London, 26 January 2016

IN THE GENERAL COURT OF THE EUROPEAN UNION

TESTBIOTECH

Applicant

Represented by Kassie Smith QC and Julianne Kerr Morrison (nee Stevenson), Barristers, Monckton Chambers; Richard Stein, Partner, Leigh Day

against

THE EUROPEAN COMMISSION **Defendant**

APPLICATION FOR A JUDICIAL REVIEW
Case No. [ ]

Testbiotech e.V.
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Germany

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Annexes are referred to as **"[A. (Annex No.)/Page no.]"**

I. INTRODUCTION

(a) Summary of the Claim

1. The Applicant (**"Testbiotech"**) challenges the European Commission's decision, dated 16 November 2015, refusing Testbiotech's request for it to review its implementing decisions of 24 April 2015 granting three market authorisations under Regulation 1829/2003 on genetically modified food and feed ("**the GM Regulation**") to Monsanto or Pioneer for their genetically modified soybeans MON 8879, MON 87705 and/or 305423 ("**the Soybeans**"). This decision will hereinafter be referred to as the **"Commission Decision" [A.2/25-32]**. Testbiotech's request for review is at **[A.1/1-24]**.

2. The request for review was made pursuant to Article 10 of Regulation 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Environmental Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (**"the Aarhus Regulation" [A.13/178-184]**).

3. The three implementing decisions are Decisions 2015/686 **[A.3/33-38]**, 2015/696 **[A.4/39-44]** and 2015/698**[A.5/45-50]** (**"the Market Authorisations or the Implementing Decisions"**). The Market Authorisations permit the importing, processing and use of the Soybeans for feed and food uses, but excludes cultivation in the EU.

4. The Grounds upon which Testbiotech challenges the Commission Decision are, in summary:

    a. The Commission's conclusion that the vast majority of the request for internal review related to matters falling out with the scope of the Aarhus Regulation violates Article 10(1) read in conjunction with Articles 2(f) and (g) and Recitals (11) and (18) to (21) of that Regulation.

    b. The Commission's failure to respond to the request for internal review, submitted on 29 May 2015, until 16 November 2015 violated Article 10(3) of the Aarhus Regulation.

5. Testbiotech's request for internal review asked the Commission to review the substantive compatibility of the Market Authorisations with key environmental laws **[A.1]**. Given the Commission's failure to treat the vast majority of the request for internal review as falling within the scope of the Aarhus Regulation, it has failed to address these issues of substance in a decision which can be challenged pursuant to the Aarhus Regulation. Testbiotech therefore reserves its position in relation to the substantive matters raised in its request for internal review.

(b) Relief sought

6. Testbiotech requests that the Court:

    a. declare the application admissible and well-founded;

b. annul the contested decision;

c. order the Commission to pay Testbiotech's costs; and

d. order any other measure deemed appropriate.

(c) Testbiotech's standing

7. Testbiotech, Institute for Independent Impact Assessment of Biotechnology, is a not-for-profit making association registered in Germany at Frohschammerstr. 14 80807 Munich. It is included in the Register of Associations at the Amtsgericht Muenchen (local court, Munich) VR 202119 (see Statute/Articles of Association at **[A.20/393-403]** and Registration Document at **[A.21/404]**. 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.

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

(d) Testbiotech's existing application for annulment and proposal for joint management of the issues raised in relation to the interpretation of the Aarhus Regulation

9. Testbiotech is also one of the applicants in Case T-177/13. In Section V below, Testbiotech has set out proposals for the future joint handling of the applications. Testbiotech envisages providing the Court with confirmation from its co-applicants in T-177/13 that they are happy with its proposals shortly.

II. APPLICABLE LAW

(a) The TFEU

10. Article 43 Treaty on the Functioning of the European Union (**"TFEU"**), ex Article 37 of the Treaty establishing the European Community (**"TEC"**) **[A.22]**, is one of the Treaty provisions relating to Agriculture and Fisheries. That provision addresses the manner in which proposals relating to the common agricultural policy should be processed. Article 114 TFEU, ex Article 95 TEC **[A.22/409]**, makes provision for the approximation of laws in order to achieve the establishment and functioning of the internal market.

11. Article 168 TFEU, ex Article 152 TEC **[A.22/411-412]**, makes specific provision for public health measures, stating:

> *"1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. …

3. …

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use."

12. The term phytosanitary means of, relating to or being measures for the control of plant diseases especially in agricultural crops. Article 6(a) TFEU provides that the EU has competence to carry out actions to support, coordinate or supplement the actions of the Member States in relation to the protection and improvement of human health **[A.22/406]**. The EU and the Member States share competence in respect of environmental matters (Article 4(2)(e) TFEU **[A.22/405]**).

13. Article 191 TFEU provides, insofar as relevant, that:

"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.*
>
> *In this context, harmonisation measures answering environmental protection requirements shall include, where appropriate, a safeguard clause allowing Member States to take provisional measures, for non-economic environmental reasons, subject to a procedure of inspection by the Union."*[1]

14. Article 192 provides for proposals to achieve the objectives set out in Article 91 TFEU to be considered and enacted in accordance with the ordinary legislative procedure by the European Parliament and the Council, except in relation to certain areas such as those affecting town and country planning, which the Council may adopt unanimously **[A.22/415-416]**.

(b) The Aarhus Convention

15. The Convention on access to information, public participation in decision-making and access to justice in environmental matters (**"the Aarhus Convention"**) was signed in Aarhus on 25 June 1998 and approved on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005 (OJ 2005 L 124, p. 1) **[A.12/153-177]**.

16. The Recitals to the Aarhus Convention state, insofar as relevant, that:

> *"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 that, in the field of the environment, improved access to information and public participation in decision-making enhance the quality and the implementation of decisions, contribute to public awareness of environmental*

1 **[A.22/415]**.

issues, give the public the opportunity to express its concerns and enable public authorities to take due account of such concerns, Aiming thereby to further the accountability of and transparency in decision-making and to strengthen public support for decisions on the environment,

Concerned that effective judicial mechanisms should be accessible to the public, including organizations, so that its legitimate interests are protected and the law is enforced,

Recognizing the concern of the public about the deliberate release of genetically modified organisms into the environment and the need for increased transparency and greater public participation in decision-making in this field…"[2]

17. Article 1 explains the objective of the Aarhus Convention, as follows: *"In order to contribute to the protection of the right of every person of present and future generations to live in an environment adequate to his or her health and well-being, each Party shall guarantee the rights of access to information, public participation in decision-making, and access to justice in environmental matters in accordance with the provisions of this Convention."*[3]

18. Article 2(3) defines the term *"environmental information"* as being *"any information in written, visual, aural, electronic or any other material form on"*:

"(a) The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;

(b) Factors, such as substances, energy, noise and radiation, and activities or measures, including administrative measures, environmental agreements, policies, legislation, plans and programmes, affecting or likely to affect the elements of the environment within the scope of subparagraph (a) above, and cost-benefit and other economic analyses and assumptions used in environmental decision-making;

(c) The state of human health and safety, conditions of human life, cultural sites and built structures, inasmuch as they are or may be affected by the state of the elements of the environment or, through these elements, by the factors, activities or measures referred to in subparagraph (b) above".[4]

19. Article 3 sets out the *"General Provisions"*, which include *"Each Party shall take the necessary legislative, regulatory and other measures, including measures to achieve compatibility between the provisions implementing the information, public*

2 Emphasis added; **[A.12/154-155]**.

3 Emphasis added; **[A.12/155]**.

4 Emphasis added; **[A.12/156]**.

participation and access-to-justice provisions in this Convention, as well as proper enforcement measures, to establish and maintain a clear, transparent and consistent framework to implement the provisions of this Convention."

20. Article 4 of the Aarhus Convention enshrines the right of access to environmental information, as defined above. Article 6 establishes rules for public participation on specific activities, namely those specified in Annex I and decisions on other proposed activities which may have a significant effect on the environment. The requirements for public participation include giving notice to the public about the potential decision and the procedure through which the decision will be made. Article 6(11) provides: *"Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment."*[5]

21. Article 9 sets out the access to justice requirements imposed by the Aarhus Convention. Article 9(1) sets out the necessary appeal structure in relation to requests for information that have been wholly or partially refused. Article 9(3) provides:

> *"3. In addition and without prejudice to the review procedures referred to in paragraphs 1 and 2 above, each Party shall ensure that, where they meet the criteria, if any, laid down in its national law, members of the public have access to administrative or judicial procedures to challenge acts and omissions by private persons and public authorities which contravene provisions of its national law relating to the environment."*[6]

(c) The Aarhus Regulation

22. Recital (1) of the Aarhus Regulation explains that: "*Community legislation in the field of the environment aims to contribute inter alia to preserving, protecting and improving the quality of the environment and protecting human health, thereby promoting sustainable development."*[7] The protection of human health is one of the key aims of environmental legislation. Recital (3) makes clear that provisions of EU law should be consistent with the Aarhus Convention.[8] Recitals (10) and (11) state:

> *"In view of the fact that environmental law is constantly evolving, the definition of environmental law should refer to the objectives of Community policy on the environment as set out in the Treaty.*

5 Emphasis added; **[A.12/163]**.

6 **[A.12/165]**.

7 **[A.13/178]**.

8 **[A.13/178]**.

Administrative acts of individual scope should be open to possible internal review where they have legally binding and external effects…" [9]

23. Recitals (18) to (21) address the issue of access to justice, as provided for in Article 9(3) of the Aarhus Convention. They state:

> *"(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.*
>
> *(20) Non-governmental organisations active in the field of environmental protection which meet certain criteria, in particular in order to ensure that they are independent and accountable organisations that have demonstrated that their primary objective is to promote environmental protection, should be entitled to request internal review at Community level of acts adopted or of omissions under environmental law by a Community institution or body, with a view to their reconsideration by the institution or body in question.*
>
> *(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."*[10]

24. Article 1 of the Aarhus Regulation confirms that *"[t]he objective of this Regulation is to contribute to the implementation of the obligations arising under the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, hereinafter referred to as 'the Aarhus Convention', by laying down rules to apply the provisions of the Convention to Community institutions and bodies, in particular by:… (d) granting access to justice in environmental matters at Community level under the conditions laid down by this Regulation."* [11]

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9 **[A.13/179]**.

10 Emphasis added; **[A.13/180]**.

11 **[A.13/180]**.

25. Article 2(1)(d) of the Aarhus Regulation defines the term *"environmental information"* in the same way as Article 2(3) of Directive 2003/4/EC, see below. Article 2(1)(f) of the Aarhus Regulation defines *"environmental law"* as meaning:

> *"… 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…"*[12]

26. Article 2(g) defines an *"administrative act"* as *"any measure of individual scope under environmental law, taken by a Community institution or body, and having legally binding and external effects."*[13]

27. Article 10 of the Aarhus Regulation provides that:

> *"1. Any non-governmental organisation which meets the criteria set out in Article 11 is entitled to make a request for internal review to the Community institution or body that has adopted an administrative act under environmental law or, in case of an alleged administrative omission, should have adopted such an act.*
>
> *Such a request must be made in writing and within a time limit not exceeding six weeks after the administrative act was adopted, notified or published, whichever is the latest, or, in the case of an alleged omission, six weeks after the date when the administrative act was required. The request shall state the grounds for the review.*
>
> *2. The Community institution or body referred to in paragraph 1 shall consider any such request, unless it is clearly unsubstantiated. The Community institution or body shall state its reasons in a written reply as soon as possible, but no later than 12 weeks after receipt of the request.*
>
> *3. Where the Community institution or body is unable, despite exercising due diligence, to act in accordance with paragraph 2, it shall inform the non-governmental organisation which made the request as soon as possible and at the latest within the period mentioned in that paragraph, of the reasons for its failure to act and when it intends to do so.*
>
> *In any event, the Community institution or body shall act within 18 weeks from receipt of the request."*[14]

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12 **[A.13/181]**.

13 Emphasis added; **[A.13/181]**.

14 Emphasis added; **[A.13/183-184]**.

28. Article 11 of the Regulation establishes the criteria for a non-governmental organisation to be entitled to request an internal review. There is no dispute that the Applicant meets these criteria.[15] Article 12 makes provision for non-governmental organisations to challenge the outcome of requests for internal review in the following terms:

> *"1. The non-governmental organisation which made the request for internal review pursuant to Article 10 may institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty.*
>
> *2. Where the Community institution or body fails to act in accordance with Article 10(2) or (3) the non-governmental organisation may institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty."*[16]

(d) The Aarhus Directive

29. In the Decision, the Commission refers to the definition of environmental information in the Aarhus Regulation in support of its arguments. That definition is taken from Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (**"the Aarhus Directive"**).[17] Recital (1) the Aarhus Directive explains the rationale for the Aarhus Directive: *"Increased public access to environmental information and the dissemination of such information contribute to a greater awareness of environmental matters, a free exchange of views, more effective participation by the public in environmental decision-making and, eventually, to a better environment."*[18] As to the definition of environmental information, Recital (10) explains that:

> *"The definition of environmental information should be clarified so as to encompass information in any form on the state of the environment, on factors, measures or activities affecting or likely to affect the environment or designed to protect it, on cost-benefit and economic analyses used within the framework of such measures or activities and also information on the state of human health and safety, including the contamination of the food chain, conditions of human life, cultural sites and built structures in as much as they are, or may be, affected by any of those matters."* [19]

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15 **[A.13/184]**.

16 **[A.13/184]**.

17 **[A.14/185-191]**.

18 **[A.14/185]**.

19 Emphasis added; **[A.14/185]**.

30. Article 2(1) of the Aarhus Directive defines *"environmental information"* as *"any information in written, visual, aural, electronic or any other material form on"*:

> *"a) the state of the elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites including wetlands, coastal and marine areas, biological diversity and its components, including genetically modified organisms, and the interaction among these elements;*
>
> *(b) factors, such as substances, energy, noise, radiation or waste, including radioactive waste, emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment referred to in (a);*
>
> *(c) measures (including administrative measures), such as policies, legislation, plans, programmes, environmental agreements, and activities affecting or likely to affect the elements and factors referred to in (a) and (b) as well as measures or activities designed to protect those elements;*
>
> *(d) reports on the implementation of environmental legislation;*
>
> *(e) cost-benefit and other economic analyses and assumptions used within the framework of the measures and activities referred to in (c); and*
>
> *(f) the state of human health and safety, including the contamination of the food chain, where relevant, conditions of human life, cultural sites and built structures inasmuch as they are or may be affected by the state of the elements of the environment referred to in (a) or, through those elements, by any of the matters referred to in (b) and (c)."* [20]

(e) Interpreting the Aarhus Regulation and the Aarhus Directive

31. The object and purpose of both the Aarhus Regulation and Aarhus Directive is to ensure consistency with or contribute to the implementation of the Aarhus Convention. It follows that, for the purposes of interpreting these legislative acts, account should be taken of the wording and aim of the Aarhus Convention, see paragraphs 16 to 17 above.[21]

(f) Legislation regulating the placing of genetically modified food and feed on the European market

32. Regulation 1829/2003 on genetically modified food and feed ("**the GM Regulation**" **[A.15]**) 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 safety assessment before it is placed on the market in the European Union.

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20 Emphasis added; **[A.14/187]**.

21 *Fish Legal v Information Commissioner* (C-279/12) [2014] 2 C.M.L.R. 36; [2015] All E.R. (EC) 795; [2014] Env. L.R. 18, paragraphs 36 to 37 **[A.17/326]**; see, by analogy, paragraphs 46 to 52 of C-240/09 *Lesoochranárske zoskupenie VLK v Ministerstvo ivotného prostredia Slovenskej republiky* [2011] 2 C.M.L.R. 43; [2012] All E.R. (EC) 1; [2011] Env. L.R. 28 **[A.18/367].**

33. *"Genetically modified organism"* is defined in Article 2(2) of Directive 2001/18 (**"the Deliberate Release Directive"**)[22] 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*", where an "*organism"* is defined in Article 2(1) as "*any biological entity capable of replication or of transferring genetic material*".

34. As the Recitals to the GM Regulation explain:

> *"(2) A high level of protection of human life and health should be ensured in the pursuit of Community policies.*
>
> *(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community….*
>
> *(9) The new authorisation procedures for genetically modified food and feed should include the new principles introduced in Directive 2001/18/EC. They should also make use of the new framework for risk assessment in matters of food safety set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety. Thus, 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 the European Food Safety Authority (Authority), of any risks which they present for human and animal health and, as the case may be, for the environment. This scientific evaluation should be followed by a risk management decision by the Community, under a regulatory procedure ensuring close cooperation between the Commission and the Member States….*
>
> *(30) It is necessary to establish harmonised procedures for risk assessment and authorisation that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from genetically modified foods and feed..."*[23]

35. Food and/or feed that consists of, contains, or is produced from, genetically modified organisms must not:

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22 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC **[A.16/238]**.

23 Emphasis added; **[A.15/193-194 & 197]**.

a. "*have adverse effects on human health, animal health or the environment*" (Articles 4(1)(a) and 16(1)(a) GM Regulation[24]); or

a. *"differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer"* and/or *"differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans"*(Articles 4(1)(c) and 16(1)(d) respectively[25]);

b. be placed on the market "*unless it is covered by an authorisation granted in accordance with"* the GM Regulation (Articles 4(2) and 16(2) GM Regulation[26]).

36. Article 5(3) of the GM Regulation requires applications for authorisation to be accompanied by (see also Article 17(3):

"(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;

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24 **[A.15/201 & 210-211.**

25 **[A.15/201 & 210-211.**

26 **[A.15/202 & 211]**.

(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."[27]

37. Accordingly, the application, and ultimately the assessment, must consider studies on the composition of the genetically modified organism in various environments and analyses of how the biologically diverse organism compares with other organisms. The assessment considers matters such as allergenicity, toxicity and the impact of processing.

38. An application for a market authorisation under the GM Regulation must also be accompanied by (Article 5(5); see also 17(5) in respect of feed):

"(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."[28]

39. The Recitals to the Deliberate Release Directive explain:

"(4) Living organisms, whether released into the environment in large or small amounts for experimental purposes or as commercial products, may reproduce in the environment and cross national frontiers thereby affecting other Member States. The effects of such releases on the environment may be irreversible.

(5) The protection of human health and the environment requires that due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms…

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27 Emphasis added; **[A.15/202-203]**.

28 **[A.15/203 & 212]**.

(19) A case-by-case environmental risk assessment should always be carried out prior to a release. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment.

(20) It is necessary to establish a common methodology to carry out the environmental risk assessment based on independent scientific advice. It is also necessary to establish common objectives for the monitoring of GMOs after their deliberate release or placing on the market as or in products. Monitoring of potential cumulative long-term effects should be considered as a compulsory part of the monitoring plan."[29]

40. Article 1 sets out the Deliberate Release Directive's objective as follows: "*In accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:*

— carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,

— placing on the market genetically modified organisms as or in products within the Community." [30]

41. Annex III to the Deliberate Release Directive sets out what an environmental risk assessment must include so as to ensure that the authorities meet their obligations to avoid adverse effects on human health and the environment (Articles 4(1) and (2)). The Annex requires information about, for example, the comparison of the genetically modified organism with its parents and other counterparts if relevant, its compositional characteristics, studies on the impact of different seasons on the growth of the organism and information about the potential allergenic or toxic effects of the release on human health. For example, in this case the focus of the 'environmental risk assessment' under the Deliberate Release Directive was "*mainly with ingestion by animals and their manure and faeces leading to exposure of the gastrointestinal tract and soil microorganisms to recombinant DNA and with accidental release into the environment of viable soybean 305423 grains during transport and processing."*[31]

42. Accordingly, the purpose of the GM Regulation is to provide for a single assessment of the impact of authorising genetically modified organisms on human health, animal health and the environment generally, in accordance with the objectives of EU policies. Taken together the two aspects of the GM Regulation, the safety assessment and the 'environmental risk assessment', have a common goal of controlling the risks posed by the release of genetically modified organisms into the general environment through

29 **[A.16/231 & 233]**.

30 **[A.16/238]**.

31 EFSA 1, section 6.1 **[A.24/444]**.

their deliberate release/cultivation and vi the food/feed chain (through direct or indirect consumption). As a result, there is a substantial overlap in the issues to be considered, and therefore the evidence and assessment undertaken by European Food Safety Authority (the **"EFSA"**), in relation to both aspects of the GM Regulation.

43. Once submitted, the application is considered by EFSA which will then provide an opinion on, among other matters, whether the food/feed complies with the criteria referred to in Articles 4(1) / 16(1) (Articles 6(3)(a) and 18(3)(a) GM Regulation).[32] On the basis of EFSA's opinion, any relevant provisions of Union law and other legitimate factors relevant to the application under consideration, the Commission produces a draft decision (Articles 7(1) and 19(1) GM Regulation).[33]

44. The Commission's draft decision is submitted to the Standing Committee on the Food Chain and Animal Health. This Standing Committee assists the Commission in accordance with the procedure outlined in Article 5 of Decision 1999/468 laying down the procedures for the exercise of implementing powers conferred on the Commission (Articles 7(3), 19(3) and 35(2) GM Regulation).[34] This provides for the Standing Committee to issue an opinion on the application. If the opinion is in accordance with the Commission's draft decision the Commission adopts the decision. If it is not, the Commission has to submit a proposal to the Council: Article 5(3) and 5(4) of Decision 1999/468. If the Council neither adopts nor opposes the proposal within the relevant period, the Commission adopts the decision (Article 5(6) of Decision 1999/468).

III. FACTUAL BACKGROUND

45. Mon 87769, produced by Monsanto, is a stearidonic acid (SDA)- producing soybean. Mon 87705, also produced by Monsanto, is a glyphosate-tolerant low-linolenic, high-oleic soybean known as Vistive Gold. 305423, produced by Pioneer, is a herbicide-tolerant (to (ALS)-inhibiting herbicides), high-oleic acid soybean, known as Plenish. This means in summary that the Soybeans have all been genetically engineered to express different fatty acids which alter the oil composition of the final crop. The manufacturers applied for authorisation to market the Soybeans for food and feed uses, importing and processing.

46. The EFSA GMO Panel performed the pre-market risk assessment of these three soybeans for the scope of food and feed uses, import and processing, and published opinions in December 2013 in relation to 305423 (**"EFSA 1"**),[35] in October 2012

32 **[A.15/204 & 213]**.

33 **[A.15/205 & 214]**.

34 **[A.15/205, 214 & 222]**.

35 Scientific Opinion on application EFSA-GMO-NL-2007-45 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer; EFSA Journal 2013;11(12):3499 **[A.24]**.

(**"EFSA 2"**)[36] and December 2013 (**"EFSA 3"**)[37] in relation to MON 87705, and in May 2014 in relation to MON 87769 (**"EFSA 4"**)[38], respectively. These opinions will be referred to collectively as **"the Opinions"**.

47. As EFSA accepted, the Soybeans are not considered to be substantially equivalent to existing conventional crops. Accordingly, the standard comparative approach to the assessment under the GM Regulation is inapplicable. This means that decisions on whether to authorise the entry of such genetically modified organisms into the EU market, whether through deliberate release, transportation or consumption, poses new and significant challenges.

48. EFSA concluded, however, that the Soybeans are as safe as their conventional counterparts and are therefore unlikely to have adverse effects on human and animal health and the environment (see, for example, Recital (4) of Decision 2015/686[39]). The Implementing Decisions were based on the cumulative assessment of the risk posed by the release of the Soybeans into the food/feed chain and the general environment (see, for example, Recitals (4) to (8) of Decision 2015/686[40]). The Market Authorisations do not extend to cultivation (see, for example, Article 2 of Decision 2015/686[41]).

49. Testbiotech (and Genewatch) had and has significant concerns about the inadequate assessment of the Soybeans in the light of the above challenges. There remains an absence of guidance on how non-comparative assessments of organisms, which are accepted to be nutritionally and compositionally different to conventional organisms, should be assessed. In any event, the analysis in fact undertaken by EFSA as documented in the Opinions is inadequate for the reasons developed in the request for internal review.[42]

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36 Scientific Opinion on application EFSA-GMO-NL-2010-78 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean MON87705 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2012; 10(10):2909, 34 pp. **[A.9]**.

37 Statement complementing the scientific opinion on application EFSA-GMO-NL-2010-78 to cover the safety of soybean MON87705 oil for commercial frying. *EFSA Journal* 2013; 11(12):3507, 9pp. **[A.10]**.

38 Scientific Opinion on application EFSA-GMO-UK-2009-76 for the placing on the market of soybean MON87769 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2014; 12(5):3644, 41 pp. **[A.11]**.

39 **[A.3/33]**.

40 **[A.3/33]**.

41 **[A.3/35]**.

50. On 29 May 2015, Testbiotech submitted a request for internal review of the Marketing Authorisations pursuant to Article 10 of the Aarhus Regulation (the request was made in conjunction with the organisation GeneWatch UK, which is not a party to these proceedings).[43] The Commission summarised Testbiotech's request for internal review as about:[44]

    a. the lack of guidance from EFSA in relation to health impacts of GM crops with significantly altered nutritional content;

    b. the inadequate and inconsistent nutritional assessment (this summary is materially incomplete as the request complained that there was an inadequate and inconsistent safety and nutritional assessment, see pages 4 to 16), ;

    c. the inadequate and inconsistent provision made for the labelling of GM food with altered nutritional assessment;

    d. the inadequate and inconsistent post-market monitoring proposals for GM food with altered nutritional composition;

    e. the failure to consider the health impact of herbicide residues through the consumption of the GM food and feed; and

    f. the inadequate assessment carried out of the unintended effects of Ribonucleic acid (RNA) interference.

51. On 4 August 2015, the Commission wrote to Testbiotech simply asserting that it could not provide a response within the period of 12 weeks.[45] The Commission stated that it would provide its reply within 18 weeks as foreseen by Article 10(3) of the Aarhus Regulation.

52. On 1 October 1015, the Commission emailed Testbiotech stating that its reply had been prepared but that it still needed to go through the administrative procedure for signature.[46]

53. The Commission did not issue the Decision until 16 November 2015, some 24 weeks after the requests for internal review were submitted. In the Decision, the Commission refused to accept that most of the requests for internal review fell to be considered in accordance with the Aarhus Regulation. The Commission's position is that the claims

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42 **[A.1]**.

43 **[A.1]**.

44 **[A.2/25-26]**.

45 **[A.6]**.

46 **[A.7]**.

set out in (a) to (e) above and one part of the claim set out at (f) relate to *"the risk assessment of human and animal consumption of the GM soybeans"***.** Only the parts of the internal review request relating specifically the *"environmental risk assessment"* was treated as falling within the scope of the Aarhus Regulation.

54. As a result, the vast majority of the substance of Testbiotech's requests for internal review was not addressed by the Commission in the Decision. The Commission merely stated that a Technical Report of 30 July 2015 that EFSA published in response to the requests for internal review purported to address those points.[47] As noted above, Testbiotech does not accept that the substance of its requests for internal review have been addressed adequately – not least because the Commission and EFSA place the onus on Testbiotech to prove that the Market Authorisations are invalid. Testbiotech therefore reserves its position in relation to the substance of the claims made in its requests for internal review pending the Commission providing a lawful response to its requests for internal review.

55. Testbiotech also reserves its position in relation to the substance of parts of the sixth submission summarised at paragraph 50 above. As further discussed below, the assessment of the Soybeans is interrelated. The failure to address the vast majority of the claims infects the Commission's assessment of the submission which was partly considered. Accordingly, in the event that the Commission was wrong to conclude that the vast majority of the requests were out of the scope of the Aarhus Regulation, the Decision as a whole should be annulled.

IV. GROUNDS

56. Testbiotech submits that the Decision is unlawful for the following reasons.

(a) Testbiotech's request for internal review falls, in its entirety, within the scope of the Aarhus Regulation

57. Article 10(1) of the Aarhus Regulation grants qualifying non-governmental organisations the right to request an internal review of an administrative act made under environmental law (see also Recital (20)).

58. The Decision under challenge relates to a request for an internal review of administrative acts permitting genetically modified organisms to be used as food and feed within the EU. The GM Regulation provides a single unified process for assessing whether genetically modified organisms should be permitted to enter the EU. The scientific assessment undertaken seeks to establish what harm the organism, i.e. an altered element of the environment, could have on human health, animal health and the environment in general (referring to, for example, the impact on other plants). As a result, the GM Regulation contributes to the objectives of Community policy on the environment (see Article 191 TFEU and Article 2(1)(f) of the Aarhus Regulation above).

59. An administrative act made pursuant to that Regulation is therefore an act made under environmental law within the meaning of Article 10(1) of the Aarhus Regulation. The

47 **[A.8]**.

market authorisations/implementing decisions are such administrative acts. Testbiotech has the right to request an internal review of them, i.e. the authorisation in full (see also Recital (11)). This approach is consistent with the following passage from the Aarhus Convention Implementation Guide which explains what can be reviewed under Article 9(3) of the Aarhus Convention:

> *"Under the Convention, members of the public have the right to challenge acts and omissions by private persons and public authorities which contravene provisions of national law relating to the environment. First, as regards "contravening national law relating to the environment", it does not have to be established prima facie, i.e., before the review, that there has been a violation. Rather, there must have been an allegation by the member of the public that there has been an act or omission violating national law relating to the environment (see ACCC/C/2006/18 (Denmark) discussed above). Second, national laws relating to the environment are neither limited to the information or public participation rights guaranteed by the Convention, nor to legislation where the environment is mentioned in the title or heading. Rather, the decisive issue is if the provision in question somehow relates to the environment. Thus, also acts and omissions that may contravene provisions on, among other things, city planning, environmental taxes, control of chemicals or wastes, exploitation of natural resources and pollution from ships are covered by paragraph 3, regardless of whether the provisions in question are found in planning laws, taxation laws or maritime laws. This was illustrated in the Compliance Committee's findings on communication ACCC/C/2005/11 (Belgium), where the Committee assessed Belgian planning laws under article 9, paragraph 3, and in its findings on Bulgarian planning law in communication ACCC/C/2011/58."*[48]

60. As to the scope of that review, the Guide also states: *"Under the Convention, Parties must ensure that members of the public can directly enforce the law in the case of alleged violations by either private persons or public authorities. Although no explicit reference to substantive or procedural legality is made in paragraph 3, a Party cannot limit the scope of review under this provision to either procedural or substantive legality. Rather, the review procedures for acts and omissions challenged must enable both the substantive as well as the procedural legality of the alleged violation to be challenged…."*[49]

61. As the Guide suggests, the right afforded by Article 10(1), in the light of Article 9(3) and the object and purpose of the Aarhus regime, is to allow non-governmental organisations to challenge the lawfulness, on any procedural or substantive grounds, of any administrative act made under a law relating to the environment. Contrary to the Commission's arguments, see further below, in exercising the right to review or to launch a challenge under Article 12 of the Aarhus Regulation, the non-governmental organisation is not limited to bringing grounds of challenge to the elements of the act

48 Emphasis added; **[A.23/418]**, page 197. Internal references omitted. Paragraphs 37 to 37 of *Fish Legal* confirm that the Aarhus Convention Implementation Guide can be taken into account in interpreting the Aarhus Convention.

49 Emphasis added; ; **[A.23/420]**, page 199.

which are headed ‘environmental risk assessment’ or specifically refer to the environment.

62. Genetically modified organisms are altered biological elements of the environment. This fact is expressly recognised by both the Aarhus Directive and the Aarhus Regulation. For example, both pieces of legislation make clear that any information on genetically modified organisms is environmental information in accordance with Article 2(1)(a) of the Aarhus Directive and Article 2(1)(d)(i) of the Aarhus Regulation. It is information on biological diversity, so it is information on the state of the elements of the environment. Furthermore:

    a. Any information on an administrative act, i.e. an administrative measure, which affects genetically modified organisms is environmental information pursuant to Article 2(1)(c) of the Aarhus Directive and Article 2(1)(d)(iii) of the Aarhus Regulation. A market authorisation is such an administrative act. Any information on a market authorisation is environmental.

    b. Any information on the effect or potential effect of genetically modified organisms on the state of human health and safety, including the contamination of the food chain, is environmental information in accordance with Article 2(1)(f) of the Aarhus Directive and Article 2(1)(d)(vi) of the Aarhus Regulation. That this point is correct is clear from the following passage from the judgment of the Court of Justice in C-266/09 *Stichting Natuur en Milieu& Others v Bayer Crop Science BV and another*:

        “38 The contested decision is a refusal to disclose studies of residues and reports of field trials submitted in connection with a procedure for extending the authorisation of a product within the scope of Directive 91/414. In adopting that directive, the European Union legislature noted inter alia, as stated in the fourth recital in its preamble, that plant protection products can have non-beneficial effects upon plant production, and their use may involve risks and hazards for humans, animals and the environment, especially if they are placed on the market without having been officially tested and authorised and if they are incorrectly used.

        39 It is therefore undeniable that the information concerned by the contested decision, relating to residues of a plant protection product on food, forms part of an authorisation procedure whose purpose is precisely to prevent risks and hazards for humans, animals and the environment. On that basis, the information is in itself such as to concern the state of human health and safety, including where relevant the contamination of the food chain, as set out in Article 2(1)(f) of Directive 2003/4…

        [The Court then refers to Articles 2(1)(a) and (b) to which Article 2(1)(f) refers.]

        42 In the present case, the provision of information on the presence of residues of plant protection products in or on plants such as lettuce, as in the main proceedings, thus aims, by making it possible to verify the level at which the MRL was set, to limit the risk that a component of biological diversity will be

> *affected and the risk that those residues will be dispersed in particular in soil or groundwater. Although such information does not directly involve an assessment of the consequences of those residues for human health, it concerns elements of the environment which may affect human health if excess levels of those residues are present, which is precisely what that information is intended to ascertain.*
>
> *43 In those circumstances, the answer to Question 1 is that the term 'environmental information' in Article 2 of Directive 2003/4 must be interpreted as including information submitted within the framework of a national procedure for the authorisation or the extension of the authorisation of a plant protection product with a view to setting the maximum quantity of a pesticide, a component thereof or reaction products which may be present in food or beverages."*[50]

63. It must be stressed that any and all information falling within the categories of environmental information provided for under Article 2 of both the Aarhus Regulation and the Aarhus Directive must be disclosed. As the Grand Chamber of the Court of Justice held in C-279/12 *Fish Legal*: *"… the information must be 'environmental information' within the meaning of Article 2(1) the Directive… [a public authority] is obliged to disclose to any applicant all the environmental information falling within one of the six categories of information set out in Article 2(1) of the Directive that is held by or for it, except where the application is covered by one of the exceptions provided for in Article 4 of the Directive."*[51]

64. The importance of the public being permitted to participate in decision-making in relation to genetically modified organisms is also expressly recognised by Article 6(11) of the Aarhus Convention.

65. Remarkably, the Commission accepts that the GM Regulation "*can be said to contribute to the pursuit of the objectives of Community policy on the environment*" with the effect that at least some decisions or parts of decisions made under that Regulation are within the scope of the Aarhus Regulation (see page 5 of the Decision **[A.2/29]**). Despite accepting that the GM Regulation is an "environmental law", the Commission seeks to argue in the Decision that some administrative acts or parts of administrative acts made under the GM Regulation are non-environmental because they relate only to human health. Essentially, the contention is that the administrative act may be 'carved up' as somehow environment and non-environment related, even though all aspects of the decision relate to the authorisation of a genetically modified organism. No provision of the Treaty, Aarhus Regulation or the Aarhus Directive provides support for this approach, despite the Commission's convoluted arguments to the contrary.

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50 ECR-I 13154. Emphasis added; **[A.19/388-389]**.

51 *Fish Legal v Information Commissioner* (C-279/12) [2014] 2 C.M.L.R. 36; [2015] All E.R. (EC) 795; [2014] Env. L.R. 18, paragraphs 39 and 78 **[A.17/326 & 332].**

66. The first step in the Commission's argument is to argue that the term *"public health"* in Article 191 TFEU should not be interpreted as covering health issues other than those related to the state of the environment. Interpreting Article 191 as covering "human health" issues unrelated to any element of the environment would, in the Commission's submission, deprive Article 168(4) TFEU of any substance. This argument is without foundation because:

    a. The impact of genetically modified organisms on the state of human health is a health issue related to the state of the environment. The power under Article 168(4) relied upon supports this conclusion. As noted above, the term phytosanitary means of, relating to or being measures for the control of plant diseases especially in agricultural crops. Accordingly, the Commission's point that the Aarhus Regulation should not apply to public health issues unrelated to the environment does not arise on the facts, see also paragraphs 58 to 63above;; and

    b. The interpretation given to the term "environmental law", and therefore the scope of the Aarhus Regulation, has no bearing on the competencies granted by Article 168(4) or Article 192 TFEU. The Aarhus Regulation applies to any legislation which contributes to the pursuit of the objectives of Community policy on the environment, which include protecting human health, irrespective of the legal basis for that legislation. The Aarhus Regulation therefore applies, in full, to any administrative act that was made under legislation falling within the broad definition of environmental law. The legal basis for the decision, in this case, the GM Regulation enacted under Article 168(4) TFEU, is wholly irrelevant. That laws enacted under both Article 168(4) and 192 TFEU may be an *"environmental law"* within the meaning of the Aarhus Regulation is not therefore inconsistent with the Treaty. Despite quoting Article 2(1)(f) of the Aarhus Regulation (which is incorrectly referred to *"Article 2(f)"*) at page 3 of the Decision,[52] the Commission fails to address the implication of its terms.

67. The second step in the Commission's argument, set out at pages 4 to 5 of the Decision, is to attempt to narrowly construe the definition of environmental information insofar as it relates to genetically modified organisms.

68. At page 4 of the Decision, the Commission quotes Article 2(1)(d)(vi) of the Aarhus Regulation (see Article 2(1)(f) of the Aarhus Directive above).[53] Although the Commission highlights the relevant part, which makes clear that environmental information includes information on how the state of human health and safety is affected or is likely to be affected by elements of the environment such as genetically modified organisms, it fails to explain how this provision is said to support its argument. It does not. On the contrary, this provision supports Testbiotech's argument that it may request a review of the entirety of the decision to authorise the Soybeans based on the flawed assessment of these elements of the environment on the state of human health, animal health and the general environment.

52 **[A.2/27]**.

53 **[A.2/28].**

69. Perhaps recognising the obvious flaw in its argument, the Commission attempts to draw a distinction between information on genetically modified organisms as elements of the environment and information on their properties as food and feed for the purposes of Article 2(1)(d)(i). Yet, the latter is a subset of the former. It is still information on such organisms. Contrary to the Commission's submission, Article 2(1)(d)(i) does not need to refer expressly to the properties of genetically modified organisms as food or as feed in order for these aspects of the organisms to be considered environmental. Article 2(1)(d)(i) enacts an inclusive definition which has to be interpreted purposively so as to allow the public to obtain information about and participate in decision-making on environmental matters such as the authorisation of genetically modified organisms. In any event, the points made at paragraph 62 above are repeated.

70. Next, the Commission argues that information on measures on the nutritional aspects of food and feed are not environmental information within the meaning of Article 2(1)(d)(iii). However, this submission is fact dependent. In this case: (a) the nutritional characteristics under consideration are those of an element of the environment, i.e. a genetically modified organism, see paragraphs 58 to 62 above; and (b) the measures in question are the Market Authorisations/the Implementing Decisions. Those measures deal with, even on the Commission's own case, environmental matters and must therefore be considered to affect or be likely to affect the environment.

71. Accordingly, <u>any</u> information on the relevant measure, i.e. in this case the Market Authorisations/Implementing Decisions, constitutes environmental information. It would be contrary to the express terms, as well as the object and purpose of Article 2 for there to be further stage in the analysis requiring consideration of whether different sub-pieces of information on that measure could be said to individually relate specifically to elements of the environment. This would operate to deprive individuals of information on a measure affecting or likely to affect the environment and, accordingly, hinder public participation in the relevant decision-making process.

72. Finally, the Commission relies on one of the criteria a non-governmental organisation must meet in order to be entitled to request an internal review, namely the requirement that the primary objective of the organisation must be the promotion of environmental protection in the context of environmental law, as supporting its case. While it is correct to say that an organisation with the primary stated objective of the protection of human health may not meet this criterion, the relevance of this for the scope of what is to be considered an administrative act made under environmental law for the purposes of Article 10(1) of the Aarhus Regulation is unclear.

73. Based on the submissions addressed above, the Commission contends in essence that: (a) allegations relating to the food and feed safety assessment of the Soybeans, i.e. the analysis of the impact of the consumption of the food and feed, is out of scope of the Aarhus Regulation; and (b) allegations relating to the 'environmental risk assessment' carried out in accordance with Articles 5(5) and 17(5) of the GM Regulation and the Deliberate Release Directive are in scope (see pages 5 to 6 of the Decision). This approach is wrong in law for the reasons given above. The Market Authorisations were made under an "environmental law" or laws, and as such are amenable to a review and challenge under the Aarhus Regulation.

74. The Commission's approach is also not borne out on the facts due to the nature and basis of the assessment of the Soybeans carried out by EFSA.

75. The Opinions focus, unsurprisingly, on evidence about the composition of the genetically modified organisms and the traits they displayed in field or other studies, irrespective of the aspect of the assessment under consideration. The Opinions are about or are "on" the impact of the Soybeans' genetic modification. Further, EFSA's assessment of the impact of the Soybeans largely had a common evidence base, and its consideration of the safety and environmental assessments was intertwined. For example, in Section 6.1.1 of EFSA 1, which is part of the 'environmental risk assessment', EFSA considered the unintended effects of the Soybeans on plant fitness due to the genetic modification. In doing so, EFSA cross-refers to the food/feed safety assessment which considered common issues such as the evidence of studies conducted abroad and the assessment of the compositional traits of the relevant Soybean (referring to sections 4.1.2 and 4.1.3). This intertwined assessment resulted in the overall conclusion to grant the authorisations, see paragraph 48 above. There are no wholly severable elements of the overall assessment of the Soybeans or the relevant evidence base, even if this approach was correct as a matter of law, which it is not.

76. Further, none of the Commission's arguments engage with or address the fact that the safety assessment was not limited to considering the impact of the use of the Soybeans as food on human health; it also considered the impact of the use of feed on animal health. In particular, the Commission's arguments in relation to Article 168(4) TFEU have no bearing on this issue.

77. In summary, for the reasons given above the Commission's suggestion that a *"systematic interpretation"* of the Aarhus Regulation supports its attempt to carve up different parts of a market authorisation of a genetically modified organism as environmental and non-environmental is misplaced. On the contrary, the Commission's approach contradicts the clear terms, as well as the object and purpose, of the Aarhus Regulation.

78. Accordingly, the Commission's failure to address the vast majority of the submissions made in Testbiotech's request for internal review is contrary to Article 10(1) of the Aarhus Regulation read in conjunction with Articles 2(f) and (g) and Recitals (11) and (18) to (21) of that Regulation.

(b) The Commission failed to comply with the applicable time limits

79. The Decision is unlawful because contrary to Article 10(3) of the Aarhus Regulation:

    a. the Commission failed to provide reasons for its inability to provide its reply within 12 weeks of the submission of the request for internal review; and

    b. in any event, the Commission failed to comply with the absolute limit of 18 weeks to act upon the request for internal review.

80. To the extent that the Commission's failure to comply with the above requirements stemmed from the real and substantive concerns raised by Testbiotech in the request for

internal review requiring further consideration, the appropriate course of action would have been for the Commission to:

a. respond to the request in accordance with Article 10(3) of the Aarhus Regulation; and

b. withdraw the Market Authorisations pending a full and proper assessment of the risks posed by the Soybeans, in accordance with the precautionary principle and the GM Regulation.

V. PROPOSAL FOR FUTURE HANDLING OF THE APPLICATION

81. As noted above, Testbiotech is one of three applicants in the on-going claim T-177/13. In that case the Commission has raised two points on the interpretation and scope of the Aarhus Regulation, namely:

a. The Commission argues that some of the sub-grounds advanced by the applicants in the T-177/13 proceedings are manifestly inadmissible because they were not contained in the underlying requests for internal review.

b. The Commission argues that the standard of review applicable to the application for annulment *"should be especially light"* because the applicants do not have standing to directly challenge the underlying market authorisation/implementing decision at issue in that case. Essentially, the Commission argues that an application to the Court under Article 12 of the Aarhus Regulation should be limited to procedural grounds.

82. The applicants contest the above points as a matter of fact and/or law. In particular, the applicants rely on Recitals (18) to (21) and Articles 10 and 12 of the Aarhus Regulation, as well as relevant provisions of the Aarhus Convention, in arguing that: (a) they are entitled to adduce further points and evidence in support of their application to the Court; and (b) the Commission is wrong to attempt to limit the review undertaken pursuant to Article 12 of the Aarhus Regulation.

83. In its intervention, the United Kingdom further argues that many of the applicants claims are inadmissible because the applicants only have standing to bring claims against the aspects of the GM Regulation which relate to the environmental risk assessment carried out under the Deliberate Release Directive involve issues of environmental law. The applicants contend that this point cannot be run by the United Kingdom, as it is contrary to Article 116(3) of the General Court's Rules of Procedure which provides that an Intervener *"must accept the case as he finds it at the time of his intervention"*. However, the applicants' substantive response to this argument, unsurprisingly, raises many of the core points and submissions as outlined in this Application.

84. In short, both this application and T-177/13 raise vitally important issues about the interpretation of the scope of the power granted by the Aarhus Regulation to environmental non-governmental organisations to challenge decisions made under environmental laws. As a consequence, Testbiotech invites the Court to:

a. Join this application and T-177/13.

b. Direct that the Court hear as preliminary issues, as soon as possible, the questions raised as to the scope and interpretation of the Aarhus Regulation. In particular, the following issues should be determined:

i. Should an Article 10 request for internal review of a market authorisation made under the GM Regulation be limited to the 'environmental risk assessment' carried out in accordance with the Deliberate Release Directive?

ii. Should a challenge brought under Article 12 of the Aarhus Regulation be limited to the community institution's consideration of the 'environmental risk assessment' carried out in accordance with the Deliberate Release Directive?

iii. What standard of review should the Court apply the challenges brought under Article 12 of the Aarhus Regulation?

85. The written procedure in T-177/13 closed on 11 March 2014, coming up to two years ago. Testbiotech asks the Court to ensure that the above preliminary issues are heard as soon as possible so that the important substantive environmental issues underlying them can be addressed.

VI. CONCLUSION

86. For the reasons given above, Testbiotech invites the Court to: (a) issue the directions sought in Section V above; and (b) grant the relief sought in Section I(b) above.

KASSIE SMITH QC

JULIANNE KERR MORRISON (nee STEVENSON)

Monckton Chambers

RICHARD STEIN

LEIGH DAY

26 January 2016

Schedule of Annexes

Annex No.	Description	Annex Page No.	Page Reference and Paragraph No. in the Application
A.1	Testbiotech's request for internal review to the Commission of May 2015	1-24	Paragraphs 1-2 & 5, page 2 Paragraphs 49 to 50, pages 16 to 17
A.2	The Commission's Decision of 16 November 2015 on Testbiotech's request for review under the Aarhus Regulation	25 - 32	Paragraph 1, page 2 Paragraphs 53 to 54, page 17 Paragraphs 66 to 77, pages 21 to 23
A.3	Commission Decision 2015/686 authorising MON 87769	33 - 38	Paragraphs 1 & 3, page 2 Paragraph 48, page 16
A.4	Commission Decision 2015/696 authorising MON 87705	39 - 44	Paragraphs 1 & 3, page 2
A.5	Commission Decision 2015/698 authorising MON 305423	45 - 50	Paragraphs 1 & 3, page 2
A.6	Letter of 4 August 2015 from the Commission to Testbiotech acknowledging receipt of the request for internal review and extending the applicable deadline.	51	Paragraph 51, page 17
A.7	Email of 1 October 2015 from the Commission to Testbiotech stating that its decision on the request had still to go through the administrative procedure.	52	Paragraph 52, page 17
A.8	Technical Report, EFSA scientific assistance to EC on the internal review submitted under Regulation (EC) No.1367/2006 on the application of the provisions of the Aarhus Convention against Commission Decisions to authorise genetically modified soybeans 305423, MON 87705 and MON	53 - 68	Paragraph 54, page 17

	87769 31 July 2015		
A.9	Scientific Opinion on application EFSA-GMO-NL-2010-78 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean MON87705 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2012; 10(10):2909, 34 pp.	69 - 102	Paragraph 46, page 15
A.10	Statement complementing the scientific opinion on application EFSA-GMO-NL-2010-78 to cover the safety of soybean MON87705 oil for commercial frying. *EFSA Journal* 2013; 11(12):3507, 9pp.	103 - 111	Paragraph 46, page 15
A.11	Scientific Opinion on application EFSA-GMO-UK-2009-76 for the placing on the market of soybean MON87769 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2014; 12(5):3644, 41 pp.	112 - 152	Paragraph 46, page 15
A.12	The Convention on access to information, public participation in decision-making and access to justice in environmental matters (OJ 2005 L 124, p. 1).	153 - 177	Paragraphs 15 to 21, pages 5 to 7 Paragraph 61, page 19
A.13	Regulation 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Environmental Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies	178 - 184	Paragraphs 2 & 4, page 2 Paragraphs 22 to 28, pages 7 to 9 Paragraphs 57 to 59, pages 18-19 Paragraphs 61 to 63, pages 19 to 20 Paragraphs 79 to 80, page 24
A.14	Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC	185 - 191	Paragraph 25, page 8 Paragraphs 29 to 30, pages 9 to 10

			Paragraphs 61 to 63, pages 19 to 20
A.15	Regulation 1829/2003 on genetically modified food and feed (Consolidated version)	192 - 229	Paragraphs 32 to 38 , pages 11 to 13 Paragraphs 42 to 44, pages 14-15.
A.16	Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (Consolidated version)	230 - 289	Paragraph 33, page 11 Paragraphs 39 to 41 Pages 13 to 14
A.17	*Fish Legal v Information Commissioner* (C-279/12) [2014] 2 C.M.L.R. 36; [2015] All E.R. (EC) 795; [2014] Env. L.R. 18	290 - 333	Paragraph 31, footnote 15, pages 10 to 11
A.18	C-240/09 *Lesoochranárske zoskupenie VLK v Ministerstvo ivotného prostredia Slovenskej republiky* [2011] 2 C.M.L.R. 43; [2012] All E.R. (EC) 1; [2011] Env. L.R. 28	334 - 368	Paragraph 31, footnote 15, pages 10 to 11
A.19	C-266/09 *Stichting Natuur en Milieu& Others v Bayer Crop Science BV and another* ECR-I 13154	369 - 395	Paragraph 62(b), pages 19 to 20
A.20	Testbiotech's Statute/Articles of Association	396 - 403	Paragraph 7, page 3
A.21	Testbiotech's Registration Document	404	Paragraph 7, page 3
A.22	Articles 4(2)(e), 6(a) 43, 114, 168 and 191-192 of the Treaty on the Functioning of the European Union	405 - 416	Paragraphs 10 to 14, pages 3 to 5 Paragraph 66, page 21
A.23	Aarhus Convention Implementation Guide, June 2004, pages 196-199.	417 - 420	Paragraphs 59 to 60, pages 18 to 19
A.24	Scientific Opinion on application EFSA-GMO-NL-2007-45 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer; EFSA Journal 2013;11(12):3499.	421-455	Paragraph 46, page 15