

Department for Environment, Food and Rural Affairs

The UK Expert Committee on Pesticides (ECP)

Advice to Ministers:

## Emergency Authorisation of 'Cruiser OSR' and 'Modesto' as a seed treatment on oilseed rape

### Background

The Committee has considered further applications received by HSE for emergency authorisations for products containing neonicotinoid active substances for use as seed treatments on winter oilseed rape (OSR), to reduce damage caused by Cabbage Stem Flea Beetle (CSFB) (*Psylliodes chrysocephala*) and improve crop establishment. The products are 'Cruiser OSR' (containing the active substance thiamethoxam and two other fungicide active substances) and 'Modesto' (containing the active substance clothianidin, and the pyrethroid insecticide beta-cyfluthrin). The use requested under these applications is currently prohibited as a result of Regulation (EU) No. 485/2013, which was adopted in order to protect bees from the potential adverse effects of these chemicals. Under Article 53 of Regulation (EC) No. 1107/2009 Member States are permitted to issue emergency authorisations for a period of up to 120 days where necessary 'because of a danger which cannot be contained by any other reasonable means' and where the authorisation is for a 'limited and controlled use'.

The National Farmers Union (NFU) and Agriculture and Horticulture Development Board (AHDB) made the applications for these emergency authorisations. The authorisation holders Bayer CropScience Limited (Modesto) and Syngenta Crop Protection UK Limited (Cruiser OSR) support the submissions.

The applicants have applied for authorisations sufficient to treat a sown area of 120,000ha (which represents 22% of the last year's OSR cropped area in England). The application is based on AHDB data suggesting that last year this area of crop exceeded the UK advisory threshold level for foliar applications of pyrethroid insecticides for CSFB control at crop emergence. Nationally, crop loss at establishment attributed to CSFB was estimated at around 1%.

The previous applications considered by the Committee at its May meeting were for authorisations sufficient to treat 33% of the cropped area. The ECP advised that these applications did not meet the criteria necessary in order to grant an authorisation.

The applicants propose limiting the availability of seed to fifteen counties in England having: the greatest level of CSFB infestation according to AHDB estimates (Yorkshire, Norfolk, Cambridgeshire, Oxfordshire, Leicestershire, Berkshire, Lincolnshire, Herefordshire, Kent, Suffolk, Hampshire and Nottinghamshire); and known pyrethroid resistance (Herefordshire, Cambridgeshire, Bedfordshire, Suffolk, Norfolk, Yorkshire,

Essex, Buckinghamshire, Lincolnshire and Leicestershire). The requested authorisation would allow approximately 35% of the winter OSR crop in these counties to be treated.

Distribution of seed treated under the proposed authorisation would be accompanied by product stewardship arrangements. The arrangements are similar to those used under the previous emergency authorisation granted in 2015. In addition the applicants have proposed that agronomists will only be able to recommend use of treated seed if they have completed a new AHDB on-line training module on CSFB. The 'Grower' form also includes a stewardship check sheet to prompt the grower/agronomist to consider specific adverse conditions which may indicate that an alternative crop choice may be suitable.

### **The Committee noted:**

- That Regulation (EC) No. 1107/2009 allows emergency authorisations to be permitted in 'special circumstances... because of a danger which cannot be contained by any other reasonable means' and that such use must be 'limited and controlled'.
- That the papers submitted by Non-Governmental Organisations offered commentary on the existing evidence base but did not provide any new evidence that could be considered in evaluating the emergency authorisation application.
- That HSE considers that:
  - The proposed uses would not cause harm to human health and/or have an unacceptable effect on the environment. This view is based on previously authorised uses of these products, which was supported by data assessed in accordance with the Uniform Principles of Regulation (EC) No. 1107/2009 and associated guidance documents.
  - There are no other reasonable and effective alternatives to control CSFB and reduce damage at crop establishment in high risk areas;
  - There are no alternative chemical seed treatments to provide protection of the germinating seed from adult feeding damage. Pyrethroid foliar sprays are available after crop emergence, primarily targeting subsequent larval populations after egg hatch. A case exists for use of neonicotinoid seed treatments in areas where pyrethroid resistance has been confirmed, as a means to reduce adult population levels to assist in optimising IPM; and
  - The applicant has provided some justification for the use of a damage threshold for treatment and the extent of pyrethroid resistance in identifying the limited area requiring this treatment.
- The view of Defra and HSE advisors was that:
  - The limited guidance which was available on 'limiting' and 'controlling' use suggested that the criteria were to be determined on a case-by-case basis
  - Resistance management should not be the primary, nor sole, reason to grant an emergency authorisation;

- The reference in legislation to granting an authorisation where there ‘appeared’ to be an emergency did not take away the requirement to take full account of the evidence available, including that submitted in support of the application.
- On the need for an authorisation because there was a ‘danger which cannot be contained by any other reasonable means’ the Committee noted that:
  - CSFB was a pest which caused economic damage and that the authorised label claims, to reduce damage and aid crop establishment, were supported by data assessed in accordance with Uniform Principles of Regulation (EC) No. 1107/2009;
  - Crops which had struggled to establish could, in favourable conditions, still be managed to deliver ‘acceptable’ yields, but with associated cost and extra time management;
  - CSFB was a factor/pest likely to result in the failure of crop establishment. Background populations of the pest were, apparently, increasing year on year, with widespread pyrethroid resistance a major contributory factor. Their impact on crop establishment would differ from season to season, being affected by the interplay of a range of environmental and other factors, and effectiveness or otherwise of integrated control measures; and
  - Integrated approaches may help suppress/avoid the peak of CSFB populations at the time of sowing, but would not by themselves suppress existing local populations. The increased use of pyrethroid sprays would have a detrimental impact on natural predators.
- On the stewardship arrangements the Committee noted that:
  - The on-line training contained some useful elements but was, overall, insufficiently robust (i.e. no clear ‘pass’ mark, insufficiently precisely worded questions, multiple correct answers to two questions) and had yet to be accredited;
  - The Grower checklist included an apparently arbitrary cut-off of satisfying four of the six criteria, and no indication if there should be weighting of importance of some of the questions;
  - Supply of treated seed required completion of the checklist and an agronomist’s commentary, but was not defined or restricted according to the outcome of a risk assessment (i.e. not tied to a clearly defined need); and
  - Consequently, there was no evidence that treated seed would be supplied to areas at greatest risk, with no mechanism for assessing the respective merits of agronomists’ recommendations.
- On the documentation submitted in support of the application the Committee noted that:

- The ADAS Report did not contain information/detail to enable the impact of the treatment on yield to be detected because these data are not yet available.
- The statistical techniques employed to analyse the data were inappropriate in several aspects. For example:
  - o a focus purely on the statistical significance of mean differences between treated and untreated sites neglected to consider the size of absolute effects relative to meaningful thresholds (for example the proportions of sites where plants per m<sup>2</sup> were unacceptably low by some reasonable definition) and how these compared by treatment condition (for example, the difference in such proportions, with 95% confidence intervals).
  - o The Committee considered the use of a t-test to be inappropriate. In the study design, the unit of replication was the plot, strip or unpaired field. The data consisted of repeated observations within the units of replication and are therefore pseudo-replicates. An average per plot, strip or paired field is the appropriate count.
  - o Further, since experimental conditions varied systematically and by design, this complexity should have led to a multivariable analysis (this was promised for the future, but not available to the Committee).
- The AHDB Report sought to justify use in a number of counties on the basis of a very limited number (in some cases a single) of data points in each county. Information supplied previously by AHDB and restated further to the meeting explained that 56 agronomists, covering 42 counties in Great Britain, were employed to collect the data. Each agronomist was required to report on about 10,000 ha of crop with the aim of obtaining a 10% representation of the winter OSR area across Great Britain. In locations where the neonicotinoid seed treatments were supplied in 2015 data was only collected from crops that had not received the seed treatment to ensure that results from treated crops did not distort the results from untreated crops. Nonetheless, it was noted that in Figure 12 of the Report that estimates of mean CSFB larvae per plant were, for 14 of the 22 assessed counties, based on data from a single farm per county; and for all 22, an average of fewer than two farms per county. The Committee did not accept that representative information on a county with several thousand farms could be assured from such limited observations. The ECP has reservations concerning the representativeness of the information, and the soundness of extrapolating findings to the county and national level, to the extent of allowing 22% of the OSR area of England to receive emergency seed treatments.
- The Committee considered that the applicant's use of a threshold for a foliar insecticide as a means of determining the scale of damage risk that could justify the use of a seed treatment was unsupported in the application, and a questionable methodology used for the determination of the area at risk.
- The Defra Economist had advised that the economic impact assessment was not sufficiently robust. The assessment had identified appropriate impacts to consider, but failed to analyse/present the information appropriately. The Defra Economist

was, however, inclined to consider that there has been a real impact on farm incomes as a result of the neonicotinoid restrictions.

- The Committee were of the view that recommending refusal of these applications would not be inconsistent with the advice provided in 2015. The emergency authorisations were granted in 2015 with the expectation that this might afford the applicants the opportunity to demonstrate effective targeting of the seed treatments to areas of highest need. Industry had, however, failed to use the opportunity provided by the 2015 authorisations to generate an enhanced case for the emergency authorisation this year. Furthermore, there was insufficient:
  - information given in the application to support the proposed scale of use or define a more targeted area of use, supported by the data.
  - Evidence on work being undertaken to develop alternative approaches to control of CSFB to give the Committee confidence that industry would not in future become reliant on repeated emergency use authorisations.

### **The Committee considers that:**

- As emergency authorisations are to be granted in 'special circumstances' or 'exceptional cases', it is appropriate to subject 'repeat' applications to a thorough assessment in those cases where the Committee has sought specific supporting information or data, or where there is a substantial change in the scale or other nature of the application relative to the original. The requirements for emergency authorisation mean that an authorisation can only be granted if the product has substantial benefits which cannot be achieved by other means.
- A range of factors (both predictable and unpredictable) determine whether the use of seed treated with these products will be effective. Whilst it may be possible to seek an emergency authorisation on the grounds of resistance management, that should not be the primary nor sole reason on which to base an application.
- However, the applicants had not taken sufficient opportunity of the emergency authorisations granted in 2015 to generate more robust information to establish clear benefits of use and to enable better targeting of use. The updated and new information supplied by the applicants in support of the proposed authorisation contained insufficient detail to justify the proposed scale of use and to provide assurances it would be possible to target use at areas of greatest need (at a spatial scale significantly lower than County level).
- The proposed product stewardship arrangements offered insufficient assurances that even if use could be more precisely targeted it would be appropriately 'controlled'.
- Use of integrated controls may result in reduced reliance on seeds treated with these products in the medium to longer term, but did not offer a solution to the immediate case for need.

## **Committee advice**

The Committee, therefore, advises that whilst it recognises the potential for damage to crops by CSFB the new applications do not meet the criteria for an emergency authorisation, as:

- there is still insufficient information to ensure that use will be limited only to those areas where there is greatest danger or threat to plant protection; and
- The stewardship arrangements proposed by the applicant do not offer adequate assurance that the use will be controlled in an appropriate fashion.

**UK Expert Committee on Pesticides**

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