

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 two applications received by HSE for emergency authorisations for products containing neonicotinoid active substances for use as seed treatments on winter oilseed rape (OSR) to control Cabbage Stem Flea Beetle (CSFB) (*Psylliodes chrysocephala*). The products are 'Cruiser OSR' (containing the active substance thiamethoxam) and 'Modesto' (containing the active substance clothianidin). 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 195,000ha (which represents 33% of the average OSR cropped area in England in the last two years (591,000ha)). The application was based on AHDB data suggesting that over the last two years an average of 33% of the OSR crop grown in England exceeded the guideline threshold level for CSFB control using post emergence insecticide sprays and suffered moderate to severe pest pressure. The data also suggested that an average of 8.5% of the OSR crop grown in England suffered 'high to severe' pest pressure. An average of 2% of the OSR crop grown in England was said to suffer 'severe' pest pressure.

The only chemical control alternatives are foliar sprays of pyrethroid containing products, and there are now instances of resistance in CSFB populations to this pesticide group.

The applicants have proposed that supply of seed to areas of greatest risk would be assured by only providing seed to growers who received a written recommendation from a BASIS qualified agronomist who has undertaken a short on-line training course specifically for this purpose. All growers purchasing treated seed would need to agree to terms and conditions contained in a stewardship form provided by the companies.

The applicants also provided details of initial findings of studies undertaken following the granting of the 2015 emergency authorisations on the impact on adult and larval numbers and crop establishment/damage. They also provided an update on the incidence of pyrethroid resistance in CSFB populations in 2016. Information is not yet available on effects on crop yields from the 2015 autumn drilled oilseed rape.

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'.
- There is evidence (data supporting previously-granted on-label authorisations) to demonstrate that the use of seed treated with these products provide moderate control of CSFB, a reduction in damage and can improve crop establishment in certain circumstances. Factors such as weather, soil type and slug populations were also identified as key and could, depending on circumstances, be more important, factors in crop establishment.
- Farmers and growers carefully considered whether it was necessary to use seed treated with these products and took additional steps (such as preparing seedbeds) to help crop establishment.
- A lack of access to seed treated with these products may subject some farmers and growers to significant economic pressures. The applicants argued that seeking to determine the effectiveness of neonicotinoid seed treatments on the basis of overall yield figures was problematic given that a proportion of crops which failed to establish would not be taken to yield and hence their total loss would not necessarily be reflected in the data. It was however additionally stated that these crops could be replanted. It was also noted that there could be increased costs associated with the management/harvest of crops grown from seed which was not treated with these products. However, the likely economic impact of preventable losses from CSFB was unclear from the evidence provided.
- The direct benefit of the seed treatment is at establishment to protect the crop from significant damage at the early susceptible growing stages. This can, in extreme cases, prevent complete crop loss and the need to re-drill (if possible to do so), or having patchy establishment and poorly growing crops less able to tolerate further adverse conditions that may occur during the season. These benefits are described on the previously authorised label and supported by the underlying regulatory trials evidence previously assessed by HSE. This was confirmed by the conclusions of the ADAS monitoring study.
- Whilst it would be of interest to have yield data at harvest, it would be very difficult to establish a causal relationship between seed treatment efficacy against CSFB and yield due to the wide range of other factors during the course of the season that can influence final yield.

- Evidence demonstrates that the lack of access to seed treated with these products has resulted in an increased use of pyrethroid products.
- In survey data presented by the applicants, there was only a weak relationship between regional crop infestation by CSFB and regional patterns of crop damage and loss. Also, in survey data presented by the applicants, relatively few fields assessed for damage from CSFB in any region reached guidance thresholds for treatment, with no important differences between crops sown with treated and untreated seed. This suggests a lack of predictability regarding the targeting of treatments and their likely impact under field conditions, when using damage assessments alone to define an area for treatment.
- The weight of evidence suggests that targeted use of these products may improve the probability of successfully establishing a crop, but the mobile nature of CSFB populations, and influence that local agronomic and environmental factors at time of drilling have on risk of damage (independent of CSFB populations), make it difficult to reliably predict the value of treatments in any particular location.
- The current AHDB thresholds relate to treatment of damaged crops with foliar sprays. There are presently no reliable methods available to predict which crops will be at greatest risk from CSFB attack prior to sowing the seed.
- The applicants had provided insufficient evidence to enable the ECP to determine an appropriate scale of use and where or how this should be targeted.
- The product stewardship arrangements proposed to control distribution of treated seed in 2016 differed from those used in 2015 (with growers providing returns directly to Bayer and Syngenta, rather than (as previously) growers providing returns to distributors, who then supply returns to the companies).
- The decision as to whether to sow seed treated with these products would rest with agronomists. Agronomists would only be able to participate in the arrangements if they had undertaken the on-line training module on CSFB control. No details had been provided on the content of this training and it had yet to be approved by BASIS.
- Both the applicant and Friends of the Earth had submitted interesting and useful information on how various IPM methods can be used to mitigate CSFB damage.

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 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 is appropriate. It may be possible to justify a case for the use of these products on resistance management grounds, but it would be difficult to define an area based on the information provided.
- The applicants had not made sufficient opportunity of the emergency authorisations granted in 2015 to generate more robust information to enable better targeting of use. In particular, it was noted that the assessments accompanying the application did not appear to have been subjected to any statistical analysis to enable estimates of the likely magnitudes of effects beyond chance. This made it difficult to assess the robustness of these data, particularly in terms of the different categories of damage, and be assured that use of any emergency authorisation would be appropriately 'limited'. Information (in this application and more widely) on the relationship between pest pressure and economic loss was also lacking, an uncertainty currently unaddressed.
- The proposed product stewardship arrangements offered insufficient assurance that use of any emergency authorisation would be appropriately 'controlled'. In particular, it was noted that the proposed arrangements:
 - were not as robust as those used in 2015 for tracking treated seed through the supply chain;
 - did not appear to include a mechanism for prioritising agronomists' recommendations which would likely result in product being allocated on a 'first-come/first-served' basis (rather than to areas of greatest need);
- The criteria that agronomists would apply in deciding need were not well defined and could vary widely in practice. They would be challenging to define given scientific uncertainties that were unresolved by the data supplied.
- 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 applications do not meet the criteria for an emergency authorisation, as:

- there is insufficient information to ensure that use will be limited only to those areas where there is a 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.