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LAWS, DECREES, DECISIONS AND OTHER NORMS

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LAWS AND DECREES

PARLIAMENT OF ROMANIA

CHAMBER OF DEPUTIES

SENATE

LAW

On the approval of Government Ordinance no. 49/2000 regarding the regime of obtaining, testing, using and marketing organisms modified genetically through modern biotechnology techniques as well as of products resulted from them

The Parliament of Romania adopts the present law:

Art. I. – The Parliament adopts Governmental Ordinance no. 49 of 10 January 2000 on the regime of obtaining, testing, using and marketing organisms modified genetically through modern biotechnology techniques as well as of products resulted from them, based on Art. 1, paragraph D, entry 2 of Law no. 206/1999 authorizing the Government to pass ordinances, published in Monitorul Oficial al Romaniei Part I, no. 48 of January 31 2000, with the following alterations and completions:

1. Article 1 will have the following contents:

“Art. 1. – Activities of obtaining, testing, using and marketing organisms modified genetically through modern biotechnology techniques are subject to a special regime of regulations, authorizations and administration, in accordance with provisions in the present ordinance and in international legal norms to which Romania is part, regarding:

a) activities on using genetically modified microorganisms in conditions of isolation;

- b) under conditions of deliberate introduction into the environment and on the market of genetically modified organisms and of products resulted from them, these activities should proceed in observance of perfect safety for human society and environment protection;
- c) under conditions of import/export of genetically modified organisms and of products resulted from them.”

2. After Article 1, Article 1¹ is introduced with the following contents:

Art. 1¹. – (1) The special regime for regulations, authorization and administration establishes the legal and institutional frame for the proceeds and monitoring of activities mentioned in Article I.

(2) The present ordinance does not apply to:

- a) organisms obtained through genetically modification techniques mentioned in Annex 1, Part B, and in Annex ??, Part A;
- b) processed products;
- c) activities of transportation, irrespective of the means and routes
- d) trade and import/export operations that are the object of other norms.”

3. Article 2 is abrogated.

4. Title of chapter is abrogated.

5. Article 3 will have the following contents:

Art. 3. – According to the meaning of the present ordinance, terms are defined as follows:

- a) *organism* – any biological entity capable to transfer or replicate genetic material, including viruses and viroids;
- b) *genetically modified organism (GMO)* – any organism, except the human one, whose genetic material was modified other than by cross-breed and/or general

recombination. According to the meaning of this definition, the genetic modification is a consequence of using techniques specified in Annex 2, Part A;

- c) *micro-organism* – any microbiological cellular or non-cellular entity, capable of replication or transfer of genetic material, including viruses, viroids, and plant cells, and animals in cultures;
- d) *modern biotechnology* – in vitro application of techniques of nuclear acids recombination and of cellular fusion, other than the ones typical to selection and functional improvement, that remove natural physiological barriers of reproduction or genetic recombination;
- e) *use under conditions of isolation* – any operation by which microorganisms are modified genetically, cultivated, replicated, stored, used, transported, destroyed and/or annihilated under controlled conditions in closed space/environment. For these operations, typical conditions for isolation are created to avoid/limit their contact with people and the environment;
- f) *user* – any physical or legal person carrying and being responsible of activities connected to the obtaining, testing, producing and marketing of genetically modified organisms under conditions of isolation or non-isolation, as well as to the obtaining, testing, producing and marketing of products resulted from these;
- g) *deliberate introduction into the environment* – any intentional/voluntary introduction into the environment of a genetically modified organism or of a GMO combination which does not need typical isolation conditions to limit contact with it and which presents a high degree of safety to the population and the environment;
- h) *introduction on the market* – supplying GMOS or their products for a price or not to a third party;
- i) *product resulted from a genetically modified organism* – a specific result containing a GMO or a combination of a GMO, that is introduced on the market;
- j) *processed product* – a product obtained by processing of genetically modified organisms, of parts of them or of metabolites and substances produced by these;
- k) *purified product* – any product obtained from a genetically modified organism by processing that includes purification, for example: insulin, various enzymes, oil and similar others;

- l) *evaluation of risks to the environment* – evaluation of effects that GMOS or components of them may show directly or indirectly, immediately or belatedly, in human health or the environment;
- m) *risk management* – creation and implementation of a set of measures to monitor risks and to intervene in case of accidents;
- n) *notification* – the document by which a person notifies the Ministry of Waters and Environmental Protection about activities he/she intends to carry, in order to obtain an authorization;
- o) *notifier* – the author of the notification.”

6. Article 4 will have the following contents:

“Art. 4. – (1) The institutional frame is provided by:

- a) The Ministry of Waters and Environmental Protection, as an authority responsible with the issuance of authorizations/agreements and with the monitoring of activities regulated by the following ordinance;
- b) The Commission for Biological Safety, as the scientific authority with consulting role before the Ministry of Waters and Environmental Protection in the decision making process;
- c) Central public authorities in the fields of agriculture, food, health and the National Authority for Consumer Protection, with responsibilities in the approval and monitoring of activities regulated by the present ordinance.

(2) The Commission for Biological Safety is made up of 12 members, specialists in the fields regulated by the present ordinance, recipients of academic recognition and degrees and acknowledged scientific personalities.

(3) Members of the Commission for Biological Safety will come from the following institutions:

- a) 3 members of the Romanian Academy and/or institutions under its coordination;
- b) 3 members of the Agricultural and Forest Studies Academy “Gheorghe Ionescu Sisesti” and/or scientific institutions under its coordination;

- c) 3 members of the Medical Studies Academy and/or scientific institutions under its coordination;
- d) 3 members of universities and/or other institutes in the field of biological, agricultural or medical research.

(4) The composition of the Commission for Biological Safety is established based on written proposals made by heads of the institutions mentioned at (3), is approved by order of the minister of waters and environmental protection, at the same time with the regulations on the organization and operation of the Commission, and is published in the “Monitorul Oficial” of Romania (the Official Monitor), Part I.

(5) In the exercise of its attributions, the Commission for Biological Safety plays a consultative part, decisions being made by consensus.”

7. The title of Chapter III has the following contents:

“CHAPTER III

Using genetically modified organisms under conditions of isolation”

8. Articles 5, 6, and 7 are abrogated.

9. Article 8 will have the following contents:

“Art. 8. – (1) Before authorizing the use of a genetically modified organism under conditions of isolation, the Ministry of Waters and Environmental Protection will check through the documentation provided by the user that adequate measures were taken to avoid negative effects on human health and on the environment:

(2) For this purpose, the user shall make an evaluation of GMO use under conditions of isolation in terms of risks to human health and the environment, using minimum elements of evaluation and the procedure established in Annex 3, Sections A and B.

(3) The evaluation mentioned in paragraph (2), using procedure provided by Annex 3, shall lead to a division of use under conditions of isolation into one of the following classes:

- a) class 1: activities with negligible risk or no risk, that is activities for which level 1 of isolation is adequate for the protection of human health and of the environment;
- b) class 2: activities with low risk, that is activities for which level 2 of isolation is adequate for the protection of human health and of the environment;
- c) class 3: activities with moderate risk, that is activities for which level 3 of isolation is adequate for the protection of human health and of the environment;
- d) class 4: activities with high risk, that is activities for which level 4 of isolation is adequate for the protection of human health and of the environment.

(4) The division into one of the 4 classes will indicate and confirm level of isolation, according to provisions of Art. 9.

(5) When there is uncertainty about the class of risk for the proposed use, more severe precaution measures shall be taken, except in case that there are sufficient proofs justifying enforcement of less severe measures, in consensus with the competent authority.

(6) The evaluation which paragraph (2) refers to shall take into account especially the aspects regarding waste release, safety measures shall be taken for the protection of human health and the environment.

(7) Users are compelled to keep records of the evaluations stipulated in paragraph (2) and shall make them available to the Ministry of Waters and Environmental Protection.”

10. Article 9 shall have the following contents:

“Art. 9. – (1) Except in the situation that provisions of entry 1 in Annex 4 allow other measures, the user shall apply the general principles, the adequate isolation and

other measures of protection established in Annex 4, in conformity with the use class under conditions of isolation, so that the work place and the outside environment shall be exposed to the minimum possible to genetically modified organisms.

(2) The evaluation which Art. 8, paragraph (2) refers to, as well as the level of isolation and the other precaution measures will be revised periodically and whenever necessary, if:

- a) measures for isolation are not adequate anymore or the class established for usage under conditions of isolation is no longer accurate;
- b) there is indication that the evaluation is no longer adequate, by new scientific and technical knowledge.”

11. Article 10 shall have the following contents:

“Art. 10. – When the usage installations under isolation conditions are used for the first time, the user shall submit to the Ministry of Waters and Environmental Protection, prior to the initiation of the usage as such, a notification containing at least the information described in Annex 5, part A.”

12. Article 11 shall have the following contents:

“Art. 11. – (1) After the notification mentioned in Art. 10, usage under isolation conditions attributed to class 1 may be done without such notification.

(2) Users of genetically modified organisms in class 1 of usage under isolation conditions shall keep records of each evaluation mentioned in Art. 8, paragraph 6, which shall be placed at the disposal of the Ministry of Waters and Environmental Protection.”

13. In Article 12, paragraphs (1), (3) and (4) shall have the following contents:

“Art. 12. – (1) For the first and subsequent uses under isolation conditions attributed to class 2, which are to be executed in installations notified according to Art. 10, the

user shall send the Ministry of Waters and Environmental Protection also a notification containing the information requested in Annex 5, part B.

(3) In the situations covered by paragraph (2), the user may request authorization from the Ministry of Waters and Environmental Protection which shall communicate its decision 5 days after the notification.

(4) In situations that installations were not subjected to notification prior to usage under isolation conditions attributed to class 2 or higher, usage may start only at the end of a 45 days period since the notification is submitted as per paragraph (1), if there is no express interdiction from the Ministry of Waters and Environmental Protection, or during this period, if authorization was granted.”

14. Article 13 shall have the following contents:

“Art. 13. – (1) For the first and subsequent uses under isolation conditions attributed to class 3 or class 4, which are to be executed in installations notified according to Art. 10, the user shall send the Ministry of Waters and Environmental Protection also a notification containing the information requested in Annex 5, part C.

(2) Use under isolation conditions attributed to class 3 or above cannot take place without prior consent from the Ministry of Waters and Environmental Protection, which shall communicate its decision in writing:

- a) within 45 days since the receipt of the new notification, in the situation of installations subjected to a previous notification for use under isolation conditions of class 3 or above, and in the situations that all associated requirements were met, as agreed for use in same class or higher class for use under isolation conditions intended for work;
- b) within 90 days since the receipt of the notification in the other situations.”

15. Article 14 shall have the following contents:

“Art. 14. – (1) Ministry of Waters and Environmental Protection shall examine conformity of notification with provisions in the present ordinance, accuracy of

evaluation, and class of use under isolation conditions, precaution measures and response to emergency cases, as well as waste management.

(2) If necessary, the Ministry of Waters and Environmental Protection may:

- a) request the user to provide additional information, alter conditions of proposed use or correct the class of isolation attributed for use. In this case, the Ministry of Waters and Environmental Protection may dispose that the use, if proposed, should not start, or if started, should be suspended or closed until the Ministry of Waters and Environmental Protection gives its approval based on additional information received or on altered conditions for use;
- b) limit the period for which use under isolation conditions was permitted, or impose certain specific terms for the use.

(3) In calculations of periods provided in Art. 12 and 13, periods of time shall not be taken into account during which the Ministry of Waters and Environmental Protection:

- a) waits for additional information requested from the notifier, in accordance to provisions of paragraph (2) letter a);
- b) performs an inquiry or public consultation, in accordance to the provisions of Art. 49, paragraph (3).

(4) Approvals for activities of the use under isolation conditions of genetically modified organisms, according to Articles 12-15, are granted under the form of an authorization as established by the Ministry of Waters and Environmental Protection.”

16. In Article 15, paragraph (1) shall have the following contents:

“Art. 15. – (1) Every time it possesses new, relevant information, or alters conditions to an extent that might have significant consequences in terms of risks involved, the user is compelled to inform immediately the Ministry of Waters and Environmental Protection, and to alter notifications provided in Art. 10, 12 and 13.”

17. Article 16 is abrogated.

18. Article 17 shall have the following contents:

“Art. 17. – (1) The Ministry of Waters and Environmental Protection, prior to the beginning of the use under isolation conditions, shall check whether:

- a) an emergency plan is made for the use under isolation conditions, where the inefficiency of isolation measures might lead to serious danger with immediate or late effects upon human health and/or the environment outside the installation placed;
- b) the emergency plan provided under letter a) is not made if the notifier places at the disposal of the Ministry of Waters and Environmental Protection a similar emergency plan issued by and being valid for the European Union;
- c) the information on such emergency plans, including adequate safety measures to be enforced, is presented in explicit terms. The information shall be updated at adequate periods of time and shall be made public.

(2) The Ministry of Waters and Environmental Protection shall place at the disposal of authorities competent in the field, information that shall refer to paragraph 1, in accordance to international regulations in the field.”

19. Article 18 shall have the following contents:

“Art. 18. – (1) In the case of an accident, the user shall immediately inform the Ministry of Waters and Environmental Protection and provide all information:

- a) circumstances of the accident
- b) identity and amount of genetically modified microorganisms;
- c) any other data necessary in the evaluation of the effects of the accident upon people’s health and the environment;
- d) measures taken.

(2) In situations provided under paragraph (1), the Ministry of Waters and Environmental protection is compelled:

- a) to get informed so as to make as complete evaluation as possible of the accident and, by case, to make recommendations for future avoidance of similar accidents and for the elimination of potential resulting effects;
- b) to make sure that all necessary measures were taken, and by case, to immediately inform competent international authorities in the states that might be affected by such accidents.”

20. Article 19 shall have the following contents:

“Art. 19. – (1) The Ministry of Waters and Environmental Protection is compelled to:

- a) consult with competent national authorities and with international authorities of other countries on issues related to causing an accident, including on intervention plans in emergency cases;
- b) inform immediately competent international authorities on any accident in the meaning of the present ordinance, providing details on the circumstances of the accident, the identity and amount of genetically modified microorganisms in case, the response measures taken, as well as an analysis of the accident with recommendations to limit the effects and to avoid similar accidents in the future.

(2) The M shall put to practice procedures for exchange of information, according to paragraph (1), for which purpose it will initiate and keep a log on accidents to examine the causes and record measures taken to avoid similar accidents in the future.

21. Articles 20 and 21 are abrogated.

22. The Title of Chapter IV shall have the following contents:

“CHAPTER IV

Deliberate introduction into the environment and on the market of organisms genetically modified through modern biotechnology techniques and of products resulted from these”

23. Articles 22 and 23 are abrogated.

24. The Title of Section 1 shall have the following contents:

“Section 1

Deliberate introduction into the environment of genetically modified organisms”

25. Article 24 shall have the following contents:

“Art. 24. – (1) Any legal persona, before introducing into the environment a genetically modified organism or a combination of such organisms, shall submit a notification to the Ministry of Waters and Environmental Protection.

(2) The notification stipulated in paragraph (1) shall include:

a) technical documentation containing information specified in Annex 8, necessary to evaluate environment risks, especially:

- general information – data on the personnel and its qualifications
- information on the genetically modified organism(s)
- information on terms of introduction and the characteristics of the potential receiving environment
- information on the impact of the genetically modified organism(s) upon the environment
- the monitoring plan, in agreement with relevant parties of Annex 12², for the identification of the effects of genetically modified organisms on human health and the environment;
- information on the control, recovery methods and treatment of waste and action plans in emergency cases
- summary of the documentation file.

b) evaluation of environment risks study, according to Annex 12¹, and every bibliographical reference and indication of methods used;

c) information on the results of the introduction of the same genetically

modified organisms or of the same combinations of genetically modified organisms on Romanian territory or outside it.

(3) The notifier shall refer to data or results of notifications previously submitted by other notifiers, on condition that the information should be non-confidential or that the notifier have their consent.

(4) The Ministry of Waters and Environmental Protection may accept that the introduction into a certain place in the environment of a combination of genetically modified organisms or the same genetically modified organism with one purpose and a limited period of time should be announced in a single notification.

(5) In the case of the after introduction of the same genetically modified organism or of the same combination of genetically modified organisms, previously notified as part of the same testing-research program, the notifier shall submit a new notification in which to present data in the previous notifications and/or data on results registered in previous introductions.

(6) In the case of a change in the deliberate introduction which might have consequences on human health and/or the environment, or in the case of new information on risks, the notifier is compelled to:

- a) revise measures specified in the notification;
- b) inform the Ministry of Waters and Environmental Protection on these;
- c) take necessary measures for the protection of human health and the environment.

(7) To facilitate decision making on the approval of deliberate introduction into the environment of genetically modified organisms whose introduction was already notified and/or approved for the countries in the European Union and the Organization for Cooperation and Economic Development, the notifier shall on its own initiative or upon request by the Ministry of Waters and Environmental Protection submit:

- a) either a copy of the summary of notification submitted to the European Union and the Organization for Cooperation and Economic Development by the competent national authorities in the member states;
- b) or a copy of the document of the European Union and the Organization for Cooperation and Economic Development in which the introduction of the genetically modified organism is approved.”

26. Article 25 shall have the following contents:

“Art. 25. – (1) Upon receipt of the notification, the Ministry of Waters and Environmental Protection, based on information in the notification and in the documents mentioned in Art. 24, shall:

- a) inform and consult the public on the notification received;
- b) consult the Commission for Biological Safety;
- c) request approval from the central public authorities in the fields of: agriculture, food, health and consumer protection.

(2) Having established the procedure to follow, the Ministry of Waters and Environmental Protection shall respond to the notification no later than 90 days since its receipt, indicating that:

- a) the notification received is in accordance with provisions of the present ordinance and authorization is issued;
- b) in order to make the decision provisions in the paragraph (1) letter a) and c) shall be observed;
- c) the notifier shall also submit other information;
- d) the activity proposed does not comply with terms provided in the present ordinance and is denied;
- e) the activity proposed does not come under the incidence of provisions in the present ordinance.

- (3) In the calculation of the 90 day period provided under paragraph (2), periods shall not be taken into account while the Ministry of Waters and Environmental Protection:
- a) waits for information from the notifier, according to paragraph (2) letter c);
 - b) waits for the approval of the Commission for Biological Safety;
 - c) makes a public survey, consults with other organizations or with the public;
- (4) The notifier may begin activity only after having obtained authorization issued by the Ministry of Waters and Environmental Protection and in observance of the terms set by the latter;
- (5) If the Ministry of Waters and Environmental Protection decides that enough experience was acquired in the introduction into the environment of certain genetically modified organisms and taking into account criteria set in Annex 10, may decide to apply simplified procedures for the introduction into the environment of such organisms.
- (6) The authorization for deliberate introduction into the environment of a genetically modified plant, issued by the Ministry of Waters and Environmental Protection is obligatory upon registration of the species for examination at the State Institute for Testing and Registration of Species.”

27. Article 26 shall have the following contents:

“Art. 26. – If some information that may have significant consequences regarding potential risks of the introduction into the environment of a genetically modified organism is known after the issuance of the authorization by the Ministry of Waters and Environmental Protection, the latter shall request the user to change the terms for the introduction into the environment and in case of non-compliance it may suspend or cancel the activities.”

28. Article 27 shall have the following contents:

“Art. 27. – (1) After the introduction into the environment of a genetically modified organism, the notifier shall submit periodically to the Ministry of Waters and Environmental Protection reports on the results of the introduction, mentioning any

risk to human health or the identified environment, especially to the introductions that the notifier intends to do at large scale.

(2) Periods of time for the submission of reports referred to in paragraph (1) shall be specified in the authorization issued.”

29. Title of Section 2 shall have the following contents:

**“Section 2
Introduction on the market of genetically modified organisms and of products
resulted from these”**

30. Article 28 is abrogated.

31. Article 29 shall have the following contents:

“Art. 29. – (1) Before the introduction on the market for the first time of a genetically modified organism or of a combination of genetically modified organisms as a product or as part of a product, a notification shall be submitted to the Ministry of Waters and Environmental Protection, including:

- a) information requested in Annex 8 and 9, and data and results registered during the research-development activities in accordance to provisions of Section 1 of the present chapter;
- b) the study of risk evaluation on the environment with information as provided in Annex 12¹;
- c) conditions for the introduction on the market of the product, including conditions for use and handling, as well as proposals for labeling and packaging, which shall include at least the requirements set in Annex 9. The label shall specify clearly whether the genetically modified organism is present. The label bearing the inscription: “This product contains genetically modified organisms” is obligatory. In 10 year time, procedures will be established to allow labels informing that “This product does not contain genetically modified organisms.”

- d) a monitoring plan according to Annex 12²;
- e) a summary of the notification.

(2) If, based on the results of any introduction into the environment notified and approved according to provisions of the present ordinance, or independently, based on scientifically explained results, a notifier believes that the introduction on the market of a product does not present any risk to human health and the environment, he may propose in the notification not to comply to one or several requirements provided in Annex 9, Part B.

(3) The notifier shall include information on data or results on the introductions into the environment of the same genetically modified organisms or of combinations of genetically modified organisms previously notified and performed by the notifier on Romanian territory or outside it.

(4) The notifier may refer also to data and results in notifications previously submitted by other notifiers if the latter have given their consent in writing.

(5) Each new product, although containing or being made up of the same genetically modified organisms or combinations of them, is made for different use shall be notified separately.

(6) Introduction on the market is done only after having obtained authorization issued by the Ministry of Waters and Environmental Protection, and in observance of the terms of this authorization.

(7) Registration in the State Registry and on the Official List of the species resulted from genetically modified plants is made only after having obtained authorization from the Ministry of Waters and Environmental Protection for introduction into the environment for experiment purposes.

(8) In the case that a renewal of the authorization is desired, at least 9 months prior to expiration the notifier shall submit a new notification to the Ministry of Waters and Environmental Protection. The notification shall include:

- a) a copy of the received authorization;
- b) a report on the results of monitoring activity;
- c) any new information that has become accessible after receiving authorization
- d) when the case, a proposal for amending terms specified in the authorization.”

32. Article 30 is abrogated.

33. Article 31 shall have the following contents:

“Art. 31. – Provisions of Art. 24 paragraph (7) and of Art. 26 apply also with regard to the introduction on the market of genetically modified organisms.”

34. Article 32 is abrogated.

35. Title of Chapter V shall have the following contents:

“CHAPTER V

Terms for the organization and proceeds of import/export operations of genetically modified organisms and/or of products resulted from these”

36. Article 33 and Article 34 are abrogated.

37. Under Article 35, paragraphs (1), (2) and (4) shall have the following contents:

“Art. 35. – (1) Importers are compelled to notify the Ministry of Waters and Environmental Protection in writing prior to executing any import of live genetically modified organisms or of products resulted from these.

(2) The Ministry of Waters and Environmental Protection shall establish the procedures of notification, in accordance with provisions in paragraph (1) and shall place them at the disposal of interested parties.

.....
(4) Notifiers are responsible for the accuracy of the information provided to the Ministry of Waters and Environmental Protection by way of notification or by any other way, upon its request.”

38. Under Article 38, paragraph (5) is abrogated.

39. Article 36 shall have the following contents:

“Art. 36. – (1) The Ministry of Waters and Environmental Protection confirms in writing the receipt of the notification to the notifier 90 days since the receipt.

(2) Confirmation includes the following:

- a) date notification was received
- b) whether the notification contains all the necessary information to make a decision
- c) other mentions, by case.

(3) Non-compliance with the confirmation procedure by the Ministry of Waters and Environmental Protection shall not be interpreted as a tacit approval for the execution of the import.”

40. Article 37 shall have the following contents:

“Art. 37. – (1) The Decision of the Ministry of Waters and Environmental Protection regarding approval of an import destined to activities regulated by the present ordinance shall be based on data referring to risk evaluation, in accordance with provisions of Art. 39, a careful evaluation based on scientific approach that shall take

into account the negative effects upon preservation and durable use of the biological diversity, the risks for human health and, by case, social and economic criteria.

(2) The Ministry of Waters and Environmental Protection shall inform the notifier within the period of time stipulated under Art. 36, paragraph (1), if:

- a) the import may take place without written consent and under what terms;
- b) the import may take place only after the Ministry of Waters and Environmental Protection gives its consent in writing.

(3) The Ministry of Waters and Environmental Protection shall communicate in writing to the notifier the decision made regarding the execution of the import, within the legal period of time since the confirmation of the notification receipt, indicating:

- a) consent to execute the import with or without conditions, mentioning how to apply the consent to further imports of the same genetically modified organism or of the same product resulted from genetically modified organisms, or
- b) interdiction of import, or
- c) necessity for additional relevant information, according to provisions of Annexes 11 and 12, or
- d) necessity to extend the period needed for the evaluation of the additional information received from the notifier or from other sources in order to make a documented decision.

(4) The communication by the Ministry of Waters and Environmental Protection, in accordance to paragraph (3), shall include the reasons for the decision made, except in the case that the consent for import is given unconditionally.”

41. Article 38 is abrogated.

42. Article 39 shall have the following contents:

“Art. 39. – The evaluation of risks shall be done through a scientific and transparent procedure, taking into account the provisions of Annex 12 and the techniques adequate to risk evaluation, and shall have the purpose to identify and evaluate potential negative effects of the genetically modified organism and/or of the product resulted from it upon the biological diversity and the human health, considering also the social and economic aspects.”

43. Article 40 is abrogated.

44. Article 43 is abrogated.

45. Title of Chapter VI shall have the following contents:

**“CHAPTER VI
Information to and consulting with the public”**

46. Article 44 is abrogated.

47. Section 1 is abrogated.

48. Title of Section 2 is abrogated.

49. Article 49 shall have the following contents:

“Art. 49. – (1) The authorization procedure for activities of deliberate introduction into the environment and on the market of genetically modified organisms is public. Publicizing through the media of activities for which authorization is requested shall be done by the Ministry of Waters and Environmental Protection.

(2) Within 20 days since the date notification was received, the Ministry of Waters and Environmental Protection shall inform the public about it, specifying the ways information may be reached.

(3) Public observations shall be received within 30 days since the date it was informed and shall be taken into account by the Ministry of Waters and Environmental Protection when making the decision on the authorization of the proposed activity. Depending on the observations received, public debates may be organized on aspects concerning the field regulated by the present ordinance.”

50. After article 49, Article 49^f is introduced with the following contents:

“Art. 49^f. – (1) In the notifications to the Ministry of Waters and Environmental Protection, the notifier may indicate the information that need to be treated as confidential with the accompanying justification.

(2) The Ministry of Waters and Environmental Protection shall decide, after consultations with the notifier, which information is confidential and shall inform the notifier on the decision made.

(3) The following information cannot be termed confidential:

- a) the general characteristics of the genetically modified microorganisms, the name and address of the notifier, the purpose and place for the activity;
- b) the class attributed to the use under isolation conditions and the measures of isolation;
- c) the conclusions of studies of risk evaluation concerning the environment and human health;
- d) monitoring methods and plans as well as the response in case of an accident.

(4) The Ministry of Waters and Environmental Protection shall not reveal to a third party any of the information established as confidential and shall protect intellectual copyrights related to the information received.

(5) If, irrespective of reasons, the notifier withdraws the notification, the Ministry of Waters and Environmental Protection shall observe the confidentiality of the information received.”

51. After Article 49¹ Chapter VI¹ is introduced with the following contents:

**“CHAPTER VI¹
Financial mechanisms”**

Art. 49². – (1) For the examination of documentation in order to issue consent and authorizations necessary to organize and carry out activities regulated under this ordinance, the Ministry of Waters and Environmental Protection establishes corresponding fees which are approved by order of the Minister of Waters and Environmental Protection, with consent from the Minister of Agriculture, Food, and Forests, and are published in Monitorul Oficial al Romaniei, Part. I.

(2) Sums collected from fees set according to paragraph (1) are extra-budget income in the account of the M which will open at State Treasury.

(3) Extra-budget achieved according to paragraphs (1) and (2) shall be used to cover:

- a) expenses and equipment necessary to put into practice provisions of the present ordinance
- b) honoraria of members of the Commission for Biological Safety
- c) other expenses according to legal provisions to be set by order of the minister of Waters and Environmental Protection.

(4) The Commission for Biological Safety shall organize itself and begin to operate in 60 days since the date the law approving this ordinance goes into effect.

(5) Upon issuance of agreements and authorizations taxes are to be paid as per Annex 13, which shall become revenues to the state budget. The quantum of taxes

on the issuance of agreements and authorization necessary to organize and carry activities regulated through the present ordinance shall be updated based on inflation rate by Governmental decision at the proposal of the Ministry of Waters and Environmental Protection.

(7) Procedures for the payment of the taxes on the issuance of agreements and authorizations necessary to organize and carry activities regulated through the present ordinance shall be approved in joint order of the Minister of Waters and Environmental Protection, of the Minister of Health and Family, and of the Minister of Agriculture, Food and Forests, and of the Chief of the National Authority on Consumer Protection, with approval from the Minister of Public Finance, in 60 days since the date of the publication of the law approving the present ordinance, and will be displayed at the headquarters of these authorities.”

52. Article 50 shall have the following contents:

“Art. 50. – (1) Are considered offences the following actions unless they were committed under such circumstances to be considered crimes, and are sanctioned as follows:

- a) violation of provisions of article 8 paragraph (7), Art. 9, 10, 11 paragraph (2), Art. 12 paragraph (1) and (4), Art. 13, Art. 14 (2), Art. 15, Art. 18 (1), Art. 24 (1) and (6), Art. 27 (1), with a 10 million lei fine and/or temporary or final suspension of activity, by case;
- b) violations of provisions of Art. 29 (1), (3), and (6), Art. 35 (1), Art. 38 (3), Art. 41. (1) and (2), Art. 49 (2) and Art. 49¹ (5) with a fine from 50 million to 100 million lei and/or temporary or final suspension of activity, by case.

(2) Note of the offence and enforcement of sanctions provided under paragraph (1) are done by specialized personnel authorized by the Ministry of Waters and Environmental Protection, Ministry of Health and Family and Ministry of Agriculture, Food and Forests, and by the National Authority for Consumer Protection.

(3) Sanctions provided under paragraph (1) are applicable per dispositions of Governmental Ordinance 2/2001 on the legal status of sanctions.”

53. Article 51 shall have the following contents:

“Art. 51. – (1) If damage results from activities regulated through this ordinance, detrimental to human or animal health, or to the biological diversity or to the environment, the user is responsible for the damage.

(2) The nature and size of the damage are established by a commission of experts appointed by the chief of management of the Ministry of Waters and Environmental Protection.

(3) Corrective measures for the damage, established by the commission of experts are communicated to the user by order of the Minister of Waters and Environmental Protection. Against this order, interested persons may submit complaint in administrative court, under the law.

(4) When at the origin of the damage there is the import and the use in the territory of the country of a live genetically modified organism or of a product derived from it, international norms to which Romania is part are applicable, which regulate the regime of cross-border transportation of live genetically modified organisms and of derivate products.”

54. After Art. 52 Article 521 is introduced with the following contents:

“Art. 52¹. – All species resulted from genetically modified plants and registered in the State Registry and in the Official List of Species through a procedure not complying with the provisions of the present ordinance shall be erased and by December 31, 2002 shall be taken off the market.”

55. In Annex 1, part A, the introductory part shall have the following contents:

“Techniques of genetic modification to which Art. 3 b) refers are.”

56. In Annex 1, Part B, the introductory part shall have the following contents:

“Techniques to which Art. 1 (2) a) refers are not considered as causing genetic modifications provided they should not be involved in the use of molecules of recombinant nucleic acid or of genetically modified microorganisms obtained through means other than the techniques/methods excluded through Annex 2, part A.”

57. In Annex 2, part A, the introductory part shall have the following contents:

“Techniques or methods of genetic modification that Art. 1¹ paragraph (2) letter a) refers to and which do not fall under the provisions of the present ordinance, provided that these should not involve use of molecules of recombinant nucleic acid or others than the ones obtained through one or several techniques/methods bellow.”

58. Annexes 6 and 7 are abrogated.

59. In Annex 8, sub-annex 8A shall have the following contents:

SUB-ANNEX A

INFORMATION

necessary in notifications on deliberate introduction into the environment and on the market of genetically modified organisms other than superior plants

I. General information:

A. name and address of the notifier (company or institute)

B. name, qualifications and experience of the researcher/s responsible

C. title

II. Information on the genetically modified organism

A. Characteristics of: a) donor; b) receiver or (where the case) of the parental organism(s)

1. scientific name
2. taxonomic classification
3. other names (frequently used name, name of stem, species, breed, culture, etc.)
4. phenotype and genetic marks
5. degree of relativity between donor and receptacle or between parental organisms
6. description of techniques of identification and detection
7. sensitivity, accuracy (from quantity point of view), specificity of identification and detection techniques
8. description of geographical distribution and natural habitat of the organism, including information on predators, parasites, competitors, colonies, hosts
9. potential of transfer and genetic change with other organisms
10. check of genetic stability of organisms and the factors affecting it
11. pathological, physiological, and ecological characters
 - a) risk classification by rules applied internationally and in the EU on the protection of human and/or environment health
 - b) duration of generations in natural ecosystems as well as the reproductive sexual or asexual system
 - c) information on survival, including seasons, capacity to create structures and to survive, example: seeds, spores, sclerotes
 - d) pathogenicity: infectivity, toxicogenicity, virulence, allergenicity, pathogenic carriers (vectors), potential vectors, host spectrum, including non-target organisms, potential activation of latent viruses (pro-viruses), capacity to colonize other organisms
 - e) resistance to antibiotics used in human and animal therapy and prophylaxis
 - f) involvement in environment processes: primary production, transforming of nutrients, organic matter disintegration, respiration, etc;
12. nature of indigenous vectors:
 - a) sequence
 - b) mobilization frequency

- c) specificity
- d) presence of genes that convey resistance

13. History of previous genetic modification

B.Characteristics of the vector:

1. nature and source of vector
2. sequence of transposons, vectors and other non-coding genetic segments used to build the genetically modified organism and to achieve introduction of vector and of inserted functions into the genetically modified organism
3. frequency of the mobilization of the inserted vector and/or capacities of genetic transfer and methods of determination

4. information on the degree the vector is limited to the DNA to fulfill the intended function.

C.Characteristics of the genetically modified organism:

- a)method used for modification
 - b)method used for construction and introduction of insert(s) into the receptacle or to eliminate a sequence
 - c) description of the construction of the vector and/or insert
 - d) purity of the insert in any unknown sequence and information on the degree to which the inserted sequence is limited to the requested DNA
 - e) sequence, functional identity and localization of the segment(s) of altered/inserted/eliminated nucleic acid with special reference to any sequence known as damaging
- ### 2. Information on the genetically modified organism resulted
- a) description of the genetic character(s) or of the phenotype characteristics and particularly of new characters and characteristics that may be expressed or may no longer be expressed
 - b) structure and amount of any vector and/or donor nucleic acid that remains in the final construction of the genetically modified organism
 - c) stability of the organism in terms of genetic characters
 - d) degree and level of expression of the new genetic material and the sensitivity of the measurement
 - e) activity of proteins/expressed proteins

- f) description of techniques of identification and detection, including techniques for the identification and detection of sequence of inserts and vector
- g) sensitivity and accuracy (in terms of quantity) and the specificity of the techniques of identification and detection
- h) history of introductions or previous uses of the genetically modified organism
- i) considerations on health:
 - (i) toxic or allergic effects of nonviable genetically modified organisms and/or of their metabolic products
 - (ii) risks of the product
 - (iii) comparison of genetically modified organism with the donor, receptacle or (when the case) with the parental organism in terms of pathogenicity
 - (iv) capacity of colonization
 - (v) if the organism is pathogenic for humans with normal immunity:
 - diseases caused and the mechanism of pathogenicity, including the capacity of invasion or virulence
 - transmissibility degree
 - dose of infection
 - host spectrum, possibility of modification
 - possibility of survival outside human host
 - biological stability
 - models of resistance to antibiotics
 - allergenicity
 - existence/application of adequate therapies

III. Information on the conditions of introduction and place of introduction

A. Information on introduction:

1. description of the deliberate introduction proposed, including purpose(s) and expected results
2. dates for execution of introduction and timeframe of experiment, including frequency and duration of introduction
3. preparation of site (place, ground) for the introduction
4. size of site (place, ground)
5. method(s) used for introduction

6. quantity of genetically modified organisms to be introduced
7. modifications of ground (type and method of cultivation, irrigation, other activities)
8. safety measures during introduction
9. post-introduction treatments of ground
10. techniques provided for elimination or inactivation of genetically modified organisms at the end of experiment
11. information and data on previous introduction of genetically modified organisms, especially at different scales and in various ecosystems

B. Information on environment, both the place of experiment and a larger area:

1. geographical location and references of grounds (in the case of notification according to part C, introduction ground(s) will be area(s) provided for the introduction of the product)
2. physical and biological proximity of humans and significant life
3. proximity of significant bio-types or of multi-layered areas
4. size of local population
5. economic activities of local population organized on local resources of the area
6. distance to the nearest protection areas for drinking water and/or other environment purposes
7. climate characteristics of regions likely to be affected
8. geographic, geologic and pedologic characteristics
9. flora and fauna, including cultures, live stock and species
10. description of target ecosystems and of those likely not to be affected
11. comparison between natural habitat of the recipient organism and the ground(s) proposed for introduction
12. any planned development known or changes of the ground used in the regime that may influence the impact upon introduction

IV. Information on interactions between the genetically modified organism and the environment

A. Characteristics affecting survival, multiplication, dissemination

1. biological characteristics affecting survival, multiplication and dissemination

2. knowing or anticipating environment conditions that may affect survival, multiplication and dissemination (wind, water, air, soil, temperature, pH, etc.)

3. sensitivity at specific agents

B. Interaction with the environment:

1. habitat provided for genetically modified organisms

2. studies on the behavior and characteristics of genetically modified organisms and their ecological impact, executed under simulated conditions like: micro-systems, growing rooms, hot-houses

3. capacity for genetic transfer

a) post-introduction transfer of genetic material from genetically modified organisms into organisms in the affected ecosystems

b) post-introduction transfer of genetic material in indigenous organisms into genetically modified organisms

4. probability of post-introduction selection leading to expression of surprising and/or uncalled for characters in the genetically modified organism

5. measures taken to provide genetic stability: description of genetic material which may raise or diminish dispersion

6. ways for biological dispersion, known and unknown, potential interaction with the disseminating agent, including inhaling, swallowing, contact with the surface, hiding ways, etc.

7. description of ecosystems in which the genetically modified organism may be disseminated

C. Potential ecological impact:

1. potential for excessive growth of the population in the environment

2. competitive advantages of the genetically modified organisms as compared to the ones of unmodified recipient or parental organisms

3. identification and description of target organisms

4. anticipated mechanism and results of the interaction between the genetically modified organism introduced and the target organism

5. identification and description of non-target organisms which may be affected involuntarily

6. probability of post-introduction changes in biological interactions or in the host spectrum

7. known or anticipated effects upon organisms which are not targets in the environment, the impact at population level of competitors: predators, hosts, colonies, enemies, parasites, pathogenic agents.

8. known or anticipated implications in biochemical processes

9. other potentially significant interactions with the environment

V. Information on monitoring, control and treatment of waste and plans of measures in emergency cases

A. Monitoring techniques

1. methods to detect genetically modified organisms and monitor their effects

2. specificity (to identify the genetically modified organism and to distinguish it from the donor, recipient, or, where the case, from parental organisms), sensitivity and accuracy of monitoring techniques

3. techniques for the detection of transfer of donor genetic material to other organisms

4. duration and frequency of monitoring

B. Control of introduction

1. methods and procedures for avoidance and/or reduction/minimization of spreading

2. methods and procedures to protect the site and prevent access to unauthorized persons

3. methods and procedures to prevent access of other organisms to the ground

C. Waste treatment

1. types of generated waste

2. quantity of anticipated waste

3. potential risks

4. description of provided treatment

D. Plans of measures in emergency cases

1. methods and procedures to control genetically modified organisms in case of unexpected spread

2. methods to decontaminate affected areas, for example eradication of the genetically modified organism
3. methods to eliminate and/or sanitize plants, animals, etc., which were exposed during pregnancy or after spreading
4. methods to isolate the zone affected with dissemination
5. plan of measures to protect human health and environment, in the case of an unwanted effect.”

60. Title of Annex 9 shall have the following contents:

**“ADDITIONAL INFORMATION
necessary in the case of notifications about introduction on the market of
genetically modified organisms, in accordance with provisions in Art. 29
paragraph (1) a) and c) and paragraph (2)”**

61. Title of Annex 10 shall have the following contents:

**“CRITERIA
to enforce simplified procedures for the approval of deliberate introduction of
genetically modified plants into the environment, according to provisions of
Art. 25, paragraph (5)”**

62. Title of Annex 11 shall have the following contents:

“INFORMATION”

that must be presented to the competent national authority in notifications concerning preliminary authorization to execute import/export activities of genetically modified organisms, according to provisions of Art. 35, paragraph (3)”

63. After Annex 12, Annexes 12¹ and 12² are introduced having the following contents:

PRINCIPLES

In carrying out study evaluating risks to the environment

Objective

The objective of the evaluation of the risks to the environment (ERE) is to identify and evaluate potential negative effects that the genetically modified organism (GMO) may have on human health or on the environment during deliberate introduction into the environment or on the market, effects that may be direct or indirect, and that may appear immediately or in time. ERE must be done to establish whether it is necessary or not to develop a risk management plan and in the case it is necessary, the best protection methods shall be specified.

General rules

In accordance with the principle of caution, the following general rules shall be followed during the proceeds of the environmental risk evaluation study:

1. identified characteristics of GMOS that may determine negative effects during utilization shall be compared to the characteristics of the genetically non-modified organisms from which they derive and for similar uses
2. the study evaluating risks to the environment shall be done scientifically and transparently, based on existing data.
3. the study evaluating risks to the environment shall be carried for each case , because information may vary depending on the type of genetically modified organism, purpose of use and characteristics of the environment into which it is introduced, keeping into account, inter alia, the results of previous introduction into environment of the genetically modified organisms;
4. when new information on the genetically modified organisms and its effects upon the environment appear, the study evaluating risks to the environment must be reviewed to establish if:
 - a) risks modify
 - b) risk management plan needs to be modified

Methodology

C.1.Characteristics of genetically modified organisms and of the environment in which they are introduced

By case, the study ought to take into account existing technical and scientific information referring to:

1. parental organism(s) or recipients
2. genetic modification(s) resulted from insertion or elimination of genetic material, and relevant information about the donor and the vector
3. the genetically modified organism
4. proposed introduction or use including the scale of the activity
5. potential recipient environment
6. interaction between these.

Information on introduction of organisms into the environments of similar organisms may be taken into account in the evaluation of risks posed to the environment.

C.2. Stages of the study evaluating risks to the environment

Conclusions of the study evaluating risks to the environment shall refer to the following aspects:

1. Identification of characteristics that may cause negative effects

Any characteristics of genetically modified organisms that may cause negative effects on human health or the environment shall be identified. To identify them, one must compare characteristics of the modified organism with characteristics of the non-modified organism, under similar conditions. It is important not to omit in the examination any negative effect on accounts that its occurrence is the least likely.

Potential negative effects of genetically modified organisms vary from case to case and may consist in:

- a. diseases of people, including allergic effects, toxicity
- b. diseases of animals and plants, including allergic effects, toxicity
- c. effects on the dynamics of the population of species in the recipient environment and on the genetic diversity of each of these populations
- d. a potential modification of pathogenic agents which may facilitate infectious disease transmission and/or new sources of pathogenic vectors

e. compromised prophylactic/therapeutic action in treatments, like: transfer of genes convey resistance to antibiotics used in human and veterinary medicine

f. effects on the bio-geo-chemical circuits of carbon and nitrogen by modifying soil acidity of organic matter disintegration.

Negative effects may appear directly or indirectly in various ways like:

a. spreading of genetically modified organisms into the environment

b. transfer of genetic material inserted to other organisms or to the same type of organisms non-modified genetically

c. phenotype and genetic instability

d. interaction with other organisms

e. changes in management, including where the case, in agricultural practices

2. Evaluation of potential consequences of negative effects

Magnitude of consequences of each potential negative effect must be evaluated. The evaluation must be done for each negative effect taking into account that the magnitude of consequences may be influenced by the environment into which the genetically modified organism is introduced and the way the introduction is made

3. Evaluation of frequency of occurrence of each potential negative effect identified

A very important factor in evaluating frequency or probability of negative effects occurrence is characterization of the environment into which it is intended to introduce the genetically modified organism and the way the introduction is made.

4. Estimation of the risk posed by each new element of the genetically modified organism

Depending on the existing knowledge, it is obligatory to make an estimation of the risks that each new character of the genetically modified organism may pose to human health and to the environment, by combined analysis of frequency of negative effects occurrence and their magnitude.

5. Application of risk management strategies

Evaluation of risks must identify the risks for which it is necessary to create risk management plans and the most efficient plan for implementation

6. Establishing the risk that the genetically modified organism poses per ensemble
Evaluation of the general risk that the genetically modified organism poses is done taking into account each strategy proposed for risk management

Conclusions on the impact study of the activities of introduction into the environment or on the market of genetically modified organism(s)

D.1. In the case of genetically modified organisms except for superior plants::

1. frequency of cases that the genetically modified organism has become persistent and has invaded the natural habitats and the conditions in which this happened
2. any selective advantage or disadvantage of the genetically modified organism and the frequency of occurrence of this phenomenon in conditions established for the proceeds of the proposed activity
3. possibility for gene transfer to other species under the conditions set for the proposed activity, and any selective advantage or disadvantage that it may convey to these species
4. potential instant or time impact on the environment as result of direct or indirect interaction of the genetically modified organism and the target organisms, if the case
5. potential instant or time impact on the environment as result of direct or indirect interaction of the genetically modified organism and the non-target organisms, including the impact on the complex relations at biocenosis level (competitors, predators, colonies, parasites, pathogenic agents.)
6. potential negative effects on human health that may occur instantly or in time as result of the direct and indirect interactions between the genetically modified organism and the persons working with, coming in contact with or who are in the proximity of the site where the organism is introduced
7. potential negative effects on animal health that may occur instantly or in time as result of the consumption of fodders consisting in or containing genetically modified organisms, and the consequences of these consumption on the fodder/food chain

8. potential negative effects on the bio-geo-chemical processes that may appear instantly or in time as result of direct and indirect interactions between the genetically modified organism and the target and non-target organisms in the proximity of the site where this is introduced

9. potential impact on the environment that may occur instantly or in time, directly or indirectly, as result of the management techniques of these organisms in case they are different from the ones used for genetically modified organisms.

D.2.

1. frequency of cases that the persistence in agricultural systems and the invasive capacity of the GMOS is higher than in the case of parental or recipient plants

2. any selective advantage or disadvantage conveyed by genetically modified plants

3. the possibility of gene transfer to the same species of plants or to sexually compatible plants in conditions accepted for the cultivation of the genetically modified plants, and whether this transfer conveys to plants any selective advantage or disadvantage

4. potential impact on the environment instantly and/or in time as result of the direct and indirect interactions between genetically modified plants and target organisms like: predators, parasites and/or pathogens.

5. potential negative effects on the environment instantly and/or in time as result of the direct and indirect interactions between genetically modified plants and the non-target organisms, taking into account also organisms interacting with target-organisms, including the impact on population level of competitors, herbivores, colonies, parasites, and/or pathogens

6. potential negative effects on human health that may occur instantly or in time as result of direct and indirect interactions between the genetically modified plants and the persons working, getting into contact with or being in the proximity of the site where the genetically modified plants are introduced

7. potential negative effects on animal health as result of the consumption of fodder consisting in or containing genetically modified plants and the consequences of this consumption on the fodder/food chain

8. potential negative effects on the bio-geo-chemical processes that may occur

instantly or in time as result of the direct and indirect interactions between the genetically modified plants and the target and non-target species in the vicinity of the site where these are introduced

9. potential negative impact on the environment that may occur instantly or in time, directly or indirectly, as result of the techniques used for cultivation, management of the genetically modified plants, if these are different from the ones used for superior plants genetically non-modified.

ANNEX 12²

MONITORING PLAN

A. Objective

The objective of the monitoring plan consists in:

1. confirmation that the existence and the impact of any potential negative effects of the use of the genetically modified organism, highlighted in the evaluation of the risks to the environment, are right or not right
2. observation of occurrence of other negative effects of the use of the genetically modified organism on human health and on the environment, that were not anticipated in the evaluation of risks to the environment.

B. General rules

Monitoring activity is executed after release of the authorization to introduce on the market the genetically modified organism.

Data collected in the monitoring system must provide new information on the impact of the introduction of a genetically modified organism into the environment or on the market, in different conditions. When such new data appear, these must automatically taken into account in the next evaluations of risks to the environment. Experience and data obtained through the monitoring of the activities of deliberate introduction into the environment of genetically modified organisms must be the

basis of the design of the monitoring system for the introduction of GMOS on the market as such or as products.

C. Creating a monitoring plan

The monitoring plan must:

1. be detailed per each case, based on the evaluation of risks to the environment
2. take into account the characteristics of the genetically modified organism, scale and environment conditions in which the GMO is introduced
3. include the general plan of the monitoring of negative effects identified in the evaluation of risks to the environment
 - 3.1. extend for each case on a sufficiently large period of time to detect immediate and direct effects, and, where possible, effects that show in time or indirect effects that were already identified in the evaluation of risks to the environment
 - 3.2. use routine monitoring practices already set, like the monitoring of agricultural crops, plant protection, human or veterinary medical products
4. facilitate observation of effects on human health and the environment
5. anticipate attribution of responsibilities (for notifier, user) and achievement of various tasks provided in the monitoring plan, and responsibilities for noticing and failing to report the negative effects on the environment or human health to the holder of the authorization and to the central public authorities on environment protection, or for delays in reporting this data.
6. anticipate mechanisms to identify and confirm any noticed negative effects on the environment and human health and enforce the measures necessary to the protection of people and the environment set by the holder of the authorization and by the central public authority for environment protection.”

64. In Annex 13 item 6 shall have the following contents:

“6. For authorization of introduction on the market of a genetically modified organism or of a product containing or deriving from a genetically modified organism, according to Art. 29.”

Art. II. – The Government Ordinance no. 49/2000, with modifications and completions brought by the present law shall be republished in the “Monitorul Oficial” of Romania (Official Monitor), Part I, under different numbering.

This law was adopted by the Chamber of Deputies in the session of February 7, 2002, in observance of Art. 74 paragraph (20) in the Constitution of Romania

PRESIDENT OF THE CHAMBER OF DEPUTIES
VALER DORNEANU

This law was adopted by the Senate in the session of March 27, 2002, in observance of the provisions of Art. 74 paragraph (2) in the Constitution of Romania.

PRESIDENT OF THE SENATE
DORU IOAN TARACILA

Bucharest, April 19, 2002

No. 214

PRESIDENT OF ROMANIA

DECREE

on the promulgation of Law for the approval of Government Ordinance no. 49/2000 on the regime of obtaining, testing, using and marketing genetically modified organisms through modern biotechnology techniques, as well as products resulted from them

On the basis of provisions under Art. 77 paragraph (1) and of Art. 99 paragraph (1) in the Constitution of Romania,

the President of Romania d e c r e e s:

Unique Article: -- Law on the approval of Government Ordinance no. 49/2000 on the regime of obtaining, testing, using and marketing genetically modified organisms through

modern biotechnology techniques, as well as products resulted from them is promulgated and shall be published in the Monitorul Oficial of Romania, Part I.

PRESIDENT OF ROMANIA

ION ILIESCU

Bucharest, April 18, 2002

No. 321