

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

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,

when he has received the written consent of the competent authority, and in conformity with any conditions required in that consent.

Having regard to the Treaty establishing the European Community,

(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.

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,

(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.

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.

(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.

(2) In accordance with Directive 2001/18/EC, the notifier may proceed with the placing on the market only

(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.

⁽¹⁾ OJ L 106, 17.4.2001, p. 1.

⁽²⁾ OJ L 268, 18.10.2003, p. 1.

- (7) Council Decision 2002/811/EC⁽¹⁾ 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:

Article 1

The reporting formats set out in Annexes I and II shall be used as technical guidance notes in order to facilitate the implementation and explanation of Annex VII to Directive 2001/18/EC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 13 October 2009.

For the Commission
Stavros DIMAS
Member of the Commission

⁽¹⁾ OJ L 280, 18.10.2002, p. 27.

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 processing: Yes No

Food/Feed: Yes No

2. Executive summary

[Empty rectangular box for 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

[Empty rectangular box for description of general surveillance]

3.1.2. Details of surveillance networks used to monitor environmental effects during general surveillance and description of other methodologies

[Empty rectangular box for details of surveillance networks]

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

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3.1.4. Results of general surveillance

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3.1.5. Additional information

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3.1.6. Review of peer-reviewed publications — Appendix

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3.2. Case-specific monitoring

3.2.1. Description and results of case-specific monitoring (if applicable)

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

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3.3. Concluding remarks

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4. **Summary of results and conclusions**

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

Signed:

Date:

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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

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

Area of the environmental risk assessment

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

Area of the environmental risk assessment

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

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.

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:

- (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 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, 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.

ANNEX II

MONITORING REPORT FOR GMO USES OTHER THAN CULTIVATION

Format for presenting the monitoring results for GMO uses other than cultivation 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:

Cultivation: Yes No

2. **Executive summary**

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The following sections must be completed in accordance with Appendix 2.

3. **Uses of GMOs other than cultivation**

Please note that this section relates to the monitoring of the environmental effects of GMO uses other than cultivation. Such uses include the use of Food and Feed containing or consisting of GMOs (living organisms).

- 3.1. Commodity imports into the Community
- 3.1.1. Commodity crop (GM + non-GM) imports into the Community by country of origin

Country of origin	Quantity (tons)	Estimated data of GMO share in imports (where not possible approximate share of cultivation in the country of origin)

3.1.2. Commodity Crop (GM + non-GM) imports into the Community by country of destination

Country of destination	Quantity (tons)

3.1.3. Analysis of data provided in tables 3.1.1 and 3.1.2

3.2. General surveillance

3.2.1. Description of general surveillance

3.2.2. Details of industry, environmental, food and/or feed related surveillance networks used during general surveillance

3.2.3. Details of information and/or training provided to importers, traders, handlers, processors, etc.

3.2.4. Results of general surveillance

3.2.5. Additional information

3.2.6. Review of peer-reviewed publications — Appendix

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3.3. Case-specific monitoring

3.3.1. Description and results of case-specific monitoring (if applicable)

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3.3.2. Processing (if applicable)

EU Member State	Point of entry/site of cultivation	Point of processing	Distance from point of entry/site of cultivation	Transport used

3.3.3. Monitoring and reporting of adverse effects resulting from accidental spillage (if applicable)

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3.4. Concluding remarks

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4. Summary of results and conclusions

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

Signed:

Date:

REVIEW OF PEER-REVIEWED PUBLICATIONS

Some publications may contain material relevant to more than one area of the environmental risk assessment (see Section 3.2.6 of Appendix 2). If so, the material should be described separately in each relevant table.

Area of the environmental risk assessment

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

Area of the environmental risk assessment

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

Area of the environmental risk assessment

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

*Appendix 2***EXPLANATORY NOTES****A. General comments**

Case-specific monitoring will 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);
- (b) altered gene transfer:
 - potential reduction of pollination,
 - increased frequency of horizontal gene transfer from plant to microbial populations;
- (c) interaction between GMP and non-target organisms:
 - direct/indirect impact on non-target organisms,
 - changes of susceptibility to non-target pests and diseases,
 - impact on habitat diversity and biodiversity;
- (d) changes in biogeochemical processes;
- (e) 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.

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 Cultivation must also be completed.

The decisions concerning 1507 maize (OJ L 291, 5.11.2005), MON 863 maize (OJ L 207, 10.8.2005) and NK603 maize (OJ L 295, 18.9.2004) were adopted pursuant to Directive 2001/18/EC for import and use as any other maize excluding cultivation.

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. GMO USES OTHER THAN CULTIVATION

3.1. Commodity imports into the Community

3.1.1. Commodity Crop (GM + non-GM) imports into the Community by country of origin

3.1.2. Commodity Crop (GM + non-GM) imports into the Community by country of destination

Details of the following should be provided in Tables 3.1.1 and 3.1.2. Actual data should be provided as opposed to estimated data (with the exception of GMO share in imports into the Community):

(a) exporting country where GM crop is cultivated;

(b) quantity in tons of commodity crop (GM + non-GM) exported;

(c) Community Member States into which the commodity crop (GM + non-GM) is imported;

(d) quantity in tons of commodity crop (GM + non-GM) imported.

3.1.3. Analysis of data provided in tables 3.1.1 and 3.1.2

Such analysis should outline the source of the data provided, whether the imports have increased or decreased on previous years and the reasons for any change, the largest suppliers of extra-Community crops to the Community as well as the main importers of extra-Community crops into the Community, any alteration in trends in relation to significant import markets compared to previous years and the reasons therefore.

3.2. General surveillance

3.2.1. Description of general surveillance

A description of the general surveillance carried out, including but not limited to details of all methodologies used including parameters observed, data collection methodologies, types of location.

3.2.2. Details of industry, environmental, food and/or feed related surveillance networks

Details of industry, environmental, food and/or feed-related surveillance networks used during the course of the general surveillance carried out should be provided. The following information in relation to each surveillance network identified should be provided:

- (a) name, identifying whether it is an industry, environment, food and/or feed related network;
- (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 the authorisation/consent holder;
- (g) criteria used to select the surveillance network.

3.2.3. Details of information and/or training provided to importers, traders, handlers, processors, etc.

Details of the information made available to importers, traders, handlers, processors etc., when and how this information was made available and the provisions for keeping the aforementioned user groups abreast of any changes to existing information or new information should be provided.

3.2.4. 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 observed parameters for all monitoring methodologies 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. This section of the report should be as detailed as possible to allow proper interpretation of the data.

3.2.5. Additional information

Where adverse or unanticipated effects were observed, additional information should be provided, such as the relevant region or location, steps taken to confirm the adverse effect, remedial action 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 and any other conclusions drawn. This section of the report should be as detailed as possible to allow proper interpretation of the data.

3.2.6. Review of peer-reviewed publications — Appendix

Peer-reviewed publications including peer-reviewed journal articles, conference proceedings, review papers and any additional studies or other sources of information relevant to the importation and processing and to food and/or feed use 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.

3.3. Case-specific monitoring

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

3.3.2. Processing (if applicable)

The information set out in this section should only be provided where the authorisation or the monitoring plan requires the monitoring of accidental spillage and:

- (a) where processing takes place at sites other than within the confines of the port of importation; or
- (b) in respect of processing locations for GM crops cultivated within the Member State/the Community.

3.3.3. Monitoring and reporting of adverse effects resulting from Accidental Spillage (if applicable)

An overview of the measures taken to monitor accidental spillage should be provided where the authorisation/ consent or the current monitoring plan requires such monitoring, e.g. the frequency with which monitoring is carried out, monitoring methodologies used, measures employed to minimise spillage and the clean-up procedures in place. In addition, any unusual, adverse or GMO-related effects observed should be noted. This information should be provided in respect of the following:

- (a) ports through which the GM crops are being imported and where processing takes place within the port boundaries;
- (b) those processing sites identified under Section 3.3.2.

3.4. Concluding remarks

Documentation received from surveillance networks or other surveillance methods in support of any aspect of the monitoring carried out should be annexed to the report and where relevant cross-referenced within the report. A summary of the monitoring results obtained via networks, the literature review and the overall conclusions drawn should be provided.

4. SUMMARY OF RESULTS AND CONCLUSIONS

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

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.
