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WORKING GROUP ON GUIDANCE NOTES ON MONITORING SUPPLEMENTING ANNEX VII OF DIRECTIVE 2001/18/EC

TERMS OF REFERENCE

1. INTRODUCTION

At the meeting of the Competent Authorities under Directive 2001/18/EC[1] which was held on 29 April 2003, the German delegation proposed that a working group be set up to address post-market monitoring of genetically modified organisms (GMOs).In particular, the German delegation proposed that the working group address the issues of EU-wide harmonisation of monitoring plans for certain GMOs or groups of GMOs, EU-level monitoring concepts and parameters, and the possibility of EU-wide coordination of data resulting from post-market monitoring of GMOs. This proposal was welcomed by UK, AT, SP, NL, IT, IRL and N. The Commission committed itself to set up this working group.

2. TERMS OF REFERENCE

According to Directive 2001/18/EC, the notifier must ensure that monitoring and reporting on the deliberate release of GMOs are carried out in accordance with the conditions specified in the authorisation for the placing on the market of a GMO pursuant to Article 13(2), Article 19(3) and Article 20 of that Directive. Therefore, such notifications must contain a plan for monitoring, including a proposal for the time period of the monitoring plan, in accordance with Annex VII to Directive 2001/18/EC. Annex VII to Directive 2001/18/EC should be supplemented by notes providing detailed guidance on the objectives, general principles and design of the monitoring plan referred to in this Annex.

[1] Directive 2001/18/EC[1] of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 106, 17.4.2001, p. 1

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On 3 October 2002 the Council of the European Union has adopted a Decision[2] establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. These guidance notes expand on the objectives and general principles for post-market monitoring of GMOs as wells as on a general framework for the development of appropriate post-market monitoring plans, but explicitly do not attempt to provide details for the development of monitoring plans to cover all GMOs. Instead, this Decision refers to the possible need to complement the existing '*framework with more specific, supplementary guidance on monitoring plans or checklists with regard to particular traits, crops or groups of GMOs*'.

3. OBJECTIVE(S)

The working group shall elaborate monitoring concepts, plans, methods and parameters for case specific monitoring as well as for general surveillance on the basis of previous work in other fora with a view to provide further guidance for notifiers and competent authorities for the set up and auditing of monitoring plans and to harmonise the monitoring of GMOs in the EU. The main objective is to elaborate details of monitoring plans for certain GMOs or groups of GMOs. To this aim specific sets of monitoring parameters, criteria and methods shall be developed, leading to checklists for individual groups of GMOs (e.g. plant species as maize, oilseed rape, potatoes) and for different transgenic phenotypes (e.g. herbicide tolerance, insect resistance, etc.). The possibility of EU-wide coordination of data resulting from post-market monitoring of GMOs should be addressed as well.

4. APPROACH

- The working group should address all species of GMOs and types of genetically modified traits authorised for placing on the market under Directive 90/220/EEC or currently in the authorisation process under part C of Directive 2001/18/EC.

- A priority list of species of GMOs and genetically modified traits for which monitoring plans and methods are needed shall be established. Criteria for prioritisation should be the advancement in the authorisation process of GMOs - taking into consideration probable future notifications - and the likelihood of interactions with the environment and human health. The working group will start its work with genetically modified higher plants.

- In view of the above, the working group shall gather, from all relevant sources within and outside of the European Community, information on monitoring concepts, plans and methodologies, as well as databases already developed by international or national bodies (e.g. the OECD, European Enforcement Project), research institutions, non governmental organisations, including notifiers, particularly taking into account previous activities of the Member States, including experience gathered through national monitoring programmes.

- On this basis the working group shall develop proposals for specific sets of monitoring criteria, parameters, indicators and methods for individual groups of GMOs and for different

[2] Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. OJ L 280, 18.10.2002, p. 27

transgenic phenotypes, taking into account different environments, where appropriate. Comprehensive combinations of the different previously existing approaches to workable checklists, outlining minimum standards, shall be established. Possible gaps shall be identified and filled as far as possible or research needs identified.

- The needs and possibilities of an EU-wide coordination of data resulting from post-market monitoring of GMOs on the basis of existing legislation and initiatives as well as capacities (information networks, reporting activities, registers, data bases etc.) in this field shall be identified and proposals for future co-ordinated activities elaborated accordingly.

The working group will build up its work on the current scientific knowledge as well as keep in mind the relevant Articles and Annex VII of Directive 2001/18/EC and the above mentioned Council Decision.

In general, the structure and substance of the work, as well as the prioritisation of the tasks assigned to the Working Group should be decided in consultation with the Competent Authorities under Directive 2001/18/EC.

The outcome of the working group will be presented to the meeting of the Competent Authorities It shall be reviewed and updated in the light of new scientific information, methodological progress and future authorisations of GMOs.

5. SETTING UP OF THE WORKING GROUP

The Competent Authorities were required to nominate national experts as members of the working group by 15 January 2004 at the latest.

There has been an opportunity for a first discussion on the terms of reference in the Competent Authority meeting on 3 December 2003, including comments on the expertise, which should be represented in the working group (e.g. officials from the Member States including inspectors, researchers covering different fields of expertise, experts on statistics). Written comments from the Competent Authorities were welcome thereafter by 31st January 2004.

A final version of the terms of reference, amended according to the comments received from the Competent Authorities, is circulated for endorsement by the Competent Authorities at their meeting on 1st April 2004.

The work of the working group will be carried out by working group meetings preceded and followed by work coordinated via e-mail.

Further information as regards the structure and the substance of the work progress will be provided on a regular basis to Member States.