

Neutral Citation Number: [2015] EWHC 3283 (Admin)

Case No: CO/3995/2015

IN THE HIGH COURT OF JUSTICE QUEEN'S BENCH DIVISION ADMINISTRATIVE COURT

Royal Courts of Justice Strand, London, WC2A 2LL

Date: 12/11/2015

Before:

THE HON. MRS JUSTICE PATTERSON DBE

Between:

THE QUEEN on the application of FRIENDS OF THE EARTH LIMITED

Claimant

- and -

SECRETARY OF STATE FOR THE ENVIRONMENT, FOOD AND RURAL AFFAIRS

Defendant

- and -NATIONAL FARMERS UNION

Interested Party

Gerry Facenna and Daisy Mackersie (instructed by Friends of the Earth) for the Claimant Richard Kimblin (instructed by Government Legal Department) for the Defendant Hugh Mercer QC and John Robb (instructed by National Farmers Union) for the Interested Party

Hearing date: 5 November 2015

Approved Judgment

Mrs Justice Patterson:

Introduction

- 1. The claimant, Friends of the Earth Limited, is a leading environmental campaigning organisation and part of Friends of the Earth International. It is currently working on a campaign known as the "Bee Cause" which focuses on the decline in bee numbers and the continuing threat to the bee population caused by the loss of natural habitat and the use of harmful pesticides in intensive farming methods.
- 2. The defendant is the Secretary of State for the Environment, Food and Rural Affairs who is the competent authority designated by the United Kingdom in respect of England and Wales for the purposes of Regulation (EC) Number 1107/2009 of 21 October 2009 concerning the placing of plant protection products ('PPPs') on the market.
- 3. The interested party, (the National Farmers Union ('NFU')), is the leading industry association for farmers in England and Wales. It was the successful applicant for the authorisations that are under challenge.
- 4. The interested party made an application to the defendant in April 2015 for authorisation for emergency use of neonicotinoids to reduce possible damage to the 2015-16 winter oilseed rape crop caused by cabbage stem flea beetle ('CSFB') and the peach potato aphid. The first applications were refused in May 2015.
- 5. The second applications were made in June and were granted on 24 July 2015.
- 6. The claimant seeks judicial review of the defendant's decision to grant the emergency authorisations for the use of two pesticides, 'Modesto' and 'Cruiser OSR', containing active substances known as neonicotinoids. Certain neonicotinoids are restricted under EU law so as to exclude high risks to bees.
- 7. Permission was refused on the papers by Blake J on 15 September 2015.

Legal Framework

- 8. There is an EU regime requiring all pesticide products containing active substances to be tested and authorised before they can be placed on the market. In 2009 Regulation (EC) 1107/2009 replaced earlier Directives. The Regulation came into effect in June 2011 and lays down harmonised rules for the approval of active substances and the placing on the market of PPPs.
- 9. So far as relevant the recitals to the Regulation provide:
 - "(8) The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture. Particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children. The precautionary principle should be applied and this Regulation should ensure that industry demonstrates that

substances or products produced or placed on the market do not have any harmful effect on human or animal health or any unacceptable effects on the environment.

- (9) In order to remove as far as possible obstacles to trade in plant protection products existing due to the different levels of protection in the Member States, this Regulation should also lay down harmonised rules for the approval of active substances and the placing on the market of plant protection products, including the rules on the mutual recognition of authorisations and on parallel trade. The purpose of this Regulation is thus to increase the free movement of such products and availability of these products in the Member States.
- (10) Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment. In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level on the basis of harmonised criteria. These criteria should be applied for the first approval of an active substance under this Regulation. For active substances already approved, the criteria should be applied at the time of renewal or review of their approval.

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- (32) In exceptional cases, Member States should be permitted to authorise plant protection products not complying with the conditions provided for in this Regulation, where it is necessary to do so because of a danger or threat to plant production or ecosystems which cannot be contained by any other reasonable means. Such temporary authorisations should be reviewed at Community level."
- 10. Article 1(3) and (4) of the Regulation provide as follows:
 - "3. The purpose of this Regulation is 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.
 - 4. 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. In particular, Member

States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory."

- 11. The Regulation provides a range of derogations for active substances.
- 12. Chapter 3 of the Regulation deals with authorisation of PPPs. It is the Member State which gives authorisation for the placing of a PPP on the market: see Article 28.
- 13. Article 53, at issue in this claim, provides, where relevant, as follows:

"Emergency situations in plant protection

- 1. By way of derogation from Article 28, 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.
- 14. Measures required pursuant to Article 72 of the 2009 Regulation are set out in the Plant Protection Products Regulations 2011 (SI 2011/2013) which contains various relevant provisions including those that grant specific enforcement powers and create offences.
- 15. Clothianidin, thiamethoxam and imidacloprid are neonicotinoids. They are active substances which are deemed to have been approved for the purposes of the Regulation.
- 16. There is a disagreement between Member States as to the effects of the three substances on certain invertebrates including insects. In the absence of agreement the European Commission made a Commission Implementing Regulation (EU) No. 485/2013 of 24 May 2013 (the 2013 Regulation). It entered into force subject to transitional provisions on 26 May 2013.
- 17. While recognising the approval of the three neonicotinoids set out, the effect of the 2013 Regulation is to impose restrictions on the uses of those substances which does not allow the use of seeds treated with pesticides containing the active substances.
- 18. The recitals to the 2013 Regulation explain the legislative background. Where relevant they are as follows:
 - "(4) In spring 2012, new scientific information on the sublethal effects of neonicotinoids on bees was published. The Commission, in accordance with Article 21(2) of Regulation (EC) No 1107/2009, asked the European Food Safety Authority, hereinafter 'the Authority', for scientific and technical assistance to assess this new information and to

review the risk assessment of neonicotinoids as regards their impact on bees.

- (5) The Authority presented its conclusions on the risk assessment for bees for clothianidin, thiamethoxam and imidacloprid on 16 January 2013.
- (6) The Authority identified for certain crops high acute risks for bees from plant protection products containing the active substances clothianidin, thiamethoxam or imidacloprid. The Authority identified in particular high acute risks for bees from exposure via dust as regards several crops, from consumption of residues in contaminated pollen and nectar as regards some crops and from exposure via guttation fluid as regards maize. In addition, unacceptable risks due to acute or chronic effects on colony survival and development could not be excluded for several crops. Furthermore the Authority identified a number of data gaps for each of the evaluated crops. In particular as regards long term risk to honey bees from dust exposure, from residues in pollen and nectar and from exposure from guttation fluid.

. . .

- (10) The Commission has come to the conclusion that a high risk for bees cannot be excluded except by imposing further restrictions.
- (11) It is confirmed that the active substances clothianidin, thiamethoxam and imidacloprid are to be deemed to have been approved under Regulation (EC) No 1107/2009. In order to minimise the exposure of bees, it is, however, appropriate to restrict the uses of those active substances, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing those active substances to professional users. In particular the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid should be prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals. **Foliar** treatments with plant protection products containing clothianidin, thiamethoxam or imidacloprid should prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering. Crops which are harvested before flowering are not considered attractive to bees.

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(14) Risks for bees from treated seeds have been identified in particular from exposure via dust as regards several crops, from consumption of residues in contaminated pollen and nectar as regards some crops and from exposure via guttation fluid as regards maize. Taking into consideration those risks linked with the use of treated seeds, the use and the placing on the market of seeds treated with plant protection products containing clothianidin, thiamethoxam or imidacloprid should be prohibited for seeds of crops attractive to bees and for seeds of cereals except for winter cereals and seeds used in greenhouses."

- 19. The restricted approval means that a Member State cannot, pursuant to Articles 28 and 29 of the Regulation, authorise the placing on the market of pesticide products that contain those active substances, except in accordance with the restricted approval conditions that preclude their use with crops attractive to bees, or pursuant to the emergency derogation in Article 53.
- 20. The European Commission has circulated a Note to members of the Standing Committee on the Food Chain and Animal Health about the interpretation of Article 53 of the 2009 Regulation. That Note explains that it is the understanding of the Commission that Article 53 allows member states "to grant an exception for the use of PPPs for the treatment of seeds and also an exception for the placing on the market and use of the treated seeds, as otherwise in the case of PPPs used for seed treatment, Article 53 would be without purpose."

21. The Note continues:

"Nevertheless we would like to remind Member States that according to Article 53(2) and (3) if necessary the Commission may take a decision concerning an emergency authorisation in accordance with the regulatory procedure. The Commission may consult EFSA for advice and where the Commission concludes its intervention is justified, it may present a proposal to the Standing Committee, providing for the Member States to extend or repeat the authorisation or not, or requiring the Member State to withdraw it."

Factual Background

- 22. On 14 April 2015 the interested party made two applications for emergency authorisations. The applications for Cruiser OSR and Modesto were to seek control of both the CSFB and the aphid. There was a further application for Lumiposa to control the CSFB only which was made in May 2015.
- 23. Many of the functions of the Secretary of State as authorising authority are delegated to the Health and Safety Executive ('HSE'). HSE's work on pesticide authorisation is carried out by the Chemicals Regulation Directorate ('CRD') of HSE.
- 24. Experts from CRD carry out an initial evaluation of applications for emergency authorisation. Their assessment is passed to the UK Expert Committee on Pesticides ('ECP') which is a body of scientific and technical experts set up to provide ministers with independent advice. Their remit includes the provision of independent scientific

advice on matters relating to the effective control of pests, including advice on approval and authorisation of pesticides.

- 25. The ECP's advice goes to the regulatory departments: DEFRA, Department of Health (DH), Food Standards Agency (FSA), Department of Work and Pensions (DWP) and the devolved administrations for a final decision. This reflects the fact that pesticide authorisations may have implications for the environment, human health, food safety, or the safety of those who may be exposed to pesticides during the course of their work.
- 26. In addition, Ministers receive advice from DEFRA's Chief Scientific Advisor Professor Ian Boyd. He advised on all applications made by the interested party. In 18 May 2015 his opinion was that the documentation presented fell considerably short of what would be needed to have confidence that an emergency authorisation was based upon appropriate consideration of risk. The data and presentation did not have appropriate levels of robustness and the stewardship scheme fell short. He continued at [17]:
 - "17. This is especially unfortunate because there are likely to be specific instances where there is a real need for application of crops with neonicotinoids. I have seen for myself what I believe are the effects of pests on winter OSR crops in Suffolk. Growers that can demonstrate that they have adopted low risk behaviours (e.g. in terms of choice of variety, time of drilling etc) but have still encountered demonstrable (i.e. evidence-based) severe pest problems are likely to be in greatest need for chemicals issued under Emergency Authorisation. This is most likely to satisfy the need for such an authorisation to be 'limited and controlled'."
- 27. The applications were refused by the defendant in June 2015 on the basis of advice from the ECP that the proposed use of the restricted pesticides was not "limited and controlled" and, therefore, the requirements of the Regulation were not satisfied.
- 28. The advice of the Committee continued:

"However, given the potential for significant localised crop damage that has been identified the ECP would be willing to consider a revised application for use in the areas of highest need for control of cabbage stem flea beetle."

The report went on to identify specific information that would be required to support a revised application.

29. The recommendations to Ministers on the first applications were:

"Recommendations: That you:

• note the assessment by the Health and Safety Executive (HSE) and the UK Expert Committee on Pesticides (ECP) that the three applications do not meet the

standards for emergency authorisation although, particularly in the case of the neonicotinoids, it might be possible that a case for a much more targeted authorisation could be made:

- note there is no basis for issuing the requested emergency authorisations and therefore, based on the evidence, agree that the three applications should be refused;
- agree that the NFU should be provided with broad advice on what might be required to meet the standards for emergency authorisation for the neonicotinoids (without any commitment on the Government's part that a fresh application would be successful)."
- 30. Further applications for emergency authorisation were made by the interested party on 30 June 2015. The covering letter explained how the applications were different from the earlier ones:

"However, we have focused these new applications to enable protection of crops in the county most severely affected in the current growing season, for which we have data i.e. Suffolk. This amounts to 5% of the OSR (oilseed rape) crop area."

The scale of the application, coupled with proposed stewardship arrangements to target and control use was said to meet the standard required as "limited and controlled" within the meaning of Article 53 of the 2009 Regulation.

- 31. The application explained that the Cruiser OSR and Modesto treated seed had to be available for crops in Suffolk that may be drilled as early as the end of July.
- 32. On 9 July 2015 Professor Boyd gave his opinion on the later applications. He said:
 - "5. The NFU is seeking emergency authorisation for the use of neonicotinoids on Oil Seed Rape (OSR) in Suffolk. This is around 5% of England's OSR crop area. The application describes procedures to control the use of neonicotinoids within this region. I advise that such an authorisation is likely to meet the standard required of being 'limited and controlled'.

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- 8. Granting the application will also increase our knowledge of the effects of neonicotinoids because we will have one treated region (Suffolk) to compare with other untreated regions."
- 33. On the second applications the ECP advised that:

- i) There was evidence to demonstrate the need to control CSFB in some geographic areas and there were limited realistic alternatives available for the control of that pest.
- ii) However, the current scientific evidence was not robust enough to identify precisely the areas at highest risk. Historic practice had been to treat the majority of oilseed rape sown and the industry has collected limited data by which to identify those areas at most risk of crop and yield loss.
- target the most "at risk" areas as it would include fields in Suffolk that are not at risk but omit high risk areas beyond the county's boundaries. However, the size of the area proposed and the stewardship arrangements (with the additional data collection specified below) were considered to meet the criteria of being "limited and controlled".
- iv) Any authorisation should be limited instead to the total volume of seed that may be treated. The applicant and authorisation holders must then aim to ensure within prevailing constraints, that such seed is distributed in such a way as to target areas of highest risk, while also maximising the quality and quantity of data that can be generated to better inform future assessment of benefits and risk.
- v) The Committee advised Ministers that it supported the requested applications without the proposed county restriction. The authorisation should, however, be restricted so that only sufficient seed to plant 31,700 hectares (equivalent to 5% of the OSR crop in England) (or by weight 127,000 kilograms or 127 tonnes of seed based on the applicant's stated sowing rate of 4 kilograms per hectare) may be treated with the applicant ensuring this is distributed to the areas considered to be at highest risk. The authorisation should also be conditional upon appropriate stewardship and the generation of data by the applicant to augment the evidence base in this area.
- 34. The briefing to Ministers contained the following recommendation:

"Recommendations: That you:

- note the assessments by the Health and Safety Executive (HSE) and the UK Expert Committee on Pesticides (ECP). As summarised in paragraphs 5 and 6, both bodies now support the granting of emergency situation authorisations, on terms which are slightly different from those in the NFU's revised case;
- agree that the applications for emergency situation authorisations should be granted on the basis proposed by the ECP (discussion on the options is at paragraphs 7 to 10); and
- agree the proposed Comms lines (paragraphs 11 and 12)."

The case was summarised as follows:

- "3. The NFU submitted on 30 June 2015 a revised case (the core document is at Annex 2) to support new applications for emergency authorisation to allow the use on oilseed rape of Cruiser OSR and Modesto, which contain restricted neonicotinoids. The main elements of the revised case are:
 - The emergency situation authorisation would only allow use in Suffolk. This means that it covers a much more <u>limited</u> area – around 5% (33,000 Ha) of England's OSR crop area of 634,000 Ha.
 - The NFU have sought to justify this area as having the greatest need for the product because of the <u>danger</u> to crops.
 - The NFU propose to translate the proposed area limit into a maximum amount of treated seed of 132,648kg (sufficient to treat the Suffolk OSR area at a planting rate of 4kg/Ha).
 - In terms of <u>control</u>, the NFU propose the following stewardship arrangements:
 - o Customers sign a stewardship agreement at the point of purchase, stating the exact usage restrictions granted for appropriate use.
 - Rape seed is provided to growers in bags of approximately 8kg, with labelling to indicate that the product is only approved for use in Suffolk.
 - o The details of all those purchasing treated seed to be kept by those selling directly to the grower or to seed retailers. All sales information to be held for a minimum of 12 months and made available on request.
 - All retailers of treated OSR seed would also be required to record: the location of grower and intended planting area; the number of units sold; information on variety and seed treatment information; and a BASIS-qualified agronomist's recommendation for treated seed in each field where the products may be used.
- 4. The choice of Suffolk is based on Cabbage Stem Flea Beetle (CSFB) county trials data, which indicate that Suffolk showed the highest level of leaf area loss at the 3-4 leaf stage (64%) out

of the 14 counties tested. Suffolk also showed high levels of CSFB larvae and levels of Turnip Yellows Virus in OSR were also above the English average. The NFU also noted that specifying Suffolk would simplify the control of seed distribution and provide a clear area of comparison with neighbouring untreated areas of high threat. This is potentially useful – a limited authorisation like this would provide a good opportunity to evaluate the efficacy of neonicotinoids relative to other treatments.

- 5. HSE, as the regulator, carried out an initial assessment of the revised case (Annex 3). HSE concluded that, despite the justified needs and targeted approach set out above, the applications did not meet the precondition in article 53 of Regulation 1107/2009 as being for 'limited and controlled use'. This was because they would include areas which are not at highest risk whilst excluding some which are.
- 6. The applications were considered by the ECP on 7 July. The ECP's advice is set out in full at Annex 4. The Committee advises Ministers that it supports authorisation on the basis of the NFU applications but without specifying that use must be in Suffolk (they consider that such a restriction would only partially target the areas most at risk). Instead, they propose that the authorisations should be restricted so that only sufficient seed to plant 31,700 Ha (equivalent to 5% of OSR crop in England) (or by weight 127 tonnes of seed based on the applicant's stated sowing rate of 4kg/ha) may be treated. The applicant should be required to ensure that this is distributed to the areas considered to be at highest risk. The authorisations should also be conditional upon appropriate stewardship and the generation of data by the applicant to augment the evidence base in this area. HSE regard the ECP recommendations as addressing their concerns about the NFU applications. Ian Boyd is also content to accept the applications (his note in Annex 5)."
- 35. The June applications were duly granted on 24 July 2015.

Grounds of Challenge

- 36. Although originally the claimant raised four grounds of challenge it has been able, in the light of disclosure, to focus its challenge on three main points. Its overarching point is that issues relating to the correct application of the Regulation and the lawfulness of the defendant's actions are clearly arguable. There is a clear public interest in ensuring the proper legal tests are being applied when the Secretary of State authorises the use of pesticides whose use is restricted under EU law. The three grounds can be summarised as follows:
 - i) That no proper consideration was given by the defendant as to whether the risk posed to oilseed rape was an emergency such as to justify authorisation;

- ii) That no consideration was given as to whether the risk posed could be contained by any other means; and
- iii) That there was no compliance with the requirement that the authorisation should be limited and controlled.
- 37. Underlying all grounds was the principle of proportionality which had to be borne in mind.

Ground One: Was the risk posed by an emergency situation such as to justify authorisation of the neonicotinoids?

- 38. The claimant submits that the defendant failed to consider the correct legal test and whether there were exceptional circumstances to justify authorisation. Professor Boyd had spelt out the problems in the first applications and there was no change in the second. The use of the emergency authorisation process by the interested party was to circumvent the prohibition on pesticides that EU legislation had put in place.
- 39. The advice from Professor Boyd did not address the language of the derogation. There was not a set of special circumstances nor any analysis of how much crop loss there might be expected from the withdrawal of pesticides. Although more material was added in the 30 June applications there was no evidence.
- 40. To proceed on the basis that there was likely to be some damage to the winter oilseed rape crop from CSFB as a result of the restriction on the use of the neonicotinoids contained two serious errors.
- 41. First, it ignored the fact that some increase in damaged crops was to be expected following the restriction, particularly for growers who had not adapted to the restriction by using alternative pest control methods. That had been highlighted by Professor Boyd in paragraph 7 of his opinion on the May applications:
 - "7. The current system for growing winter OSR has been developed under the assumption that chemical pest controls are widely available. This means that it would be reasonable to predict widespread damage to crops should these chemicals be withdrawn from use. However, the application comes at a time when the crop has not yet been harvested so judgements about the end point costs in terms of both yield and profit cannot be made."
- 42. The 2014/15 winter oilseed rape crop was the first winter crop to be planted after the restriction had been introduced and it was not, therefore, surprising that there may have been some additional damage to the crop from CSFB. That was not exceptional or special, it was to be expected.
- 43. The argument that the loss of oilseed rape crop was in itself exceptional cannot be sufficient to support the emergency authorisation given that the ECP concluded that the large CSFB population in the 2014/15 winter drilling season was as a result of particularly unfavourable weather conditions.

44. Further, the use of the authorisation to, at least in part, trial the effectiveness of restricted pesticides with a view to making it easier to obtain further emergency authorisations is an improper way of proceeding. In August 2015 the interested party's agricultural policy officer asked for growers to take part in trials of neonicotinoid seed treatments. Part of that request said:

"The information gathered from these trials will be absolutely essential as evidence for need for future seed treatments and hence it is vital that they are successfully completed to ensure that any future applications are considered by the regulators. Without enough growers taking part, the case for future EUAs will be severely compromised."

45. The decision to grant the authorisation does not comply with the principle of proportionality or the precautionary principle where it is not clear what damage would in fact be sustained to the winter oilseed rape crop without using restricted pesticides.

Ground Two: Was there a failure to consider non-chemical alternatives?

- 46. In his advice on the May applications Professor Boyd had stated that there was no assessment by the NFU of how practices such as delayed drilling could mitigate CSFB damage and how that compared with chemical treatments. No such evidence was provided in the June applications.
- 47. The advice provided to the defendant by the ECP and the CRD on the June applications contained no analysis of non-chemical alternatives. It considered only the lack of alternative chemical control options.
- 48. The regulation required that the danger proposed could not be "contained by any other reasonable means". That required a consideration of the evidence that growers had used alternative methods and still suffered CSFB damage.
- 49. The approach also demonstrated a disregard for the Sustainable Use Directive which required the Secretary of State, "to take all necessary measures to promote low pesticide input pest management, giving wherever possible priority to non-chemical methods".

Ground Three: Whether the use of the restricted pesticides was "controlled"?

- 50. The claimant accepts that the authorisations are limited. Its concern is that the authorisations apply to the whole of England. It is left to the discretion of the interested party to decide what the controls would be and how they would be applied.
- 51. Mr Gagen, who is the chief arable advisor to the interested party, refers to sampling undertaken at farms across England in the autumn of 2014 which identified that Bedfordshire, Cambridgeshire and Hertfordshire were amongst the worst affected where oilseed rape leaves in each of them were found to have a very high presence of the CSFB larvae with over 25% of the total oilseed rape crop damaged as a result. Suffolk and Hertfordshire in particular had average leaf losses of 64% and 40% respectively. The problem with the approach adopted is that the pesticides would be available to some who needed them but not all. The HSE had said that they could not

support a county-specific approach and it was difficult to see how the NFU could then use one based on four counties. There were no criteria in the authorisations that meant that farmers should have tried alternative methods before being able to gain authorisation. That meant that the controls were left to the subjective decision of the agronomist and farmer.

Submissions of the Defendant and Interested Party

- 52. The defendant submits that it is vital to consider the material that was before the decision maker at the relevant time. That was summarised in the briefing Note to Ministers of 13 July 2015. There the issue was clearly set out, namely, that the interested party had revised its case for emergency authorisation of two seed treatments to protect oilseed rape against insect pests. The recommendation was clear and based upon the assessment carried out by the HSE, the ECP and Professor Boyd's opinion.
- 53. The fact of the earlier application was clearly set out in paragraph 2 which reads:
 - "2. The UK Expert Committee on Pesticides (ECP) considered that the original applications from the National Farmers Union (NFU) for the products Cruiser OSR and Modesto did not meet the requirements for emergency situation authorisation. It was highly likely that some growers would have a strong need for the seed treatments and so there appeared to be 'a danger which cannot be contained by any other reasonable means'. However, the application did not provide a good basis for identifying these growers. The application covering 79% of the English oilseed rape cropping area and with no real proposed stewardship was also not 'limited or controlled' as required in order for such an authorisation to be granted."

The revised application was then summarised, namely, the more limited area and the choice of Suffolk as having the greatest need for the product because of the danger to crops. The information that was being placed before Ministers involved the experience of specialists going out on to site and seeing the effects of the pests on oilseed rape. Although the claimant had contended there was no evidence Professor Boyd had been out in the field and seen matters for himself.

- 54. Having considered all matters the expert committee supported the authorisations. Those who understood the issues and had the appropriate technical and scientific experience thought it right to make a judgment.
- 55. What the claimant has done is to contend that what has been done is not consistent with the law, namely, that the facts do not fit the wording of the regulations. That involves an examination of the merits which is not for the court.
- 56. The options placed before the Ministers were either: to accept the NFU applications without amendment; accept the NFU applications but with a restriction on total area sown (as recommended by the ECP) rather than a requirement to use only in Suffolk; or to refuse the application.

57. The briefing Note continued:

"8. As set out in paragraph 6, expert advisers consider that the tests set out in EU legislation are largely met by the revised case submitted by the NFU. The requested authorisations are sufficiently limited and controlled and address a danger which cannot be controlled by any other reasonable means. HSE and the ECP feel that the adjustment to the terms of the authorisations suggested by the ECP is helpful in matching use to areas of strongest need (recognising that the available scientific data does not allow this to be done with precision). It would not prevent the NFU from operating the authorisations in the manner they originally proposed if they consider that this is an effective way of targeting treated seed to where it is needed."

The recommendation was to proceed with the second option.

58. In addition, the Ministers had before them a discussion and advice paper from the HSE. Attached to that was an assessment by CRD of the technical case of need for authorisation. That concluded that emergency authorisation was justified on the basis of CSFB control.

59. It said:

"It is CRD's overall view that, despite the justified needs and targeted approach set out above the applications do not meet the criteria in Regulation 1107/2009 as being for 'limited and controlled use' since they would include areas which are not at highest risk when excluding some which are. We expect that an area in excess of 5% of the total sown area of oilseed rape is likely to meet the criteria across the county as a whole but the applicant has not demonstrated how those areas might be targeted."

It then posed the question "Does the ECP consider the emergency authorisation under the requirements of Regulation 1107/2009 would be appropriate in the circumstances outlined in this paper and the attached applications?"

- 60. Advice to Ministers was from an expert body consisting of ecologists, agricultural professors and environmental scientists on whether or not the risk was of a sufficient magnitude to grant the authorisations. When the advice is considered in the context of the expert body it provides a complete answer to the claimant's allegation.
- 61. The issue of alternatives and absence of any other reasonable means were dealt with in the notifications to the EC as required after an authorisation had been granted. These said:

"There is a critical lack of chemical control options except foliar pyrethroid sprays to which resistance has now developed in the UK. The 2014 autumn season was both particularly favourable to cabbage stem flea beetle and coincided with a period of unfavourable conditions for crops drilled during mid-August and mid-September in some regions. This combination of factors led to the failure of 5% of the national crop at establishment, but the effects were localised in 'hotspot' areas. Regardless of this the underlying issue of pyrethroid resistance is likely to spread and the build-up of populations not controlled by pyrethroid foliar sprays season by season will cause increasing problems in the medium to long term. ...Further losses in terms of total yield may yet occur as a consequent and current presence of high larval populations which will damage the plants further. This was in part due to a combination of conditions, but also the confirmed presence of pyrethroid resistant CSFB populations in the local hotspot. Currently pyrethroid foliar sprays are the only chemical control option. In the UK, uniquely at present, metabolic mechanisms have been identified and these are the primary cause of loss of field performance."

62. Under rationale the following appeared:

"The case for early drilled crops and high risk from CSFB is accepted. The rationale for the use of seed treatments lies in their inherent practical advantages over foliar sprays. They provide available protection at the time of sowing to the emerging seedling at the critical time of crop establishment. Seedlings are most vulnerable to pest damage in their growing tips and first true leaves. Providing protection at this point allows the plants to develop and grow away from this susceptible stage. In the worst case situations, insufficient crop establishment may lead to crop failure and subsequent redrilling. Population build up can also lead to impacts on final yield."

63. On research activities the notifications said:

"Funding an alternative to pesticides and pesticides resistances remained a significant proportion of the DEFRA pesticides research and development expenditure. There is also work in other government research programs relevant to the development of integrated approaches such as on identification of genetic resistance and tolerance to pests and diseases and work to inform and develop integrated control systems. However there are no other viable control methods at present."

- 64. The time of drilling, the defendant submits, is for assessment by an expert committee understanding the impact of all of the options.
- 65. The interested party submits that the special circumstances required to be found is a factual finding. The test is broadly textured; it is, do the facts amount to special circumstances? The claimant has mischaracterised the position by saying that the

- basis of the authorisations was that there was likely to be some damage to crops whereas the findings of the ECP was that there was severe damage at localised areas.
- 66. The work done by the Agriculture and Horticulture Development Board (AHDB) investigated the extent of the damage by CSFB and demonstrates that in the eastern region 7% of the crop was lost and 16% was at high risk and in the south-east region 6% was lost and 12% was high risk. Professor Boyd himself had visited the farms.
- 67. The claimant has been unable to show any arguable error of law in the approach of the decision maker to special circumstances. There was evidence before the ECP to enable it to come to its conclusion and it is not for the court to deal with the degree of weight to be attached to that evidence.
- 68. On ground two what qualifies as "reasonable alternative means" is a matter of judgment for the Secretary of State. In fact, evidence submitted by the interested party demonstrates that alternative means were considered. Cultural management strategies in the experience of Mr Gagen, are always the first point of call for farmers growing arable crops including oilseed rape.
- 69. As to ground three the conditions in the authorisations which deal with the stewardship plan to be signed by all seed distributors and growers, data collection and targeting of areas of highest risk show that there was adequate control. The assessment as to the worst affected counties was on the basis of 64% leaf loss in Suffolk, 40% in Hertfordshire and 18% in Cambridgeshire. The individual growers have to keep detailed records of where they have drilled so that there are detailed controls in place when the seed is distributed.

Discussion and Conclusions

Ground One

- 70. In the grounds for reconsideration the claimant contended that there would only be "special" circumstances sufficient to justify emergency authorisation under Article 53 of the EU Regulation where it can be shown that growers have, following the ban on neonicotinoids, tried to control crop damage using alternative methods and this has not worked. It was not put in quite that way at the oral renewal hearing but that there had been a failure to consider the appropriate legal test to justify emergency authorisation.
- 71. There is no dispute that Article 53 as a derogation from Article 28 of the Regulation is to be strictly construed. The meaning of the words "special circumstances" is not defined. Their application is a matter of judgment for the decision maker in the relevant factual context before her. What is a special circumstance in one set of circumstances may not be in another.
- 72. The 30 June revised applications were assessed by the HSE and the ECP. The ECP advice referred to the earlier applications where the case on need for an emergency authorisation had been accepted in some geographic areas. Not only that, in some localised areas of the country severe impact on crop establishment had occurred through a failure to control the CSFB. There were documents attached to the application for authorisation both photographic, tabular and other supporting research

which provided a comprehensive basis to enable the decision maker to come to a judgment on whether what was before her constituted special circumstances. The decision maker concluded that it did. It cannot be said that such a finding was without an adequate evidential basis.

- 73. There is nothing in Article 53 which defines special as occurring "where it can be shown that growers have, following the ban on neonicotinoids, tried to control crop damage using alternative methods and this has not worked".
- 74. The claimant contends that some damage to the crop was to be expected, as Professor Boyd pointed out in his May opinion. That is true, but the extent of that damage and whether it was sufficient to constitute a "special circumstance" is again a matter of judgement for the decision maker.
- 75. The decision maker came to her decision taking into account considerable technical and scientific advice on the situation. Professor Boyd had carried out a personal visit to Suffolk and saw for himself what he believed to be the effect of the pests on the winter oilseed rape crops. His opinion was taken into account in the assessment by the ECP. The briefing Note records that he was content to accept the revised application.
- 76. In the circumstances I can see no argument that the defendant misdirected herself or misunderstood the meaning of Article 53. She was entitled to give appropriate deference to the expert and scientific evidence before her and make her own judgement as to whether "special circumstances" existed. The ground is not arguable.

Ground Two: Whether there were any other reasonable means?

- 77. The claimant contends that it is obvious that "any other reasonable means" refers to the use of non-chemical methods. Further, the interested party has provided no evidence on that and failed to address Professor Boyd's criticism in May. Its only consideration is of chemical alternatives.
- 78. There was evidence before the decision maker from the ECP including presentations by Syngenta and the AHDB. In addition, there was further evidence available to and expertise within the expert and scientist members of the ECP, in particular, with regard to agronomy and pesticides.
- 79. The question of what is, in the particular circumstances, a reasonable alternative is a matter of fact and degree. It is also a matter which is closely related to the issue of need. In the advice to ministers the ECP concluded that:

"There is a need to control this pest and there were no suitable plant protection products available, with no other insecticide seed treatments and only pyrethroid foliar sprays. There is a developing resistance in CSFB to pyrethroid insecticides but with no alternative chemicals authorised it is likely pyrethroid usage will continue and heighten resistance pressures. Using cultural methods, for example sowing at times to avoid peak CSFB activity, can be a successful option. However, this is dependant of a complexity of agronomic, environmental and

practical factors during the season. Hence the requirement of the regulation that there is a danger which cannot be contained by any other reasonable means was considered to be fulfilled."

- 80. Mr Gagen's witness statement is to the effect that farmers use cultural methods so far as reasonably practicable in order to try to control pests including CSFB. The ECP with its expert composition would have been aware of farmers' general practices with regard to cultural practices.
- 81. The notifications to the Commission set out above illustrate clearly that there was consideration of the absence of any other reasonable means. It concluded that there were no other viable control methods at present. The notifications were part of a process whereby the European Commission may take a decision concerning an emergency authorisation in accordance with the regulatory procedure. It may consult EFSA for advice and where the Commission concludes its intervention is justified it may present a proposal to the standing committee providing for the Member State to extend or repeat the authorisation, or not, or requiring the Member State to withdraw it. The case of **R** (**Rotherham Metropolitan Borough Council**) **v Secretary of State for Business, Innovation and Skills** [2005] UKSC 6 at [24] is authority for the proposition that the national court should be extremely cautious before accepting that a proposal is inconsistent with a regulation which the Commission charged with applying it has found to be consistent with it.
- 82. The claimant seeks support from the Sustainable Use Directive 2009/128/EC. That Directive is intended to be complementary to measures laid down in other community legislation: see paragraph 3 of its recital. Article 2(2) of the Sustainable Use Directive provides that "this Directive shall apply without prejudice to any other relevant community legislation". It is, therefore, not arguable that the Sustainable Use Directive qualifies or otherwise affects the criteria of Article 53 of the Regulation.
- 83. The claimant refers also to Article 14 of the Sustainable Use Directive but that places no obligation on the defendant. In any event, the wording of Article 53 is to admit authorisation only where there is a danger which cannot be controlled by any other reasonable means. What is reasonable again is a matter for judgment in the circumstances of each case by the decision maker. There is no legislative requirement to have exhausted cultural methods before being able to conclude that there are no other reasonable alternatives.
- 84. There is nothing in this ground.

Ground Three: Was the authorisation "limited and controlled"?

- 85. The claimant accepts that the authorisation is limited in that the authorisations limit the quantity of treated seed to 5% of the national oilseed rape crop area. The issue is whether the authorisation is appropriately controlled.
- 86. The complete answer to this ground is to be found within the authorisations themselves. Appendix 1 to the authorisations contains a series of obligatory conditions. Failure to comply with any of them results in the withdrawal or amendment of the emergency authorisation.

87. The first part of the conditions read as follows:

"The Authorisation Holder is required to keep records(location of grower and intended planting area, units of treated seed sold, variety and seed treatment, information and a copy of the BASIS qualified agronomists recommendation for each field to be planted) of all sales made and all product supplied under the terms of this Authorisation. These records should be compiled and summarised into a report with analysis of where the seed has been used. The raw data and summary report must be provided to the Chemicals Regulation Directorate (CRD) of the Health and Safety Executive (HSE) within 6 weeks of the expiry date of this Emergency Authorisation.

This authorisation is conditional upon all purchasers of treated seed accepting and signing a copy of the agreed stewardship plan. These documents must be retained and be made available to the Chemicals Regulation Directorate (CRD) of the Health and Safety Executive (HSE) within 6 weeks of the expiry of this authorisation.

This authorisation is conditional upon the Authorisation Holder using the authorised area to generate robust, detailed data on both treated and untreated crops. The nature of this data to be as agreed with the Chemicals Regulation Directorate (CRD) of the Health and Safety Executive (HSE) but should include impact on adult and larval numbers, crop establishment/damage and effects on crop yields, resistance occurrence and management. A system should be established to monitor trends in these factors over time that includes the co-ordinates of the treated fields. This data will be required to support any future consideration of an emergency authorisation of this product on this crop.

This authorisation is conditional upon the applicant and Authorisation Holder ensuring, within prevailing constraints, that the seed is distributed in such a way as to target areas of highest risk, while also maximising the quality and quantity of data that can be generated to better inform future assessments of benefits and risks."

- 88. That is followed by a series of further conditions relating to placing on the market, classification and labelling and use. There are then further general conditions of authorisation. Failure to comply with the conditions will or can result in withdrawal or amendment of the authorisation or other enforcement action including prosecution.
- 89. The fact that there is a 5% limit necessarily also imposes a control on the use.
- 90. Further, Professor Boyd in his July opinion is quite clear that the revised applications were likely to meet the standard required by the "limited and controlled" test.

- 91. The form of the stewardship agreements were agreed between the licence holders and CRD, and were to be signed by the seed distributors and the growers. The worst affected counties were where the treated seed was going to be distributed.
- 92. It is unarguable that the authorisations were not "controlled".

Other Matters

- 93. The claimant contended that it was important to gain guidance from the court in relation to authorisation so that it could be used in further applications that may be made for authorisation. First, that is not a ground for judicial review. Second, as is evident all these applications are going to be fact sensitive so what is apposite in relation to the instant authorisations is not necessarily going to be the case in relation to another.
- 94. Whilst the principle of proportionality is in play in considering the Regulation there is nothing which indicates that the measure in question, in the circumstances, is not appropriate to achieve the objective pursued and that it is not necessary to achieve that objective. It is said by the claimant that there was no consideration given by the decision maker to a shorter time period than 120 days or where the authorisation should apply. In relation to the latter consideration was given in that the quantity of the neonicotinoids was restricted and subject to agreement with CRD and the stewardship plans. As to the former it is right that there was no overt consideration given to a shorter period than 120 days but, given that the determination was that need had been established, it can be inferred that the need extended over the entirety of the time for which the authorisation was granted.
- 95. There is reference in the claimant's grounds to a mistake of fact as a basis for judicial review. No oral submissions were made on that to the court. The inference is that it is not pursued.

Conclusion

96. Accordingly, I find this case unarguable on all the grounds that have been the subject of oral argument before me. The application is dismissed.