compliance with residue rules may be affected with subsequent health impacts.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?

- (i) yes, rules on residues should become more aligned with those on food and feed control
- (ii) yes no obligation to follow an annual approval procedure
- (iii) yes on all third countries willing to export animals or food of animal origin to the EU

E. Planning of further impact assessment work

When will the impact assessment work start?

April 2010

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when?

(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

(i) What information and data are already available?

- Outcome of the Reflection Paper on residues of veterinary medicines and its follow-up (2003-2006)
- Data in the Residue database plans and results (since 2005)
- Outcome of the annual residue experts-network
- Eu-RLs information: workshops and PTs.

(ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out?

No

(iii) What further information needs to be gathered?

- Questionnaires to the established network MS and stakeholders to gather their views.
- Data on cost for MS and stakeholders of the current system and consequences of the different options.

(iv) How will this be done (e.g. internally or by an external contractor) and by when?

The possibility of an external consultation with experts with the view of gathering targeted data is not ruled out and financial resources have already been set aside for this purpose. However, this will be dependant on the development of the options and the inability to gather data elsewhere.

(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

It is expected that data will be analysed relating to :

- the cost to MS (and when relevant to Third Countries) of the current regime (split by compliance cost (e.g. sampling and analysis costs) and administrative burden cost (completing and sending annual control plans) to public bodies mainly)
- the cost of sampling for regulated businesses and competent authorities;
- the consequences on the number and type of samples that the new options will have;

the indicators to be used are e.g. no. of inspections carried out related to the intensity of sampling activity and the no. of laboratory tests performed, which are expected to be reduced due to a more efficient and risk based controls .

Which stakeholders & experts have been/will be consulted, how and at what stage?
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DG SANCO and DG ENTR launched in 2003 a broad consultation process to review the legislation on residues of pharmacologically active substances used for the treatment of animals (*Reflection Paper on residues in foodstuffs of animal origin*). A lengthy consultation process was managed by the two DGs and Member States, third countries and stakeholders provided substantive encouraging feedback. During the meeting with the Member States on 13 December 2004 on the follow-up of the Reflection Paper on residues in food, conceptual ideas for legislative amendments were discussed and it was agreed to continue the discussion in six Working Groups of experts that were organised during spring 2005.

A discussion paper on residues including proposals for changes in the legislation on residues of pharmacologically active substances used in food producing animals of foodstuffs of animal origin following the conclusions of the 6 working groups were discussed on 11.7.2005 with all MS. This meeting was followed by a stakeholder meeting on 18.7.2005, 21 European organisations attended. In order to assess the impact of the different possible options, the Commission consulted stakeholders through a specific questionnaire ranking the different potential solutions identified by the six expert working Groups. The questionnaire was sent to the working groups' experts and to professional organizations' representatives. On 21.9.2006, a "non paper" based on the outcome of the working groups, the feedback from the MS and the answers to the questionnaire on impact assessment was submitted to the MS and discussed during a WG organised on 5.10.2006. Feedback was also provided by the MS on the document discussed at this meeting.

It is proposed to use material collected during these previous consultations.

In addition it is planned to consult:

- MS residue experts annual meeting in June and if necessary end of 2010.
- Meeting with stakeholders during the IA process
- Questionnaires both to MS and stakeholders, initial phase of the IA.