Teosinte plants in the European environment and its implication for market authorisation of genetically engineered maize

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Executive summary

The appearance of teosinte plants in the Spanish and French environment which are capable to hybridize with conventional maize plants, constitutes "new information" under EU GMO legislation. None of the applicants for authorisation or prolongation of authorisation of maize MON 810, Bt 11, 1507or GT 21 for cultivation had taken teosinte into consideration in the application; all had excluded the possibility of genetically modified maize being capable of hybridizing with wild relatives in Europe. It is therefore necessary to review in all cases the environmental risk assessments which were submitted together with the application file. An authorisation or a prolongation of the authorisation to cultivate GM maize without a risk assessment that includes the teosinte aspects is not in compliance with EU GMO legislation. The authorisation for the cultivation of maize MON 810 has expired in the EU.

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Introduction

At present, several genetically modified maize plants are on the EU market; however, only maize MON 810 was, until now, authorized by the European Commission for cultivation. Several other genetically modified maize plants, either in single events or in stacked events, wait for their authorisation for cultivation in the EU[1]. Hereafter, the question of the impact which the appearance of teosinte plants in Spain and France has on the authorisation process for GMOs, will mainly be discussed with regard to maize MON 810.

The authorisation of maize MON 810

On request of the company Monsanto Europe SA, the Commission authorized, in 1998, the placing on the market, including cultivation, of genetically modified maize (Zea mays L.line 810)[2] pursuant to Council Directive 90/220[3]. MON 810 is a genetically modified maize designed to combat crop loss due to certain insects of the Lepidoptera order (butterflies and moths) and the European corn borer. The authorisation was given for all uses, including cultivation, except for food.

Monsanto's application was submitted, in conformity with Directive 90/220, to the French authorities. The file which consists amongst others of the application and the favourable opinion of the French authorities on the application, as well as the later French consent for use and cultivation, were not published. However, Article 11(1) of Directive provided: "This notification shall contain: - the information contained in Annex II... and an assessment of any risks for human health or the environment related to GMO..."[4]. And according to Annex II to Directive 90/220, Monsanto had, together with its application, to inform the French - and subsequently the EU - authorities of the following circumstances:

- Potential for genetic transfer and exchange with other organisms (Annex II, A.II.no 9);

- Flora and fauna, including crops, livestock and migratory species which could be affected (Annex II, no. III B no.9);

- Description of target and non-target ecosystems likely to be affected (Annex II, no.III B.no.10);

- Genetic transfer capability: (a) post-release transfer of gene material from GMO into organisms in affected ecosystems (Annex II, no.IV.B.no.3);

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1 See European Commission, Genetically modified organisms, EU register of authorized GMOs, ec.europa.eu/food/dyna/gen_register/index:en.cfm

2 Commission Decision 98/294 concerning the placing on the market of genetically modified maize (Zea mays L. line 810), pursuant to Council Directive 90/220, OJ 1998, L 131 p.32

3 Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, OJ1990, L 117 p.15.

4 Directive 90/220 (n.2), Article 11(1).

- Techniques for detecting transfer of the donated genetic material to other organisms (Annex II, no V. A no.3);

- Plan for protecting human health and the environment in case of the occurrence of an undesirable effect (Annex II, no. V D.no.5).

Article 11(6) of Directive 90/220 stated: "If new information has become available with regard to the risks of the product to human health or the environment, either before or after the written consent, the notifier shall immediately: - revise the information and conditions specified in paragraph 1; - inform the competent authority; and - take the measures necessary to protect human health and the environment".

In 2001, Directive 2001/18 replaced Directive 90/220[5]; the provision of Article 11(6) of Directive 90/220, mentioned above, was almost word by word repeated in Article 20(2) of Directive 2001/18. For genetically modified food and feed, a Regulation was adopted in 2003[6]. In 2007, Monsanto asked, in conformity with that Regulation, to have the authorisation for maize MON 810 renewed. Until October 2016, the EU had not decided on this request. According to Article 23(4) of Regulation 1829/2003, the period of authorisation was thus automatically extended, until a decision on the request is taken. The Commission asked the European Food Safety Authority (EFSA) for an opinion on the request. EFSA delivered its opinion in 2009[7].

As regards gene transfer, this Opinion stated: "in the European Union, no cross-compatible wild/weedy relatives with which maize can hybridize, and from backcross progeny exist.. Thus, cross-pollination in maize is not considered an environmental risk"[8]. The overall conclusion of EFSA was that maize MON 810 did not constitute a risk for human health or the environment.

Monsanto grew maize MON 810 in EU Member States since 2003; at present, such maize is grown in the Czech Republic, Portugal, Romania, Slovakia and Spain. Since 2005, Monsanto submitted annual post-marketing environmental monitoring reports (PMEM) to the Commission. Since 2010, the Commission asked EFSA to assess these reports. All EFSA opinions concluded that its previous conclusions that maize MON 810 did not present a risk for human health or the environment, remained valid.

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5 Directive 2001/18 on the deliberate release into the environment of genetically modified organisms, OJ 2001, L 106 p.1.

6 Regulation1829/2003 on genetically modified food and feed, OJ 2003, L 268 p.1.

7 EFSA, Scientific Opinion of the Panel on Genetically Modified Organisms on application(EFSA-GMO-RX-MON 810) for the renewal of authorisation for the continued marketing of (1) existing feed and food ingredients produced from genetically modified insect resistant maize MON 810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and (3) food additives and feed materials produced from maize MON810, all under Regulation(EC) No.1829/2003 for Monsanto; EFSA Journal2009;7(6):1149, p.25.

8 EFSA (n.7), section 6.1.22.

In June 2016, the Commission asked Monsanto to report on the appearance of teosinte plants, a wild relative of maize, in Spain and France and expressed its surprise that Monsanto had not considered to report on its own on that plant under Article 21 of Regulation 1829/2003[9]. Monsanto answered by letter of 1 July 2016 that it had learned of the presence of teosinte plants in Spain from a Spanish industrial association[10]. According to Monsanto, teosinte in Spain was a weed. Maize MON 810 did not possess any characterization that would result in increased weediness or persistance compared to conventional maize. Teosinte did not appear to be invasive in areas outside cultivation. This finding was confirmed, according to Monsanto, by the farmers' questionnaires in 2014 which had indicated no difference between MON 810 maize and conventional maize. Therefore, there was no reason to differentiate between maize MON 810 and conventional maize; the focus should be on the agronomic control and potential eradication of teosinte in the EU. For these reasons, Monsanto had not considered it necessary to inform the competentent national authorities or the EU Commission of the presence of teosinte in Spain.

In its PMEM for 2015, Monsanto mentioned, for the first time, the presence of teosinte in the EU[11]. It explained that it had learned from a Spanish industrial association in 2014 of the existence of teosinte, and referred to the reasons in its letter of 1 July 2016, in order to explain, why it had not informed the Commission or the competent authorities of Spain or France on the presence of teosinte.

Also in 2016, the Commission asked EFSA to assess, whether in view of the appearance of teosinte plants in Spain and France, genetically modified maize MON 810, Bt 11, maize 1507 or GA 21 presented a risk for human health or the environment. EFSA's opinion was that such a risk was very low and did not change its previous conclusions.[12]

Teosinte in Spain

"Teosinte is the common name for a group of annual and perennial species of the genus Zea, a member of the grass family (Poaceae), native to Mexico and central America. Teosinte comprises seven taxa that are divided into two sections and five species"[13]. Some of the species are further subdivided into subspecies, one of them being maize. Cultivated maize hybridizes with other teosinte plants.

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9 Regulation1829/2003 (n.6), Article21(3): "The authorisation-holder shall forthwith inform the Commission of any new scientific or technical information which might influence the evaluation of the safety in use of the feed". See also Directive 90/220 (n.3), Article 11(6).

10 Monsanto Europe SA, letter of 1July 2016 to the European Commission, DG Santé, Ares(2016)3185001-04/07/2016.

11 Monsanto Europe SA, Annual monitoring report on the cultivation of MON 810 in 2016, September 2016, p.36.

12 EFSA, Relevance of new scientific evidence on the occurrence of teosinte in maize fields in Spain and France for previous environmental risk conclusions and risk management recommendations on the cultivation of maize events MON 810, Bt 11, 1507 and GA26. Technical Report of 23-9-2016. EFSA supporting publication 2016:EN-1094.

13 EFSA (n.12), section 3.1.

Teosinte appeared in France (Poitou-Charente) in 1990, where it continues to exist until now and even appears to be expanding[14]. Its existence in Spain (Aragon and Catalunya) was officially discovered in 2014, though farmers and cooperative workers report its existence since 2009. While the regional government of Aragón indicated in 2014 that an area of about 200 to 300 hectares in Aragón were affected[15], more recent figures of 2016 indicate an affected area of about 650 hectares in Aragón and 80 hectares in Catalunya[16]. Whether teosinte is also being found in the region of Navarra, is unclear.

The regional government of Aragón asked farmers to take measures against teosinte - cleaning of technical material, crop rotation etc - and asked scientific bodies to look at the teosinte problem. The regional government of Catalunya established a technical committee on questions related to teosinte[17]. The Spanish central government launched two scientific studies in Aragon and Catalunya on the phenomenon of teosinte[18]. None of the measures taken referred to genetically modified maize (MON 810) which was grown in quantities of more than 100.000 hectares in Spain, including in Aragón and Catalunya. Teosinte was considered by the Spanish authorities a weed that affected the cultivation of maize. The fact that farmers in Aragón estimated that teosinte had hybridized with genetically modified maize which explained its expansion[19], was of no relevance.

As Monsanto declared that it had learned of the existence of teosinte within the European Union only in 2014, it can be safely assumed that the Monsanto environmental risk assessment which had accompanied its original application for maize MON 810, did not discuss the environmental consequences of the presence of teosinte in Spain.

The appearance of teosinte as "new information"

The question what kind of new information concerning the risk from genetically modified plants to human health or the environment triggers the requirement of taking measures under Article 11(6) of Directive 90/220 can be answered with relative certainty: any factual circumstance for which Annex II to Directive 90/220

14 France does not allow the cultivation of genetically modified maize. It appears that no research has been made on the question, how teosinte could survive and even expand in France during a quarter of a century, despite attempts to eradicate it.

15 Government of Aragon, Directorate General for Food and Agri-Food Development, Teosinte, Technical Information 4/14 of 2014.

16 Pardo a.o.:El teosinte: descripción, situación actual en el Valle del Ebro y resultados de los primeros ensayos. Vida Rural 2016, 42.

17 Government de Catalunya, Departament d'Agricultura, Ramaderia, Pesca y Alimentació, Decision of 27 November 2015.

18 Government of Spain, Resolution of 8 February 2016, attributing a study of 85.000 euro to the Centro de Investigación Agroalimentaria de Aragón and a study of 44.000 euro to the University of Lerida, BOE no.46 of 23 February 2016.

19 See D.Placer: Los productores de maiz disparan las alarmas por una nueva amenaza transgénica, economía digital of 5 July 2016, who reports that farmers affected by teosinte relate the expansion of this plant to its hybridization with maize MON 810.

had explicitly asked, was considered by the legislator to be significant. Therefore any change in these factual circumstances induced the obligation of the notifier to take the measures under Article 11(6).

Monsanto's argument that it considered it unnecessary to inform the competent authorities of the existence of teosinte in Spain and take any measures as a consequence thereof, cannot be accepted. It cannot be left at the discretion of the notifier to decide whether certain factual circumstances are relevant or not, as the public authorities have to weigh all circumstances in a given case and then decide, whether a deliberate release into the environment may be authorized.

It is also irrelevant that the Spanish farmers' answers to questionnaries from Monsanto had not mentioned the existence of teosinte. This omission might reveal a lack of sufficient surveillance of the environmental monitoring of maize MON 810 or a lack of care on the side of farmers. However, it cannot discharge Monsanto from its responsibility to constantly observe the environment in which its maize MON 810 was grown.

As Annex II to Directive 90/220 had explicitly asked for the capacity of gene transfer of maize MON 810, this was thus considered an essential information for the authorizing authorities in the EU Member States and the European Commission. Monsanto's original application and the Commission's decision to authorize the cultivation of maize MON 810 within the European Union, had been based on the assumption that there were no wild relatives to maize within the European Union to which a gene transfer could happen.

As soon as Monsanto learned of the existence of teosinte, a wild relative of maize, and thus of the possibility that a gene transfer from maize to teosinte could occur, it should therefore, in accordance with Article 11(6) of Directive 90/220, have reviewed its original environmental risk assessment with regard to teosinte and inform the competent authorities.

This obligation was not changed by the subsequent adoption of Directive 2001/18 and Regulation 1829/2003. Directive 2001/18 which was adopted in 2001, contained in Annex II provisions on the environmental risk assessment of genetically modified plants. These provisions were further detailed by a guidance note on the environmental risk assessment which the Commission adopted in 2002[20].

Article 20(2) of Directive 2001/18 provided: "If new information has become available.. with regard to the risks of the GMO(s) to human health or the environment after the written consent has been given, the notifier shall immediately take the measures necessary to protect human health and the environment and inform the competent authority thereof. In addition, the notifier shall revise the information and conditions specified in the notification". Thus, this provision was very similar to Article 11(6) of Directive 90/220. Though it is not mentioned that the environmental risk assessment shall have to be completed (updated), this follows indirectly of the objective of Article 20(2).

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20 Commission Decision 2002/623 establishing guidance notes supplementing Annex II, OJ 2002, L 200, p.22.

Indeed, in order to identify the measures which are necessary to protect the environment from a gene transfer between maize MON 810 and teosinte, the spreading of genetically modified teosinte plants and their further behaviour in the environment, it is necessary to identify exactly the nature of the teosinte plants, their capacity to proliferate and other characteristics. This is only possible with a risk assessment targeted at the relationship between maize, maize MON 810 and teosinte.

The need to review the original environmental risk assessment also becomes obvious in the light of the Commission's Guidance note to Annex II to Directive 2001/18, mentioned above; this Guidance note stated[21]:

"If new information on the GMO and its effects on human health or the environment becomes available, the environmental risk assessment may need to be readdressed in order to - determine whether the risk has changed; - determine whether it is necessary to amend the risk management accordingly. In the case of new information, irrespective of whether immediate measures need to be taken, there may have to be a new environmental risk assessment to assess the need to change the terms of authorisation for the GMO release or placing on the market or to ajust risk management measures".

Similarly, the EFSA guidance on the environmental risk assessment of genetically modified plants of 2010[22] stated: "If adverse effects have been detected in areas where genetically modified plants are grown or where there is a suspicion that the genetically modified plants may be associated with an incident...(T)he applicant should immediately take the measures necessary to protect human health and the environment, and inform the competent authority thereof. In addition, the applicant should revise the information and conditions specified in the application... Where adverse effects on the environment are observed, further assessment should be considered to establish, they are a consequence of the genetically modified plant or its use, as such effects may be the result of environmental factors other than the placing on the market of the genetically modified plant in question"[23].

The provisions in Directive 2001/18 and these different guidance notes on environmental risk assessment and new information may be considered to represent the state of the art of making and updating an environmental risk assessment of genetically modified organisms. Independently thus, whether Monsanto's obligations flow exclusively from Article 11(6) of Directive 90/220 or also from the environmental risk assessment provisions of Directive 2001/18 and the Commission's and EFSA's guidance, it remains that Monsanto was under the legal obligation to adapt its environmental risk assessment - or make a new one -

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21 Ibidem, section 3, p.25.

22 EFSA, Guidance on the environmental risk assessment of genetically modified plants, EFSA Journal 2010; 8(11):1879,section 4.5, p.92.

23 See also, in almost identical terms, already EFSA, Guidance document of the Scientific Panel on genetically modified organisms for the risk assessment of genetically modified plants and derived food and feed, May 2006. EFSA Journal (2006) 99, p.1 (p.36).

in order to take into consideration the existence of wild relatives (teosinte) of maize in the Spanish environment.

This obligation has not changed, because of an obligation of a post-marketing control provided for under Article20(1) of Directive2001/18. Indeed, the post-marketing control might contribute to the finding of new information. However, it does not replace the necessity, laid down in Article 20(2) of Directive 2001/18, to take the necessary measures in order to protect the environment. It follows from all this, that Monsanto was, by virtue of Article 11(6) of Directive 90/220 and Article 20(2) of Directive 2001/18, obliged to update its original environmental impact assessment with an assessment of the environmental effects of teosinte in the Spanish environment.

This impact assessment did not become superfluous, because some measures had been taken by Spanish public authorities to combat the presence of teosinte. Indeed, the measures apparently did not address the interaction between maize MON 810 and teosinte; the term "genetically modified" is nowhere even mentioned and there is no question in all the measures that there might be specific problems with genetically modified maize and teosinte. None of the measures adopted by the public authorities addressed the question of a possible gene transfer from genetically modified maize to teosinte. Also, nothing is said in any of the publications from Spanish authorities or Spanish researchers, whether teosinte plants have been searched to exist outside cultivated maize fields. The Spanish publications do not even yet know exactly, which subspecies of the Zea genus had appeared in Spain[24], though the hybridization between maize and teosinte spp parviglumis seems to be significantly different from the hybridization between maize and spp. mexicana[25] It is not either clear, how the expansion of teosinte occurs and whether teosinte seeds are transported by birds, other -wild or domesticated - animals or by other means. The Spanish research is concentrated on maize fields which contain teosinte plants, and neglects other fields and areas. Different publications report of a considerable expansion of teosinte plants between 2014 and 2016[26], though it is unclear, whether this is based on intensified control measures, natural expansion or other factors.

It is uncontested that hybridizing between maize MON 810 and teosinte plants and thus also a gene transfer may occur. According to Annex II C.2 no.2 to Directive 2001/18 the evaluation of the effects of adverse effects of a genetically modified plant "should assume that such an adverse effect will occur". Monsanto

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24 Considerations vary between Zea mays spp parviglumis and spp.mexicana. See Pardo a.o.: Teosinte, una mala hierba queamenaza al maíz. Tierras de Castilla y Leon: Agricultura 2014, no. 223, p.52; Pardo a.o.: Presencia de teosinte (Zea spp) como mala hierba en los regadios del valle del Ebro, 2015; XV Congreso de Malherbología SEMH, Junta de Andalucía,Sevilla2015, p.417.

25 See Haut Conseil des Biotechnologies, Comité Scientifique (France): Avis en réponse à la saisine HCB- dossier BE-2015-125 of 18 December 2015, section 1.1.5.2; this avis concerned an application of a new genetically modified maize.

26 The Aragón regional government (n.14) reported of 200 to 300 hectares affected in 2014. Pardo a.o. (n.16, above) mentioned, in 2015, about 500 hectares in Aragón and 18 hectares in Catalunya to be affected. In 2016, Pardo a.o. (n.16), reported of 684 affected hectares in Aragón and 80 hectares in Catalunya.

was thus obliged to examine the consequences of genetically modified teosinte plants spreading in the wild in Spain - as they had apparently done in Mexico -and look at the consequences for the natural environment in Spain.

The EFSA Report of September 2016

The EFSA Technical Report of 29 September 2016[27] did not relieve Monsanto of its obligations under Directive 90/220. EFSA did not undertake an environmental risk assessment of maize 810 with regard to teosinte. Its task was to assess such assessments made by an applicant and to make recommendations as to risk management measures. However, as Monsanto did not undertake an environmental risk assessment, EFSA did not comply with its task either. The different hypothetical scenarios which EFSA considered in its Report, did not substitute a complete risk assessment and in particularly did not work under the assumption that an adverse effect - a gene transfer - of maize MON 810 on teosinte would occur; however, as mentioned above, this is explicitly required under Annex II to Directive2001/18 for a risk assessment. Also, the repeated reference to the intermediate publications of one research team of Aragón[28] - which does not even mention the cultivation of genetically modified maize - is not sufficient.

The knowledge of teosinte and its behaviour in the European environment is, at present, more than rudimentary within the EU. It is not even known with certainty, which subspecies of the Zea genus has appeared in Spain or in France. Also its interaction with maize in general and with maize MON 810 in particular has, as far as can be seen, until now not been examined. Under these circumstances, an environmental risk assessment of maize Mon 810 with regard to teosinte is necessary. It would in particular have to address the following questions:

- which species or subspecies of teosinte have been found in Spain (and in France)?

- has teosinte spread outside cultivated maize fields in the environment in Spain or in France; has it occurred in other EU Member States, where maize MON 810 is cultivated?

- has maize MON 810 already transferred its genetic material to teosinte plants?

- have genetically modified teosinte plants a selective advantage over other teosinte plants?

- did hybridization occur between genetically modified teosinte plants and conventional maize?

- what immediate or delayed impact have or may have genetically modified teosinte plants on target or non-target organisms?

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27 EFSA (n.12, above).

28 Pardo 2014 (n.24,above), Pardo 2015 (n.24 above), Pardo 2016 (n.16, above)

- the potential immediate or delayed environmental impact of the direct or indirect interactions between genetically modified teosinte plants with non-target organisms, including impact levels of competitors, parasites and pathogens.

Consequences for authorizing the cultivation of GMO maize

The appearance of teosinte in the Spanish environment constitutes a "new information" under Articles11(6) of Directive 90/220 and 20(2) of Directive 2001/18. Applying the worst-case scenario which is required by annex II to Directive 2001/18, it has to be assumed that maize MON 810 hybridizes with teosinte plants and that such genetically modified teosinte plants spread in the Spanish environment, build feral populations outside maize fields and cross-fertilize with conventional maize.

Therefore, Monsanto was under a legal obligation to complete its original environmental risk assessment concerning maize MON 810 by examining the interrelationship with teosinte spp. parviglumis and spp.mexicana, along the lines of annex II to Directive 2001/18, as these requirements constitute the present state of the art of environmental risk assessments for GMOs.

In the same line of reasoning, applicants for the cultivation of other events of genetically modified maize - in particular of maize Bt 11, 1507, GA21 - will need to complete their environmental risk assessments by examining the interrelationship between their form of genetically modified maize and teosinte[29]. As long as such an environmental risk assessment has not been made, an authorisation of the cultivation of genetically modified maize is not possible, as such an authorisation would not be in compliance with the requirements of Directive 2001/18.

The presence of teosinte plants in the Spanish environment constitutes a new risk. According to Directive 90/220 the risk assessment of an applicant has to cover "an assessment of *any* risks for human health and the environment related to the GMO"[30]. Similarly, Directive 2001/18 requires that the environmental risk assessment identifies and evaluates "potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment"[31]. When new information on the GMO and its effects on the environment becomes available, the environmental risk assessment is to be re-addressed in order to determine, whether the risk has changed and risk management measures are necessary[32].

29 See in the same way the conclusion of the French Haut Conseil des Biotechnologies (n.25, above) concerning maize genetically modified MON 87403, section 1.1.55: "Populations of teosinte compatible with cultivated maize are known to exist in the European Union. The risk associated with potential gene transfer from maize 87403 to teosintes should be taken into account by the applicant" (author's translation).

30 Directive 90/220 (n.3), Article 11(1), emphasis added.

31 Directive 2001/18 (n.5), Annex II A.

32 Directive 2001/18 (n.5), Annex II B.

Before taking any decision as regards the authorisation of genetically modified maize to be cultivated within the EU, the competent authorities have thus to require the applicants to make a detailed environmental risk assessment with regard to teosinte. A new authorisation of genetically modified maize plants without such a supplementary environmental risk assessment is not in compliance with the provisions of Directives 90/220 and 2001/18, as a specific, known risk would not be covered by an environmental risk assessment.

The renewal of the authorisation for maize MON 810

The next question is, whether the cultivation of maize MON 810 should continue to be allowed. At present, Monsanto Europe benefits from the provision of Article 23(4) of Regulation 1829/2003 which reads: "Where, for reasons beyond the control of the authorisation-holder, no decision is taken on the renewal of an authorisation before the expiry date, the period of authorisation of the product shall automatically be extended until a decision is taken".

In the past, it could be assumed that this provision applied since Monsanto had introduced its request for prolonging the authorisation before the expiry of the authorisation given under Decision 98/294, and the EU institutions had not decided on it until now. One could reasonably argue that the absence of a decision on Monsanto's request for renewal was beyond Monsantos control.

However, with the appearance of teosinte in the European environment, this situation has changed. Monsanto could and should have been aware of the appearance of teosinte in France since 1990. The fact that France did not authorize the cultivation of maize MON 810 does not relieve it from its obligation, as Monsanto explicitly declared in its original application for authorisation to cultivate maize MON 810 that there were no wild relatives to maize in France and in the whole of Europe. This declaration was already wrong when it was made in 1995, as teosinte plants were reported as early as 1990.

Since 2014 when the regional government of Aragón introduced measures against teosinte plants in Spain, the presence of these plants was also known with regard to this country. In its letter of 1 July 2016 to the Commission, Monsanto declared itself that it had learned of the existence of teosinte in the Spanish environment in 2014. As teosinte plants existed in Spain already earlier, Monsanto should have taken steps to learn of their existence, and not wait until it was informed by a voluntary information from an industrial association. It was and is not up to the public authorities- here the regional government of Aragón - to draw the attention of Monsanto and other private persons or bodies on the existence of wild relatives to maize. Rather, this task is a task which lies on Monsanto itself as the responsible company which cultivated genetically modified maize in Spain.

Furthermore, as mentioned above, the appearance of teosinte constituted a new information and a new risk. Monsanto should therefore at the latest in 2014, have taken measures to review and update its original environmental risk assessment.

It has not done so, for reasons which it explained in its letter of 1 July 2016, but which are not convincing at all. In these circumstances, it cannot be seriously argued that the delay in the prolongation of the authorisation - which will now be inevitable until the results of the environmental riskassessment with regard to teosinte are known -, is beyond Monsanto's control. Rather, the reasons for any delay in the decision on the prolongation lie now in Monsantos sphere of influence.

Monsantos original application and the corresponding authorisation of the Commission (decision 98/294) remained valid for a period of ten years[33]. Since Monsanto applied, according to Article 23 of Regulation 1829/2003, for a renewal of the authorisation, and the EU did not decide on it in time, the authorisation was automatically extended (Article 23(4). However, this automatic extension only applied as long as the reasons for the non-decision on the renewal of the authorisation were beyond the control of Monsanto. Since Monsanto knew of the presence of teosinte in the European environment at the latest since 2014 - even leaving aside the presence of teosinte in France since 1990 - at the latest since 2014 the reasons for not renewing the authorisation were no longer beyond the control of Monsanto; the fact that the national competent authorities and the Commission were not informed of the presence of teosinte at that time does not change this situation.

At least at present, at the end of 2016, the conditions for renewal of the authorisation of maize MON 810 are no longer fulfilled, as an environmental risk assessment on a new risk - the presence of teosinte in the European environment - has not been made.

It cannot be argued that a refusal to renew the authorisation would be disproportionate. The whole GMO-legislation of the EU - Directive 90/220, Directive 2001/18 and Regulation 1829/2001 - is based on the precautionary principle which is in particular mentioned in Article 12(1) of Directive 90/220, established in Recital 8, Articles 1 and 4 and Annex II of Directive 2001/18 and referred to in Recital 9 of Regulation 1829/2003. This principle means that in cases of scientific or technical uncertainty, measures may be taken in order to protect human health or the environment.

In the present case, the uncertainty lies in the fact that it is not known how genetically modified maize and teosinte plants will interact in the European environment. In such a case, Annex II to Directive 2001/18 explicitly provides that a worst case scenario should be assumed. This means that it must be assumed that a gene transfer from maize MON 810 to teosinte plants occurs, that teosinte plants spread in the environment, build feral populations and again transfer genes to conventional maize plants. It is up to Monsanto to dissipate such uncertainties by a complete and thorough environmental risk assessment.

EU legislation explicitly provides that authorisations for the placing on the market and the cultivation of genetically modified plants shall be given for a limited period of time only, which is another expression of the precautionary principle. From this limited authorisation, Article 23(4) of Regulation 1829/2003 makes an

33 See the transitional provisions of Regulation 1829/2003, Article 20(1)(a)

exception for those cases, where a request for renewal of an authorisation was not decided in time, for reasons beyond the control of the applicant. At least since 2014, such reasons do not exist any more and the automatic extension of Article 23(4) becomes inapplicable. the original authorisation of decision 98/294 expired.

Monsanto could have updated and completed its original environmental risk assessment by identifying and evaluating also the risks that stem from the appearance of teosinte in the European environment. As it has not done so, it may not invoke that the compliance with the existing legal provisions as regards the renewal of the authorisation for MON 810 is disproportionate.

Conclusion

1. The appearance of wild teosinte plants in the European environment (France and Spain) constituted new information and a new risk for the environment.

2. New authorisations for the cultivation of genetically modified maize may not be granted before an environmental risk assessment is made as to the risks stemming from the appearance of teosinte plants in Europe.

3. The authorisation for cultivating maize MON 810 has expired at the latest, when Monsanto learned in 2014 that wild relatives (teosinte plants) had appeared in the European environment, as the reason for not deciding on Monsantos application for the renewal of the authorisation of 1998 were no longer beyond the control of Monsanto; rather, it was Monsantos decision not to make an environmental risk assessment with regard to the appearance of teosinte plants.

4. After having made an environmental risk assessment with regard to the teosinte plants, Monsanto will have to introduce a new application for the authorisation of cultivating genetically modified maize MON 810 within the European Union.

Madrid, 17 November 2016

Prof. Dr. Ludwig Krämer