London, 18 March 2013

IN THE GENERAL COURT OF THE EUROPEAN UNION

(1) TESTBIOTECH

(2) EUROPEAN NETWORK OF SCIENTISTS FOR SOCIAL AND ENVIRONMENTAL RESPONSIBILITY ("ENSSER")

(3) SAMBUCUS

Applicants

Represented by Kassie Smith QC and Julianne Kerr Stevenson, Barristers, Monckton Chambers

against

THE EUROPEAN COMMISSION **Defendant**

SUMMARY

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1. Testbiotech, ENSSER and Sambucus challenge the European Commission's decision, dated 8 January 2012, refusing to review its Decision 2012/347 granting a market authorisation under Regulation 1829/2003 on genetically modified food and feed ("GM Regulation") to Monsanto Europe SA for its genetically modified soybean "MON 87701 x MON 89788" ("**the Soybean**") **[PD/7]**. This Decision will hereinafter be referred to as the **"Commission Decision" [PD/7]**.

2. Regulation 1829/2003 on genetically modified food and feed ("**the GM Regulation**") **[AU/1]** 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.

3. The genetically modified soybean "MON 87701 x MON 89788", the "**Soybean**", is a hybrid product. It is created by traditional breeding methods, used to combine the genetic material of two parent plants: soybean MON 87701 and soybean MON 89788 ("**the Parents**"). The Parents are also both genetically modified plants.

4. Monsanto Europe SA ("**Monsanto**") filed application EFSA-GMO-NL-2009-73 ("**the Application**") in the Netherlands, seeking authorisation under the GM Regulation for the Soybean and its derived products for food and feed uses, import and processing in the European Union **[PD/1]**. The Application excludes cultivation within the EU.

5. Following a period of consultation with the representatives of the Member States, EFSA issued an Opinion on the Application on 26 January 2012 ("**the EFSA Opinion**") **[PD/3].** That Opinion recommended granting Monsanto's application because EFSA had a reached a positive conclusion based on its risk and safety assessment of the Soybean.
6. Testbiotech understands that the Council failed to reach a decision on the Application because the matter was reverted to the Commission. Accordingly, in the absence of a decision by the

Council, and on the basis of the EFSA Opinion, the Commission decided on 28 June 2012 to grant the market authorisation **[PD/5]**.

7. The Applicants each sought an internal administrative review of that decision, on 6 August 2012, under Article 10 of the Aarhus Regulation and Article 36 of the GM Regulation ("**Request for Internal Review**") **[PD/6]**. The Applicants contended that the authorisation of the Soybean is unlawful and/or based on a manifest error. The Applicants drew attention to the fact that in a number of areas EFSA failed to comply with its own Guidance in carrying out the safety and risk assessment of the Soybean. The Applicants submitted that this frustrated their legitimate expectation that EFSA would comply with its own Guidance. The Commission had failed to remedy these concerns in granting Monsanto' application for a marketing authorisation for the Soybean.

8. The Commission responded to the Applicants' Requests for Internal Review on 8 January 2013. The Commission rejected the submissions made by the Applicants in their Requests for Internal Review. ("**the Commission Decision**") **[PD/7]**.[1]

9. The Grounds upon which Testbiotech, ENSSER, and Sambucus challenge the Commission's decision are, in summary:

    a. **Ground A:** EFSA's assessment that the Soybean is 'substantially equivalent' to its appropriate comparators is unlawful, is based on a scientific assessment which was not carried out in accordance with its own guidance, and/or is based on a manifest error of assessment;

    b. **Ground B:** EFSA's failure to give adequate or any consideration to the potential synergistic/combinatorial effects between the Soybean and other factors, and/or to require an adequate toxicity assessment to be conducted is contrary to its own guidance, legal obligations and/or it constitutes a manifest error of assessment;

    c. **Ground C:** EFSA's failure to require an adequate immunological assessment to be carried out is contrary to its own guidance, legal obligations and/or constitutes a manifest error of assessment.

    d. **Ground D:** EFSA's determination that no post-market authorisation monitoring of the consumption of the Soybean is manifestly in error and/or is vitiated by the flaws identified by Grounds A to C.

10. The Applicants request that the Court:

    a. Declare the application admissible and well-founded;
    b. Annul the contested decision;
    c. Order the Commission to pay Testbiotech, ENSSER and Sambucus' costs; and
    d. Order any other measure deemed appropriate.

[1] ENSSER and Sambucus received identical copies of Commission Decision barring the name of the addressee, see: **[PD/10]** and **[PD/12]**