Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (notified under document C(2009) 7680) (Text with EEA relevance) (2009/770/EC)

COMMISSION DECISION

of 13 October 2009

establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council

(notified under document C(2009) 7680)

(Text with EEA relevance)

(2009/770/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 the second sentence of the first paragraph of Annex VII thereto,

Whereas:

(1) In accordance with Directive 2001/18/EC, before a Genetically Modified Organism (GMO) is placed on the market, a notification shall be submitted to the competent authority of the Member State where the GMO is to be placed on the market for the first time. That notification shall contain a plan for monitoring in accordance with Annex VII to that Directive.

(2) In accordance with Directive 2001/18/EC, the notifier may proceed with the placing on the market only when he has received the written consent of the competent authority, and in conformity with any conditions required in that consent.

(3) The written consent for the placing on the market of a GMO shall explicitly specify monitoring requirements in accordance with Annex VII to Directive 2001/18/EC, including obligations to report to the Commission and competent authorities.

(4) In accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed[(2)], in the case of GMOs or food and feed containing or consisting of GMOs, the application for

authorisation shall also be accompanied by a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(5) Annex VII to Directive 2001/18/EC describes in general terms the objectives to be achieved and the general principles to be followed when designing the monitoring plan.

(6) In accordance with that Annex technical guidance notes may be developed in accordance with the regulatory procedure laid down in Article 30(2) of Directive 2001/18/EC in order to provide explanations concerning Annex VII and thus facilitate the implementation of that Annex.

(7) Council Decision 2002/811/EC[(3)] sets out guidance notes supplementing the information provided in Annex VII to Directive 2001/18/EC. In order to ensure that the objectives of Annex VII to Directive 2001/18/EC are fulfilled in the most consistent, transparent and thorough manner, it is appropriate to further supplement that Annex by adopting formats for the presentation of monitoring results for the placing on the market of GMOs, with a particular focus on genetically modified higher plants.

(8) Given the different requirements for monitoring the cultivation of GMOs and monitoring the import and processing and food and feed uses of GMOs, separate formats should be established.

(9) In view of the need to consider adverse effects in the light of the crop, the new trait, the receiving environment as well as the conclusions of the environmental risk assessment, the reports should take into consideration the non-exhaustive list of effects, consequences and outcomes that could result in adverse environmental effects as listed in the explanatory notes.

(10) It may be necessary to adapt the existing reporting formats or develop new formats so as to take into account the authorisation of new types of GMOs or new approaches to monitoring and surveillance.

(11) The measures provided for in this Decision are in accordance with the opinion of the Committee established pursuant to Article 30(2) of Directive 2001/18/EC,

HAS ADOPTED THIS DECISION:

(**1**) OJ L 106, 17.4.2001, p. 1.

(**2**) OJ L 268, 18.10.2003, p. 1.

(**3**) OJ L 280, 18.10.2002, p. 27.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are outstanding changes not yet made to Commission Decision of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (notified under document C(2009) 7680) (Text with EEA relevance) (2009/770/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.