UK Expert Committee on Pesticides			ECP 14 (1/2015)
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For discussion and advice: Emergency authorisation of *Cruiser OSR* and *Modesto* on oilseed rape

A paper by: [redacted]

Cleared by: Dave Bench on 15 May 2015

Previous documents: none

Related documents:
ACP 17 (321/2006) Emergency pesticides authorisations;
ACP 13 (358/2012) Consideration of Effects of any Potential Restrictions on the Use of Neonicotinoids;
ACP 7/6 (359/2013) Analysis of Potential Restrictions on the Use of Neonicotinoids;
ACP 14 (367/2014) Emergency Authorisation of Cruiser OSR on oilseed rape and mustard seeds;
ACP 6 (372/2015) Emergency authorisations: legislative and policy issues.

Company attendance: [redacted] will be in attendance to answer any questions from the Committee. The NFU may also be present for the same purpose.

Issue for the Committee:

1. To consider whether the criteria for an emergency authorisation specified in Regulation 1107/2009 are met in these applications.

Timing

2. Urgent. A decision is needed by mid-June for crops to be sown in August/September 2015.

Background

3. In 2013 the European Commission adopted legislation which required member States to withdraw the authorisation of all uses of plant protection products based on three neonicotinoid insecticides (clothianidin, imidacloprid and thiamethoxam) involving crops attractive to bees. The measure was justified by the Commission as a precaution required to protect bees until further studies had been undertaken by crop protection companies to address newly identified risks. The withdrawal would remain in place at least until these studies

had been completed and reviewed by the European Food Safety Authority and the Commission, a process expected to begin in 2015.

4. Based on scientific advice from this Committee and from Defra's Chief Scientific Advisor, the then Secretary of State took the view that the measure was disproportionate and the UK did not support it. Nevertheless, the restrictions were adopted and came into force on 1 December 2013.

Emergency authorisation requirements

5. Regulation (EC) No 1107/2009 on the placing of plant protection products on the market permits member States a degree of discretion to deal with emergency pest or disease situations. In essence, this provision allows member States to authorise products which are not otherwise authorised under the Regulation if this is necessary 'because of a danger which cannot be contained by any other reasonable means' and for 'limited and controlled use' (Art. 53(1)). The term 'limited and controlled use' is not defined, but reflects the fact that emergency authorisations do not satisfy the safety requirements of standard authorisations. The intention is therefore to restrict their use as far as possible and provide for alternative means of ensuring their proper control. They should not amount to 'business as usual'.

6. The Commission has advised that member States can in principle issue emergency authorisations for uses prohibited by the restrictions on neonicotinoids. The Commission does, however, have powers to 'call in' and to propose the amendment or withdrawal of any member State's emergency authorisation.

Proposal for emergency authorisation of *Cruiser OSR* and *Modesto*

7. The NFU has submitted applications for emergency authorisation of *Cruiser OSR*, which contains the active substance thiamethoxam, and of *Modesto*, which contains the active substance clothianidin, for use on seeds of oilseed rape (OSR) in autumn 2014. These uses are intended to control cabbage stem flea beetle (CSFB) and aphid vectors of turnip yellows virus (TuYV) and are prohibited under the EU restrictions on neonicotinoids. The applicant estimates that 54% of England's current 634,000 ha of OSR crops are under threat (very high pest presence) with another 25% under risk (high pest presence). These areas are based on the following three criteria:

- crops which are drilled during July and the first week of August, since these are at most risk of damage from both CSFB and peach-potato aphids (*Myzus persicae*) transmitting TuYV;
- Norfolk and Lincolnshire, where the cropping consists of both a large area of potatoes followed by an early cropping of OSR, allowing the *Myzus persicae* population to move from one crop to the next when the principle hosting potato crop is burnt down at the end of the season;

- areas likely to have high levels of CSFB.

8. The applicant has applied for emergency authorisation to permit use of these products in areas which are both under threat and under risk, amounting to 79% of OSR crops in England. The applicant's proposals for stewardship are set out at Annex A.

9. Compliance with the restrictions could be monitored by requiring records of sales from the authorisation holder, through the supply chain to distributors, seed merchants and growers. This would enable verification of both the quantity of product placed on the market and the areas in which seed treated with it was grown. Any concerns identified from those records could be followed up with those concerned. However the Committee will wish to consider whether this offers sufficient controls under the regulatory requirements.

10. CRD's assessment of the technical case of the need for authorisation is at Annex B. It concludes that the case for emergency authorisation for the calculated areas based on high risk areas for TuYV alone is not considered proven. But in high risk TuYV situations combined with high risk cabbage stem flea beetle (CSFB), then this is considered justified. Of the other scenarios presented, the case for early drilled crops and high risk from CSFB is also considered justified.

11. An update on the latest information relating to the risk to bees from the use of neonicotinoids is in paper ECP 8 for this meeting. This outlines how recent studies will be considered in the forthcoming EU review of neonicotinoids. The ECP may wish to consider whether the latest information affects their overall view of the risk to bees and other pollinators.

12. However, it is CRD's overall view that despite the justified needs set out above, the applications do not meet the criteria in Regulation 1107/2009 as being "limited and controlled."

Action required

13. Does the ECP consider that emergency authorisation under the requirements of Regulation 1107/2009 would be appropriate in the circumstances outlined in this paper and the attached applications?

Contact:

[redacted]

Annex A

Product stewardship and controlling adherence to the emergency use guidelines (extract from applicant's justification)

Effective stewardship schemes for both products were in place during approval period without any incident. On this basis the question has to be asked as to why additional, stewardship should be required over and above an agreement to be reached on the crop area to be treated under the emergency approval. Both companies have control of where the product is supplied to and the conditions by which the seed is treated and sold on but not how and where it is sown by the growers.

Both companies' seed treatment products are only supplied to a relatively small number of specialist companies who are treating the seed for direct supply to growers, or seed suppliers.

Additional information is available from Bayer (seed treatment engineers) that enables the identification of the specific locations of seed treatment machinery used to treat oil seed rape in England. Additional information is available from Syngenta detailing the limited number of specialist companies that were treating the seed for direct selling to seed suppliers or growers. During seasons in which Cruiser OSR was commercially available Syngenta enforced and monitored a comprehensive product stewardship plan at all commercial locations treating OSR.

Thus controls over the supply of product into the trade are relatively straight forward and fully traceable. Further evidence of where the treated seed has been grown is obtainable from the sales records of treated seed held by the treater. It is proposed that the conditions of sale of both the Bayer and Syngenta seed treatment products includes a requirement that the details of all customers purchasing neonicotinoid treated OSR are kept by the organisations selling directly to the grower or where appropriate wholeselling to seed retail organisations. All transactional information must be held for a minimum of 12 months and made available upon request.

All rape seed is provided to growers in bags of approximately 8kg. These bags also have a seed tag stitched into the seam which contains the relevant seed treatment product information. To ensure seed is not sown in areas outside of the permitted use it is proposed that both companies would add additional text (exact wording to agreed with CRD) to this effect.

> e.g. Seed treated with [product], in accordance with the approved use of this product seed must only be sown in the County/Region listed below. Any use outside these areas is not approved and would therefore be considered as being "illegal use".

To ensure that this detail is captured and traceable all retailers of neonicotinoid treated OSR will be required to record the following parameters:

1. Location of grower and intended planted area
2. Number of units sold (thereby determining the intended planted area)
3. Variety and seed treatment information

Moreover, it is expected that the grower signs a stewardship agreement at point of purchase which will state the exact use restrictions granted for appropriate use of the products as determined by the CRD. This documentation will be kept by the retailers for a period of 12 months and made available on request.

Annex B

Application for use of *Cruiser OSR* and *Modesto* on oilseed rape seed

CRD Assessment of the case for 120 Day Emergency for the use of 'Cruiser OSR' (M14496 – Syngenta Crop Protection UK Ltd – COP 2015/00790) and 'Modesto' (M14029 – Bayer CropScience Ltd – COP 201500792) as seed treatments of Winter Oilseed Rape against Cabbage Stem Flea Beetle (Psylliodes chrysocephala) and aphids (Myzus persicae) – Application made by the NFU

Background

'Cruiser OSR' contains the neonicotinoid insecticide thiamethoxam, and two fungicide actives (fludioxonil and metalaxyl-M), and previously held on-label authorisation for use as a seed treatment in oilseed rape (OSR), fodder rape and mustard. (No further consideration is given to the fungicide uses because there are a range of alternatives).

'Modesto' contains the pyrethroid insecticide beta-cyfluthrin and the neonicotinoid insecticide clothianidin. The combination of the pyrethroid (non-systemic) with clothianidin (systemic) increases effectiveness. It held on-label authorisation as a seed treatment in winter oilseed rape.

The case put forward for both products focusses on the key pest uses against cabbage stem flea beetle and the Turnip Yellows Virus (TuYV) aphid vector *Myzus persicae* in winter oilseed rape (see below).

<u>Overview of requested Neonicotinoid Seed Treatment Uses in Oilseed Rape and available authorised alternatives</u>

Requested Seed Treatment uses in OSR	**Alternatives Authorised Uses (On-label)**
reduction of damage by early attacks by flea beetles (*Phyllotreta* and *Psylliodes*), principally Cabbage stem flea beetle	Various pyrethroid (IRAC* Group 3A) actives foliar sprays No seed treatments.
Early season control of Peach-potato aphids (*M. persicae*)	Foliar sprays: • Tau-fluvalinate (pyrethroid) (IRAC group 3A) • Pirimicarb (carbamate) (IRAC group 1A) • Pymetrozine (IRAC group 9B) • Thiacloprid (neonicotinoid) (IRAC group 4A) No seed treatments

*Insecticide Resistance Action Committee mode of action

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 to 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, the insufficient crop establishment may lead to crop failure and subsequent re-drilling. Population build up can also lead to impacts on final yield.

The other principal use, as in this case, is to prevent virus infection caused by the Peach-potato aphid (Myzus persicae) which can also impact on total yield.

The period of protection provided by a neonicotinoid seed treatment usually lasts for a number of weeks. This may in itself be sufficient (depending on aspects such as environmental factors and pest pressures) or, if not, may reduce the number of subsequent required foliar sprays. (This may have additional benefits in reducing resistance pressures).

Foliar sprays tend to be less effective in targeting the seedlings; the application timing is critical and can be disrupted, for example if adverse weather conditions prevent spraying.

All of the current alternatives are foliar sprays, and it is therefore accepted there are practical limitations. The differences between the effectiveness of foliar and seed treatments is demonstrated in the data provided by Syngenta (titled 'Overview of available data to demonstrate impact of neonicotinoid removal in UK WOSR crop'). Further to this, in some cases there are resistance issues (either established or developing), and this impacts significantly on the effectiveness of some of these alternatives.

The nature of the key pests, the impact on OSR yields, and demonstrable benefits in control using neonicotinoid seed treatments (including justification for the use of prophylactic treatments) were considered in the original CRD Efficacy assessment at the time of first product authorisation. These assessments were conducted in accordance with Uniform Principles. This consideration reviews specifically the applicants' arguments in relation both to the need for these emergency authorisations; and specifically the requested area of use.

In doing so, CRD has also reflected on the previous 120 day emergency request made last year for 'Cruiser OSR' (COP 2013/01138; ACP 14 (367/2014), highlighting where the situation has changed. That request was based on a proposed nearly 200,000 ha, whereas the area requested now (combing threat/risk) is 79% (just over 500,000 ha) of the total national OSR crop area (633,000 ha). This proposal for over double the previously requested area is driven by the significant increased threat posed by cabbage stem flea beetle (see below), and an argued case on increasing importance of TuYV and its vector, the peach-potato aphid.

Transmission of Turnip Yellows Virus (TuYV) by the Peach potato aphid, *Myzus Persicae*

The need for the control of the peach-potato aphid is as the main vector of the Turnip Yellows Virus (TuYV), which impacts on total yield of OSR. The applicant submission acknowledges that there is still variability over the degree of yield losses, which is in part dependent on varietal differences. Evidence is provided (HGCA research, 2008) on the growing evidence of the potential for increasing yields of OSR if TuYV is more effectively controlled, although realising the potential yield for OSR under commercial growing is a complex issue of which pest control is one component.

The submission includes results from a Bayer survey (85 sites) for the 2014-15 season, indicating widespread (but variable) presence of TuYV (% site infection), and from which an average is taken estimating likely country % infection. At this point in time however these plots of OSR have not been harvested so it is not possible to link this to eventual yield impacts. No historical evidence has been provided summarising any previous yield losses caused by TuYV on a regional basis for comparison.

Until recently, the only alternatives to neonicotinoid seed treatment against the peach-potato aphid were pyrethroid and pirimicarb foliar sprays. Myzus persicae has developed long established resistance to both these (chemical) groups of actives, via target site and metabolic mechanisms, rendering field control ineffective. The incidence of these mechanisms is stable and remains at high levels in the population. It is therefore accepted that neither provides an appropriate, viable alternative. It was on this basis that emergency status for the use of a neonicotinoid seed treatment on winter oilseed rape against the peach potato aphid was recognised under the previous consideration.

However, authorisations have since been issued for two foliar applied products; pymetrozine (‘Plenum WG’) and thiacloprid (‘Biscaya’). (Reference is made under 2.2.3 also to flonicamid, but this was an emergency authorisation for 2014 not an on-label authorisation). Thiacloprid was authorised only last autumn and therefore is unlikely to have been used commercially in significant amounts. Pymetrozine was available however, but no information has been provided on its’ use during the drilling season of 2014. As described in the introduction, the limitations of foliar sprays are acknowledged, but in the context of considering an emergency authorisation, there are alternatives available providing some degree of control provided optimal timing for applications can be made.

In summary, it is difficult under these circumstances to quantify specifically the degree of impact of, and therefore justification based on, TuYV alone for emergency status for the coming season, given the number of variables: % infection at different sites; the degree of yield losses; the potential under favourable conditions to apply foliar sprays; the widespread geographical presence of Myzus across the UK on a wide range of host crops making it

particularly difficult to identify regions at greatest risk; and the inability at this point to predict whether the coming autumn conditions will be favourable for aphid populations. On balance, emergency authorisation for calculated hectares based on high risk areas for TuYV alone is not considered proven. But in high risk situations combined with high risk cabbage stem flea beetle, then this is considered justified in terms of area treated. Most of the identified high risk areas coincide with CSFB high risk.

Cabbage stem flea beetle (CSFB)

A series of comparisons is provided between areas of Winter OSR sown with seed treated with 'Cruiser OSR', no insecticide seed treatment but with foliar spray applications of pyrethroids, and untreated. ('Overview of available data to demonstrate impact of neonicotinoid removal in UK WOSR crop' REF). This illustrates consistently that during early crop establishment the seed treatment is not only very effective (compared to untreated) against CSFB, but also generally gives better protection from damage than foliar sprays. It should be noted that these differences become less consistent as the crop grows, which reflects the decline of activity of the seed treatment over time.

The 2014-15 season is one where for various reasons (discussed below) the cabbage stem flea beetle population was very high in some regions. All treatments struggled to reduce crop damage and larval numbers. (CRD also are aware that a similar situation occurred in Germany this crop year, with high CSFB population levels arriving early into the crop resulting in significant damage).

In some areas damage was significant, resulting in a need to re-drill, yet in other areas there was little impact, if any. It is considered that this was due to a number of factors. Conditions this drilling season (i.e. late summer/autumn 2014) initially favoured cabbage stem flea beetle populations, and also crop germination, the period where crops are particularly susceptible. Between mid-August and mid-September, the weather remained cool and dry. Crop emergence and seedling growth slowed, and seedlings continued to be susceptible to damage. Seed drilled outside this period (either earlier or later) were in most areas largely unaffected.

However, an important additional factor is the confirmation of pyrethroid resistance in the UK (discussed more below). The areas worst hit by cabbage stem flea beetle damage included the Eastern and South Eastern areas, where there had been control failures the year before, and where pyrethroid resistant individuals have now been confirmed.

The submission includes the Syngenta data described above from a number of sites, along with an HGCA presentation reporting a funded ADAS study conducted in the autumn of 2014 as a 'snapshot' assessment. This includes further evidence of the damage cabbage stem flea beetle can cause, alongside evidence provided by NFU (references to both). (Photographs provide some of the evidence, illustrating damage caused and in some cases almost complete crop loss).

A more updated, comprehensive study has been published by AHDB/HGCA 'Assessing the impact of the restrictions on the use of neonicotinoid seed treatments' (April 2015). The report summarises results from a winter planting survey for winter OSR growers in England and Wales, to report on changes in area grown, area lost to cabbage stem flea beetle damage, and areas successfully replanted. The responses were based on 1300 growers, equivalent to 8% of the National OSR area grown. The report notes that the 633,000 ha grown was a decrease from the 2012 area of 741,000, which may reflect less treated seed available ahead of the restrictions, or various other factors. Losses from adult CSFB damage were reported as 5% of the original area (with 1.5 % successfully replanted). This 5% would equate nationally to 22,000 ha. It is important to reiterate this as not evenly spread, but there were significant regional variations. The report highlighted South/South Eastern regions as worst affected. (The report published on 20th April this year was not specifically discussed in the applicant submission).

Monitoring and surveys are continuing to look at the impact of the subsequent larval population, particularly in those areas which suffered the heaviest adult damage. This will include assessments of the final yield for this season. A 2015 spring survey published by FERA in Crop Monitor has been included in the applicants' submission, and illustrates the very high figures of larvae being recorded compared with previous recent years.

Resistance to pyrethroids

As mentioned above, following reports of control failures in recent seasons using pyrethroid sprays, sampling was conducted and work at Rothamsted has identified at least some of the resistance mechanisms. Initially target site kdR resistance had been confirmed, but this in itself does not confer complete loss of field performance. (For example in Germany well timed applications of pyrethroid foliar sprays are still providing reasonable larval control). Further investigation has confirmed, as noted in the applicants submission (and discussed recently at UK-IRAG) that metabolic resistance mechanisms are also present. Further work is undergoing to understand better the genetic basis for this, but the key points so far are:

- it is these metabolic mechanisms that are more significant in conferring loss of field effectiveness

- A 'super Kdr' form of resistance has also developed, which impairs more on field performance than kdr, but remains relatively rare in populations at the moment

- Metabolic resistance has been confirmed only in the UK at present, and not for example in Germany where target site resistance was first discovered. The implication therefore is the impact on UK OSR yields is likely to be greater than in other MS.

- The development of resistance in some cabbage stem flea beetle populations is likely to spread, given that there are no insecticide alternatives to pyrethroid spray applications currently available.

Summary

The need for emergency authorisation is justified, with 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 to 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 'hot spot' 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.

Justification of Cropping Area Required

The submission presents three scenarios, with two categories of 54% 'under threat' (highest risk) and 24% 'under risk'.

Early drilling

It is agreed that these represent a high risk both from cabbage stem flea beetle, and also when combined with Myzus persicae /TuYV transmission. From a practical perspective it is also straightforward to define the use by a given time period. This is proposed to be the last week in July and first week in August, for an area 97,600 ha. The area is based on15% of the National crop area , and is the same figure used in the last application for emergency use. (Reference, Pesticide Usage Survey report 250 – Arable crops in the UK 2012). However, the overall hectare figure for winter OSR has fallen – as noted in the submission to the 634,000 figure.

Proximity to potato crops

As explained above, the emergency case for areas at risk from TuVY alone is not considered sufficient. Within that is the specific scenario which relates to the fact that potato is one of the major host crops of Myzus persicae. When the potato crop is "burnt off"/dessicated prior to harvest, the aphids will migrate to a new host. The timing of this migration coincides with autumn drilled OSR crops, and hence their argument this is a high risk situation. Specifically, Norfolk and Lincolnshire are significant areas for potato growing. Whilst there is merit in the argument, no evidence has been provided that supports this risk in practice in terms of yield losses in these areas. The Bayer sampling, for example, has projected % county estimates of TuYV infection of 76% in Lincolnshire (11 samples), which is towards the higher end of infection levels, but there are other regions with similar or higher values. Further, the possibility of controlling Myzus on the potato crop (where there

are a range of other actives available) prior to desiccation has not discussed. This case is not considered to be sufficiently supported by data.

High risk flea beetle areas

As described previously, this scenario is accepted as a valid emergency authorisation. It is acknowledged that defining this area is difficult. The proposal (Table 3.2) has attempted to define each county by under threat or risk, based on

- the flea beetle damage data from Syngenta and HGCA regional survey (it is not completely clear if the submission used the snapshot survey, or the final report)

- presence of larvae (Crop Monitor) - which largely as expected correlates with the HGCA regional survey

- presence of TuYV (areas where the risk is only TuYV would not be supported, as explained above)

Areas based particularly on the HGCA data would be an appropriate point of reference, based on largest survey, particularly the 'under threat' category which is based on the highest levels of CSFB damage and larval populations. However, as presented it is not possible to directly compare the regions to those used in the AHDB/HGCA report due to differences in the implemented breakdown of areas. Table 3.2 presents individual counties, stating HGCA data is split out from regional data. The AHDB/HGCA report has broad regions.

The 'under risk' category is more difficult to validate, and is based on combined predictions of 'high' larval populations and TuYV risk.

The unknown factor is how the developing pyrethroid resistance situation will impact on next season, particularly how quickly and widespread it will become. This makes defining the 'under risk' category particularly difficult.

Overall summary of Case

Emergency authorisation is justified on the basis of cabbage stem flea beetle control. Localised areas of significant damage occurred in Eastern and South Eastern regions. The estimate was 5% crop loss (and 3.5% area was re-planted). Further losses in terms of total yield may yet occur because of the 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 hot spots. 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.

The case for TuYV control, whilst recognising there are practical difficulties, has changed since last considered in that there are now foliar options and so emergency requirements is less clear. In most cases, areas of high risk would be included in high risk areas for the CSFB and therefore a seed treatment would be used. The area should be reduced to remove the TuYV only high risk areas (e.g. from Table 3.2, Cheshire, Lancashire, West Yorkshire), although that criteria only removes a small proportion of the area requested.

Of the other scenarios presented, the case for early drilled crops and high risk from CSFB is accepted, but further discussion would be required to refine the proposal for the area which may be sown with neonicotinoid treated seed. Firstly in seeking clarification on the figures quoted, compared to the available AHDB/HGCA survey (it is not clear whether this recent source, or the 'snapshot assessment' of last autumn was used).

Possible scenarios would be:

a) restrict the use only to those areas directly under threat larvae ('red' under threat for CSFB) (which can be more easily related to the survey). There is a strong argument for these areas which have been significantly affected and currently have the highest levels of surviving larvae. The use of neonicotinoid treated seed would reduce the population reservoir. This may otherwise, as pyrethroid resistance establishes cause further significant and more widespread problems, and actually lead to further pyrethroid usage in the coming 2015 season. This could be seen as a resistance management measure. The area to be treated would be in this scenario, based on the described HGCA data split, would be around 300,000 ha (just under 50% of the National crop)

b) include the wider, less easily defined 'under risk' areas. The difficulty is quantifying the risk as it is always subject to a range of factors at the time of drilling; as well as the speed at which the resistance situation may develop. Adding this category would result in a further estimated 25% area.

One further complicating factor would need to be reflected in any stewardship plan. 'Modesto' is a mixture of clothianidin and the pyrethroid beta-cyfluthrin, and further consideration will be needed on the use of this product with regard to areas where pyrethroid resistance has been confirmed or is suspected.