II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 11 February 1992

concerning the summary notification information format referred to in Article 12 of Council Directive 90/220/EEC

(92/146/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [1], and in particular Article 12 thereof,

Whereas the competent authorities appointed by the Member States shall forward to the Commission dossiers for notifications received under Part C of Directive 90/220/EEC;

Whereas each dossier forwarded to the Commission shall include a summary of the notification;

Whereas the Commission is required to establish, before 23 October 1991, the format of this summary;

Whereas the provisions of this Decision have received the favourable opinion of the Committee of Member State Representatives in accordance with the procedure laid down in Article 21 of Directive 90/220/EEC,

HAS ADOPTED THIS DECISION:

Article 1

The competent authorities appointed by Member States under Directive 90/220/EEC must use the annexed Summary Notification Information Format when sending to the Commission the summary of a notification received, as specified under Part C of Directive 90/220/EEC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 11 February 1992.

For the Commission

Carlo RIPA DI MEANA

Member of the Commission

[1] OJ No L 117, 8. 5. 1990, p. 15.

ANNEX

SUMMARY NOTIFICATION INFORMATION FORMAT FOR PRODUCTS CONTAINING GENETIALLY MODIFIED ORGANISMS (GMOS)

in accordance with Article 12 of Directive 90/220/EEC

INTRODUCTION

The present document is designed to serve as the format of the summary of the dossier submitted to the Commission for the placing on the market of a product containing GMOs (Part C, Article 12 (3) of Directive 90/220/EEC) and does not prejudice the provisions of Directive 90/220/EEC.

The summary notification information format for products containing GMOs when completed will contain a summary of the information entered under the corresponding points of the full dossier. It is, therefore, recognized that the risk assessment stipulated by Directive 90/220/EEC, Article 12, cannot be carried out on the basis of the summary.

A. *GENERAL INFORMATION*

1. *Details of notification*

(a) Member State of notification .....

(b) Notification number .....

(c) Name of the product (commercial and other names) .....

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(d) Date of acknowledgement of notification .....

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2. *Notifier / manufacturer / importer*

(a) Name of notifier .....

(b) Address of notifier .....

(c) The notifier is :

domestic manufacturer ☐

importer ☐

(d) In case of import

(i) Name of manufacturer .....

(ii) Address of manufacturer .....

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3. *Characterisation of the GMOs contained in the product*

Indicate the name and nature of each type of GMO contained in the product

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4. *General description of the product*

(a) Type of product

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(b) Composition of the product

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(c) Specificity of the product

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(d) Types of users

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(e) Exact conditions of use and handling

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(f) Geographical areas for which the product is intended

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(g) Type of environment for which the product is suited

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(h) Annual estimated production in and/or imports into the Community

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5. *Has the combination of GMOs contained in the product been notified under part B of Directive 90/220/EEC?*

Yes ☐ No ☐

(i) If *yes,* give country and notification number:

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(ii) If *no,* refer to risk analysis data on the basis of the elements of Part B of Directive 90/220/EEC.

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6. *Is the product being simultaneously notified to another Member State?*

Yes ☐ No ☐

If *yes,* please specify

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7. *Has another product with the same combination of GMOs been placed on the EC market by another notifier?*

Yes ☐ No ☐ Not known ☐

If *yes,* please specify

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8. *Information on releases of the same GMOs or of the same combination of GMOs previously or currently notified and/or carried out by the notifier either inside or outside the Community*

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9. *Specify instructions and or recommendations for storage and handling*

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10. *Proposed packaging*

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11. *Proposed labelling*

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12. *Measures to take in case of unintended release or misuse*

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13. *Measures for waste disposal and treatment*

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B. *NATURE OF THE GMOS CONTAINED IN THE PRODUCT*

INFORMATION RELATING TO THE RECIPIENT OR PARENTAL ORGANISM(S) FROM WHICH THE GMO IS DERIVED

14. *Scientific name and other names*

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15. *Phenotypic and genetic traits*

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16. *Geographical distribution and natural habitat of the organisms*

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17. *Genetic stability of the organism and factors affecting it*

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18. *Potential for genetic transfer and exchange with other organisms*

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19. *Information concerning reproduction and factors affecting it*

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20. *Information on survival and factors affecting it*

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21. *Ways of dissemination and factors affecting it*

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22. *Interactions with the environment*

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23 (a) *Detection techniques*

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23 (b) *Identification techniques*

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24. *Classification under existing Community rules concerning the protection of human health and/or the environment*

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25 (a) *Pathogenic characteristics*

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25 (b) *Other harmful characteristics of the organism living or dead, including its extracellular products*

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26. *Nature and description of known extrachromosomal genetic elements*

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27. *History of previous genetic modifications*

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INFORMATION RELATING TO THE GENETIC MODIFICATION

28. *Methods used for the genetic modification*

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29. *Characteristics of the vector*

(a) Nature and source of the vector

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(b) Description of the vector construction

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(c) Genetic map and/or restriction map of the vector

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(d) Sequence data

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(e) Information on the degree to which the vector contains sequences whose product or function area is not known

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(f) Genetic transfer capabilities of the vector

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(g) Frequency of mobilization of the vector

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(h) Part of the vector which remains in the GMO

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30. *Information on the insert*

(a) Methods used to construct the insert

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(b) Restriction sites

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(c) Sequence of the insert

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(d) Origin and function of each constituent part of the insert in the GMO

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(e) Information on the degree to which the insert is limited to the required function

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(f) Location of the insert in the GMO

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INFORMATION ON THE ORGANISM(S) FROM WHICH THE INSERT IS DERIVED (DONOR)

31. *Scientific and other names*

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32 (a) *Pathogenic characteristics of the donor organism*

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32 (b) *Other harmful characteristics of the organism living or dead, including its extracellular products*

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33. *If the door organism has any pathogenic or harmful characteristics, indicate whether the donated sequences are in any way involved in them*

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34. *Classification under existing Community rules relating to the protection of human health and the environment*

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35. *Potential for natural exchange of genetic material between the donor(s) and recipient organism*

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INFORMATION RELATING TO THE GMO(S) CONTAINED IN THE PRODUCT

36. *Description of genetic traits or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed*

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37. *Genetic stability of the GMO*

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38. *Rate and level of expression of the new genetic material*

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39. *Activity of the expressed proteins*

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40 (a) *Description of detection techniques for the GMO in the environment*

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40 (b) *Description of identification techniques*

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41. *Health considerations*

(a) toxic or allergenic effects of the non-viable GMOs and/or their metabolic products

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(b) product hazards

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(c) comparison of the GMO with the donor, recipient or parental organism regarding pathogenicity

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(d) capacity for colonization

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(e) If the organism is pathogenic to humans who are immuno-competent, supply the information specified in Annex II, Part II C 2 (i) (v)

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INTERACTIONS OF THE GMO WITH THE ENVIRONMENT

42. *Survival, multiplication and dissemination of the GMO(s) in the environment*

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43. *Interactions of the GMOs with the environment*

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44. *Environmental impacts of the GMO(s)*

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C. *PREDICTED BEHAVIOUR OF THE PRODUCT*

1. ENVIRONMENTAL IMPACT OF THE PRODUCT

2. HUMAN HEALTH EFFECTS OF THE PRODUCT

D. *INFORMATION RELATING TO PREVIOUS RELEASES*

I. HISTORY OF PREVIOUS RELEASES NOTIFIED UNDER PART B OF THE DIRECTIVE

1. *Notification number:* .....
2. *Release site:* .....
3. *Aim of the release:* .....
4. *Duration of the release:* .....
5. *Duration of post-release monitoring:* .....
6. *Aim of post-release monitoring:* .....

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7. *Conclusions of post-release monitoring:* .....

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8. *Results of the release in respect to any risk to human health and the environment (submitted to the competent authority according to Article 8 of Directive 90/220/EEC):*

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II. HISTORY OF PREVIOUS RELEASES CARRIED OUT INSIDE OR OUTSIDE THE COMMUNITY

1. *Release country:* .....
2. *Authority overseeing the release:* .....
3. *Release site:* .....
4. *Aim of the release:* .....
5. *Duration of post-release monitoring:* .....
6. *Aim of post-release monitoring:* .....
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7. *Conclusions of post-release monitoring:* .....
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8. *Results of the release in respect to any risk to human health and the environment:*
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III. HISTORY OF PREVIOUS WORK RELEVANT TO RISK ASSESSMENT PRIOR TO COMMERCIALIZATION