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**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. (See end of Document for details) [View outstanding changes](#)

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## ANNEX I

### MONITORING REPORT FOR CULTIVATION **Format for presenting the monitoring results for the Cultivation of genetically modified organisms in accordance with: Articles 19(3), 20(1) and Annex VII to Directive 2001/18/EC and Articles 9(1) and 21(1) of Regulation (EC) No 1829/2003**

#### 1. General information

- 1.1. Crop/trait(s): ...
- 1.2. Decision authorisation number pursuant to Directive 2001/18/EC, and number and date of consent pursuant to Directive 2001/18/EC: ...
- 1.3. Decision authorisation number and date of authorisation pursuant to Regulation (EC) No 1829/2003: ...
- 1.4. Unique identifier: ...
- 1.5. Reporting period from xx/xx/xx to xx/xx/xx
- 1.6. Other monitoring reports have been submitted in respect of:
 

Import	and	:	Yes	#
processing			No	#
Food/Feed		:	Yes	#
			No	#

#### 2. Executive summary

#### 3. Monitoring results

*The following sections should be completed in accordance with Appendix 2*

- 3.1. General surveillance
  - 3.1.1. Description of general surveillance
  - 3.1.2. Details of surveillance networks used to monitor environmental effects during general surveillance and description of other methodologies
  - 3.1.3. Details of information and/or training provided to operators and users, etc.
  - 3.1.4. Results of general surveillance
  - 3.1.5. Additional information
  - 3.1.6. Review of peer-reviewed publications — Appendix
- 3.2. Case-specific monitoring
  - 3.2.1. Description and results of case-specific monitoring (if applicable)
  - 3.2.2. Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable)

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3.3. Concluding remarks

4. **Summary of results and conclusions**

5. **Adaptation of the monitoring plan and associated methodology for future years**

Signed: ...

Date: ...

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## Appendix 1

### REVIEW OF PEER-REVIEWED PUBLICATIONS

Some publications may contain material relevant to more than one area of the environmental risk assessment (see Section 3.1.6 of Appendix 2). If so, the material should be described separately in each relevant table.

#### AREA OF THE ENVIRONMENTAL RISK ASSESSMENT

<b>Publication</b>	<b>Summary of research and results</b>	<b>Protection goal</b>	<b>Observed parameter</b>	<b>Adverse effects</b>	<b>Feedback on initial environmental risk assessment</b>

#### AREA OF THE ENVIRONMENTAL RISK ASSESSMENT

<b>Publication</b>	<b>Summary of research and results</b>	<b>Protection goal</b>	<b>Observed parameter</b>	<b>Adverse effects</b>	<b>Feedback on initial environmental risk assessment</b>

#### AREA OF THE ENVIRONMENTAL RISK ASSESSMENT

<b>Publication</b>	<b>Summary of research and results</b>	<b>Protection goal</b>	<b>Observed parameter</b>	<b>Adverse effects</b>	<b>Feedback on initial environmental risk assessment</b>

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## Appendix 2

### EXPLANATORY NOTES

#### A. General comments

Case-specific monitoring should be carried out in accordance with the conditions set out in the consent/authorisation and in accordance with the monitoring plan specified in the notification.

General surveillance for unanticipated or unforeseen adverse effects should also be considered as a compulsory part of the monitoring plan.

Adverse effects should be considered in the light of the crop, the new trait, the receiving environment as well as the conclusions of the environmental risk assessment which is carried out on a case-by-case basis. The following constitutes a non-exhaustive list of effects and consequences or outcomes that could result in adverse environmental effects:

- (a) persistence and invasiveness, selective advantage or disadvantage, including:
  - increased occurrence of volunteers,
  - increased establishment of the genetically modified (GM) plant outside of the fields,
  - increased spread, persistence and accumulation of the GM plant in the environment (including out-crossing with wild relatives),
  - increased spread of GM plant products in the environment;
- (b) altered gene transfer:
  - potential reduction of pollination,
  - increased frequency of horizontal gene transfer from plant to microbial populations;
- (c) interaction between GM plant and target organisms:
  - reduced abundance and diversity of weeds,
  - development of resistance in pest populations,
  - development of resistance in plants,
  - development of secondary pests;
- (d) interaction between GM plant and non-target organisms:
  - direct/indirect impact on non-target organisms,
  - changes in susceptibility to non-target pests and diseases;
  - impact on habitat diversity and biodiversity;
- (e) changes in biogeochemical processes;
- (f) changes in cultivation practices;
- (g) impact on human and animal health resulting from environmental exposure.

#### B. Instructions for completing the format

The report must be completed by the consent holder pursuant to Directive 2001/18/EC or the authorisation holder pursuant to Regulation (EC) No 1829/2003.

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The report must be completed according to the format, to the provisions of the consent or authorisation issued pursuant to Directive 2001/18/EC or Regulation (EC) No 1829/2003 respectively and to the relevant monitoring plan.

The reported data must be illustrated as much as possible by means of diagrams, figures and tables. Statistical data should also be provided where relevant.

The space provided after each item is not indicative of the depth of the information required for the purposes of the report. Relevant supporting documentation should be provided in the form of attachments, which should be clearly cross-referenced to the relevant sections of the report.

Where the information required by the particular consent or authorisation or monitoring plan, as appropriate, cannot be reported, a detailed justification should be given.

## C. Confidentiality

*Confidential parts of the report should be submitted in separate documents.*

### C.1. Applications submitted pursuant to Directive 2001/18/EC

Without prejudice to the provisions of Article 25 of Directive 2001/18/EC, the information provided in this report is not considered confidential.

This does not prevent the competent authority that issued the consent in accordance with Article 19 of Directive 2001/18/EC and the Commission from requesting additional information from the notifier, both confidential and non-confidential.

As far as possible, the report should not contain confidential data. In the case of confidential data, it should be provided in an Annex to the report, with a non-confidential summary or general description of these data, which will be made available to the public.

### C.2. Applications submitted pursuant to Regulation (EC) No 1829/2003

As far as possible, the report should not contain confidential data. The report should clearly state which parts of the information provided are considered to be confidential, together with a verifiable justification for confidentiality in accordance with Article 30 of Regulation (EC) No 1829/2003. A non-confidential summary or general description of these data should be provided in the Annex to the report which will be made available to the public.

## 1. GENERAL INFORMATION

Where a crop is cultivated and processed or used for food/feed purposes, within the EU, a monitoring report for GMO uses other than Cultivation must also be completed.

## 2. EXECUTIVE SUMMARY

A summary of the monitoring results obtained and the overall conclusions drawn should be provided. Any proposed adaptation of the monitoring plan and associated methodology on the basis of these results and conclusions should be described.

## 3. MONITORING RESULTS

### 3.1. General surveillance

#### 3.1.1. Description of general surveillance

A description of the general surveillance should be provided, including but not limited to the following:

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- (a) details of all methodologies used, including parameters observed, survey methods, location and frequency;
- (b) the use of hotlines;
- (c) company representatives in each Member State;
- (d) websites;
- (e) the use of farmer questionnaires or other surveillance methods;
- (f) the number of farmers that completed questionnaires, the location of cultivation and the criteria used to select these farmers;
- (g) the third parties involved, and the criteria used to select these parties.

The area under cultivation which is subject to monitoring should be proportional to and representative of the total regional area under GMO cultivation. A description and details of the proportionality and representativeness of the monitored environment and the criteria by which these areas were considered representative and thereby selected for monitoring should be provided.

#### 3.1.2. Details of surveillance networks used to monitor environmental effects during general surveillance

Details of all surveillance networks used to monitor environmental effects during the course of the general surveillance should be provided. The following information should be provided in relation to each surveillance network identified:

- (a) name;
- (b) Member States where the surveillance network is active and whether it is active at local, regional or national level;
- (c) website address;
- (d) protection goal;
- (e) how the network collects information relevant to general surveillance;
- (f) procedure for notifying adverse effects to authorisation/consent holder;
- (g) details of any agreements in place between the authorisation/consent holder, the network and/or other third party, where applicable;
- (h) criteria used to select the surveillance network.

#### 3.1.3. Details of information and/or training provided to operators and users, etc.

Details of the information made available to operators and users in particular in relation to the introduction of this GM crop into the Community, the safety and general characteristics of the product and the conditions pertaining to monitoring should be provided. Details of when and how this information was made available to operators and users should also be provided, and the measures for keeping operators/users abreast of any changes to existing information or new information should be notified.

With regard to Bt maize products and where indicated in the environmental risk assessment (ERA), details of the education and training and product information provided to farmers in

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order to make them aware of their obligations to prevent the development of insect resistance should be provided. A copy of the product information should be annexed to the report.

#### 3.1.4. Results of general surveillance

Results of the general surveillance carried out including direct, indirect, delayed and/or cumulative effects observed, and in particular the nature of any adverse effects observed and conclusions drawn should be provided. The parameters of all monitoring methodologies, including the location of monitoring, should be analysed, interpreted and discussed in detail, while simultaneously demonstrating how these results support the overall conclusions arrived at by the authorisation/consent holder.

Where farmer questionnaires are used, an analysis of the results obtained should be provided in an Annex to the report. This analysis should encompass general farm information such as data on fertiliser usage, crop rotations/performance/yields, pests and diseases, pesticide use, weed abundance and the occurrence of wildlife, where the questionnaires provide for this type of information as well as field-specific information, with particular reference to any information indicative of unanticipated effects. Correlations should be established by comparing questionnaires between regions or linking answers to observations made by surveillance networks or other surveillance methods.

The consent or authorisation holder should specifically evaluate whether the information gained from general surveillance is adequate and of relevance for the monitoring/detection of direct, indirect, delayed and/or cumulative effects. This evaluation should also identify areas (e.g. field edges, non-target species groups) where more or better data could be needed.

This section of the report should be as detailed as possible to allow proper interpretation of the data.

#### 3.1.5. Additional information

Where adverse or unanticipated effects were observed, additional information should be provided, such as the relevant region or location, stage of the growing season, remedial actions or risk-reducing measures that have been or will need to be implemented in view of the adverse effect, consequent implications for the environmental risk assessment (ERA) and any other conclusions that were drawn. This section of the report should be as detailed as possible to allow proper interpretation of the data.

#### 3.1.6. Review of peer-reviewed publications

Peer-reviewed publications including peer-reviewed journal articles, conference proceedings, review papers and any additional studies or other sources of information relevant to the cultivation of the crop/trait combination for which the report is being drafted, should be considered and analysed in the context of the monitoring results and the monitoring plan. These publications should be listed, summarised and details provided as per the Appendix. The literature review should identify all relevant publications which have emerged during the reporting period. Conference proceedings, review papers and additional studies carried out by the consent holder which have not been subject to peer review may be provided where they are deemed to be relevant.

### 3.2. Case-specific monitoring

#### 3.2.1. Results of case-specific monitoring (if applicable)

Case-specific monitoring requirements identified in the environmental risk assessment (ERA) and the corresponding decision, and the results of the case-specific monitoring carried out should be outlined, including detailed information on the methodology, frequency, duration,

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monitoring results, analysis and conclusions. Under this section the authorisation/consent holder should demonstrate how the information was gathered and analysed in order to support the conclusions arrived at. Furthermore, this section of the report should be as detailed as possible to allow proper interpretation of the data.

### 3.2.2. Monitoring/reporting of adverse effects resulting from accidental spillage (if applicable)

An overview of the measures taken to monitor adverse effects following accidental spillage should be provided where the authorisation or the current monitoring plan requires such monitoring, namely the frequency with which such monitoring is carried out, monitoring methodologies used, measures employed to minimise spillage and the clean-up procedures in place where accidental spillage has occurred. Any unusual, adverse or GMO-related effects observed should be noted.

### 3.3. Concluding remarks

A summary of the monitoring results obtained via questionnaires, networks or other surveillance methods and stakeholders, and the literature review should be provided as well as the overall conclusions drawn.

Documentation received from surveillance networks or other surveillance methods in support of any aspect of the monitoring carried out and a comprehensive report of the responses provided in the farmer questionnaires should be annexed to the report including a copy of the manual to assist farmers completing the questionnaire, and where relevant cross-referenced within the report.

## 4. SUMMARY OF RESULTS AND CONCLUSIONS

A summary of the monitoring results obtained and the overall conclusions drawn should be provided. That summary should clearly demonstrate how the findings of the monitoring carried out and the interpretation of the data support those conclusions.

In this section of the report the authorisation/consent holder should also follow up on the main findings of monitoring activities carried out during preceding years, in order to analyse and to assess the possibility or likelihood of interactive or cumulative effects occurring which may be difficult to assess fully during a single monitoring year.

## 5. ADAPTATION OF THE MONITORING PLAN AND ASSOCIATED METHODOLOGY FOR FUTURE YEARS

An assessment of the monitoring plan and associated methodology used for the purposes of the report should be provided. The effectiveness and limitations of the methodologies used to detect adverse effects should be considered and it should be specified whether the monitoring plan and the associated methodology may need to be modified or adapted in light of the monitoring information with respect to relevance and quality of the data collected and uncertainty of the results presented in the report.



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### Changes and effects yet to be applied to the whole legislation item and associated provisions

- Annex 1 Appendix 2s. C.2para. 3.1.1(c) words substituted in earlier amending provision S.I. 2019/90, reg. 11(9)(b)(iv) by [S.I. 2020/1421 Sch. para. 6\(3\)\(a\)](#)
- Annex 1 Appendix 2s. C.2para. 3.1.3 words substituted in earlier amending provision S.I. 2019/90, reg. 11(9)(b)(vi) by [S.I. 2020/1421 Sch. para. 6\(3\)\(b\)](#)
- Annex 2 para. 3 words substituted in earlier amending provision S.I. 2019/90, reg. 11(13)(a) by [S.I. 2020/1421 Sch. para. 6\(4\)\(a\)](#)
- Annex 2 para. 3.3.2 words substituted in earlier amending provision S.I. 2019/90, reg. 11(13)(d)(ii) by [S.I. 2020/1421 Sch. para. 6\(4\)\(b\)](#)
- Annex 2 Appendix 2s. Cpara. 3 words substituted in earlier amending provision S.I. 2019/90, reg. 11(16)(d)(i) by [S.I. 2020/1421 Sch. para. 6\(5\)\(a\)](#)
- Annex 2 Appendix 2s. Cpara. 3.1.2(d) words substituted in earlier amending provision S.I. 2019/90, reg. 11(16)(d)(ii)(dd) by [S.I. 2020/1421 Sch. para. 6\(5\)\(b\)](#)
- Annex 1 para. 1.2 omitted by [S.I. 2019/90 reg. 11\(6\)](#)
- Annex 1 para. 1.3 omitted by [S.I. 2019/90 reg. 11\(6\)](#)
- Annex 1 Appendix 2s. C.1 omitted by [S.I. 2019/90 reg. 11\(9\)\(a\)](#)
- Annex 1 Appendix 2s. C.2 heading omitted by [S.I. 2019/90 reg. 11\(9\)\(b\)\(i\)](#)
- Annex 1 words omitted by [S.I. 2019/90 reg. 11\(5\)](#)
- Annex 1 Appendix 2s. B words omitted by [S.I. 2019/90 reg. 11\(8\)](#)
- Annex 1 Appendix 2s. C.2 words omitted by [S.I. 2019/90 reg. 11\(9\)\(b\)\(ii\)\(aa\)](#)
- Annex 1 Appendix 2s. C.2para. 1 words omitted by [S.I. 2019/90 reg. 11\(9\)\(b\)\(iii\)](#)
- Annex 1 Appendix 2s. C.2 words substituted by [S.I. 2019/90 reg. 11\(9\)\(b\)\(ii\)\(bb\)](#)
- Annex 1 Appendix 2s. C.2para. 3.1.1(c) words substituted by [S.I. 2019/90 reg. 11\(9\)\(b\)\(iv\)](#)
- Annex 1 Appendix 2s. C.2para. 3.1.2(b) words substituted by [S.I. 2019/90 reg. 11\(9\)\(b\)\(v\)](#)
- Annex 1 Appendix 2s. C.2para. 3.1.3 words substituted by [S.I. 2019/90 reg. 11\(9\)\(b\)\(vi\)](#)
- Art. 1(1)(d) omitted in earlier amending provision S.I. 2019/90, reg. 11(2) by [S.I. 2020/1421 Sch. para. 6\(2\)](#)
- Annex 2 para. 1.2 omitted by [S.I. 2019/90 reg. 11\(12\)](#)
- Annex 2 para. 1.3 omitted by [S.I. 2019/90 reg. 11\(12\)](#)
- Annex 2 para. 3.1.2 omitted by [S.I. 2019/90 reg. 11\(13\)\(b\)](#)
- Annex 2 Appendix 2s. C.1 omitted by [S.I. 2019/90 reg. 11\(16\)\(a\)](#)
- Annex 2 Appendix 2s. C.2 heading omitted by [S.I. 2019/90 reg. 11\(16\)\(b\)\(i\)](#)
- Annex 2 Appendix 2s. Cpara. 3.1.2 heading omitted by [S.I. 2019/90 reg. 11\(16\)\(d\)\(ii\)\(aa\)](#)
- Annex 2 Appendix 2s. Cpara. 3.1.2(b)(c) omitted by [S.I. 2019/90 reg. 11\(16\)\(d\)\(ii\)\(cc\)](#)
- Annex 2 Appendix 2s. Cpara. 3.1.3 word substituted by [S.I. 2019/90 reg. 11\(16\)\(d\)\(iii\)\(bb\)](#)
- Annex 2 para. 3.3.2 words inserted by [S.I. 2019/90 reg. 11\(13\)\(d\)\(ii\)](#)
- Annex 2 Appendix 2s. Cpara. 3.1.2(d) words inserted by [S.I. 2019/90 reg. 11\(16\)\(d\)\(ii\)\(dd\)](#)
- Annex 2 words omitted by [S.I. 2019/90 reg. 11\(11\)](#)
- Annex 2 para. 3.3.2 words omitted by [S.I. 2019/90 reg. 11\(13\)\(d\)\(i\)](#)

- Annex 2 Appendix 2s. B words omitted by S.I. 2019/90 reg. 11(15)
- Annex 2 Appendix 2s. C.2 words omitted by S.I. 2019/90 reg. 11(16)(b)(ii)(aa)
- Annex 2 Appendix 2s. Cpara. 1 words omitted by S.I. 2019/90 reg. 11(16)(c)(i)
- Annex 2 Appendix 2s. Cpara. 1 words omitted by S.I. 2019/90 reg. 11(16)(c)(ii)
- Annex 2 Appendix 2s. Cpara. 3.1.3 words omitted by S.I. 2019/90 reg. 11(16)(d)(iii)(dd)
- Annex 2 para. 3 words substituted by S.I. 2019/90 reg. 11(13)(a)
- Annex 2 para. 3.1.3 words substituted by S.I. 2019/90 reg. 11(13)(c)
- Annex 2 Appendix 2s. C.2 words substituted by S.I. 2019/90 reg. 11(16)(b)(ii)(bb)
- Annex 2 Appendix 2s. Cpara. 3 words substituted by S.I. 2019/90 reg. 11(16)(d)(i)
- Annex 2 Appendix 2s. Cpara. 3.1.2 words substituted by S.I. 2019/90 reg. 11(16)(d)(ii)(bb)
- Annex 2 Appendix 2s. Cpara. 3.1.3 heading words substituted by S.I. 2019/90 reg. 11(16)(d)(iii)(aa)
- Annex 2 Appendix 2s. Cpara. 3.1.3 words substituted by S.I. 2019/90 reg. 11(16)(d)(iii)(cc)
- Annex 2 Appendix 2s. Cpara. 3.2.2 (b) words substituted by S.I. 2019/90 reg. 11(16)(d)(iv)
- Annex 2 Appendix 2s. Cpara. 3.3.2 (b) words substituted by S.I. 2019/90 reg. 11(16)(d)(v)