26 July 2019 *

IN THE GENERAL COURT OF THE EUROPEAN UNION

TESTBIOTECH

Applicant

Represented by Kassie Smith QC and Alfred Artley, Barristers, Monckton Chambers

against

THE EUROPEAN COMMISSION

Defendant

APPLICATION FOR JUDICIAL REVIEW
Case No. [ ]

Testbiotech e.V, Frohschammerstraße 14, 80807 München, Germany

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I. INTRODUCTION

(a) Summary of the Claim

1. Testbiotech hereby seeks judicial review of the European Commission's decision, dated 20 May 2019, ("**the Decision**") refusing to revoke or amend its Decision 2018/2046. Decision 2018/2046 ("**the Commission Implementing Decision**") granted an authorization under Regulation (EC) No 1829/2003 on genetically modified food and feed ("**the GM Regulation**") permitting Monsanto Europe SA to market genetically modified maize MON 87427 x MON 89034 x1507 x MON 88017 x 59122 and its sub-combinations ("**the Maize**").

2. The essence of Testbiotech's complaint is that, in both the Decision and the antecedent Commission Implementing Decision, the Commission erred in law in conducting its assessment of the maize in accordance with Commission Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 ("**the 2004 Regulation**") and not in accordance with Commission Implementing Regulation (EU)

* Date corrected.

No 503/2013 on application for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 ("**the 2013 Regulation**") as required.

3. By failing to assess the Maize against the more stringent standards required by the new regime under Regulation 503/2013, the Commission failed to conduct an adequate risk assessment of the new product. This was especially important given that it was only under the new regime that the specific risks associated with 'stacked' GM events (such as the Maize in the present case) could be addressed properly. As such, the Commission has failed to ensure the high degree of environmental protection required under Article 191 TFEU and other legislation.

(b) Relief sought

4. Testbiotech therefore requests that the Court:

4.1. Declare the application admissible and well-founded;

4.2. Annul the Decision;

4.3. Order the Commission to pay Testbiotech's costs; and

4.4. Order any other measure deemed appropriate.

(c) The Applicant's Standing

5. Testbiotech, Institute for Independent Impact Assessment of Biotechnology, is a not-for-profit association registered in Germany at Frohschammerstr. 14, 80807 Munich. It is included in the Register of Associations at the Amtsgericht München (local court, Munich) VR 202119 (see Statute/Articles of Association at [**SU/19**] and Registration Document at [**SU/20**]. Testbiotech was founded in 2008 by a group of experts and registered as a non-profit organisation to promote independent research and public debate on the impacts of biotechnology. Testbiotech is a centre of expertise concerned mainly with the ecological, social and ethical consequences of modern biotechnology. Special emphasis is placed on genetic engineering applications in agriculture. Testbiotech is included on the EU transparency register, identification number 151554816791-61.

6. Testbiotech is a non-governmental organisation which meets the criteria set out in Article 11 of the Aarhus Regulation. This is not disputed.

II. APPLICABLE LAW

(a) The Aarhus Regulation

7. The Aarhus Regulation is intended to implement the Aarhus Convention. The cornerstone of the Aarhus Convention is the principle that environmental NGOs are deemed to have a legal interest of their own to bring certain judicial proceedings 'on behalf of' the environment. This principle is enshrined in Article 2(5) read with Article 9 of the Convention. The preamble to the Aarhus Convention provides as follows:

> *… Recognizing that adequate protection of the environment is essential to human well-being and the enjoyment of basic human rights, including the right to life itself,*
>
> *Recognizing also that every person has the right to live in an environment adequate to his or her health and well-being, and the duty, both individually and in association with others, to protect and improve the environment for the benefit of present and future generations,*
>
> *Considering that, to be able to assert this right and observe this duty, citizens must have access to information, be entitled to participate in decision-making and have access to justice in environmental matters, and acknowledging in this regard that citizens may need assistance in order to exercise their rights…*
>
> *Recognizing further the importance of the respective roles that individual citizens, non-governmental organizations and the private sector can play in environmental protection…*
>
> (emphasis added)

8. Recitals (18), (19) and (21) of the Aarhus Regulation in turn provide that:

> *(18) Article 9(3) of the Aarhus Convention provides for access to judicial or other review procedures for challenging acts and omissions by private persons and public authorities which contravene provisions of law relating to the environment. Provisions on access to justice should be consistent with the Treaty. It is appropriate in this context that this Regulation address only acts and omissions by public authorities.*
>
> *(19) To ensure adequate and effective remedies, including those available before the Court of Justice of the European Communities under the relevant provisions of the Treaty, it is appropriate that the Community institution or body which issued the act to be challenged or which, in the*

case of an alleged administrative omission, omitted to act, be given the opportunity to reconsider its former decision, or, in the case of an omission, to act.

(21) Where previous requests for internal review have been unsuccessful, the non-governmental organisation concerned should be able to institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty.

(emphasis added)

9. Articles 10 and 12 of the Aarhus Regulation are designed to fulfil the Aarhus Convention's goal of allowing access to justice in environmental matters. These Articles thus establish administrative and judicial review procedures which enable NGOs meeting the requirements of Article 11 of the Regulation to challenge the acts and omissions of the Community institutions which contravene provisions of European environmental law.

10. 'Environmental law' is defined as follows:

Community legislation which, irrespective of its legal basis, contributes to the pursuit of the objectives of Community policy on the environment as set out in the Treaty: preserving, protecting and improving the quality of the environment, protecting human health, the prudent and rational utilisation of natural resources, and promoting measures at international level to deal with regional or worldwide environmental problems.

(d) The GM Regulation

11. The GM Regulation provides that, in order to protect human and animal health, food and feed that consists of, contains, or is produced from genetically modified organisms should undergo a risk and safety assessment before it is placed on the market in the European Union. As the Recitals (2), (3) and (9) make clear, it reflects the core Union objective of environmental protection

A high level of protection of human life and health should be ensured in the pursuit of [Union] policies…

In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms...should undergo a safety assessment through a [Union] procedure before being placed on the market within the [Union]…

…genetically modified food and feed should only be authorised for placing on the Community market after a scientific evaluation of the highest

possible standard, to be undertaken under the responsibility of [EFSA], of any risks which they present for human and animal health and, as the case may be, for the environment…

12. 'Genetically modified organism' is defined in Article 2(2) of Directive 2001/18 as '*an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination*' ('organism' being defined in Article 2(1) as '*any biological entity capable of replication or of transferring genetic material*'.)

13. Food or feed derived from genetically modified organisms ("**GMOs**") must not have adverse effects on human health, animal health or the environment (Article 4(1)(a) and 16(1)(a) of the GM Regulation). This is ensured, inter alia, by a strict licensing regime: pursuant to Article 4(2) of the GM Regulation, GMOs may not be placed on the market for food use unless an authorisation has been granted in accordance with the requirements set out in the remainder of the Regulation.

14. Article 5 specifies how an application for such an authorisation is to be made. In the first instance, the application is submitted to the competent authority of a Member State (Article 5(2)).

15. Article 5(3) specifies what information is to be submitted accompanying the application:

(a) the name and the address of the applicant;

(b) the designation of the food, and its specification, including the transformation event(s) used;

(c) where applicable, the information to be provided for the purpose of complying with Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (hereinafter referred to as the Cartagena Protocol);

(d) where applicable, a detailed description of the method of production and manufacturing;

(e) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any other material which is available to demonstrate that the food complies with the criteria referred to in Article 4(1);

(f) either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics and to the criteria specified in

Article 13(2)(a), or a proposal for labelling the food in accordance with Article 13(2)(a) and (3);

(g) either a reasoned statement that the food does not give rise to ethical or religious concerns, or a proposal for labelling it in accordance with Article 13(2)(b);

(h) where appropriate, the conditions for placing on the market the food or foods produced from it, including specific conditions for use and handling;

(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;

(j) samples of the food and their control samples, and information as to the place where the reference material can be accessed;

(k) where appropriate, a proposal for post-market monitoring regarding use of the food for human consumption;

(l) a summary of the dossier in a standardised form.

16. Furthermore, pursuant to Article 5(5), in the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by:

(a) the complete technical dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and 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;

(b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.

17. Once the application is received, it is then transferred to the European Food Safety Authority ("**EFSA**") for an Opinion. According to Article 6:

1. In giving its opinion, the Authority shall endeavour to respect a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant as provided for in paragraph 2.

2. The Authority or a national competent authority through the Authority may, where appropriate, request the applicant to supplement the particulars accompanying the application within a specific time limit.

(emphasis added)

18. EFSA then evaluates the application, consults competent authorities in Member States and produces an Opinion on whether the GMO should be authorised (Articles 6 and 18). On the basis of this Opinion, any relevant provisions of EU law and any other legitimate factors relevant to the application, the Commission produces a draft decision, which is submitted to the Standing Committtee on the Food Chain and Animal Health, and becomes final in accordance with the comitology procedure (Articles 7(1), 19(3) and 35(2)).

(e) Implementing Regulations

19. While the GM Regulation provides the overarching framework, applications for a marketing authorisation must also comply with the detailed legislative rules specified in the appropriate Implementing Regulation in force. The 2004 Regulation came into force on 18 April 2004. As regards GM plants for food and feed uses, the 2004 Regulation was replaced by the 2013 Regulation, which provides a considerably more comprehensive and detailed set of rules, particularly for stacked events, such as the Maize in the present case. The 2013 Regulation came into force on 28 June 2013.

20. As to the contents of an application for authorisation, the 2004 Regulation simply cross-refers to what was already required by the GM Regulation. There are no specific provisions relating to stacked GM products in the 2004 Regulation. However, the need for a new regulatory structure to reflect scientific advances in this area is explained in the Recitals to the 2013 Regulation and was apparently one of the factors prompting the regulatory reform.

> *(4) Commission Regulation (EC) No 641/2004 (3) on detailed rules for the implementation of Regulation (EC) No 1829/2003 provides for certain detailed rules concerning applications for authorisation submitted in accordance with Regulation (EC) No 1829/2003. To facilitate the preparation of applications and ensure that they contain all the information needed for their assessment, it is necessary to provide for more comprehensive and systematic rules concerning applications for authorisation, which should also be specific to each type of genetically modified organisms (GMO), namely plants, animals and micro-organisms.*
>
> *(18) The harvest of segregating genetically modified plants (segregating crops) containing stacked transformation events contains various subcombinations of transformation events. In addition, current control procedures do not allow identifying the origin of combinations of transformation events. Therefore, in order to ensure that authorisations are coherent with the products of which the placing on the market is*

unavoidable and for the feasibility of controls, the applications for genetically modified food and feed from segregating crops should include all subcombinations independently of their origin and not yet authorised.

(emphasis added)

21. The scope of the 2013 Regulation is set out in Article 1 thereof:

> *This Regulation shall apply to applications submitted under Articles 5, 11, 17 and 23 of Regulation (EC) No 1829/2003 for the authorisation of:*
>
> *(a) genetically modified plants for food or feed uses;*
>
> *(b) food or feed containing or consisting of genetically modified plants;*
>
> *(c) food produced from or containing ingredients produced from genetically modified plants or feed produced from such plants.*

22. Chapter II sets out 'General Requirements' for the applications. Under Article 3(1),

> *1. The application submitted under Articles 5(1) and 17(1) of Regulation (EC) No 1829/2003 shall:*
>
> *(a) be submitted in accordance with the requirements for the preparation and presentation of applications set out in Annex I;*
>
> *(b) contain all the information required by Annex I, in accordance with the specific requirements of Articles 4, 5 and 6.*

23. Annex I sets outs extensive requirements for the scientific and other information that must be contained in an application. Annex II then sets out a detailed list of the scientific requirements on information to be provided for the purposes of the risk assessments conducted by EFSA and the Commission prior to authorisation being granted. Annex III provides further criteria for the validation methods to be employed.

24. In particular, under Annex I, amongst the information to be provided for the purposes of hazard identification and characterisation is the following:

> ***1.1. Information relating to the recipient or (where appropriate) parental plants***
>
> *(e) Additional information relating to the recipient or parental plants required for the environmental safety aspects:…*
>
> *(ii) sexual compatibility with other cultivated or wild plant species;*

25. Under Annex II, the following is required:

I. INTRODUCTION

2.2. The risk assessment of genetically modified food and feed containing stacked transformation events shall also include an assessment of the following aspects:

(a) stability of the transformation events;

(b) expression of the transformation events;

(c) potential synergistic or antagonistic effects resulting from the combination of the transformation events shall be subject to an assessment in accordance with Sections 1.4 (Toxicology), 1.5 (Allergenicity) and 1.6 (Nutritional assessment).

For genetically modified food and feed containing, consisting of or produced from genetically modified plants, whose cultivation is associated with the production of genetically modified material containing various subcombinations of transformation events (segregating crops), the application shall include all subcombinations independently of their origin which have not yet been authorised. In such a case, the applicant shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations or, in the absence of such scientific rationale, provide the experimental data.

II. SCIENTIFIC REQUIREMENTS:

1.2.2.3. Information on the expression of the insert(s)

The applicant shall provide information:

— *to demonstrate whether the inserted/modified sequence results in intended changes at the protein, RNA and/or metabolite levels;*

— *to characterise the potential unintended expression of new ORFs identified under point 1.2.2.2(f) as raising a safety concern.*

For those purposes, the applicant shall provide the following information:

...(e) Protein expression data, including the raw data, obtained from field trials and related to the conditions in which the crop is grown…

1.3.1. Choice of the conventional counterpart and additional comparators

In the case of herbicide tolerant genetically modified plants and in order to assess whether the expected agricultural practices influence the expression of the studied endpoints, three test materials shall be compared: the genetically modified plant exposed to the intended herbicide; the conventional counterpart treated with conventional herbicide management regimes; and the genetically modified plant treated with the same conventional herbicide management regimes.

1.3.2.1(b) Specific protocols for experimental design

The different sites selected for the field trials shall reflect the different meteorological and agronomic conditions under which the crop is to be grown; the choice shall be explicitly justified. The choice of non-genetically modified reference varieties shall be appropriate for the chosen sites and shall be justified explicitly…

1.3.6. Effects of processing

When appropriate, depending on the nature of the newly expressed protein(s), it shall be necessary to assess the extent to which the processing steps lead to the concentration or to the elimination, denaturation and/or degradation of these protein(s) in the final product.

1.4. Toxicological assessment

The toxicological impact of any changes on the whole genetically modified food/feed resulting from the genetic modification such as the introduction of new genes, gene silencing or over-expression of an endogenous gene shall be assessed.

Toxicological assessment shall be performed in order to:

(a) demonstrate that the intended effect(s) of the genetic modification has no adverse effects on human and animal health;

(b) demonstrate that unintended effect(s) of the genetic modification(s) identified or assumed to have occurred based on the preceding comparative molecular, compositional or phenotypic analyses, have no adverse effects on human and animal health…

1.4.4.1. 90-day feeding study in rodents with whole genetically modified food/feed

…An additional 90-day feeding study with whole food and feed in rodents with the genetically modified plant with the stacked transformation events shall be included where indications of potential adverse effects are identified during the assessment of: (i) the stability of the inserts; (ii) the expression of the inserts; and (iii) the potential synergistic or antagonistic effects resulting from the combination of the transformation events.

1.4.4.2. Animal studies with respect to reproductive and developmental toxicity testing

…When information required in Sections 1.4.1, 1.4.2 and 1.4.3 on the genetically modified food and feed suggest the potential for reproductive, developmental or chronic toxicity or in case of indications of adverse effects from the 90-day feeding study in rodents (such as functional and/or histological modifications of nervous, endocrine, reproductive or immunological tissues/organs), appropriate testing shall be performed.

1.5.1. Assessment of allergenicity of the newly expressed protein

The applicant shall verify whether the source of the transgene is allergenic. When the introduced genetic material is obtained from wheat, rye, barley, oats or related cereal grains, the applicant shall also assess the newly expressed proteins for a possible role in the elicitation of gluten-sensitive enteropathy or other enteropathies which are not IgE-mediated. Where transformation events have been stacked, the applicant shall provide an assessment of any potential for increased allergenicity to humans and animals on a case-by-case approach. These potential effects may arise from additive, synergistic or antagonistic effects of the gene products.

1.5.3. Adjuvanticity

Adjuvants are substances that, when co-administered with an antigen, increase the immune response to the antigen and therefore might increase as well the allergic response. In cases when known functional aspects of the newly expressed protein or structural similarity to known strong adjuvants may indicate possible adjuvant activity, the applicant shall assess the possible role of these proteins as adjuvants. As for allergens, interactions with other constituents of the food matrix and/or processing may alter the structure and bioavailability of an adjuvant and thus modify its biological activity

3.3. The result of risk characterisation

In accordance with the requirements of Articles 4 and 16 of Regulation (EC) No 1829/2003, the applicant shall ensure that the final risk characterisation clearly demonstrates that:

(a) the genetically modified food and feed has no adverse effects on human and animal health…

26. Finally, under Annex III, the following is required:

3.1. Information about the method

C. The applicant shall demonstrate that the method(s) fulfils the following requirements:

1. The method(s) shall be specific to the transformation event (hereafter referred to as 'event-specific') and thus shall only be functional with the genetically modified organism or genetically modified based product considered and shall not be functional if applied to other transformation events already authorised; otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised transformation events and conventional counterparts. This testing shall include closely related transformation events…

27. The 2013 Regulation thus sets detailed standards for the information to be provided by the applicant, and for the methods and assessment processes to be employed by EFSA and the Commission when considering whether to grant a market authorisation. If the

criteria in the Annexes to the 2013 Regulation are not followed, it cannot be concluded that a product derived from a genetically engineered plant has been demonstrated to be safe.

(f) Transitional provisions

28. Article 9 of the 2013 Regulation contains transitional provisions to reflect the move from the 2004 Regulation to the current regime. Under Article 9(1):

> *Until 8 December 2013, applicants may choose to submit applications falling under the scope of this Regulation under Regulation (EC) No 641/2004 in the version of that Regulation in force on 8 June 2013.*

(g) The standard of review applied by the General Court to challenges to market authorisation

29. The standard of review applicable to challenges to a Commission refusal to reconsider a marketing authorisation decision was discussed by the General Court in Case T-177/13 *TestBiotech eV v Commission*, judgment of 15 December 2016[1] [**AU/26**]. While acknowledging that the Commission should enjoy a considerable margin of discretion in granting marketing authorisations and examining requests for internal reviews, the Court stressed that this discretion is not unlimited and importantly the precautionary principle still applies:

> *76. …it should be observed at the outset that the objective of the Aarhus Convention to give the public broad access to justice requires that the EU Courts do not conduct a more limited or less strict examination of a decision rejecting a request for internal review made pursuant to Article 10 of Regulation No 1367/2006 as unfounded than what it would do in a case in which a natural or legal person seeks annulment of an authorisation decision under Regulation No 1829/2003. Moreover, when a case has been brought before it concerning such a decision, the General Court is also bound by the precautionary principle…*
>
> *80. Moreover, where the EU institutions have a broad discretion, respect for the rights guaranteed by the EU legal order in administrative procedures is of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case, the right of the person concerned to make his views known and also his right to have an adequately reasoned decision (see, by analogy, judgments of 21 November 1991, Technische Universität München, C-269/90,*

[1] This judgment is currently under appeal. As at the date of this Notice of Application, the written procedure and oral hearing have taken place and judgment is awaited.

EU:C:1991:438, paragraph 14, and of 13 July 2006, Shandong Reipu Biochemicals v Council, T-413/03, EU:T:2006:211, paragraph 63).

(emphasis added)

30. As to the evidentiary burden placed on applicants, they are not required to prove that the GMO in question is unsafe; rather (contrary to the Commission's submissions in that case), they are only required to provide a set of material raising serious doubts as to the lawfulness of the authorisation decision. The Court explained that this reflected the information asymmetry faced by applicants in comparison to the Commission, and the general precautionary principle under EU environmental law:

84. However, it should be noted that, under Regulation No 1829/2003, in the area of marketing authorisations for genetically modified food and feed, non-governmental organisations' access to relevant information is usually restricted to information that is publicly available and to which the Commission also had access at the time of its in-depth assessment of the risks in terms of the conditions laid down in Article 4(1) and Article 16(1) of that regulation.

85. Where the Commission concludes that the evidence adduced by a party requesting an internal review is substantial and liable to raise serious doubts as to the lawfulness or well-foundedness of the grant of that authorisation, it is required to examine all relevant information of its own motion, since its role in an internal review under Article 10 of Regulation No 1367/2006 is not that of an arbitrator, whose remit is limited to making an award solely on the basis of the information and the evidence provided by the party requesting the review (see, by analogy, judgment of 22 March 2012, GLS, C-338/10, EU:C:2012:158, paragraph 32).

86. That remit also follows from the fact that the Commission is bound by the precautionary principle, which is a general principle of European Union law. That principle, as interpreted in the Court's case-law, means that where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent (judgment of 9 September 2003, Monsanto Agricoltura Italia and Others, C-236/01, EU:C:2003:431, paragraph 111).

87. It should also be borne in mind that Article 168(1) TFEU requires that a high level of human health protection be ensured in the definition and implementation of all EU policies and activities. The protection of human health takes precedence over economic considerations, with the result that it may justify adverse economic consequences, even those which are substantial, for certain traders (see judgment of 9 September 2011, Dow AgroSciences and Others v Commission, T-475/07, EU:T:2011:445, paragraph 143 and the case-law cited).

> *88. Therefore, and contrary to the Commission's assertions in the first contested decision, the first applicant cannot be required '[to] prove that the [authorisation] decision is in breach of Regulation (EC) No 1829/2003'; rather, it must provide a set of material raising serious doubts as to the lawfulness of the authorisation decision.*
>
> (emphasis added)

III. FACTUAL BACKGROUND

31. The Maize is a genetically modified variety of maize produced by crossing MON 87427 and MON 89034 x 1507 x MON 88017 x 59122 using traditional breeding methods. MON 89034 x 1507 x MON 88017 x 59122 was obtained by conventional breeding of four single-event maize products: MON 89034, 1507, MON 88017 and 59122. As the parent organisms are both GMOs and the Maize combines their modified genetic material, it is referred to as a 'stacked event' (in contrast to an organism that contains only one mutation, which is known as a 'single event'). The combination of genetic material used in the present case results in a variety of maize that produces six insecticidal 'Cry' proteins and is resistant to both glyphosate and glufosinate herbicides.

32. Cry proteins are toxins derived from the bacterium *Bacillus thuringiensis*. They can be extracted and used as a biological pesiticide. These toxins are commonly referred to as 'Bt toxins'.

33. Glyphosate is the active ingredient in some agricultural herbicides. Glyphosate kills plants by inhibiting the enzyme EPSPS. This enzyme catalyses a critical step in the shikimic acid pathway for biosynthesis of aromatic amino acids in plants and microorganisms, and its inhibition leads to reduced protein synthesis and plant growth. The CP4 EPSPS protein has a low affinity for the glyphosate compared to the wild-type EPSA enzyme, so allows plants treated with glyphosate-based herbicides to continue to grow

34. Glufosinate (often sold as an ammonium salt) is a naturally occurring broad-spectrum systemic herbicide produced by several species of *Streptomyces* soil bacteria. It inhibits glutamine synthetase, an enzyme necessary for the production of glutamine and for ammonia detoxification. This leads to reduced glutamine and elevated ammonia levels in plant tissues, halting photosynthesis and ultimately killing the treated plant.

35. Monsanto purported to file an application in Belgium under the GM Regulation seeking market authorisation for the Maize and its segregating progeny (i.e. subcombinations that do not contain all the possible mutations). The Application Letter is dated 15 November 2013; however, the date endorsed on the technical dossiers that were required as part of the application indicates that these were not finalised until February 2014.

36. This chronology is reflected in the 'Background' section of the EFSA GMO Panel Scientific Opinion dated 28 June 2017 ("**the EFSA Opinion**") [**PD/4**], which describes what happened after the Belgian authorities passed on what they had received from Monsanto to EFSA (p. 6):

> *EFSA initiated a formal review of the application to check compliance with the requirements laid down in Articles 5(3) and 17(3) of Regulation (EC) No 1829/2003. EFSA requested additional information under completeness check on 17 January 2014 and received it on 17 February 2014. On 10 March 2014, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003…*
>
> (emphasis added)

37. In considering the application, EFSA was required to determine (*inter alia*) whether the Maize would have adverse effects on human health, animal health or the environment, contrary to Articles 4(1)(a) and 16(1)(a) of the GM Regulation. EFSA also consulted the appropriate national authorities of Member States in accordance with Articles 6(4) and 18(4) of the GM Regulation.

38. Following the consultation, EFSA issued the EFSA Opinion dated 28 June 2017 [**PD/4**]. EFSA concluded that the different combinations of the single events would not raise environmental concerns. Rather, the EFSA Panel's view was that the five-event stack maize (the Maize) was as safe and nutritious as the non-genetically modified (GM) comparator and the tested non-GM reference varieties.

39. It is apparent from the EFSA Opinion that, at this stage, EFSA believed that the application was subject to the 2013 Regulation, not the 2004 Regulation (p. 6):

> *1.1 Background*
>
> *…The GMO Panel carried out the scientific risk assessment of the five-event stack maize MON 87427 x MON 89034 x 1507 MON 88017 x 59122 and subcombinations (referred to as 'subcombinations independently of*

their origin' according to the Commission Implementing Regulation (EU)No 503/2013).

(emphasis added)

40. By contrast, the 2004 Regulation is not referred to at all in the EFSA Opinion, save in a footnote indicating that it had been amended by the 2013 Regulation (fn. 5, p. 6).

41. The Commission then issued the Commission Implementing Decision on 19 December 2018 [**PD/5**], authorising the Maize and its subcombinations to be marketed for food and feed use. Following publication of the Commission Implementing Decision, Testbiotech issued a request for internal review of the Implementing Decision under Article 10 of the Aarhus Regulation on 28 January 2019 [**PD/6**].

42. Testbiotech's request was based on a detailed technical and legal assessment of the Commission Implementing Decision set out in an Annex thereto, but in summary Testbiotech's grounds of complaint were as follows:

    42.1. Since EFSA and the applicant had not ensured that the final risk characterisation clearly demonstrated that the genetically modified food and feed would have no adverse effects on human and animal health, the Commission's decision to allow the Maize to be marketed was not in accordance with the EU regulations.

    42.2. Furthermore, the Commission had not requested methods specific to the transformation event in its post-market monitoring plan, such that in practice it would be impossible to distinguish the Maize from other similar GM events that had previously been authorised.

    42.3. The Commission should also have requested the publication of validated measures allowing the Bt concentration of the maize to be measured by independent scientists as is the case with other plant protection compounds used in food and feed production. This was necessary to make sure that the humans and animals coming into contact with the material (via dust or consumption) are not exposed to higher quantities of Bt toxins than described in the application.

43. The Commission acknowledged receipt of the request on 4 February 2019, and referred the scientific aspects of Testbiotech's complaints to EFSA for a further Opinion ("**the EFSA Technical Report**") [**PD/8**]. The EFSA Technical Report dated 18 March 2019

concluded that no new information invalidating the conclusions of the previous EFSA Opinion had been put forward and as such that the original risk assessment remained valid.

44. The Commission then issued its Decision on 20 May 2019 [**PD/9**]. The Commission acknowledged that Testbiotech fell within the ambit of Article 11 of the Aarhus Regulation and was therefore entitled to lodge a request for internal review. The Commission also accepted that Testbiotech had complied with Title IV of the Aarhus Regulation, having lodged its request within the specified time limit and having indicated the grounds upon which review was sought. However, the Commission rejected the substance of Testbiotech's complaint, on the basis of both the EFSA Technical Report and its own legal assessment, which was set out in an Annex to the Decision.

45. In the 'Preliminary Considerations' section of the Decision (p. 1), the Commission discusses the EU law applicable to Monsanto's application for a marketing authorisation in this case:

> *Furthermore, in point 1.5 of your request you indicate that Commission Implementing Regulation (EU) No 503/2013 was applied to the risk assessment of the GM stack maize. The Commission would like to clarify that Implementing Regulation (EU) No 503/2013 is not applicable to the authorisation of the GM stack maize since that Regulation only applied with general character to applications submitted after 8 December 2013. Although the Regulation entered into force of 28 June 2013, at the moment when the application for the GM stack maize was submitted (26 November 2013) a transitional regime which allowed applicants to choose between the application of Implementing Regulation (EU) No 503/2013 or Regulation (EC) No 641/2004 was in force. In the present case, the applicant requested, at the time of submission if its application for authorisation of the GM stack maize, the application of Regulation (EC) No 641/2004. Therefore, the assessment of the GM maize was carried out under Regulation (EC) No 1829/2003 and Regulation (EC) No 641/2004.*
>
> (emphasis added)

46. In the conclusion of the Decision letter, the Commission summarises its position as follows (p. 3):

> *Based on these considerations and on the assessment set out in the annex to this letter, the Commission considers that the grounds you provided in your request do not justify the need to revoke nor amend the Commission*

Implementing Decision as a result of the comprehensive administrative review carried out following your request.

47. It is this Decision that Testbiotech now seeks to challenge before the General Court.

IV. GROUNDS OF CHALLENGE

48. Testbiotech contends that the Commission has committed manifest errors of law and assessment in refusing to review its decision to grant the market authorisation. In summary, the Commission erred in proceeding on the basis that the transitional provisions applied to Monsanto's application and in assessing it under the 2004 Regulation, when it ought rather to have conducted its assessment in accordance with the more detailed requirements of the 2013 Regulation. Set against this framework, the information provided by Monsanto was inadequate, and consequently there must be (at the very least) serious doubts about the validity of the risk assessments conducted by EFSA and the Commission in reaching the Decision.

49. Testbiotech bases its challenge upon three grounds – Grounds A, B and C – which are set out below.

(a) Ground A: Error of law in assessing the application under the 2004 Regulation

50. The essence of this ground of challenge is that the Commission misapplied the transitional provisions of the 2013 Regulation and thus wrongly took the view that Monsanto's application could be assessed under the 2004 Regulation.

51. The 2013 Regulation came into force on 28 June 2013. There is no dispute that Monsanto's application for authorisation was submitted after this date. Therefore, the application fell within the scope of the 2013 Regulation as defined by Article 1 thereof, in so far as it was an application submitted under Article 5 of the GM Regulation.

52. However, the Commission appears to have taken the view that Monsanto's application was submitted before 8 December 2013 and thus that the company could rely on the transitional provisions in Article 9(1). The Commission held that Monsanto could submit its application under the 2004 Regulation and the Commission assessed the application on the basis of the 2004 Regulation.

53. In reaching this view, the Commission apparently took the date of the application as the date on which Monsanto's application letter was sent, namely 15 November 2013.[2] However, while this letter states that '*the application contains the information required in Articles 5(3) and 5(5) and 17(3) and 17(5) of Regulation (EC) No 1829/2003, and corresponding requirements from Articles 2, 3 and 4 of the Commission Regulation (EC) No 641/2004 of April 2004'* ([**PD/9**], p. 2), it appears that this was not the case. Rather, the information submitted by Monsanto on 15 November 2013 was incomplete. Therefore, no valid application was submitted before the transitional provisions in Article 9(1) expired.

54. The deficiencies in the application as originally submitted can be seen from the following:

    54.1. First, rather than declaring the application to be valid upon receipt, the result of the compliance check conducted by EFSA was that EFSA '*requested additional information under completeness check on 17 January 2014 and received it on 17 February 2014. On 10 March 2014, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003*' ([**PD/4**], p. 6).

    54.2. It follows from this that the information contained in the original application must have been materially incomplete, in so far as it must have lacked the information required by Articles 5(3) and 5(5) of the GM Regulation. As such, a valid application was only received by EFSA on 17 February 2014, after the transitional provisions had ceased to apply. This was certainly the assessment of EFSA which only declared the application valid on 14 March 2014, i.e. after the additional material had been received from Monsanto.

    54.3. Second, the date on the Technical Annexes submitted as part of the application shows that these were only finalised after the deadline had expired: at the foot of each page of these documents is written '*Completeness Check # 2 (February 2014)*' [**PD/2**].

[2] The Commission Decision (page 2) refers to the application having been submitted on 26 November 2013. This appears to be a mistake: the application appears to have been submitted to the Belgian competent authority on 15 November 2013 and then sent by the Belgian competent authority to the Commission on 26 November 2013.

54.4. Third, it is clear from the EFSA Opinion [**PD/4**] that the additional information sought from Monsanto on 17 January 2014 went to the heart of the application's validity, and was not merely non-mandatory information sought to assist in EFSA's evaluation. As such, it may be contrasted with several other subsequent requests for additional information of the latter kind that were made by the GMO Panel over the next three years while the assessment process was ongoing (p. 6): '*The GMO Panel requested additional information from the applicant on 11 June 2015, 30 July 2015, 26 November 2015, 11 December 2015, 8 March 2016, 28 June 2016, 4 August 2016,11 August 2016, 25 October 2016, 11 April 2017 and 16 May 2017.*'

Construction of the Regulations

55. As items of secondary legislation, the GM Regulation, the 2004 Regulation and the 2013 Regulation should be construed in accordance with the EU treaties and general principles of EU law.

56. Ensuring a high level of environmental protection within the internal market is one of the core purposes of the EU as laid down by Article 3(3) TEU. This is further explained in Article 191 TFEU:

> *1. Union policy on the environment shall contribute to pursuit of the following objectives:*
>
> *- preserving, protecting and improving the quality of the environment,*
>
> *- protecting human health,*
>
> *- prudent and rational utilisation of natural resources,*
>
> *- promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change.*
>
> *2. Union policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Union. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.*
>
> *3. In preparing its policy on the environment, the Union shall take account of:*
>
> *- available scientific and technical data…*

57. As such, the need to ensure a high level of environmental protection and the importance of the precautionary principle must be recognised in the context of GM authorisations. These goals would be defeated if applicants were to be permitted to submit incomplete applications as a form of 'placeholder' in order to take advantage of transitional provisions permitting reliance on a weaker authorisation procedure, in circumstances where the Community legislature has specifically developed new and more stringent authorisation procedures to take into account scientific developments (in particular, the increased prevalence of 'stacked' GM plants; see Recital 18 to the 2013 Regulation).

58. Consequently, Testbiotech contends that, in construing Article 9 of the 2013 Regulation, for an application to be submitted before 8 December 2013, this must be interpreted to mean a complete valid application, not simply an incomplete application whose lacunae can be remedied after the deadline has passed.

59. The purpose of the transitional provisions in Article 9 is explained in Recital 27:

> *This Regulation applies to applications submitted after its entry into force. It is necessary to provide for transitional measures in order to enable the applicants to comply with those rules and for the current applications or the applications close to being submitted to proceed without unnecessary delays.*
>
> (emphasis added)

60. However, at the point at which the 2013 Regulation entered into force (28 June 2013), Monsanto's application was plainly neither a current application nor an application "*close to being submitted*". The company was only able to provide EFSA with its final technical dossiers in February the following year.

61. In this context, Testbiotech submits that "*an application close to being submitted*" should be interpreted to mean 'an application which could be submitted in complete form within six months of the date of publication of the new regulation in the Official Journal' (in other words by 8 December 2013, as per Regulation 9). A more lenient construction of Recital 27 and Article 29, permitting applicants to complete their applications after the expiry of the six-month transition period, would defeat the purpose of the transitional exception and create an unnecessary loophole in the regulatory framework.

62. The importance of an application's validity for the purpose of regulatory time limits is also reflected in the 2003 Regulation. Under Article 6(1), it is provided that '*In giving its opinion, the Authority shall endeavour to respect a time limit of six months as from the receipt of a valid application*'. This reflects that time should run from the point at which a valid application is submitted.

63. Just as it would be unrealistic to expect EFSA to produce an Opinion within six months of receipt an incomplete or invalid application, so it would be contrary to the overall regulatory scheme to allow an applicant to take advantage of derogating transitional provisions by submitting an incomplete application shortly before their expiry.

No request for transitional provisions

64. Testbiotech would also note that Monsanto did not explicitly request in its letter of 15 November 2013 [**PD/1**] that its application should be treated as falling under the 2004 Regulation, rather than under the new 2013 Regulatory framework.

65. Rather than making an express request that the Maize should be assessed under the 2004 framework, the only reference to the 2004 Regulation in Monsanto's letter of 15 November 2013 is as follows:

> *This application contains the information required in Articles 5(3) and 5(5) and 17(3) and 17(5) of Regulation (EC) No 1829/2003, and corresponding requirements from Articles 2, 3 and 4 of the Commission Regulation (EC) No 641/2004 of April 2004 on detailed rules for the implementation of Regulation (EC) 1829/2003*.

66. As such, Monsanto was merely stating what information it application purported to contain, rather than making a formal request for the transitional provisions to apply.

67. In circumstances where an applicant wishes to rely on a derogating provision allowing for a less onerous basis of assessment and thus a potentially lower degree of environmental protection, Testbiotech submits that Article 9 should again be construed narrowly, such that an applicant must make its reliance on the transitional provisions explicit, rather than expecting the recipient authorities to surmise the basis on which they wish the application to be considered.

68. As such, Monsanto's failure to make this choice explicit means that EFSA and the Commission should not have examined Monsanto's application under the 2004

Regulation, but rather should have proceeded on the default basis of applying the legislation as presently in force, namely the 2013 Regulation.

EFSA's Opinion

69. Indeed, it appears that, in its original Opinion, EFSA did in fact proceed on the basis that the 2013 Regulation applied [**PD/4**]. According to the introductory summary (p. 3):

> *Following the submission of application EFSA-GMO-BE-2013-118 under Regulation (EC) No 1829/2003 from Monsanto Company (referred to hereafter as the applicant), the Panel on Genetically Modified Organisms of the European Food Safety Authority (referred to hereafter as GMO Panel) was asked to deliver a Scientific Opinion on the safety of genetically modified glufosinate-ammonium- and glyphosate tolerant and insect resistant maize MON 87427 x MON 89034 x 1507 x MON 88017 x 59122 (referred to hereafter as 'five-event stack maize') and its subcombinations independently of their origin, according to the Commission Implementing Regulation (EU) No 503/2013 (referred to hereafter as 'subcombinations').*
>
> (emphasis added)

70. This is also reflected in the EFSA GMO panel's responses to comments from Member States submitted as part of the mandatory three-month consultation process [**PD/3**]. In its summary annex of responses, the EFSA GMO Panel does not suggest anywhere that the 2013 Regulation does not apply to Monsanto's application, or that the 2004 Regulation should be applied due to the transitional provisions. Indeed, the 2004 Regulation is not referenced at any stage in this document.

71. Moreover, the German Federal Agency for Nature Conservation raised a specific concern about the absence of a 90-day feeding study in rodents. This requirement for a 90-day feeding study was a new aspect to the regulatory regime introduced by the 2013 Regulation (the detailed provisions of which were specifically referenced by the German agency in this context). Had EFSA been of the view that the 2013 regulatory framework did not apply to Monsanto's application, it could simply have dismissed this comment as irrelevant (as it often does when a Member State comment is predicated on an incorrect legal basis). However, it did not do so, but rather proceeded to offer a substantive response ([**PD/3**], p. 104):

> *In line with the applicable EFSA guidance (EFSA GMO Panel, 2011), based on the outcome of comparative analysis and on nutritional*

> *assessment, animal feeding studies on food/feed from this five-event stack maize were not considered necessary by the GMO Panel (see reply above, Reference A.4.5). The comment by Germany on available 90-day studies applies to studies provided in the context of single events; these were considered not to raise safety concerns in the context of the respective previous assessments.*

72. In summary, not only ought EFSA and the Commission to have applied the 2013 Regulation to Monsanto's application, but EFSA for its part was apparently proceeding on this basis anyway. Indeed, it appears that the first time there was any explicit suggestion that the application could be caught by the transitional provisions was after the authorisation had been granted in the Commission's Decision in response to Testbiotech's request for internal review (where Testbiotech had raised specific concerns about aspects of the 2013 regulatory structure which had not been followed).

Conclusion under Ground A

73. In conclusion, it is clear from the matters set out above that the Commission erred in law in applying the transitional provisions contained in Article 9(1) of the 2013 Regulation to Monsanto's application and thus acted unlawfully in assessing that application under the provisions of the 2004 Regulation in reaching its Decision.

(h) Ground B: Manifest errors of scientific assessment

74. Given that the 2013 Regulation was applicable, Monsanto ought to have provided in its application the information required by the Regulation's Annexes so that EFSA could then assess the application accordingly. However, this did not occur.

75. Consequently, EFSA's overall risk assessment of the Maize did not provide a proper basis for the Commission to grant authorisation. In reaching this conclusion, Testbiotech relies on a number of sub-grounds as detailed below.

Ground B(1): Failure to request data to verify whether the source of the transgene is allergenic

76. Paragraph 1.5.1 of Annex II of the 2013 Regulation requires that

> *Where transformation events have been stacked, the applicant shall provide an assessment of any potential for increased allergenicity to humans and animals on a case-by-case approach. These potential effects may arise from additive, synergistic or antagonistic effects of the gene products.*

77. In its scientific requirements dossier [**PD/2**], Monsanto purports to present an allergenicity assessment of the new protein (p. 139). However, no data was presented to show that the composition of the Maize was unchanged in terms of allergenic potential. Rather it appears that Monsanto based its assessment on the allergenic potential of the individual transformation events, rather than the new stacked GM event.

78. However, this was not sufficient for the purposes of §1.5.1 of Annex II of the 2013 Regulation, which requires (as set out above) that, for stacked events, "*the applicant shall provide an assessment of any potential for increased allergenicity to humans and animals on a case-by-case approach. These potential effects may arise from additive, synergistic or antagonistic effects of the gene products.*"

79. There might be various reasons why allergenic potential in the stacked event is increased: higher applications of glyphosate will not only cause higher levels of residue in the harvest, but may also change the composition of the plants in regard to naturally occurring allergens. However, in this case, no data were presented to assess such potential effects. Rather Monsanto appears simply to have presumed allergen levels would remain low based on the lack of allergenic potential found in earlier studies of the individual transformations (p. 139, [**PD/2**]):

> ***5.1.1. Amino acid sequence homology comparison between the newly expressed protein and known allergens using a comprehensive database***
>
> *Taken together, these data lead to the conclusion that the Cry1A.105, Cry2Ab2, Cry1F, Cry3Bb1, Cry34Ab1, Cry35Ab1, CP4 EPSPS and PAT proteins are unlikely to have any allergenic potential, and MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is as safe as conventional maize with regards to allergenicity risk.*

80. When Testbiotech raised this concern in its request for internal review, the Commission failed to engage with the point directly. Rather, in its Decision, the Commission simply endorsed Monsanto's premise that allergenicity could be assessed by considering the antecedent single events. It then adds that:

> *In addition, no new information on allergenicity of the newly expressed proteins, which might change the previous conclusions of the GMO Panel on the single events, became available during the risk assessment of the GM stack maize.* (p. 8, [**PD/10**])

81. Testbiotech, however, submits that this response misses the point. The obligation on the GMO Panel is not simply to consider whatever information may have been made available to it at a given point in time, but rather to require that the applicant conduct a proper assessment of this factor. In other words, where there is no direct information about the allergenicity of the newly expressed proteins, the applicant should provide it. Consequently, in the absence of such data, the risk assessment of this factor cannot be relied upon.

82. Moreover, Testbiotech had demonstrated that EFSA's assessment of the most relevant publication (Santos-Vigil et al., 2018) was not conclusive. Testbiotech's correspondence with the study's authors indicated that EFSA had misunderstood crucial details (in particular the purpose of the study) (p. 25, [**PD/7**]). In its response, however, the Commission failed to come up with any new facts and findings to gainsay the evidence provided by Testbiotech, but simply repeated what had been stated already (p. 8, [**PD/10**]). As such, it was simply rejecting Testbiotech's request without considering the facts and findings put forward.

Ground B(2): Failure to require Monsanto to assess the possible role of Bt toxins as adjuvants

83. Paragraph 1.5.3 of Annex II of the 2013 Regulation requires that

> *Adjuvants are substances that, when co-administered with an antigen, increase the immune response to the antigen and therefore might increase as well the allergic response. In cases when known functional aspects of the newly expressed protein or structural similarity to known strong adjuvants may indicate possible adjuvant activity, the applicant shall assess the possible role of these proteins as adjuvants. As for allergens, interactions with other constituents of the food matrix and/or processing may alter the structure and bioavailability of an adjuvant and thus modify its biological activity*

84. In its scientific dossier [**PD/2**], Monsanto purported to present an adjuvanticity assessment of the new protein (p. 141). However, in doing so it relied on the premise that the proteins involved did not share any structural similarity to known adjuvants. However, Testbiotech disputed this. There are several studies indicating that immune responses such as adjuvanticity in mammals are triggered by Bt toxins and have to be considered in this context. Studies with the Cry1Ac toxin are especially relevant (see academic literature cited by Testbiotech, p. 26, [**PD/7**]).

85. As the Bt toxin Cry1Ac was used as a source for the synthesis of Cry1A.105 expressed in the Maize, the synthetically derived Cry1A.105 toxin produced in the Maize therefore has a structural similarity to Cry1Ac. If Cry1Ac is immunogenic, Cry1A.105 is likely to be immunogenic as well. As such, Monsanto ought to have assessed the possible role of the newly expressed proteins in the Maize as adjuvants, as required by 1.5.3 of Annex II of the 2013 Regulation.

86. Indeed, in its Opinion, the EFSA GMO Panel appears to have accepted that the newly expressed protein had a structural similarity to a known adjuvant (p. 17, [**PD/4**]):

> *3.3.3.4 For adjuvanticity, proteins derived from B. thuringiensis (Bt proteins) have been suggested to possess adjuvant activity based on animal studies on Cry1Ac when applied at relatively high doses (e.g. Vazquez et al., 1999).*

87. In these circumstances, EFSA and/or the Commission ought to have required Monsanto to conduct a proper assessment of the Bt toxins expressed in the Maize rather than simply relying on the existing evidence, which the Panel noted was in any event '*limited*' (p. 17, [**PD/4**]).

88. Monsanto also failed to properly consider the potential interaction with other aspects of the consumer's dietary intake, which was also required under 1.5.3 of Annex II of the 2013 Regulation. Rather, it simply relied on the fact that the consumption of the proteins would only be at low levels and consequently unlikely to pose any risk as regards adjuvanticity.

89. In its response to Testbiotech's complaint, the EFSA Technical Report acknowledges that there are outstanding questions and uncertainties in this area (p.8, [**PD/8**]):

> *EFSA recognises that such available evidence is limited ...*
>
> *In addition, EFSA raised the point that studies appropriately designed to provide reliable answers on adjuvant and allergenic potential and, more broadly, on the effects on the immune system of Cry and of any other novel protein in general, are desirable….*

90. However, EFSA still did not request specific data to assess the potential impact of the maize on the immune system. Instead, it simply referred to a meeting of its GMO Panel in 2018 which came to the conclusion that: "*it has been experimentally shown that at the range of expression levels of Cry proteins observed in GM plants, no adjuvant effect was*

observed (e.g. Reiner et al., 2014).” [3] See page 4 of the Minutes of the 108th meeting of the Scientific Panel on GMO, 3-14-15 July 2016, Parma [**SU/15**].

91. But this statement is contrary to the facts: Reiner et al. (2014) did not give any data on the Bt content of the maize they used for a feeding study. Further, Reiner et al. used a genetically engineered maize which only produces a single Bt toxin rather than six Bt toxins as the Maize in the present case does. Therefore, the concentration in the feeding study was much lower compared to the stacked Maize approved by the Commission: the maize used in the feeding study (MON810) is known to produce only one Bt toxin, while the stacked Maize produces six toxins that add up to a much higher concentration; this was not tested in any experiment.

92. There are recent publications showing that similar concentrations of Bt toxins as produced in the maize can indeed trigger immune system responses after consumption. However, EFSA’s Technical Report [**PD/8**] simply recycles the same inadequate arguments from its original Opinion [**PD/4**] without any discussion of the new findings provided by Testbiotech.

93. In its Decision, the Commission again neglects to deal directly with Monsanto’s failure to provide the requisite assessments, and focuses rather on how an adjuvanticity assessment could be conducted on the basis of the existing evidence from single event transformations (p. 9, [**PD/10**]). However, in circumstances where a structural similarity had been found, this was not sufficient and consequently Testbiotech submits that the risk assessment of the Maize’s adjuvanticity was <u>inadequate</u>.

94. As Testbiotech demonstrated, the Bt toxins as expressed in the plants can reach high concentrations especially in products like maize gluten, which is the most relevant product for import. As an additional cause of concern, the Maize was likely to be combined with soybeans in feed products; soybeans naturally produce enzymes that can substantially delay the degradation of Bt toxins as well as produce food allergens themselves. As such, the immune responses triggered by these allergens could be considerably exacerbated by the adjuvant effects of the Bt toxins from the Maize, thereby posing a real risk to health (p. 27, [**PD/6**]).

[3] Testbiotech would also note that a member of the GMO Panel (Michelle M. Epstein) co-authored Reiner et al. (2014).

95. In the Decision, however, the Commission simply assumes that the dosage of the Bt toxins as expressed in the Maize is likely to be too low to trigger any immune reactions (p. 9, [**PD/10**]): *"Following an analysis of the available experimental evidence (…) the EFSA GMO Panel did not consider that there was a safety concern for the health of humans or animals that consume food/feed derived from the GM stack maize containing Cry proteins*."

96. However, the Commission omits to mention that there is in fact no experimental evidence which would demonstrate safety of the overall concentration and the mixtures of the Bt toxins as expressed in the maize. Consequently, the dose-effect relationship in regard to potential immune reactions could not be safely determined.

Ground B(3): Failure to request data regarding potential synergistic or antagonistic effects resulting from the combination of the transformation events in regard to toxicology and allergenicity

97. Under Annex II of Regulation 2013, the following is required:

> *I. INTRODUCTION*
>
> *2.2. The risk assessment of genetically modified food and feed containing stacked transformation events shall also include an assessment of the following aspects:*
>
> …
>
> *(c) potential synergistic or antagonistic effects resulting from the combination of the transformation events shall be subject to an assessment in accordance with Sections 1.4 (Toxicology), 1.5 (Allergenicity) and 1.6 (Nutritional assessment).*
>
> *For genetically modified food and feed containing, consisting of or produced from genetically modified plants, whose cultivation is associated with the production of genetically modified material containing various subcombinations of transformation events (segregating crops), the application shall include all subcombinations independently of their origin which have not yet been authorised. In such a case, the applicant shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations or, in the absence of such scientific rationale, provide the experimental data.*

(emphasis added)

98. Annex II of Regulation 2013 requires the following:

> ***1.4. Toxicological assessment***
>
> *The toxicological impact of any changes on the whole genetically modified food/feed resulting from the genetic modification such as the introduction of new genes, gene silencing or over-expression of an endogenous gene shall be assessed.*
>
> *Toxicological assessment shall be performed in order to:*
>
> *(a) demonstrate that the intended effect(s) of the genetic modification has no adverse effects on human and animal health;*
>
> *(b) demonstrate that unintended effect(s) of the genetic modification(s) identified or assumed to have occurred based on the preceding comparative molecular, compositional or phenotypic analyses, have no adverse effects on human and animal health…*
>
> ***1.5.1. Assessment of allergenicity of the newly expressed protein***
>
> *The applicant shall verify whether the source of the transgene is allergenic. When the introduced genetic material is obtained from wheat, rye, barley, oats or related cereal grains, the applicant shall also assess the newly expressed proteins for a possible role in the elicitation of gluten-sensitive enteropathy or other enteropathies which are not IgE-mediated. Where transformation events have been stacked, the applicant shall provide an assessment of any potential for increased allergenicity to humans and animals on a case-by-case approach. These potential effects may arise from additive, synergistic or antagonistic effects of the gene products.*

99. First, as can be seen, Regulation 503/2013 requires that an applicant provide with its application feeding studies with whole food and feed from the parental plants in any case, even if EFSA is of the opinion that no such feeding studies are needed for the stacked event. However, contrary to the legislative requirements, EFSA did not request from Monsanto feeding studies from all parental plants used for the production of the Maize and in the present case. Furthermore, EFSA did not check whether the studies already made available to EFSA, were in line with the applicable standards.

100. Moreover, one of the fundamental aspects of risk assessment to be conducted under Annex II of Regulation 2013 is that the potential synergistic or antagonistic effects resulting from the combination of transformations events should be assessed in respect of toxicology, allergenicity, and nutrition (Introduction, §2.2c, [**AU/25**]).

101. However, the EFSA Opinion [**PD/4**] in this case cannot be said to fulfil these requirements. The hypothesis which should have been used as a starting point is that

there would be synergistic effects between the various Bt toxins and between the various Bt toxins and other stressors, such as residues from spraying. Therefore, the effects of the Bt toxins in regard to mammalian cell systems and intestinal microbiomes should have been tested in combination with other stressors.

102. Furthermore, combinatorial (adjuvant) effects triggered by Bt toxins occurring in high concentration in the Maize and especially in gluten prepared from the Maize, should have been tested in interaction with known allergens, such as the one occurring in soybeans.

103. For this purpose, EFSA should have requested that Monsanto submit data from field trials with the highest dosage of glyphosate that can be tolerated by the plants (including after repeat applications of spray). The material derived from those plants should have been assessed in regard to organ toxicity, immune responses and reproductive toxicity, also taking into account combinatorial effects with other plant components and the Bt toxins. However, no such request was made.

104. In its Technical Report [**PD/8**], EFSA continues to ignore the widely known fact that combinatorial effects can change the efficacy and selectivity of Bt toxins, rendering them much more toxic than in isolation. Instead of responding to Testbiotech's findings, EFSA refers to virtually outdated literature from 1998 (p. 9; Cassee et al., 1998, wrongly introduced by EFSA as Cassee et al. 2008). Moreover, some of its reasoning is effectively circular: EFSA refers to an industry study (Koch et al., 2015), claiming that Bt plants are safe (p. 10), despite the fact this study was itself based on previous EFSA opinions.

105. Furthermore, EFSA ignored evidence that there were certain specific hypotheses that needed to be tested. Specifically, it dismissed the need for any feeding trials with the whole food and feed derived from the maize to investigate organ toxicity, immune response and reproductive toxicity (p. 11, [**PD/8**]):

> *Regarding the use of animal feeding studies to address potential uncertainties on stacked events, EFSA underlines that the sensitivity of such studies to indicate the presence of adverse effects related to the test material is limited, due to various hurdles, such as dose level, unless a clear test-hypothesis is identified.*

106. EFSA thus ignores that there are that in fact several hypotheses that do need to be tested, such as whether the consumption of Bt toxins as produced in the plants in combination with other stressors (such as residues from spraying) can make them make them even more toxic and whether depending on the dosage, the consumption of Bt toxins produced in the plants can cause immune system responses. Again, the EFSA position reveals a lack of scientific rigour and fails to comply with the requirements of the 2013 Regulation.

107. Instead of investigating the effects of these mixtures of toxins, the most relevant question (the effect of residues from spraying in combination with the insecticidal proteins) is largely excluded from the EFSA Technical Report [**PD/8**]:

> *Regarding Testbiotech's consideration that pesticides residues (and their metabolites) and related amounts should be considered in the assessment of GM crops, EFSA recalls that the assessment of residues is not under the remit of the EFSA GMO Panel.* (p. 10)

108. In view of the foregoing, then, no reliable conclusion could be drawn on health effects triggered by the consumption of products derived from the maize, and the safety of food and feed derived from the maize as required by law has not been demonstrated. The EFSA assessment therefore failed to comply with the requirements of the 2013 Regulation.

109. In its Decision (p.11, [**PD/10**]), the Commission simply tries to explain why the lack of any risk on these grounds could be inferred from existing evidence, which, in the circumstances, Testbiotech submits was inadequate.

110. The Commission assumed that immune reactions or toxicity could not be enhanced by delay in degradation of the Bt toxins after consumption. Testbiotech provided publications reporting that enzymes (such as those produced by soybeans) may substantially prolong the exposure to Bt toxins and therefore substantially increase toxicity. The Commission (and EFSA) did not come up with any new facts to challenge these findings, or any data demonstrating the safety of food and feed derived from the stacked maize if fed together with plants such as soybeans. Consequently, the Commission was rejecting Testbiotech's complaint without adequate scientific reasoning and ignoring the evidence provided in breach of the requirements of the relevant legislation.

111. Furthermore, the Commission assumed that there was no need to further investigate interactions amongst the different Bt toxins or between Bt toxins and other stressors that were likely to be present in consumers' diets. However, as Testbiotech had shown, there is plenty of evidence that toxicity of Bt toxins can differ in regard to efficacy and selectivity if co-exposed in combination with other Bt toxins and chemicals.

112. Most relevant in this context are the residues from spraying with the complementary herbicides. However, contrary to what is evidenced, the Commission concluded that it was sufficient to assess the Bt toxins in isolation and no data in regard to their mixed toxicity would be necessary. In so doing so, the Commission is simply ignoring a substantial body of scientific evidence contrary to the requirements of the relevant legislation.

113. The Commission then goes on to reiterate that the residues from spraying with the complementary herbicides would have been assessed under EU pesticide regulation already (p. 14, [**PD/10**]). To justify this assumption, the Commission referred to data from herbicide applications on conventionally bred maize. As such, it fails to acknowledge that there are specific patterns of residues from the complementary herbicides in the plants in regard to the active ingredients, the additives and their combinations. Again, then, the Commission's answer proceeds on an inappropriate evidential basis contrary to the requirements of the relevant legislation.

114. Testbiotech is also aware that feeding studies with similar stacked maize indicated potential health impacts such as inflammatory reactions in the stomach (Zdziarski et al., 2018). Therefore, it had requested the testing of food and feed derived from the Maize as whole mixtures. However, no such feeding studies to investigate potential health effects with the stacked maize were conducted contrary to the requirements of the relevant legislation.

Ground B(4): Failure to request data from field trials necessary to assess effect of expected agricultural practices on studied endpoints

115. Paragraph 1.3.1 of Annex II of the 2013 Regulation requires

> ***1.3.1. Choice of the conventional counterpart and additional comparators***
>
> *In the case of herbicide tolerant genetically modified plants and in order to assess whether the expected agricultural practices influence the expression of the studied endpoints, three test materials shall be compared: the genetically modified plant exposed to the intended herbicide; the conventional counterpart treated with conventional herbicide management regimes; and the genetically modified plant treated with the same conventional herbicide management regimes.*
>
> (emphasis added)

116. The 2013 Regulation therefore requires the assessment of the studied endpoints to be conducted with reference to data from three specific comparative scenarios: (i) the GM plant treated with the intended dosage of herbicide; (ii) the plant's conventional equivalent treated with conventional herbicide; and (iii) the GM plant treated with conventional herbicide.

117. This kind of thorough assessment of possible endpoints is important, as the agricultural processes employed (and in particular herbicide use) may make a significant difference to gene expression, agronomic performance and plant composition. This data is highly relevant for the assessment of health risks because it is important that the herbicide regime and the material chosen for measuring the endpoints represents those products that will be actually used for food and feed production.

118. However, in the case of the Maize, the design of the field trials did not allow any assessment of whether the expected agricultural practices will influence the relevant endpoints: as is clear from Monsanto's application (p. 83, [**PD/2**], only one dosage of each of the complementary herbicides was sprayed onto the Maize during the field trials:

> *The application was made to all rows when plants were at approximately the V2-V4 growth stage. The glyphosate treatment was applied at approximately 1.1 kg a.i./ha (kilograms of active ingredient per hectare). Following the glyphosate treatment, a sequential treatment of glufosinate was applied (…). The application was made to all rows when plants were at approximately the V3-V6 growth stage. The glufosinate treatment was*

applied at approximately 0.45 kg a.i./ha (kilograms of active ingredient per hectare).

119. However, EFSA did not any request further data on the expected agricultural practices regarding the application of the complementary herbicides in the various regions where the Maize is to be grown. As a result, no proper assessment of whether the expected agricultural practices might influence the expression of the studied endpoints was possible. Crucially, the tested plant materials are not representative of the material that will enter the food chain.

120. The data as presented show a high number of significant differences (approximately 75% of the analytes evaluated for plant composition). Even if changes taken as isolated data might not directly raise safety concerns, the overall number of effects and their clear statistical significance should have been taken as a starting point for much more detailed investigations.

121. If the field trials had been performed under realistic conditions and with the respective herbicide regimes, a much broader range of significant differences could have been expected. Based on these data, the field trials should have been designed to assess whether the expected agricultural practices influence the expression of the studied endpoints, and to make sure that the plant materials used in the assessment of comparative plant composition and the agronomical characteristics are representative of those designed for import. Consequently, the findings based on inapposite comparative assessment of plant composition and agronomic characteristics could not be relied upon.

122. Rather, the hypothesis that should have been used as a starting point is that plant composition can be changed by the herbicide regime (dosage, number of sprayings, time of sprayings, mix of active ingredients, and the like). EFSA should have requested representative data on herbicide regimes as established in all the regions where the Maize will be cultivated. In addition, EFSA should have requested that Monsanto submit data from field trials with the highest dosage of glyphosate that can be tolerated by the plants, also including repeated spraying. The material derived from those plants should have been assessed in regard to gene expression, plant composition and agronomic characteristics. Further, the material should have been used to investigate organ toxicity, immune responses and reproductive toxicity, also taking combinatorial effects with other plant components and the Bt toxins into account.

123. In its Technical Report [**PD/8**], EFSA accepted that Monsanto's data came from field trials conducted in non-realistic conditions. Industry recommendations suggest several sprayings and dosages of the herbicides of up to 0.7 kg a.i./ha glufosinate and 3.5 kg a.i./ ha glyphosate; but in the field trials Monsanto only applied around 0,45 kg a.i./ha glufosinate and 1,1 kg a.i./ha glyphosate, with each herbicide only sprayed once. Furthermore, Monsanto only performed field trials in the US, although the intention is to grow the maize in Brazil and Argentina as well.

124. EFSA justifies its assessment by referring to a somewhat obsolete publication by Nurse et al. (2006) and by stating that '*it is considered unfeasible in practice to assess herbicide tolerant GM plants under all possible scenarios*' (p. 13, [**PD/8**]). This statement is surprising. Testbiotech did not request that all possible scenarios should have been tested. However, Monsanto should have at least applied the maximum dosages in the field trials in accordance with official recommendations. Further, field trials should have been conducted in all major genetically-engineered maize-producing regions as required by the relevant legislation.

125. Overall, then, EFSA failed to address Testbiotech's complaint that the data from Monsanto's field trials was inadequate to assess whether expected agricultural practices would influence the safety of the products derived from the Maize, as the 2013 Regulation requires.

126. In its answer on this point in the Decision [**PD/10**], the Commission does not acknowledge the regulatory requirements of 1.3.1 of the Scientific Requirements sections of Annex II of the 2013 Regulation, but instead offers similar reasons why it took the view that the field trials carried out did allow proper conclusions to be drawn as regards safety. It observes, inter alia, that '*it is considered unfeasible in practice to assess herbicide tolerant GM plants under all possible scenarios*' (p. 17, [**PD/10**]). However, this was not of course what Testbiotech was suggesting was required. Certainly, Annex II of the 2013 Regulation does not require data from all possible scenarios, but only from those in which the plant is likely to be grown. Consequently, EFSA's failure to require such data from Monsanto was a further vitiating factor in its risk assessment.

Ground B(5): Failure to request data from field trials reflecting appropriate meteorological and agronomic conditions

127. Paragraph 1.3.2.1(b) of Annex II of the 2013 Regulation requires that

> ***1.3.2.1(b) Specific protocols for experimental design***
>
> *The different sites selected for the field trials shall reflect the different meteorological and agronomic conditions under which the crop is to be grown; the choice shall be explicitly justified. The choice of non-genetically modified reference varieties shall be appropriate for the chosen sites and shall be justified explicitly…*

128. Therefore, under Annex II of the 2013 Regulation, specific protocols for experimental design are required, so as to reflect the different meteorological and agronomic conditions under which the crop is to be grown. However, the field trial data produced by Monsanto only represented a very narrow range of conditions. As such, it was wholly inadequate and failed to comply with the requirements of the relevant legislation.

129. As regards meteorological conditions, the field trials carried out by Monsanto only represent one year and one maize growing region. In addition, data from the field trials affected by more extreme weather conditions was excluded from the assessment (p. 82, [**PD/2**]).

130. As a result, given the variety of regions where the Maize will be cultivated (including Argentina and Brazil), the range of the respective data from the field trials used in the risk assessment was too narrow to reflect the real conditions of cultivation. This data considered failed to represent the different meteorological conditions under which these plants may be cultivated in other regions and over longer time periods.

131. As regards agronomic conditions, the data from field trials also fails to reflect the different conditions under which the crop is to be grown. As shown above, further data was needed on established herbicide regimes in all the regions where the Maize will be cultivated (see previous sub-ground). In addition, reactions to defined biotic stressors, such as bacterial and fungal diseases, were not tested.

132. Overall, then, the data used for assessing the expression of the additional enzymes and the comparison of the plants' composition under different agronomic conditions were only collected from field conditions in the US for one year and excludes data from more extreme weather conditions. As a result, the plants were not exposed to a sufficiently

broad range of agronomic practices and relevant stress factors (biotic and abiotic) as required by the relevant legislation.

133. Accurate data on the actual range of growing conditions is important, as variation in environmental factors may cause variation in gene expression, plant composition and phenotypical characteristics of genetically engineered plants. Environmental stress can cause unexpected patterns of expression in the newly introduced DNA. Genome x environment interactions can also cause dysfunctional reactions or other unexpected effects in transgenic plants.

134. Especially relevant in this context are the findings of Fang et al. (2018), which show that stress conditions can affect the characteristics of genetically engineered plants inheriting additional EPSPS enzymes on several levels [**SU/16**]. With this Maize, it is important to note that, compared to previous stacked events, an additional EPSPS enzyme had been added by further crossing with MON 87427.

135. Based on the scientific evidence available, EFSA should have started from the hypothesis that differences in meteorological and agronomic conditions can affect the expression rate of the additionally inserted DNA sequences, plant composition and agronomic characteristics. Thus, EFSA should have requested further studies involving, for example, field trials lasting more than one season, field trials in other maize growing regions, and field trials with the maximum possible glyphosate dose.

136. Consequently, since the data sets used in the risk assessment do not sufficiently reflect the different meteorological and agronomic conditions under which the crop is to be grown, the outcome regarding the protein expression data assessment, as well as that for the comparative assessment of plant composition and agronomic characteristics, could not be relied upon.

137. In its Decision [**PD/10**], the Commission did not dispute that the field trials relied on by Monsanto were conducted in a single year and in the United States only. Nevertheless, it maintains that these were nevertheless adequate, despite the fact that these did not represent the real range of likely growing conditions. As with the previous subground, the Commission observed that it was not feasible to assess a new GM crop under all possible ‘receiving environments’ (p. 19, [**PD/10**]).

138. Again, this misconstrues Testbiotech's complaint, which was that the trials that had been conducted were unrepresentative, not least in circumstances involving a GM plant expressing additional EPSPS enzymes (which are known to show unexpected reactions to environmental stressors) and therefore did not comply with the relevant legislation.

Ground B(6): Failure to request sufficiently reliable protein expression data from the newly introduced proteins

139. Paragraph 1.2.2.3 of Annex II of the 2013 Regulation requires the following

> ***1.2.2.3. Information on the expression of the insert(s)***
>
> *The applicant shall provide information:*
>
> — *to demonstrate whether the inserted/modified sequence results in intended changes at the protein, RNA and/or metabolite levels;*
>
> — *to characterise the potential unintended expression of new ORFs identified under point 1.2.2.2(f) as raising a safety concern.*
>
> *For those purposes, the applicant shall provide the following information:*
>
> *...(e) Protein expression data, including the raw data, obtained from field trials and related to the conditions in which the crop is grown…*

140. An important information requirement under Annex II of the 2013 Regulation is '*protein expression data, including the raw data, obtained from field trials and related to the conditions in which the crop is grown*' (1.2.2.3(e)). This assists in assessing whether an alteration in the genetic sequence results in intended changes at the protein, RNA, or metabolite levels and in identifying any potential unintended protein expressions that might raise safety concerns.

141. In its complaint [**PD/7**], Testbiotech identified evidence that (contrary to the EFSA assessment), the expression of the two enzymes conferring herbicide resistance and the expression of Bt toxins tended to be higher in the stacked Maize than the parental comparator plants (p. 35, [**PD/7**]). Consequently, EFSA ought to have requested further data to determine likely protein expression in the conditions in which the Maize would <u>actually</u> be grown.

142. In its Technical Report [**PD/8**], however, EFSA proceed to ignore the new scientific evidence in this field. Especially relevant in the context of this stacked Maize are the findings of Fang et al. (2018), showing that stress conditions can affect the

characteristics of genetically engineered plants that inherit additional EPSPS enzymes. This publication is specifically relevant because in comparison to previous stacked events, an additional EPSPS enzyme was added to the maize genome by crossing the parental plants with maize MON 87427 (another genetically modified variety).

143. The findings of Fang et al. (2018) raise specific questions on gene expression. As shown by the data available, Bt expression in the stacked maize is indeed higher under 'normal field conditions' compared to Bt expression in the parent plants. Under more extreme weather conditions than normal (increasingly likely given ongoing climate change), these effects can be considerably stronger and lead to a much higher concentration of Bt toxins than expected. Therefore, this potentially higher Bt content, together with the other changes in plant composition that may be triggered by stress conditions, ought to have been assessed in detail.

144. Indeed, EFSA's Technical Report does in fact acknowledge the need for more detailed assessment of gene expression. For example, it states (p. 18, [**PD/8**]):

> *… the possible consequences on the protein levels are unpredictable, i.e. may result in either higher or reduced protein levels.*

145. In its Decision, the Commission also accepts that environmental conditions and agricultural practices may affect protein expression (p.21, [**PD/10**]). However, it then goes on to explain why in its view the limited protein expression data Monsanto had provided was adequate.

146. However, this again glosses over the key issue, which was that the conditions under which the data was derived were <u>not</u> representative of those in which the Maize was to be grown, and consequently EFSA's conclusions on the likelihood of interactions affecting levels of the newly expressed proteins could not be relied upon.

Ground B(7): Failure to require data on subcombinations

147. Paragraph 2.2 of the Introduction to Annex II of the 2013 Regulation requires the following:

> ***I. INTRODUCTION***
>
> *2.2. The risk assessment of genetically modified food and feed containing stacked transformation events shall also include an assessment of the following aspects:*
>
> *(a) stability of the transformation events;*
>
> *(b) expression of the transformation events;*
>
> *(c) potential synergistic or antagonistic effects resulting from the combination of the transformation events shall be subject to an assessment in accordance with Sections 1.4 (Toxicology), 1.5 (Allergenicity) and 1.6 (Nutritional assessment).*
>
> *For genetically modified food and feed containing, consisting of or produced from genetically modified plants, whose cultivation is associated with the production of genetically modified material containing various subcombinations of transformation events (segregating crops), the application shall include all subcombinations independently of their origin which have not yet been authorised. In such a case, the applicant shall provide a scientific rationale justifying that there is no need to provide experimental data for the concerned subcombinations or, in the absence of such scientific rationale, provide the experimental data.*
>
> (emphasis added)

148. In its request for internal review, Testbiotech explained that the expression of Bt toxins in the Maize shows a notably different pattern of expression compared to the stacked maize MON89034 x 1507 x MON88017 x 59122, which had been assessed previously and produces the same Bt toxins (p. 36, [**PD**/**7**]).

149. Despite this divergence, Monsanto had not presented any data on subcombinations for the Maize. This was important, as some of the subcombinations might only be resistant to one of the complementary herbicides or produce toxins only for specific target pest organisms and will therefore be cultivated under certain agronomic conditions. Testbiotech also drew attention to a statement to this effect made by an expert on the EFSA GMO panel in a minority opinion in 2018 (p. 37, [**PD**/**7**]).

150. Under paragraph 2.2 of the Introduction to Annex II of the 2013 Regulation, applicants are required to produce experimental data on subcombinations unless they can provide a scientific rationale to the contrary.

151. However, Monsanto in its application merely assumed that it could rely on the data from the individual transformations as single events. In view of the complex and unpredictable effects of stacking known from previous studies, Testbiotech contends that this rationale was plainly inadequate, and EFSA ought to have required data from further field trials involving all the potential subcombinations not yet authorised.

152. In its response to this point in the Decision, the Commission does not dispute that data was not provided for each subcombination, but instead defends its approach on the grounds it took a 'weight of evidence' approach (p. 22, [**PD/10**]).

153. However, it is clear that the evidence 'weighed' was in fact data from the constituent single transformation events and certain previously examined subcombinations: consequently, such evidence provided no proper basis for concluding that some new subcombination (particular when grown under different agronomic and environmental conditions) would not have different protein expression characteristics. As such, the response fails to engage with the substance of Testbiotech's complaint and fails to comply with the relevant legislative requirements.

Ground B(8): Failure to request data on geneflow to other species

154. Articles 4(1)(a) and 16(1)(a) of the GM Regulation require that food or feed derived from GMOs must not have adverse effects on *inter alia* the environment and a marketing authorisation cannot be granted until the Commission has determined that this is the case. In reaching that determination, the Commission must apply the precautionary principle. Moreover, the Court has held that, where a party requesting internal review adduces evidence which is "*substantial and liable to raise serious doubts as to the lawfulness or well-foundedness of the grant of that authorisation, [the Commission] is required to examine all relevant information of its own motion*" and in line with the precautionary principle, i.e. "*where there is uncertainty as to the existence or extent of risks to human health, protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent*": see judgment in Case Case T-177/13 *TestBiotech eV v Commission*, cited in paragraph 29 above.

155. The potential risks from GM crops due to invasiveness and persistence from plant-to-plant geneflow are specifically considered in the EFSA Guidance on environmental risk assessment of GM plants [**AU/24**]. As the Guidance explains (p.40),

> *First, enhanced fitness of the GM plant or of transgenic (introgressed) wild relatives within production systems may make them more persistent, exacerbating weed problems that may need to be controlled by more complex weed control strategies, which themselves might cause environmental harm. Second, enhanced fitness of transgenic feral plants, or of transgenic (introgressed) wild relatives in semi-natural or natural habitats may reduce the diversity/abundance of valued flora and fauna. For instance, native plant species may be displaced, which in turn might affect species that use those plants as food, shelter, etc. Alternatively, and depending on which plant and which transgenes are involved, gene flow to wild relatives may decrease the fitness of hybrid offspring. If rates of gene flow are high, this may cause wild relatives to decline locally, or to become extinct (e.g. swarm effect, outbreeding depression). Therefore, problem formulation should focus on the potential of a GM plant to be more persistent or invasive than conventional counterparts, and on the potential for gene flow to compatible relatives whose hybrid offspring may become more weedy or invasive, or may suffer from outbreeding depression…It should also consider viable GM plant seeds or propagules spilled during import, transportation, storage, handling and processing that can lead to feral plants that colonize and invade ruderal, semi-natural and natural habitats.*

156. The Guidance then recommends a staged approach to ensure that the relevant case-specific information is supplied. This is illustrated on p.43 of the Guidance [**AU/24**]. However, for all GM plants, the first stage is as follows (p.41):

> *Stage 1 consists of providing event-specific information that enables the GM plant to be characterised, identifying intended and potential unintended differences between it and conventional counterparts. Information provided should be used to establish whether (1) the GM plant can grow, reproduce and overwinter under EU conditions, and if so (2) how its growth, reproduction and overwintering characteristics compare to its conventional counterpart. It is possible that GM traits may move to wild relatives through hybridisation within one growing season, even if the GM plant is unable to overwinter – consequently, it is important that the hybridisation potential described in the background information is considered before concluding on stage 1 information requirements. It should thus be considered whether sexual compatibility with any relative species is altered since this may result in differences in the rate of gene flow and the establishment of transgenes in other species.*

157. For GM varieties that can reproduce or overwinter in the EU, Stage 2 analysis is then required, which involves exploring whether the GM trait will enhance the potential for the GM plant to contribute to contribute to volunteer populations and persist in production systems, and hence the potential environmental consequences.

158. However, in this case the required information was not provided. In its request for internal review, Testbiotech noted that the information on potential gene flow given by Monsanto in its application was substantially incorrect or out of date (p. 38, [**PD/7**]). Importantly, it omitted consideration of teosinte, a wild ancestor of cultivated maize found in France and Spain; it underplayed the 'volunteer potential' of the Maize (potential to grow wild); and it did not consider the effect of the new crop's double resistance to glyphosate in terms of potential geneflow.

159. In response, the Commission defends Monsanto on the grounds that some of the evidence cited by Testbiotech was not available at the time of its application (p. 24, [**PD/10**]). However, this cannot mean that it is information that the Commission can ignore in its risk assessment given it is now available. Subsequently, while the Commission does acknowledge the potential for vertical gene transfer to teosintes and other weedy *Zea* species, it ultimately maintains that the chances of cross-pollination from spillage are low and the environmental effects of the spread of would be low because of the similarity to conventional maize varieties (p. 25, [**PD/10**]).

160. Testbiotech submits that this is simply supposition, and consequently that the Commission has provided no proper basis for rejecting its complaint. In particular, the Commission fails to address the point (supported by recent scientific findings) that the new Maize might behave in a significantly different manner in comparison to conventional varieties and consequently that new data was required.

161. As to the EFSA Risk Assessment Guidance, as the Maize was capable of growing under EU conditions, data should then have been requested to assess the potential for hybrid offspring from teosinte and the Maize. However, no such data were provided.

162. The consequences of unforeseen gene flow can be serious. After spillage, hybridisation can take place producing viable offspring which are able to persist and propagate further. New 'superweeds' may then emerge, with multiple resistance to herbicides and insects. Hence, in the absence of data on the potential spread from spillage, no proper environmental risk assessment could be conducted and the precautionary principle was breached.

Ground B(9): Failure to ensure the final risk characterisation clearly demonstrated the absence of adverse effects on human and animal health or the environment

163. Paragraph 3.3 of Annex II of the 2013 Regulation requires

> ***3.3. The result of risk characterisation***
>
> *In accordance with the requirements of Articles 4 and 16 of Regulation (EC) No 1829/2003, the applicant shall ensure that the final risk characterisation clearly demonstrates that:*
>
> *(a) the genetically modified food and feed has no adverse effects on human and animal health…*

164. This reflects the requirements of Articles 4(1)(a) and 16(1)(a) of the GM Regulation.

165. By way of conclusion to the eight previous sub-grounds, Testbiotech submits that the omissions in the information and data provided by Monsanto in its application meant it failed to demonstrate the absence of adverse effects of this kind, contrary to the concluding paragraph 3.3 of the Scientific Requirements section of Annex II of the 2013 Regulation.

166. As EFSA failed to require Monsanto to produce the necessary data, it was not in a position to perform an adequate risk assessment of the Maize, and consequently the Commission ought not to have relied on the conclusions of its Opinion in making the Commission Implementing Decision [**PD/5**] granting authorisation. Neither EFSA's Technical Report [**PD/8**] following the request for internal review, nor the Commission Decision [**PD/10**] based upon this, have displaced these objections.

(i) Ground C: Failure to request an event-specific post marketing monitoring plan

167. By Articles 5(3)(i) and (j) and Articles 17(3)(i) and (j) of the GM Regulation, an application for a marketing authorisation has to include

> *(i) methods for detection, sampling (including references to existing official or standardised sampling methods) and identification of the transformation event and, where applicable, for the detection and identification of the transformation event in the food and/or in foods produced from it;*
>
> *(j) samples of the food and their control samples, and information as to the place where the reference material can be accessed;*

168. Further, by Articles 5(3)(k) and 17(3)(k) of the GM Regulation, such an application also has to include "*where appropriate, a proposal for post-marketing monitoring regarding the use of food for human consumption*".

169. Article 3.1.(c) of Annex III of the 2013 Regulation requires

> ***3.1. Information about the method***
>
> *C. The applicant shall demonstrate that the method(s) fulfils the following requirements:*
>
> *1. <u>The method(s) shall be specific to the transformation event (hereafter referred to as 'event-specific') and thus shall only be functional with the genetically modified organism or genetically modified based product considered and shall not be functional if applied to other transformation events already authorised</u>; otherwise the method cannot be applied for unequivocal detection/identification/quantification. This shall be demonstrated with a selection of non-target transgenic authorised transformation events and conventional counterparts. This testing shall include closely related transformation events…*

170. The purpose of the 'event-specificity' requirement is so that the stacked event in question can be identified in the market when necessary. For example, if unexpected hazardous health effects are observed in a region where the GM product is imported and consumed, the authorisation-holder and the authorities need to be able to identify whether the stacked event was present in the food chain in order to decide whether the stacked event was responsible for those effects. The ability to trace and identify the specific GM trait is also important in case the market authorisation is withdrawn or not renewed after ten years (see Article 7(5) of the GM Regulation [**AU/21]**).

171. However, this critical element of post-marketing environmental protection was plainly absent from the monitoring plan put forward by Monsanto, which was limited to three short paragraphs in its application dossier (p. 163, [**PD/2**]):

> *As demonstrated in this application, there are no intrinsic hazards related to MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 or any of its sub-combinations. No data has emerged to indicate that MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 or any of its sub-combinations is less safe than its conventional counterpart.*
>
> *The pre-market risk characterisation for food and feed use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 demonstrates that the risks of consumption of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 or any of its sub-combinations and its derived products are no*

different from the risks associated with the consumption of conventional maize and maize-derived products.

As a consequence, specific risk management measures are not indicated and post-market monitoring of the use of MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 or of any of its sub-combinations for food and feed is not considered necessary."

172. In essence, Monsanto was simply proceeding on the basis that the new GM stacked event would be safe and no post-market monitoring was necessary. However, even in the absence of specific risks identified at this stage, there must still be the possibility of tracing a GM plant back to its source if problems arise in the future. A method based simply on identifying gene constructs (as proposed by Monsanto) fails to provide this.

173. Thus, in circumstances, where Monsanto had wholly ignored the 'event-specificity' requirement, the Commission ought have to requested an amended post-market monitoring plan, and should not have granted the market authorisation in its absence.

V. CONCLUSION

174. For the reasons given above, Testbiotech invites the Court to grant the relief sought in Paragraph 3 above.

KASSIE SMITH QC

ALFRED ARTLEY

26 July 2019