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Department for the Environment, Food and
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Our Reference: GP/Bees

**~ Urgent Pre Action Protocol Letter
Reply within 7 days~**

26th July 2015

Dear Madam,

Emergency authorisations of Cruiser and Modesto plant protection products granted 24th July 2015

Introduction

1. We write further to recent email correspondence between ourselves and David Williams of the Chemicals Regulation Directorate (CRD) in relation to the above. This letter is written in order to comply with the pre-action protocol for judicial review under the Civil Procedure Rules. Given the emergency nature of the authorisations and our understanding that the applicant (the National Farmers Union) intends to make use of them as soon as possible, we ask for a response to this letter within 7 days so that any subsequent judicial review proceedings that may prove to be necessary can be brought on an expedited basis.
2. Friends of the Earth has been in correspondence with the Department of the Environment, Food and Rural Affairs (DEFRA) and the Health and Safety Executive (HSE) seeking information about these applications since 21st May 2015, including making a request under the

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Environmental Information Regulations (EIR) to the HSE on 24th June 2015. Having received no substantive response, Friends of the Earth wrote a legal letter to David Williams on 20th July (attached) seeking clarity as to the position and asking for sight of any authorisation as soon as it was granted, along with information as to the criteria and process used, on the basis of DEFRA's duty of candour. It received the attached response from Mr Williams on the 23rd of July and was informed late in the afternoon of Friday 24th July that authorisations had been granted earlier that day. On the basis of the limited information so far disclosed, Friends of the Earth has serious concerns about the lawfulness of the grant of the authorisation and its compliance with Regulation EC 1107/2009 ('the Regulation') and in particular Article 53 of that regulation, concerning the placing of plant protection products on the market.

3. We are aware that judicial review is a remedy of last resort and write in the hope that this matter can be resolved. We therefore outline at the end of this letter the steps which we ask you to take in order to avoid the issue of legal proceedings.
4. As the matter relates to the protection of the environment and specifically the high acute risks to bees from the products authorised, this is a case that falls under the ambit of the Aarhus Convention. Therefore the costs provisions in CPR 45.41-45.44 and Practice Direction 45 apply.

The Proposed Parties

5. The prospective claimant in this case is Friends of the Earth.
6. The prospective defendant is the Secretary of State for Environment, Food and Rural Affairs
7. The National Farmers Union, the applicant for the licence, is proposed to be named as an Interested Party in any proceedings.

Details of prospective challenge

8. The matter under challenge is the granting of Emergency Authorisations Number 1949 and 1950 of 2015 under Plant Protection Products Regulation EC No 1107/2009 (the Regulation) for Cruiser OSR and Modesto Licence 'the Authorisations' (both attached). The Authorisations were granted on Friday 24th July 2015, extend over England and are due to expire on 20th November 2015. The Authorisations relate to uses of substances that are prohibited under Commission Implementing Regulation EU 485/2013 (attached).

Legal Framework and Analysis

9. The Secretary of State has granted emergency authorisations with the effect of allowing uses of neonicotinoid substances that have been banned in the European Union under the Regulation. However, no information or evidence has been provided to us (or made public more generally) in relation to whether or how the Regulation (and in particular Article 53, which governs such emergency authorisations) has been considered or applied.
10. Importantly, the Authorisations appear to contain no conditions through which the Secretary of State has addressed the concerns relating to high acute risks to bees set out in Implementing Regulation 485/2013, which have led to the prohibition of the uses in question. We have no

information on whether these concerns were considered in the course of approving the applications. The links that have been provided to the agenda item and minutes of the UK Expert Committee on Pesticides (ECP) on 7 July 2015 provide no more than an outline in the most general terms of that Committee's consideration of the applications, and do not indicate, for instance, to what extent the decisions have been taken in accordance with the Precautionary Principle under EU law, or of the role of the ECP in the overall decision-making process.

11. The decision on its face is therefore unlawful.
12. We now expand on these core points below.
13. The purpose of the Regulation is described in Article 3(1) as being to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production.
14. Article 3 (4) of the Regulation states:

“The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment.”
15. In the light of the above and the aim within the Regulation of establishing the same level of protection in all EU Member States (see Recital 10), a detailed assessment framework is set out for approving active substances and products under the Regulation. Regulation 546/2011 sets out uniform principles for the evaluation and authorisation of plant protection products.
16. Article 53 of the Regulation states:

“By way of derogation from Article 28 [which permits only authorised products to be placed on the market], in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means.”
17. This envisages a separate procedure for authorisations in emergency situations, but it is indisputable that such a procedure must still comply with the overall purpose and legal requirements of the Regulation.
18. The Authorisations purport to have been issued under the Regulation. Neonicotinoids, the active substances in the products authorised, were initially approved substances. However, in Spring 2012, new scientific information on the sub-lethal effects of clothianidin, thiamethoxam and imidacloprid, three widely-used neonicotinoids on bees, was published. The European Food Safety Authority (EFSA) identified a high acute risk for bees associated with the use of these three active neonicotinoid ingredients on certain flowering crops. Having considered this new technical and scientific evidence, the European Commission concluded that a high risk for bees could not be excluded except by imposing further restrictions in relation to seeds treated with those neonicotinoid active ingredients.
19. As a result, Implementing Regulation 485/2013 prohibited the placing on the market of seeds treated with plant protection products containing the active ingredients of clothianidin, thiamethoxam or imidacloprid (neonicotinoid substances) for seeds of crops attractive to bees and for seeds of cereals except for winter cereals and seeds used in greenhouses. The

Implementing Regulation was expressed to be binding in its entirety and directly applicable in all EU Member States. The restriction on the use of those neonicotinoids under the regulation is for an indefinite period, although the review within the two years specified in it is currently underway.

20. Despite repeated requests, we have at present very limited information as to the procedure followed by DEFRA in the present circumstances. It is our understanding from the letter of David Williams that the matter was considered by the Expert Committee on Pesticides (ECP), which appears to have expressed some reservations as to consideration of fields/farms at greatest risk. However it is entirely unclear what happened after that, or what the overall process was. Moreover, it is unclear what changed between the Committee's rejection of an earlier application in May 2015 and its approval of the application considered in July 2015, or indeed what impact its views had on the decision-making process relating to these applications.
21. It is also entirely unclear what criteria were used to assess the application. It is evident from Article 53 that the placing of unauthorised products must be limited and controlled and only take place where a measure appears necessary because of a danger which cannot be contained by any other means. The Applicant Guide to Emergency Authorisation on the CRD website¹ refers to the need to provide a reasoned case to demonstrate both "need" and "urgency". The Commission's working document on emergency authorisation² also provides, *inter alia*, that use of the Article should be exceptional, and restricted to cases of obvious dangers to plant production or ecosystems that cannot be contained by any other reasonable means.
22. We have been provided with no information as to how these criteria were assessed on this particular occasion (or generally) or how the criteria of "need" and "urgency" relate to the requirements of Article 53 above. For example, we have no information concerning how the question of "*a danger which cannot be contained by any other reasonable means*" was assessed.
23. As to the Authorisations themselves, it is difficult to see how they meet the requirements of "*limited and controlled*" set out in Article 53. The geographical area they apply to is the whole of England and the use of 950 litres per substance has been authorised without any indication of specific limitations in terms of volume or area. The Authorisations require distribution to areas of highest risk but the identification of these appears to be left to the applicant, without any involvement on the part of DEFRA, despite this having been a concern expressed specifically by the ECP. The Authorisations set various broad requirements on the applicant to keep records, generate data and notify DEFRA as to certain matters but provide little or no information as to how these will be monitored. The onus to ensure compliance with the Regulation appears to be placed entirely on the holder of the Authorisations, without any obvious means of regulatory oversight.
24. In addition, there is no reference at all to the specific circumstances behind the ban of neonicotinoid substances, or to any conditions (or even considerations) relating to limiting the high risk that they have been identified to pose to bees. Appendix 3 of the Authorisations ('Confidential Conditions') has not been disclosed to us but we are informed by the CRD that it contains "formulation and active substance details" that do not assist with the legal matters

¹ <http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-emergency-120-day-Authorisations>

² SANCO/10087/2013, http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/working_document_emergency_authorisations_article53_en.pdf

in question or explain further how the requirements of the Regulation and EU law more generally were considered.

25. It appears to us that all of the above is incompatible with the purpose of the Regulation and the requirements of Article 53 specifically, particularly when considered in the context of Implementing Regulation 485/2013.
26. Moreover, it is a matter of real concern that these authorisations have been granted without any of the relevant reasoning or details being published or disseminated, contrary to the rights of the public to have access to, and to be able to participate in, environmental decision-making.

Steps you are required to take

27. In order to resolve this matter without progressing to judicial review, Friends of the Earth asks the Secretary of State to take the following steps:
 - a) To provide information on whether (and if so how) she has considered the matters raised above, including any risk assessment which was carried out in relation to the impact on bees of granting the Authorisations;
 - b) To revoke the Authorisations presently granted and reconsider the applications made by the NFU (or, if necessary as a matter of procedure, to agree to submit to judgment on a short form application for judicial review).
28. We also repeat our request for disclosure of relevant documents, in accordance with the Secretary of State's duty of candour in judicial review proceedings. In particular please provide as a matter of urgency copies of the following documents:
 - a. the relevant applications;
 - b. the relevant material placed before the ECP at its meeting on 7 July 2015 and the record of its discussions and ultimate decision, including its consideration of the relevant science;
 - c. any document recording the reasons behind the approval decisions, including details of any consideration given to whether and how the requirements of Article 53 of the Regulation, or the requirements of EU law more generally, were fulfilled;
 - d. specifically, please provide a copy of any relevant briefing or submissions provided to Minister(s) prior to the final approval decisions being taken;
 - e. the correspondence with the NFU regarding the approval decisions and compliance with the conditions set out in the decisions.
29. Please also confirm that the Secretary of State has informed the EU Commission and other Member States of the grant of the Authorisations as required under Article 53 of the Regulation, and provide copies of the relevant correspondence.

Time for Response

30. In view of the urgent nature of this matter, we invite your response to this pre-action protocol letter by no later than 12 pm on Monday 3rd August. If we do not hear from you by then we reserve the right to revert to commence judicial review proceedings, including any applications for disclosure and/or injunctive relief that may prove necessary, without further recourse to

you.

31. You will recognise that this is a matter of grave concern and considerable public interest not merely to Friends of the Earth but to all those interested in the protection of bee species and the impact of their continuing decline on European and global agriculture. It is obviously a matter of public importance that this matter is dealt with at the earliest opportunity and, ideally, without the need for the involvement of the Courts. We very much hope that you will agree that this is a matter where DEFRA can correct the situation without the need to proceed to litigation.

Yours faithfully

Gita Parihar
Head of Legal
Friends of the Earth