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BY POST AND FAX

Health and Safety Executive
Chemicals Regulation Directorate
Mallard House
Kings Pool
3 Peasholme Green
York YO1 7PX

FAO Mr David Bench, Director

30 July 2013

Dear Sirs

Proposed Claim for Judicial Review: Application of Commission Implementing Regulation 485/2013

This is a letter before claim in compliance with the Pre-Action Protocol for Judicial Review.

1. **To**

The Health and Safety Executive, and in particular its Chemicals Regulation Directorate, (the "**HSE**").

Address as above.

2. **The Claimant**

Bayer CropScience A.G., whose registered office is at Alfred-Nobel-Str. 50, 40789 Monheim am Rhein, Germany, and Bayer CropScience Limited, 230 Cambridge Science Park, Milton Road, Cambridge, CB4 0WB, United Kingdom (together, "**Bayer**").

3. Reference details

There has been no previous correspondence between Bayer and the HSE in relation to this claim, and so there are no relevant reference details.

4. The details of the matter being challenged

Bayer manufactures the active substances imidacloprid and clothianidin, and sells plant protection products that contain imidacloprid and clothianidin in the European Union.

Bayer seeks to challenge the validity of Commission Implementing Regulation (EU) No. 485/2013 of 24 May 2013 (the "**Contested Measure**"), which places restrictions on the use of plant protection products containing clothianidin, thiamethoxam and imidacloprid (together, the "**Neonicotinoids**"). Neonicotinoids are a major class of insecticidal substances. Bayer's Neonicotinoid-based products are among the most technologically-advanced and most environmentally-friendly products available for the various plant protection applications for which they are used. Bayer intends to request the Administrative Court to refer the matter to the European Court of Justice (the "**ECJ**") in accordance with Article 267 of the Treaty on the Functioning of the European Union ("**TFEU**").

The formal object of the proposed claim for judicial review is:

The obligation of the United Kingdom Government under TFEU to give effect to the Contested Measure, insofar as it places restrictions on the use of plant protection products containing Neonicotinoids.

5. The issue

The Contested Measure, which was published in the Official Journal of the European Union on 25 May 2013, has the following principal effects:

i. It amends the conditions of approval of the Neonicotinoid active substances (clothianidin, imidacloprid and thiamethoxam) to restrict the use of plant protection products containing these substances only to crops non-attractive to bees and cereals except for uses in greenhouses and for winter cereals. Foliar treatment with plant protection products containing clothianidin, imidacloprid or thiamethoxam is prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering.

ii. It prohibits the sale and use of "seeds treated" with plant protection products containing Neonicotinoid-based products for seeds of crops attractive to bees and for seeds of cereals except for winter cereals and seeds used in greenhouses.

iii. It restricts the use of clothianidin, imidacloprid and thiamethoxam to professional users (i.e., restricting all amateur uses of the three Neonicotinoids – indoor as well as outdoor).

The Contested Measure requires that Member States withdraw national authorisations for plant protection products containing Neonicotinoids on the basis that "*there are indications that the approved uses of* [the Neonicotinoids] *no longer satisfy the approval criteria provided for in Article 4 of Regulation (EC) No. 1107/2009* [of the European Parliament and of the Council Concerning the placing of plant protection products on the market (the "**Enabling Regulation**")] *with respect to their impact on bees* [...]."

Bayer's Neonicotinoid-based plant protection products have been carefully developed (and the rules around their use have been carefully designed) in order to minimise any impact on bee health. Indeed, no scientific study of the proper use of Bayer's Neonicotinoid-based plant protection products in the field (*i.e.* under realistic exposure conditions) has ever found any biologically relevant harm to honeybee colonies. The only studies ever to have shown any link between Neonicotinoids and the health of honeybee colonies involved honeybees being exposed in the laboratory, or under otherwise unrealistic exposure conditions, to artificially-administered, and frequently exaggerated and unrealistically high, doses of Neonicotinoids to which they would never realistically be exposed in the field.

In the recitals to the Contested Measure, the Commission claims, in effect, that the Contested Measure was adopted in accordance with the applicable requirements of EU law, including, notably, the terms of the Enabling Regulation. However, for the reasons set out, Bayer contends that this is not the case and that the adoption of the Contested Measure was therefore illegal.

i. **The Contested Measure was adopted in a manner that was *ultra vires* the powers granted to the Commission by the European Parliament and the Council under the Enabling Regulation**

   The Enabling Regulation constitutes the European Parliament's and the Council's demarcation of what the Commission can, and cannot, do in the regulation of plant protection products.

   Article 21 of the Enabling Regulation sets down mandatory requirements with which the Commission must comply if it wishes to amend or withdraw approvals such as those in existence for the Neonicotinoid active substances manufactured by Bayer.

   Article 49 of the Enabling Regulation sets down mandatory requirements with which the Commission must comply if it wishes to restrict or prohibit the sale of seeds treated with plant protection products based on the Neonicotinoid active substances marketed by Bayer.

   The Contested Measure relies on Articles 21 and 49 of the Enabling Regulation as the legal basis for the amendments and withdrawals it enacts in relation to the Neonicotinoid active substances marketed by Bayer.

However, neither the requirements of Article 21, nor the requirements of Article 49, are met in relation to the Neonicotinoid-based products covered by the Contested Measure. As such, the Commission does not have a valid legal basis for the amendments to approvals for active substances, or for the prohibitions on the sale of treated seeds, which are set out in the Contested Measure. Consequently, the Contested Measure is *ultra vires* the powers granted to the Commission, lacks a proper legal basis, and must be annulled.

ii. The Contested Measure was adopted in a manner that breached Article 12(2) and Annex II, point 3.8.3. of the Enabling Regulation and denied Bayer's legitimate expectations

Under both Article 21 and Article 49, the European Union's expert risk assessment body, the European Food Safety Authority ("**EFSA**"), undertakes a critical role. The Enabling Regulation sets out clear parameters around the risk assessment role undertaken by EFSA.

At Article 12(2), the European Parliament and Council state that risk assessments in relation to plant protection products must be carried out: "using guidance documents available at the time of application".

At Annex II, point 3.8.3., the Enabling Regulation states that an active substance can only be approved "following an appropriate risk assessment on the basis of [Union] or internationally agreed test guidelines."

The applicable risk assessment guidance in force at all times of relevance to the adoption of the Contested Measure was the "Environmental Risk Assessment Scheme for Plant Protection Products, Chapter 10: honeybees" (the "**EPPO Guidance**"). The EPPO Guidance was first issued in 1992 by the European and Mediterranean Plant Protection Organization and was updated in 2002 and, most recently, in 2010.

The EPPO Guidance was the applicable guidance to which EFSA should have had regard when conducting its risk assessments in relation to Neonicotinoids.

Instead, EFSA used as guidance for its Neonicotinoid risk assessments:

a) a scientific opinion on the science behind the development of a risk assessment of plant protection products on bees dated May 2012 (the "**Opinion**") that was merely preparatory to the future drafting of proper risk assessment guidance; and

b) (to a lesser extent) a document titled "EFSA Draft Guidance Document on the Risk Assessment of Plant Protection Products on bees" (the "**Draft Guidance**") that was still in a draft consultation stage at the time that the Contested Measure was adopted.

EFSA's reliance on the Opinion and the Draft Guidance, to the exclusion of the EPPO Guidance, breached Article 12(2) and Annex II, point 3.8.3. of the Enabling Regulation.

The ECJ has also held that the right to rely on the principle of protection of legitimate expectations extends to any entity that is in a situation in which it is clear that the Union administration has, by giving it precise assurances, led it to entertain reasonable expectations.

In particular, where institutions have set out guidance as to how they will consider certain issues, the European Courts have held that private parties such as Bayer can have legitimate expectations that such guidance will be adhered to by the institution in question. EFSA's reliance on the Opinion and the Draft Guidance, as opposed to the applicable EPPO Guidance, constituted a breach of Bayer's legitimate expectations.

iii. The adoption of the Contested Measure breached Bayer's Right to Property and its Right to Conduct a Business

The adoption of the Contested Measure breached Bayer's right to property, or its right to conduct a business.

The fundamental right to property is set out in Article 17 of the Charter of Fundamental Rights of the European Union ("**Charter**")[1]. It provides as follows:

> *1. Everyone has the right to own, use, dispose of and bequeath his or her lawfully acquired possessions. No one may be deprived of his or her possessions, except in the public interest and in the cases and under the conditions provided for by law [...]. The use of property may be regulated by law in so far as it is necessary for the general interest.*
>
> *2. Intellectual property shall be protected.*

The fundamental right to conduct one's business is set out in Article 16 of the Charter, and provides that: *"The freedom to conduct a business in accordance with Community law is recognised."*

The fundamental rights set out in the Charter are binding on the Commission by virtue of Article 6 of the Treaty on the European Union ("**TEU**").

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[1] By virtue of Article 52(3) of the Charter, the Court interprets the scope of the rights set out in the Charter by reference to their equivalents in the European Convention on Human Rights ("ECHR") (and the related jurisprudence of the European Court of Human Rights ("ECtHR")).

In addition, by virtue of Article 52(1) of the Charter, the Commission must not only respect the letter of the Charter rights, but must also: *"respect the essence of [the Charter's] rights and freedoms"*. (Emphasis added.)

The rights as set out in Articles 16 and 17 of the Charter are not *"absolute"*. However, the European Courts have held that any interference with either right must not constitute *"a disproportionate and intolerable interference, which infringes upon the very substance of the rights guaranteed"*.

Bayer has significant and valuable property rights (including intellectual property and data exclusivity rights) in the Neonicotinoid-based plant protection products subject to the restrictions set out in the Contested Measure.

The adoption of the Contested Measure, which imposes significant restrictions on the use and sale of Bayer's Neonincotinoid-based plant protection products, constitutes a disproportionate and intolerable interference, which infringes upon the very substance of Bayer's right to property and its right to conduct a business.

iv. The adoption of the Contested Measure breached Bayer's right to be heard in that it was not afforded any opportunity to address data gaps that EFSA identified

Bayer had a right to be informed of the main alleged data gaps which would form the basis for the conclusions in EFSA's reports on clothianidin and imidacloprid. The failure to afford Bayer an opportunity to address such alleged data gaps in relation to approved active substances on which many of Bayer's approved plant protection products are based constitutes a breach of Bayer's right to be heard.

v. The adoption of the Contested Measure breached the principle of proportionality in that it went beyond what was appropriate to the achievement of any legitimate objectives and was not the least restrictive means of achieving its purported aims

In accordance with well established case-law, the principle of proportionality, which is one of the general principles of European Union law, requires that measures adopted by the institutions must not go beyond what is appropriate and necessary in order to attain the legitimate objectives pursued by the measure in question. Where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued.

Bayer submits that there are two particularly strong indications that the Commission's conduct in the instant case must necessarily have involved a breach of the principle of proportionality.

First, in and of itself, the break-neck speed at which the Commission rushed through the regulatory process[2] suggests that it did not give proper consideration to less restrictive measures that might have been available to it. In particular, it appears to have given no consideration whatever to the likely consequences of the introduction of the Contested Measure.

Second, certain patently absurd aspects of the Contested Measure strongly suggest that a number of the restrictions introduced by the Commission are neither appropriate to the protection of the European Union's honeybee population, nor the least restrictive means of achieving the desired level of protection.

vi. The adoption of the Contested Measure resulted from a misapplication of precautionary principle, as it involved the Commission taking a purely hypothetical approach to risk, which was founded on mere conjecture, and which was not scientifically verified

The precautionary principle constitutes a general principle of European Union law, requiring the risk manager in question, in the particular context of the exercise of the powers conferred on it by the relevant rules, to take appropriate measures to prevent specific potential risks to public health, safety and the environment, by giving precedence to the requirements related to the protection of those interests over economic interests.

The Commission does not refer to the precautionary principle in the recitals to the Contested Measure. But the measure takes such an extraordinarily conservative risk management approach to EFSA's conclusions (which related – in the main – to data gaps, as opposed to actual risks), that the Commission's adoption of the Contested Measure can only have come about as a result of a purported application of the precautionary principle.[3]

Simply refusing to refer to the precautionary principle in the recitals to a contested measure cannot render the measure in question immune from challenge under the rules on the application of the precautionary principle as set out by the European Courts.

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2 By way of example, the Commission gave itself only one weekend (26 and 27 January 2013) to reflect on third parties' comments on EFSA's risk assessment reports before circulating, on Monday 28 January 2013, a Discussion Paper announcing its intention to ban the use of Neonicotinoid-based plant protection products as seed treatments, granules and sprays for all *"bee-attractive"* crops.

3 That the Commission took a precautionary approach to its risk management function is demonstrated in the recitals to the Contested Measure themselves. By way of example, after confirming that the three Neonicotinoids *"are deemed to have been approved under Regulation 1107/2009"*, the Commission nonetheless goes on to state that *"in order to minimise the exposure of bees, it is, however, appropriate to restrict the uses of those actives substances, to provide for specific mitigation measures for the protection of bees and to limit the use of products containing those active substances to professional users..."*.

While it is understood from the case-law of the European Courts that the precautionary principle is designed to prevent potential risks, it is also clear that "*a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified*".[4]

The European Courts have also explained that: "*if it is not to adopt arbitrary measures, which cannot in any event be rendered legitimate by the precautionary principle, the* [Commission] *must ensure that any measures that it takes, even preventive measures, are based on as thorough a scientific risk assessment as possible*".[5]

In addition, the Commission's guidance on the application of the precautionary principle[6] requires that any measures that are based on the precautionary principle be: "*based on an examination of the potential benefits and costs of action or lack of action*".

The criteria for the proper application of the precautionary principle were not met in the instant case.

The adoption of the Contested Measure involved misapplication and violation of the precautionary principle since:

(i) it involved the Commission – as risk manager – taking a purely hypothetical approach to risk, which was founded on mere conjecture and which was not scientifically verified;

(ii) it was not based on as thorough a scientific assessment as possible or on the best available scientific data;

(iii) it resulted in arbitrary measures, which cannot be rendered legitimate by reference to the precautionary principle; and

(iv) it was not based on an examination of the potential benefits and costs of action (such costs being forecast to be particularly significant in the UK, where research suggests that the restrictions imposed by the Contested Measure could have adverse environmental implications, could reduce yields

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4 Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305, paragraph 143 (emphasis added).

5 Case T-71/10 *Xeda and Pace v Commission* [not yet reported], paragraph 78 (emphasis added).

6 *Communication from the Commission on the Precautionary Principle*, dated 2 February 2000, available at: http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf (emphasis added).

of important crops, such as oil seed rape, and could cause some farmers to cease growing oil seed rape altogether).[7]

6. The details of the action that the defendant is expected to take

The invalidity of EU legislation may be determined only by the European Courts. Bayer intends to seek a reference from the Administrative Court to the ECJ, pursuant to Article 267 TFEU, for a preliminary ruling on the question of whether or not the Contested Measure is valid in the respects outlined above. The HSE will be aware of the precedents for this course which include *R v Secretary of State for Health ex p. Imperial Tobacco Ltd* [2002] QB 161, *R (Intertanko) v Secretary of State for Transport* [2006] EWHC 1577 (Admin), *R (SPCM and others) v Secretary of State for the Environment, Food and Rural Affairs* [2007] EWHC 2610 (Admin), *R (Telefonica O2 Europe plc and others) v Secretary of State for Business, Enterprise and Regulatory Reform* [2007] EWHC 3018 (Admin), *Vodafone Ltd and Others v Secretary of State for Business Enterprise and Regulatory Reform* [2007] EWHC 3018 (Admin) and *Afton Chemical Ltd v Secretary of State for Transport* [2011] 1 C.M.L.R. 16.

There is no relevant administrative action which the HSE can take which bears on the question of the validity of the Regulation.

Suggested procedure

Bayer will shortly lodge an action for annulment of the Contested Measure before the General Court of the European Union ("**GCEU**") under Article 263 TFEU. Bayer believes its action for annulment has very good prospects of being declared admissible by the GCEU, even if it should be considered to lack individual concern, on the basis that Bayer is likely to have standing under the "Regulatory Acts Test". The Regulatory Acts Test, introduced by the Lisbon Treaty, states that an applicant's ability to challenge the adoption of a particular measure directly before the GCEU is dependent on whether the measure amounts to a regulatory act which is of direct concern to the applicant and which does not entail (subsequent) implementing measures. Given that the Contested Measure is likely to be considered a regulatory act, which is of direct concern to Bayer, and which does not entail implementing measures, Bayer is confident that it satisfies the Regulatory Acts Test, and that its action for annulment will be declared admissible, and be heard, by the GCEU.

The GCEU is the natural home for such an action and has procedures well-adapted for dealing with it: in particular, the GCEU applies a written procedure that allows for two rounds of responsive pleadings, in contrast to the ECJ which, in Article 267 TFEU reference proceedings, typically allows only a single simultaneous exchange of written observations.

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[7] Of the 100 UK farmers who responded to a 2012 Bayer survey regarding the possibility of a ban on the use of insecticidal seed treatment products in oil seed rape: (i) 72% thought there could be adverse environmental implications; (ii) 79% thought their oil seed rape yields would decrease; (iii) 90% thought they would need to apply some or more foliar sprays; (iv) 84% considered that their pest control costs would increase; and (v) 47% said that they would consider not growing oil seed rape in the future.

Standing before the GCEU has however been historically restrictive; there has as yet been only limited case law on the impact of the liberalisation effected by the Lisbon Treaty; and it is accordingly not possible to be completely sure that Bayer's action for annulment will be accepted as admissible by the GCEU.

Recognising this state of affairs, and the fundamental nature of the right of judicial review of administrative decisions, the ECJ urged national courts in Case C-50/00P *Unión de Pequeños Agricultores* [2002] ECR I-6677 to show the necessary procedural flexibility to accommodate claims of this nature and to refer them where appropriate to the ECJ. This guidance has been loyally and flexibly applied by the Administrative Court, for example, in Cases C-14/10 *Nickel Institute* [2011] ECR I-06609, C-366/10 *Air Transport Association of America and Others* [2012] 2 CMLR 4, and C-629/10 *TUI Travel and Others*).

The intended claim is accordingly brought as a failsafe. If the GCEU (contrary to expectations) declares Bayer's application inadmissible, Bayer anticipates that it would apply to the Administrative Court for a reference to be made to the ECJ. That is because only the European Courts may declare an EU measure to be invalid: Case C-314/85 *Foto Frost* [1987] ECR 4199.

In the (expected) event that the GCEU declares Bayer's application to be admissible, however, it will not be necessary to trouble the Administrative Court or the HSE with argument in relation to the issue of whether to make a reference, what questions to refer and how the issues should be formulated for the ECJ. Nor will it be necessary to trouble the ECJ itself with a time-consuming reference on issues that are already capable of satisfactory resolution in another forum.

Accordingly, and in order to spare the parties and the courts work and expense which is likely to prove unnecessary, Bayer proposes to apply in its claim form for a stay of the claim pending the decision by the GCEU on the admissibility of its action for annulment.

Bayer will invite the Government's formal response to this proposal in its Summary Grounds of Resistance, but puts it on notice at the earliest opportunity by referring to it also in this letter before claim. It is hoped that agreement on a stay will be possible; but should the parties disagree or the Court have reservations, a procedural hearing will be necessary for the Administrative Court to rule on how matters should progress.

7. The details of the legal advisers

Steven Pitt and Grace Cheng of Sidley Austin LLP at Woolgate Exchange, 25 Basinghall Street, London EC2V 5HA.

8. The details of any interested parties

None.

9. The details of information sought

Confirmation that the HSE is the Governmental body of the United Kingdom against which an application for Judicial Review of the Contested Measure should be brought.

10. The details of any documents that are considered relevant and necessary

None.

11. The address for reply and service of court documents

Steven Pitt and Grace Cheng of Sidley Austin LLP at Woolgate Exchange, 25 Basinghall Street, London EC2V 5HA.

12. Proposed reply date

13 August 2013.

We look forward to hearing from you.

Yours faithfully,

Sidley Austin LLP

Sidley Austin LLP

cc: Health and Safety Executive, Head Office