

Chemicals Regulation Directorate

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Application Form CRD3

Application for Extension of authorisation for a minor use of a plant protection product

Regulation (EC) No 1107/2009

When to use this form

Any applications from authorisation holders, growers or their representative organisations for **Extension of authorisation for a minor use of a plant protection product** where either **technical assessment** is required or the Authorisation can be given by **Administrative** action.

When not to use this form

Applications for authorisation of a **plant protection product** as follows:

- Commercial authorisation or permit for trial purposes via **No-Data, Data, or Data-Plus Streams** (use Form CRD1).
- Any other **Administrative Stream** authorisation (use Form CRD2).
- **Administrative permit for trial purposes**, (use form CRD7).
- **Permit for Parallel Trade** (use form CRD5 or CRD6 [own-use]).

Applications for **Official Listing of an Adjuvant** (use form CRD4).

Applications for **biocidal product** approval (see <http://www.hse.gov.uk/biocides/index.htm>)

How to complete this form

- Complete all parts of A to G as appropriate.
- **No sections of the form are protected. Take care not to delete or amend existing text.**
- To check 'tick boxes', double click on the box, select 'checked' and press 'ok'.
- 'Copy and paste' to add additional tables in Part D if necessary.
- For questions about this form, contact applicant-enquiries@hse.gsi.gov.uk.

Where to send this form

Save a copy of your completed form and submit it to CRD with all other relevant supporting information/data at:

- applications@hse.gsi.gov.uk; or
- Applications Sift, Chemicals Regulation Directorate, Mallard House, Kings Pool, 3 Peasholme Green, York YO1 7PX).

Part A – Applicant details				
1	Applicant	Contact name	[REDACTED]	
		Organisation name	National Farmers Union	
		Address	Agriculture House, Stoneleigh Park, Stoneleigh, Warwickshire, CV8 2TZ	
		Telephone	[REDACTED]	
		E mail	[REDACTED]	
		Date		
		By completing the above I confirm that the information given in this application form is true to the best of my knowledge, information and belief.		
2	Address for invoicing (if different)	Contact name	[REDACTED]	
		Organisation name		
		Address		
		Telephone		
		E mail		
3	Purchase order number (if needed)			

Part B – Product details		
4	Product name	Modesto
5	MAPP number	14029 (under revocation, Withdrawal 1572 of 2013)
6	Active substance(s) and content (list all)	400 g/l clothianidin
		80 g / l beta-cyfluthrin
7	Current Extension of authorisation number (NANUM) if appropriate	n/a

Part C – type of application – to be completed by all applicants

8 Tick box if you require Emergency status for this application. ☒

9 Tick the box(es) that best describe your application. Click for further online guidance		
Administrative authorisation (new Extension of authorisation or change to existing Extension of authorisation with no technical assessment required)	<input type="checkbox"/>	Complete Part G
New Extension of authorisation (not Mutual Recognition)	a) Based only on extrapolation	Complete Parts D & E
	b) With supporting data	
Statutory Plant Health Extension of authorisation (restricted)	<input type="checkbox"/>	
Amendment to an existing Extension of authorisation	a) Based only on extrapolation/cases	Complete Parts D, E, & F
	b) With supporting data	
	c) Following a formulation change	
Mutual Recognition of a Member State authorisation	a) A MS minor use authorisation	Complete Parts D, E, & F
	b) A MS product authorisation*	
Re-registration of an existing minor use authorisation (transition from COPR to Regulation (EC) 1107/2009 authorisation)	<input type="checkbox"/>	Complete Part D
Submitting data to meet outstanding data requirements	<input type="checkbox"/>	
Other (specify below)	<input type="checkbox"/>	Complete Parts D to G as appropriate

* Note – authorisation holders cannot apply for this as an Extension of authorisation

Part D – proposed and authorised uses

10 Use this table to list all the proposed use(s) of the product and (if appropriate) the existing authorised uses of this or other products to which the proposed use(s) are being compared

		Proposed use (delete as appropriate)	Comparable use (delete as appropriate)
Product		Modesto	
MAPP number		14029	
On-label or Extension of Use?		Emergency use	
Active substance(s) and content		400 g/l clothianidin 80 g / l beta-cyfluthrin	
Formulation type		FS	
Crop details	Identity of crop	Winter oilseed rape	
	Situation of crop	Field	
	Height of target	n/a – seed treatment	
Target pest/disease/weed		1) Cabbage stem flea beetle (<i>Psylliodes chrysocephala</i>). 2) Aphids, particularly <i>Myzus persicae</i> , as the key vector for the spread of Turnip Yellow Virus (TuYV).	
Max. individual dose/concentration		1.25 Litres product per 100 kg seed (12.5 L/tonne)	
Max. no. of treatments/max. total dose		1 treatment	
Earliest time of application		Before sowing	
Latest time of application		n/a	
Interval between applications		n/a	
Method(s) of application		Liquid seed treatment application machinery	
Water volumes		Not required	

	Proposed use (delete as appropriate)	Comparable use (delete as appropriate)
Estimated period of use	Seed treatment to commence early July 2015, as soon as authorisation received.	
Other relevant details (specify)		

NB. Consider the rates, timings and methods of application/harvest etc. of the product on-label uses and/or other Extensions of authorisation in relation to your proposed use(s). Treatment regimes more extreme than currently approved or even different methods of application (e.g. knapsack sprayer) and harvest (e.g. hand-picking) are less likely to receive authorisation or at the least require further work or requests for further information on our part. The submission of additional data or reasoned cases to address such identified areas of risk would be helpful and is expected for applications from authorisation holders. Make sure the proposed GAP is clear particularly where split applications are required and explain in full how the product will be applied. Full details must be given or worst-case assumptions will be made.

Part E –Supporting information	
11	<p>Case for ‘need’</p> <p>Your case to demonstrate the ‘need’ for the proposed use by detailing the nature and scale of the problem, and why alternative methods cannot be used (you may wish to include this under separate cover, or have it submitted by a third party).</p> <p>Please refer to the attached documents.</p>
12	<p>Safety assessment cases</p> <p>Safety assessment cases. Use the table in Part D to establish whether there is likely to be any increase in risk/hazard posed by your proposed use. Please reference any supporting data.</p> <p>On the basis that the product was fully approved by CRD (with no changes to the use proposed under this emergency approval application) all of the necessary safety assessments have been undertaken by CRD.</p>
13	<p>Emergency status</p> <p>Information to support emergency status, if required. Detail when the proposed Extension of authorisation is required (be specific); an estimation of the severity of the problem if the Extension of authorisation is not issued urgently (including crop losses and damage); and why these losses would be significant.</p> <p>This emergency application is being made in the absence of availability of any insecticide seed treatment for the 2014-15 sowing season, to protect the winter oilseed rape crop sown in July, August and September 2015 from damage caused by adult cabbage stem flea beetle (and other flea beetle species) and Aphids, particularly <i>Myzus persicae</i>, as the key vector for the spread of Turnip Yellow Virus (TuYV).</p> <p>As stated in the document referred to in Section 11 above, such damage can cause significant economic damage to winter oilseed rape crops.</p>
14	<p>Additional information</p> <p>Any relevant application information e.g. previous assessments (include COP number if available); relevant product history; and any other descriptive or supporting information e.g. methods of application or details of crop agronomy for novel crops. This is particularly useful for novel uses.</p> <p>Data to support up this application are available from a number of sources including crop surveys commissioned by NFU and additional data from Syngenta, Bayer Crop Science, IRAG, and the Rothamsted Research led Aphicide Resistance Project.</p>

Part F– Checklist of information required to support Mutual Recognition

15	Tick the box(es) to confirm the items being submitted Click for further online guidance
A copy and translation of the EU Member State product label	<input type="checkbox"/>
A copy and translation of the EU Member State product or minor use authorisation	<input type="checkbox"/>
Evidence of support from the authorisation holder of the product concerned, and their confirmation that the formulations are the same	<input type="checkbox"/>
Evidence of the climatic and agronomic comparability (if the use to be mutually recognised from another MS)	<input type="checkbox"/>
For mutual recognition of a product authorisation – support from the authorisation holder*	<input type="checkbox"/>
For mutual recognition of a product authorisation – evidence that the use has not already been authorised in the UK*	<input type="checkbox"/>
Evidence that the product has been registered to Uniform Principles	<input type="checkbox"/>

*Such applications cannot be made by authorisation holders

Part G Administrative changes

16	Tick the box that best describes your application and provide full details as requested
16a	New Extension of authorisation identical to an existing Extension of authorisation for an identical product ('back to back')
Give full details including product name, NANUM or ongoing COP no. for the identical product	
16b	Extension to the authorisation expiry date
Give full details	
16c	A new Extension of authorisation previously covered under the Long Term Arrangements for Extension of authorisation (LTAEU)
Give full details	
16d	Reinstatement of a previously approved Extension of authorisation
Give full details including NANUM	

Enclosures – to be completed by all applicants

Covering letter	<input checked="" type="checkbox"/>	Data enclosed	<input checked="" type="checkbox"/>
Relevant correspondence	<input type="checkbox"/>	Third party data to follow	<input type="checkbox"/>
Letter(s) of access	<input checked="" type="checkbox"/>	Evidence for need/urgency	<input checked="" type="checkbox"/>

Using personal data

Any personal data submitted with this application will be handled in compliance with the Data Protection Act 1998. Personal data will be used for the purpose of processing your application for an Extension of authorisation of a plant protection product and as part of the information supporting any authorisation granted; and may be used for enforcement purposes. Personal data may be disclosed to any person or organisation in circumstances where the DPA permits disclosure or where such disclosure is required by law.