

COMMISSION DECISION

of 23 February 2004

laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council*(notified under document number C(2004) 540)***(Text with EEA relevance)**

(2004/204/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC 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 ⁽¹⁾, and in particular Article 31(2) thereof,

Whereas:

- (1) Different sets of information are required for the notification of genetically modified organisms, hereinafter 'GMOs', pursuant to Directive 2001/18/EC. The data required relates to the individual GMO itself, to the environment into which the GMO is released and to the interaction between the GMO and the receiving environment, including any effects on human health.
- (2) The information required in notifications concerning the deliberate release of GMOs is listed in Annex III to Directive 2001/18/EC. Annex IV to that Directive describes in general terms the additional information to be provided in notifications for placing GMOs on the market. It also specifies the labelling information required for GMOs as products or in products to be placed on the market. Some of that additional information should be placed on one or several registers, namely information concerning genetic modifications, which can be used for detection and identification of particular GMO products, including detection methods relating to thresholds established pursuant to Directive 2001/18/EC, in order to facilitate post-marketing control and inspection.
- (3) According to Article 31(2) of Directive 2001/18/EC, the Commission is to establish one or several register(s), hereinafter 'the registers', for the purpose of recording the information on genetic modifications in GMOs specified in Section A, point 7 of Annex IV to that Directive.
- (4) That information should include, where appropriate, the lodging of samples of the GMO, as or in products, or of its genetic material, with the competent authority and details of nucleotide sequences or other types of infor-

mation necessary for the identification of the GMO product and its progeny, including the methodology for detecting and identifying the GMO product, and the experimental data demonstrating the validation parameters of the method supplied.

- (5) In establishing the list of information to be recorded in the registers, account has been taken of the fact that other sets of information — such as the environmental risk assessment, the scientific studies, including studies which demonstrate the safety of the product, including, where available, references to independent and peer-reviewed studies, and to methods for identification and detection, and all other information submitted by the notifier, methods and plans for monitoring the GMO(s) and for emergency response, and results of the post-market monitoring — are in principle accessible according to the relevant provisions of Directive 2001/18/EC, Regulation (EC) No 1946/2003 of the European Parliament and the Council of 15 July 2003 on trans-boundary movements of genetically modified organisms ⁽²⁾ and Regulation (EC) No 1049/2001 of the European Parliament and the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents ⁽³⁾, and therefore need not be recorded.
- (6) For the sake of transparency and in conformity with Regulation (EC) No 1049/2001, the registers should be available to the public as well as to Member States and the Commission. The registers should therefore contain two sets of data, one accessible to the public, and the other accessible only to the Member States, the Commission and the European Food Safety Authority. The first set of data should contain all data recorded in the registers, except for data which cannot be disclosed for reasons of confidentiality in accordance with Article 25 of Directive 2001/18/EC, in particular with a view to protecting commercial interests; the second set of data should comprise additional confidential data. Individual requests for access will have to be treated in accordance with Regulation (EC) No 1049/2001 which, however, in its exceptions provides for the protection of the same interests as Article 25 of Directive 2001/18/EC.

⁽¹⁾ OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.6.2003, p. 24).

⁽²⁾ OJ L 287, 5.11.2003, p. 1.

⁽³⁾ OJ L 145, 31.5.2001, p. 43.

- (7) The competent authorities, inspection services, control laboratories of the Member States and the Commission should have available, during the consent period and for an appropriate period after expiry of the consent, the methods for detection and identification, including detection methods relating to thresholds established pursuant to Directive 2001/18/EC.
- (8) At the time of submission of the data by the competent authority to the Commission for the sake of placing it on the registers, some data, such as the date of authorisation or the validation parameters for the identification and detection method, are or may be missing. Moreover, during the consent period, and even for some time after expiry of the consent, updates such as identification and detection methods, commercial names or responsible persons may be necessary. Provision should therefore be made for updating the registers.
- (9) Future developments in the methodology of genetic modification or the corresponding detection and identification methods, including detection methods relating to thresholds established pursuant to Directive 2001/18/EC, may make it necessary to adapt this Decision to technical progress. Likewise, further developments in Community legislation may make it necessary to adapt this Decision in the interests of consistency and efficiency.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Committee established pursuant to Article 30(1) of Directive 2001/18/EC,

HAS ADOPTED THIS DECISION:

Article 1

This Decision lays down the detailed arrangements for the operation of registers (hereinafter referred to as 'the registers') to be established by the Commission pursuant to Article 31(2) of Directive 2001/18/EC, for the purpose of recording information on genetic modifications in genetically modified organisms (hereinafter referred to as 'GMOs').

Article 2

The information referred to in Article 1 shall include, in accordance with the provisions of Article 3, details of nucleotide sequences or other types of information necessary to identify the GMO product and its progeny, such as the methodology for the detection and identification of the GMO product, including detection methods relating to thresholds established under Directive 2001/18/EC, and experimental data demonstrating the validation of the methodology.

The registers shall be consistent and compatible with those established under other relevant Community legislation.

Article 3

The following shall be recorded in the registers:

- (a) details concerning the notifier and responsible persons:
 - (i) the name and full address of the notifier,
 - (ii) the name and full address of the person established in the Community who is responsible for the placing on the market, whether it be the manufacturer, the importer or the distributor, if different from the notifier;
- (b) general information concerning the GMO(s):
 - (i) the commercial name(s) of the GMO products and the names of the GMOs contained therein, including scientific name(s) and common name(s) of the recipient or, where appropriate, parental organism of the GMO,
 - (ii) the unique identifier(s) of the GMO(s) contained in the product(s),
 - (iii) the Member State of notification,
 - (iv) the notification number,
 - (v) the decision authorising the GMO(s);
- (c) information on the insert:
 - (i) information on the nucleotide sequence of the insert used to develop the detection method, including, where appropriate, the complete sequence of the insert as well as the number of base pairs of the host flanking sequences needed to establish an event-specific detection method and detection methods relating to thresholds established pursuant to Directive 2001/18/EC as well as accession numbers for public databases and references containing sequence data of the insert or parts of it,
 - (ii) a detailed map of the inserted DNA, including all genetic elements, coding and non-coding regions as well as the indication of their order and their orientation;
- (d) information concerning the detection and identification methods:
 - (i) description of identification and detection techniques for event-specific detection, including, where appropriate, detection methods relating to thresholds established pursuant to Directive 2001/18/EC;
 - (ii) information on detection and identification tools such as PCR primers and antibodies,
 - (iii) where appropriate, information on validation parameters, in accordance with international guidelines;
- (e) information on the lodging, storage and supply of samples:
 - (i) the name and address of the person(s) responsible for the lodging, storage and supply of control samples,
 - (ii) information on the stored samples such as the kind of material, the genetic characterisation, the amount of repository material, the stability, the conditions of appropriate storage and the shelf-life.

Article 4

The registers shall be available to the public in accordance with Article 25 of Directive 2001/18/EC and with Regulation (EC) No 1049/2001.

The information recorded shall be divided as follows:

- (a) a set of data accessible to the public;
- (b) a set of data comprising additional confidential data, accessible only to the Member States, the Commission and the European Food Safety Authority.

Article 5

The competent authorities shall extract from the notifications they receive pursuant to Article 13(1) of Directive 2001/18/EC all data relating to the information listed in Article 3 of this Decision. They shall submit that data, using the submission form supplied by the Commission for that purpose, to the Commission, either at the time of submitting the assessment report or no later than two weeks thereafter, in order to enable the Commission to record it in the registers. The form may be completed by the notifier, subject to verification of its content by the competent authorities.

Links may be provided to other registers or databases, such as the summary notification information formats (SNIFs), the opinion of the European Food Safety Authority, the assessment

report of the competent authority, the Biosafety Clearing-House established pursuant to the Cartagena Protocol on Biosafety and the Molecular Register of the Joint Research Centre, in order to avoid duplication of information.

Article 6

No later than two weeks after receiving any information relating to the updating of the registers, the competent authority shall forward it to the Commission. That information shall be entered in those registers no later than two weeks after receipt.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 23 February 2004.

For the Commission

Margot WALLSTRÖM

Member of the Commission