

## **The consumption of genetically modified plants and the potential presence of herbicide residues**

1. Testbiotech e.V. (München) asked a number of questions concerning the monitoring of health effects of genetically modified plants. These questions relate to the fact that, in practice, the effects on human health of the consumption of genetically modified food (and feed) appear not to be monitored. The questions are:

1. Is the present practice of placing genetically modified plants on the market in conformity with the relevant EU provisions?
2. Do Directive 2001/18 and Regulation 1829/2003 both require that the health effects of the use and consumption of genetically modified plants be monitored?
3. Does the precautionary principle allow to disregard the residues of complementary pesticides when the risk assessment of genetically modified plants is made?
4. After the authorisation of a genetically modified plant, has a monitoring of potential adverse effects on human health to be undertaken which takes into consideration the possible presence of herbicide residues and their possible cumulative effect?

### **1. The applicable provisions of EU law**

#### **1.1 Directive 2001/18**

2. Directive 2001/18<sup>1</sup> requires that the placing on the market of a genetically modified organism (GMO) as or in a product may only take place after written consent by the competent authority was given (Article 19). The application for such consent (notification, Article 13) has to be accompanied by an environmental risk assessment, by other information, and by a monitoring plan (Article 13(2.b), 2.a, and 2.e)).

##### **1.1.a The environmental risk assessment**

3. The principles for the environmental risk assessment are laid down in Annex II to the Directive. Recital 33 of the Directive indicates that the environmental risk assessment has to be “full”. Article 13 (2.b) provides that the notification be accompanied by “the” environmental risk assessment and the conclusions required in Annex II, section D. The wording of these provisions clarifies that the environmental risk assessment must comply with all the provisions of Annex II. Despite the title of annex II – “Principles for the environmental risk assessment” –

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1 Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ 2001, L 106 p.1.

it must thus be concluded that compliance with the provisions of Annex II is mandatory and that an impact assessment is not made correctly, where it contains significant omissions or deviations from Annex II to Directive 2001/18..

4. Annex II indicates that the environmental impact assessment is not limited to examine the effects of genetically modified product containing GMO on the natural environment, but that also the effects on human health shall be examined. This follows from the general objective of Directive 2001/18 as laid down in Article 1 - *“the objective of this Directive is...to protect human health and the environment”* - , the mentioning of “human health” in Article 13(6)<sup>2</sup>, in Recital 5<sup>3</sup> of the Directive, and the reference to “human health or the environment” in Annex II itself, where this reference appears five times in the introductory remarks and in each of the four parts A to D of that Annex. Finally it is to be noted that it follows from Article 191(1) TFEU that in EU law, the “protection of the environment” includes the protection of human health<sup>4</sup>.

5. More specifically, Annex II of Directive 2001/18 on environmental risk assessments requires this assessment to examine the direct and indirect, the immediate and delayed effects of the GMO on human health or the environment; these different terms are more closely described. Furthermore, the introductory remarks state: *“A general principle of environmental risk assessment is also that an analysis of the ‘cumulative long-term effects’ relevant to the release and the placing on the market is to be carried out. ‘Cumulative long-term effects’ refers to the accumulated effects of consents on human health and the environment”*. Thus, the continued consumption of genetically modified plants, where herbicide residues might be present is, as a matter of course, also to be assessed.

6. Part C.2 of Annex II describes the “Steps in the environmental risk assessment”. As a first step that part requires to identify characteristics which may cause adverse effects and gives a general indication of what has to be done, noting that *“it is important not to discount any potential adverse effect on the basis that it is unlikely to occur”*. Part C.2 then alerts that *“Potential adverse effects of GMOs will vary from case to case and may include: - disease to humans including allergenic or toxic effects...”* Supplementary steps include the evaluation of the potential consequences of the adverse effects, the likelihood of the occurrence, risk management strategies and a determination of the overall risk.

7. The conclusions of the risk assessment shall be part of the notification, in order to allow the competent authority to draw its own conclusions (Annex II, part D). The conclusions on the risk assessment shall include *“Possible immediate and/or delayed effects on human health resulting from potential direct and indirect*

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2 Directive 2001/18, Article 13(6): *“If new information has become available with regard to the risks of the GMO to human health or the environment, before the written consent is granted, the notifier shall immediately take the measures necessary to protect human health and the environment...”*

3 Directive 2001/18, Recital 5: *“The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms (GMO)”*.

4 Article 191(1) TFEU: *“ Union policy on the environment shall contribute to the pursuit of the following objectives:... - protecting human health...”*

*interactions of the GMOs [GMHP] and persons working with, coming into contact with or in the vicinity of the GMO[GMHP] release(s)*".<sup>5</sup>

8. It follows from these provisions that the environmental risk assessment shall include all effects which the placing of a GMO on the market may have on human health, including any possible cumulative effects. This includes the potential effects of the use of herbicides or pesticides on the GMO plant or product. Of particular importance is the fact that the assessment of potential adverse effects may not be excluded, because such adverse effects are considered to be unlikely.

### **1.1.b Other information**

9. "Other information" which has to accompany every notification under Article 13 of Directive 2001/18, shall include "*considerations for human health and animal health, as well as plant health: (i) toxic or allergenic effects of the GMO and/or their metabolic products*"<sup>6</sup>, furthermore "*identification and description of non-target organisms which may be adversely affected by the release of the GMO, and the anticipated mechanisms of any identified adverse interaction*"<sup>7</sup> and, as a catch-all formula "*other potential interactions with the environment*"<sup>8</sup>. For genetically modified higher plants (GMHP), Annex IIIB applies which requires the notifier to supply, with his notification, the following information: "*Information on any toxic, allergenic, or other harmful effects on human health arising from the genetic modification*"<sup>9</sup>; "*Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs*"<sup>10</sup>; and "*Potential interactions with the abiotic environment*"<sup>11</sup>.

10. This wording with regard to the "other information" is thus again very broad and tries to cover all effects which the GMO product might have on human health or animal health. The choice of the terms "arising from the genetic modification" clarifies that information is to be supplied not only on the effects caused directly by the GMO, but also all other harmful effects which may be caused to human or animal health and which are, in one way or the other, related to the genetically modified plant.

### **1.1.c The monitoring plan**

11. According to Article 13(2.(e)), a monitoring plan has to accompany the notification; the plan shall be established in accordance with Annex VII to the Directive. Annex VII provides as the objective of the monitoring plan to confirm that *any assumption* regarding the occurrence and impact of potential adverse effects of the GMO or its use in the environmental risk assessment are correct,

5 Directive 2001/18, Annex II, part D1 no.6 and part D2 no.6. Part D1 refers to GMOs other than higher plants, part D2 to genetically modified higher plants (GMHP). For reasons of simplification the two sections D1 no. 6 and D2 no. 6 were assembled in one text.

6 Directive 2001/18, Annex III A, section II, C.2(i)

7 Directive 2001/18, annex IIIA, section IV B12.

8 Directive 2001/18, annex IIIA, section IV B.16.

9 Directive 2001/18, annex IIIB, section D no.7.

10 Directive 2001/18, annex IIIB, section D no.8.

11 Directive 2001/18, annex IIIB, section D no11.

and identify the occurrence of adverse effects of the GMO or its use on human health or the environment which were not anticipated in the environmental risk assessment. These objectives are underlined by recital 43 of Directive 2001/18 which states: *“it is necessary to introduce into this Directive an obligation to implement a monitoring plan in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOS as or in products after they have been placed on the market”*. The use of the word “any” both in the Recital 43 and in Annex VII itself demonstrates that the monitoring plan has the purpose to discover all possible impacts of adverse effects of GMOs, including even those effects that had not been foreseen in the environmental risk assessment (*“unforeseen”*). This understanding is confirmed by the provisions in Annex VII on the design of the monitoring plan: the plan has to

- be detailed on a case by case basis (Annex VII, C.1);
- take into account the relevant environmental conditions where the GMO is expected to be released (C.2);
- incorporate general surveillance for unanticipated adverse effects (C.3);
- provide for case-specific monitoring, though routine surveillance practices that *“were already established”* are allowed in appropriate cases (C.3.1 and C.3.2);
- facilitate the observation *“in a systematic manner”* of the release of the GMO in the receiving environment and the interpretation of these observations *“with respect to human health or the environment”* (C.4).

12. In 2002, the Council adopted, by way of a Decision, guidance notes *“supplementing Annex VII”*<sup>12</sup> The guidance notes *“shall be used as a supplement to Annex VII of Directive 2001/18/EC”* (Article 1). The guidance notes repeat in the introduction that the monitoring plans have the purpose to *“trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market”*.

13. The guidance notes first repeat the objective and general principle of the monitoring plan of Annex VII to Directive 2001/18 and then add: *“In addition, monitoring of potential adverse cumulative long-term effects should be considered as a compulsory part of the monitoring plan”*(part B). They clarify what is to be understood by “direct effects”, “indirect effects”, “immediate effects” and “delayed effects”.

14. With regard to unforeseen effects, the guidance notes indicate: *“it is very difficult if not impossible to predict the appearance of potential, unforeseen or unanticipated effects that were not highlighted in the risk assessment. General surveillance for potential unforeseen or unanticipated effects should, therefore, be considered as a part of the monitoring strategy”* (part C). This statement

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<sup>12</sup> Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC, OJ 2002, L 280 p.27.

indicates that notifier may not limit his monitoring plan to those risks which had been identified in the environmental risk assessment which had to be made according to Article 13(2.b) and Annex II section D to Directive 2001/18.

15. The guidance notes also expressly state that the time-period for monitoring would depend on the circumstances, but could extend to a number of years (part C- 1.5). This is another indication that potential cumulative effects of genetically modified plants and herbicide residues shall be controlled.

16. The case-specific monitoring (part C-1.3.1) should focus on "*all the potential effects on human health and the environment identified in the risk assessment*". It should begin with determining the case-specific objectives of the monitoring strategy which "include" the identification of the occurrence and impact of potential adverse effects of the GMO or its use that were made in the environmental risk assessment. The strategy should indicate that these assumptions are to be confirmed by the case-specific monitoring. With regard to potential effects on human health, the guidance notes specify that such effects will depend on the inherent nature of a GMO and its specific genetic modification.

17. For unforeseen adverse effects that were not predicted in the risk assessment, the guidance notes provide for a "general surveillance" (part C-1.3.2) which consists of "*routine observation ("look - see") approach*". Such surveillance should be carried out over a longer period and possibly a wider area than the case-specific monitoring, though the type of general surveillance would depend on the type of unforeseen adverse effects. The notes indicate that the general surveillance could make use of established routine surveillance practices "where compatible"; then the established routine surveillance practice should be described in the plan, including any necessary alignment to the general surveillance. As one example of existing systems, "food surveys" are expressly mentioned (part C -1.7).

18. The guidance notes contain a number of other indications, such as the monitoring methodology (part C- 2) and analysis, reporting and review (part C-3) which will not be presented here.

19. Overall, the monitoring plan has the main purpose to confirm the assumptions that were made in the environmental risk assessment on (the absence of) potential adverse effects. However, the guidance notes expressly indicate that the monitoring strategy should also include a strategy with regard to unforeseen events which had not been assessed in the environmental risk assessment.

#### **1.1.4 Result**

20. It follows from all these provisions that under Directive 2001/18, a notifier's documentation must contain a comprehensive environmental risk assessment of the GMO which includes the potential adverse effects on human and animal health. Unlikely occurrences must also be included. And his monitoring plan must contain a strategy on the monitoring of events that were not foreseen in the environmental risk assessment.

21. As Directive 2001/18 has the purpose to also protect human and animal health, and as GMO plants are consumed by humans, the environmental risk assessment and the monitoring plan must therefore also contain an assessment of such potential effects (risk assessment) and a strategy to verify, whether such adverse effects actually occur. Indeed, the development of allergies or other adverse effects, due to the consumption of genetically modified plants which are herbicide-resistant and which possibly contain herbicide residues, are not that unlikely that the monitoring of such effects could be omitted.

22- The competent authority has to give a written consent for the placing on the market of a GMO as or in a product (Article 19). The consent shall specify, among others, the monitoring requirements in accordance with Annex VII to the Directive (Article 19(3.f)). This provision clarifies that the competent authority is not bound, in the monitoring conditions which it puts on the consent with regard to monitoring, by the monitoring plan of the notifier. Rather, this plan is, legally, a mere proposal. Thus, the competent authority which gives the written consent, has a responsibility of its own to ensure that all direct and indirect, immediate and delayed, cumulative and unforeseen effects of the GMO on human and animal health and the environment are properly monitored.

23. Conclusion: Directive 2001/18 has the purpose to protect human health and the environment. It requires an environmental risk assessment to be made before any placing on the market of a genetically modified GMO as or in a product. This risk assessment includes the possible direct and indirect, immediate or delayed or cumulative effects of the GMO on human health. The risk assessment also has to include such effects which are not likely to occur. The monitoring plan which must be submitted for approval to the competent authorities charged to give written consent to the placing on the market of the GMO, shall contain strategies to monitor all possible effects of the GMO on human health and the environment, including those effects that were unforeseen when the risk assessment was made. The competent authorities are obliged to ensure that the monitoring plan is complete.

## **1.2 Regulation 1829/2003**

24. Regulation 1829/2003 applies to genetically modified food and feed. Articles 3 to 14 apply to genetically modified food, Articles 15 to 23 to genetically modified feed. The placing on the market of genetically modified food or feed requires an authorisation (Article 4 for food, Article 16 for feed).

25. Article 5(5) of Regulation 1829/2003 provides that an application for GMOs or food containing or consisting of GMOs must be accompanied by, among others *"information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC or, where the placing on the market of the GMO has been authorised under part C of Directive 2001/18/EC, a copy of the authorisation decision"*. Furthermore, such an application shall be accompanied by *"a monitoring plan for environmental effects"*



*conforming with Annex VII to Directive 2001/187EC...*" For such cases, Articles 13 to 24 of Directive 2001/18 are declared inapplicable.

26. Article 6(4) provides: *"In the case of GMOs or food containing or consisting of GMOs, the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs..."*

27. The European Food Safety Authority (EFSA) which has to give an opinion on the application, shall include in its opinion *" post market monitoring requirements based on the outcome of the risk assessment"* where such a risk assessment had been requested by EFSA<sup>13</sup>. In cases, where Article 5(5) applies, EFSA shall also give an opinion on the monitoring plan.

28. The authorisation of a genetically modified food is granted by the Commission by way of the so-called comitology procedure (Article 7 and Article 35). It shall include the authorisation of the monitoring plan (Article 7(2)). In its decision, the Commission is not bound by the opinion of EFSA. This follows from the provision in Article 7(1), according to which the Commission shall provide an explanation for the difference, where its decision is not in accordance with EFSA's opinion, furthermore from the fact that the Commission shall take into account the opinion of EFSA, but also *" any relevant provision of Community law and other legitimate factors relevant to the matter under consideration"* (Article 7(1)). In other words, the Commission has to examine itself, whether the monitoring plan shall include the control of potential adverse effects of the genetically modified plant during the use and consumption stage. Even when the EFSA, in any of its opinions, does not comment on the need for such a control, the Commission was obliged to decide on that issue.

29. The provisions on feed containing or consisting of GMOs mirror the provisions on genetically modified food: A provision corresponding to Article 5(5) of Regulation 1829/2003 is laid down in Article 17(5), a provision corresponding to Article 6(4) is found in Article 18(4). EFSA's opinion shall also be given with regard to the monitoring plan (Article 18(5.g)). The Commission, when authorising the genetically modified feed, shall also refer to the monitoring plan (Article 19(2)).

30. It follows from these provisions that for genetically modified food or feed information and conclusions about the risk assessment must be given. This risk assessment must have been carried out in accordance with the principles set out in Annex II to Directive 2001/18 (Article 5(5.a) and Article 17(5.a)). Also a monitoring plan shall be submitted with the application for authorisation (Article 5(5.b) and Article 17 (5.b)). Where EFSA expresses an opinion in favour of the authorisation, it shall also address the monitoring plan (Article 6(5.g) and Article 18(5.g)) and indicate *" post-market monitoring requirement based on the outcome of the risk assessment"* (Article 6(5.e) and Article 18(5.e)).

31. The European Commission which authorises the placing on the market of genetically modified food or feed, has the obligation to attach the necessary conditions to the authorisation in order to ensure that the food or feed has no adverse effects on human health, animal health or the environment (Article 4(1)). It has its own responsibility in this regard and may not rely on the – non-binding – opinion of EFSA; in the past, the Commission occasionally did add supplementary conditions on the placing on the market of genetically modified food products<sup>14</sup>.

32. Under Regulation 1829/2003, genetically modified food or feed which is placed on the market, must thus be monitored according to the principles laid down in Directive 2001/18. The monitoring plan must even attach greater importance to the potential adverse effects and to unforeseen effects of the genetically modified food or feed on human or animal health than in the case of the application of Directive 2001/18 alone, as it is the very purpose of Regulation 1829/2003, expressed in Recitals 2 and 3 and its Articles 1, 4 and 16 to protect human health. Also the information and conclusions concerning the risk assessment must take into consideration this need to protect human and animal health.

33. This understanding is confirmed by the Court of Justice which stated<sup>15</sup>: *“Regulation 1829/2003 applies to the specific field of food and feed. As regards food, its first objective, referred to in article 4(1), is also to avoid adverse effects on human health and the environment. However, Directive.. 2001/18 [was] drafted primarily from the angle of the concept of ‘deliberate release’ which is defined in article 2(3).. as an intentional introduction of a GMO into the environment, without specific containment measures designed to limit their ‘contact’ with the ‘general population and the environment’. That approach thus appears to be more general, including with regard to the placing on the market of a GMO as a product. In this respect, ... recitals 25, 28 and 32 in the preamble to Directive 2001/18 link the need to introduce an assessment and authorisation procedure to the situation in which the placing on the market includes a deliberate release into the environment. Although Regulation 1829/2003 also includes, in particular in Articles 5(5) and 6(4), aspects of environmental risk assessment of food, it is, as regards food, based overwhelmingly on an appraisal emphasizing protection of human health which is linked to the specific fact that that food is, by definition, intended for human consumption. Thus, in accordance with recital 3 in the preamble, in order to protect human health, foods containing, consisting or produced from GMOs must undergo a ‘safety’ assessment. Regulation 1829/2003 thus introduces an additional level of control. That regulation would be rendered nugatory, if the view were to be taken that an assessment carried out and an authorisation issued pursuant to Directive ... 2001/18 covered all subsequent potential risks to human health and the environment”.*

34. the least which one can conclude from these remarks by the European Court of Justice is that the safety assessment –in other words the environmental risk

<sup>14</sup> See for example Commission decision 2010/135/EU, OJ 2010, L 53 p.11, Recital 18 and Article 4(e), where additional monitoring measures were requested.

<sup>15</sup> Court of Justice, case C-442/09 *Bablok*, Judgment of 6 September 2011, paragraphs 97 – 102.



assessment and the post-marketing monitoring evaluation – must be, under Regulation 1829/2003, at least as strict as under Directive 2001/18.

## **2. The questions**

### **2.1 Is the present practice of placing genetically modified plants on the market in conformity with the relevant EU provisions?**

35. Where genetically modified plants are placed on the market and serve as food or feed or are transformed into food and feed, a monitoring plan must accompany the application for authorisation to place the plants on the market (Article 13 of Directive 2001/18, Articles 5 and 17 of Regulation 1829/2003). This plan must be organised in a way that it allows the discovery of all potential adverse effects of the plant on human or animal health. It also has to include the examination of such effects which are unlikely to occur and unforeseen effects. It is not relevant, that the potential adverse effects had previously been identified in the environmental risk assessment.

36. Therefore, the monitoring plans concerning genetically modified plants which serve for human consumption or as animal feed must, under both the Directive 2001/18 and Regulation 1829/2003, contain a section, where potential adverse effects due to the consumption of such plants are monitored. Such effects might occur by the consumption of the genetically modified plants alone, or in combination with residues of herbicides or other residues which are found on the genetically modified plants themselves or which exist in other food or feed. An extension of the monitoring of genetically modified plants is in particular in those cases necessary, where a presumption exists that the plants might have been treated with herbicides, so that herbicide residues may exist in or on the plants.

37. A practice which omits to monitor potential adverse effects of genetically modified plants during the consumption stage is not in conformity with the relevant EU provisions. Indeed, EU legislation (Directive 2001/18 and Regulation 1829/2003) has as the first objective to avoid *any* adverse effect of genetically modified organisms on human (and animal) health. The omission to control the effects of the consumption of genetically modified plants means that adverse effects on human health through consumption cannot be excluded. The legislation expressly indicates that a small likelihood that adverse health effects might occur is not a reason for omitting the monitoring of such potential adverse effects.

### **2.2 Do Directive 2001/18 and Regulation 1829/2003 both require that the health effects of the use and consumption of genetically modified plants be monitored?**

38. Directive 2001/18 provides, in its provisions on the environmental risk assessment and the monitoring plans, that the potential adverse health effects of genetically modified plants are monitored. This refers to all stages of the existence of the genetically modified plant and includes in particular its use and consumption.

39. Regulation 1829/2003 aims at a supplementary protection against adverse health effects, if possible. Thus, GMOs or food (feed) containing or consisting of GMOs must be monitored according to the principles laid down in Directive 2001/18 and its annexes. It follows from this that also Regulation 1829/2003 requires that the health effects of the use and consumption of genetically modified plants be monitored. If ever, the measures to avoid adverse effects for human (and animal) health have even to be stricter, as food is, by definition destined for human consumption and the potential risk is thus higher. And Regulation 1829/2003 is expressly also based on Article 152 EC Treaty (now Article 169 TFEU) which aims at a high level of consumer protection

40. The obligation to avoid any adverse effect of GMOs on human (and animal) health stems from the legal texts themselves. It is therefore irrelevant, whether EFSA, when giving an opinion on the application for authorisation of a genetically modified plant, identified a need for monitoring potential adverse effects at the use or consumption stage or not. Rather, the objective to avoid any adverse effect of GMOs on human health is independent from the position of EFSA.

### **2.3 Does the precautionary principle allow to disregard the residues of complementary pesticides when the risk assessment of genetically modified plants is made?**

41. It is the objective of Directive 2001/18 to avoid *any* adverse effect of the genetically modified plant on human health. The provisions of the Directive on the environmental risk assessment are very broad and try to catch - in the abstract, it is true - all possible cases, where direct or indirect, immediate, delayed or unforeseen adverse effects might occur. Then, it is only logical that, when genetically modified plants which are tolerant to certain herbicides, are exposed to pesticide or herbicide treatment, the effects of such treatment on the plant - and later on human or animal health - must be examined during the environmental risk assessment.

42. Directive 2001/18 is based on the precautionary principle (Article 1). Regulation 1829/2003 states that its objectives are "*in accordance with the general principles laid down in Regulation (EC) No 178/2002*" (Article 1). As these general principles include the precautionary principle<sup>16</sup>, also Regulation 1829/2003 intends to comply with the precautionary principle.

43. The precautionary principle applies in cases, where there is scientific uncertainty about a risk or the dimension of a risk. In such cases, it allows public authorities to adopt measures, before the reality and the seriousness of the risk becomes fully apparent<sup>17</sup>. The fact that the precautionary principle is mentioned in Article 1 both of Directive 2001/18 and Regulation 1829/2003 clearly shows

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<sup>16</sup> Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 L 31 p.1, Article 7: "*Precautionary principle. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment*".

that these legislative acts intend to provide for the taking of all possible measures in order to avoid adverse effects of genetically modified organisms on human health. Thus, as soon as there is any scientific uncertainty whether such adverse effects might occur, the competent authorities are asked to take measures, in order to “err on the safe side”, in other words rather be over-cautious than careless. This understanding of Article 1 of both legislative acts is confirmed by the express phrase in the environmental risk assessment provisions, mentioned above, that there is no reason to disregard a potential adverse effect on human health, because its occurrence was unlikely.

44. The question is thus, whether it can be scientifically excluded that herbicide residues and genetically modified plants have *any* cumulative or combinatorial effect on humans or animals. As soon as there is any scientific doubt in this regard, be it voiced by only some researchers, there is a need to monitor the consumption of the genetically modified food or feed. This follows from the necessity to exclude *any* adverse effect.

45. Large scale cultivation of herbicide tolerant genetically modified plants may lead to the increase of the amount of sprayed herbicides and to an increased frequency of spraying. This may lead to a significantly higher level of herbicide residues in the genetically modified plant than in other plants. Moreover, while most plants will be killed by the spraying of herbicides, herbicide tolerant genetically modified plants will survive the spraying. This may lead to metabolites which are specific to such plants.

46. Such risks of complementary herbicides and their residues which are specific for the usage on genetically modified plants and which might lead to specific metabolites or have combinatorial effects with other plant constituents, cannot be excluded as being completely improbable. Therefore the risk assessment of the genetically modified plant must take this aspect into account and evaluate it.

47. As thus not *any* adverse effect can be excluded, the monitoring of the consumption of genetically modified food or feed is necessary.

48. Furthermore, both legislative acts provide for genetically modified organisms to be labelled, when they are placed on the market (Article 20 of Directive 2001/18, Articles 12ss and 24ss of Regulation 1829/2003). Already these provisions show that the two legislative acts wanted to allow the consumer the choice whether he/she consumes GMO-products or not; at least part of this information is destined to take into consideration the possible concern of consumers that the consumption of GMO-products might have an effect on their health.

49. It follows that in the case of herbicide-tolerant plants, the notification which is made under Directive 2001/18 or the application for authorisation which is made under Regulation 1829/2003 must contain a monitoring plan that also provides for the monitoring of the genetically modified plants at the stage of their use or

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17 See Court of Justice case C-180/96, United Kingdom v. Commission (1998) ECR I-2265; General Court, joined cases T-74/00, T-76/00 a.o. Artegodan v. Commission (2002) ECR II-4945.

consumption, as adverse effects on human health at the use or consumption stage, due to the presence of herbicide residues, cannot completely be excluded.

50. The public authorities which have to examine the notification or application have the obligation to ensure that the monitoring plan contains such a monitoring part for the consumption stage, or be completed by such a part. Therefore, any authorisation granted without a monitoring plan that extends to the use and consumption stage of the genetically modified plants therefore does not exclude *any* adverse effect on human health of the genetically modified plants. Such an authorisation is thus not in compliance with the provisions of Directive 2001/18 or Regulation 1829/2003.

**2.4 After the authorisation of a genetically modified plant has been given, has a monitoring of potential adverse effects on human health to be undertaken which takes into consideration the possible cumulative effect of herbicide residues?**

51. Article 20 of Directive 2001/18 deals with “monitoring and handling of new information” after the authorisation to place a genetically modified plant on the market had been given. Where the applicant (the notifier) receives such new information with regard to the risks of the GMOs to human health or the environment, he shall immediately take the measures necessary to protect human health and the environment and inform the competent authorities thereof. In addition, he shall revise the conditions specified in the notification. The notifier thus has to adapt his monitoring plan in view of monitoring, whether adverse health effects due to the presence of herbicide residues and their potential cumulative effects can be detected.

52. When the authority which had given the consent to place the genetically modified plant on the market, obtains information which could have consequences for the risks of the GMO to human health or the environment, it shall send an assessment report to the Commission. This report has to indicate whether and how the conditions of the consent should be amended. The Commission has to send the report to the other EU Member States. Following a discussion among the competent authorities, the authority which had made the report, shall amend the consent as proposed, send it to the notifier and to the other Member States and the Commission<sup>18</sup>.

53. The purpose of these provisions is to ensure that the consent and the conditions attached to it, including the monitoring plan, indeed cover all potential adverse effects of the genetically modified organism and is, if necessary, updated. And the fact that the discussion among the different competent authorities on an amendment of the consent might take some time, does not allow the notifier to delay the taking of measures: he has “*immediately*” take the necessary measures (Article 20(2)).

54. Under Regulation 1829/2003, the authorisation holder “*shall forthwith inform the Commission of any new scientific or technical information which might*

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18 See for details of the procedure and for delays Article 20(3) of Directive 2001/18.

*influence the evaluation of the safety in use of the food”* (Article 9(3)); an identical provision exists in Article 21(3) for feed. EFSA is obliged, on its own initiative or following a request from a Member State or from the Commission, to issue an opinion whether an authorisation for a product still meets the requirements of the Regulation (Article 10; Article 22 for feed). The opinion shall be sent to the Commission which shall, if appropriate, modify the authorisation. Information from the authorisation holder shall be made accessible to the public (Article 29).

55. It follows from these provisions that an incomplete monitoring plan shall lead, on the request of the consent/authorisation holder or on the own initiative of the public authorities, to a revision of the consent/authorisation granted. As it is the objective of both Directive 2001/18 and Regulation 1829/2003 to exclude any even an unlikely risk to human health, it is necessary to adapt the consent/authorisation in order to monitor potential adverse effects which the cumulated risk of genetically modified plants and herbicide residues might have on human health.

56. In view of these comments, the answer to the questions posed is as follows:

1. The present practice not to monitor the potential adverse effects on human health of genetically modified plants at the use and consumption stage is not in compliance with existing EU legislation.
2. Directive 2001/18 and Regulation 1829/2003 require both that potential adverse effects on human health of genetically modified plants are controlled during the use and consumption stage, including in those cases that such effects are unlikely to occur.
3. Directive 2001/18 and Regulation 1829/2003 have both the objective to avoid *any* adverse effect on human health of genetically modified plants. Therefore, the risk assessment must provide, in both cases, that the cumulative effect of herbicide residues on genetically modified plants during the use and consumption stage is controlled.
4. When the monitoring plan for a genetically modified plant does not include the control of the cumulative effect of herbicide residues and genetically modified plants on human health during the use and consumption stage, the authorisation shall have to be amended in order to provide for such a control.

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