

Application submission Applications Sift, Chemicals Regulation Division, Room 1A, Mallard House, Kings Pool, 3 Peasholme Green, York, YO1 7PX, UK or Email: applications@hse.gov.uk	CRD contact details Telephone: 020 3028 1101 (International: (+44) 20 3028 1101) Fax: 01904 455763; (International: (+44) 1904 455763) Enquiries email: CRD.Information.Management@hse.gov.uk Website: http://www.hse.gov.uk/CRD/
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Application Form CRD 9

Submission under Article 53 Regulation (EC) No 1107/2009

When to use this form

Any applications from authorisation holders, growers or their representative organisations for an **Emergency Authorisation** under **Article 53 of Regulation EC 1107/2009**

When not to use this form

Applications for:

- **New commercial authorisation, permit for trial purposes** (use form CRD1).
- **Administrative authorisation** (use form CRD2).
- **Extension of authorisation of a minor use** (use form CRD3).
- **Official Listing of an Adjuvant** (use form CRD4).
- **Permit for Parallel Trade** (use form CRD5 or CRD6 [own-use]).
- **Administrative permit for trial purposes**, (use form CRD7).
- **Standalone Technical Equivalence** (use form CRD8).
- **Renewal of an existing plant protection product** (use form CRD-R).
- **Biocidal product** approval (see <http://www.hse.gov.uk/biocides/index.htm>).

How to complete this form

- Complete all parts of A to H as appropriate.
- All correspondence and enquiries will be sent to the contact named in the applicant section (Part A) of this form unless otherwise informed.
- **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 rows/tables in Parts D/E and Appendices.
- For questions about this form, contact CRD.Information.Management@hse.gov.uk
- All forms with supporting information must be submitted to the Applications Sift (see contact information above).
- You must ensure all information necessary to support your case has been provided, as a paper based on Parts E to G will be submitted to the Expert Committee on Pesticides (ECP) for advice on whether authorisation should be recommended or not.



Part A – Applicant details					
1	Applicant	Contact name	Simon Thorp	Title	Mr
		Organisation name	The Bracken Control Group		
		Address	c/o Vallum House, Burgh by Sands, CARLISLE CA5 6AQ		
		Telephone	01387 723201		
		E mail	simon.thorp@heathertrust.co.uk		
		Date	13 th October 2017		
			I confirm that the information given in this application form is true to the best of my knowledge, information and belief. <input checked="" type="checkbox"/> (please tick to confirm)		
2	Address for invoicing	Contact name	Andrew Speed	Title	Mr
		Organisation name	UPL Europe Ltd		
		Address	The Centre, First Floor Birchwood Park WARRINGTON Cheshire WA3 6YN		
		Telephone	01925 819999		
		E mail	andrew.speed@uniphos.com		
3	Purchase order number (if needed)	Not required. Please quote COP number			

Part B – Product details		
4	Product name	Asulox
5	MAPP number	13175
6	Active substance(s) and content (list all)	400 g/l asulam
7	Authorisation holder	UPL Europe Ltd
	Address	As above
8	Registration or Authorisation number of product (imported/ currently authorised in the UK for other uses)	



9	Plant Health Orders
If the emergency authorisation is for a Plant Health Order please provide details of the order below.	
n/a	

Part C – Repeat applications

10	Has HSE authorised a previous emergency authorisation for the proposed crop/situation and pest*.	
	Yes (This is a repeat please complete Part C section 11 to 15) <input checked="" type="checkbox"/>	No (Please go to Part D) <input type="checkbox"/>
11	COP number(s) and authorisation number(s) of previous authorisation(s)	Number 1000 of 2013 from 20 May 2013 – COP 201202227 Number 1010 of 2014 from 19 May 2014 – COP 201301566 Number 1163 of 2015 from 18 May 2015 – COP 201401797 Number 1085 of 2016 from 26 April 2016 – COP 201502454 Number 1000 of 2017 from 24 April 2017 – COP 201602558
12	If this application is not identical to the above outline any differences	The Supporting Information has been reviewed and updated

* A pest is defined as ‘Any organism harmful to plants or to wood or other plant products, any undesired plant and any harmful creature.’

13 Justification for repeat authorisation

You must provide justification why a repeat authorisation is required.	
<p>The Supporting Information contains full details. Key issues:</p> <ul style="list-style-type: none"> • Bracken is a threat to biodiversity of vegetation in sensitive areas of the UK. • Large bracken beds threaten the viability of grazing enterprises in remote rural areas of the UK. • Bracken control programmes run over many years. Continuity of supply of asulam is required to safeguard investment already made in bracken control programmes. • Human health is at risk from bracken from its spores and more significantly in connection with sheep ticks — bracken litter is an ideal habitat and bracken plants provide an ideal ladder for questing ticks looking for a host to provide a blood meal. • The registration process for asulam under Regulation (EC) No 1107/2009 is nearing completion. The continuing availability of asulam has been important to keep aerial spraying contractors in business. Without asulam it is likely that this capacity will be lost. • Bracken rhizomes can damage historic and archaeological features. Due to the risk of damage from machinery, chemical control by asulam is the preferred treatment for bracken in these areas. 	



14 Use and effectiveness of previous emergency authorisation

Geographical location	Throughout the UK	Amount of product applied per hectare	Rough Grazing, Moorland and Amenity Grassland – 11 lit / ha. Forestry – 10 lit/ha.
Total hectare of crop	Bracken only	% of crop treated	n/a
Estimated % of crop retained	n/a	Estimated value of retained crop (£)	0
Estimated % of pest(s) controlled	n/a	Estimated % yield quality	n/a

Please provide an assessment on how effective and beneficial the product has been in controlling the pest and any other supporting information.

There is no impact on the current year's plants. GEP registration trials have demonstrated up to 99% control can be achieved in the year after treatment. Larger scale practical use trials have demonstrated up to 90% of the fronds in the year after treatment are controlled. Further treatment is required to achieve full control.

15 Previous correspondence for repeat applications

Any relevant information previously discussed with HSE for the repeat authorisation (same crop and pest, (Please include references)).

None

Part D – Supporting information

16 Tick the boxes to confirm the items being submitted [Click for further online guidance](#)

Requirements	Completed	Not required
Application overview	<input checked="" type="checkbox"/>	
Cover letter	<input checked="" type="checkbox"/>	
Part C completed	<input checked="" type="checkbox"/>	
Part D completed	<input checked="" type="checkbox"/>	
Part E completed	<input checked="" type="checkbox"/>	
Part F completed	<input checked="" type="checkbox"/>	
Part G completed	<input checked="" type="checkbox"/>	
Supporting data submitted	<input type="checkbox"/>	<input type="checkbox"/>
Supporting data being sent to HSE separately	<input type="checkbox"/>	<input type="checkbox"/>
Supporting information	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Supporting information being sent to HSE separately	<input type="checkbox"/>	<input type="checkbox"/>
Letter of access with declaration that authorisation holder will take back unused stocks at the end of the 120 day period	<input checked="" type="checkbox"/>	<input type="checkbox"/>



17 Previous correspondence for this application

Any relevant information discussed with HSE for this specific application (Please include references)

None

Part E - Emergency Situation

18 Summary of available pest control options and nature of Emergency

Please summarise the nature of the emergency situation and why an emergency authorisation is required. As part of this you must explain why the pest cannot be treated by any other means, explaining where possible, whether previously authorised products were used.

See also the answer to Q13 – Justification for a Repeat Authorisation.

Asulam offers the unique attributes of aerial application and selectivity. Much bracken covers ground that is inaccessible by vehicles due to its location, gradient and rock or uneven surface. Additionally, some sites are of historic or archaeological importance so must be protected from damage by ground-based application vehicles.

Please provide details of any current authorised products with relevant claims explaining why these products are not providing sufficient control options for this season. You must provide details on why these products are not sufficient to control the pest (e.g. any practical limitations on use; resistance; sustained pest pressure; maximum number of applications already applied)

No other products offer aerial application and selectivity.

Please provide details of any available alternative non-chemical control options if relevant.

Mechanical control options are used for bracken control wherever possible. These include: ploughing, cutting, bruising, and pulling fronds. Weed wiping using other non-selective herbicides is used as an alternative chemical control.

19 Details of pest problem(s)

Please provide details of the pest(s) including life cycle, mode of action and severity of the threat posed to the crop. Include details of relevant pest threshold levels, where known, and the results of any recent or ongoing relevant monitoring or surveys of pest numbers. Please indicate whether this is a new problem.

Bracken is a characteristic moorland plant in the UK, which over the last decades has increasingly out-competed characteristic ground-cover plants such as: moor grasses, cowberry, bilberry and heathers and now covers a considerable part of upland moorland. Once valued and gathered for use as animal bedding, tanning, soap and glass making and as a fertiliser, bracken is now seen as a pernicious, invasive and opportunistic plant, taking over from the plants traditionally associated with open moorland and reducing easy access by humans. Grazing provides some control by stock trampling but this has reduced with the recent decline of stock numbers in upland areas. Global climatic changes have also suited bracken well and have contributed to its rapid increase in land coverage.



20	Potential pest risk
Please give details on the estimated risk to public health and/or economic impact of the pest should no authorisation be granted, for the proposed use for each crop/crop group.	
Bracken is toxic to cattle, dogs, sheep, pigs and horses and is linked to cancers in humans. Bracken can harbour high levels of sheep ticks, which can pass on Lyme Disease to humans and a range of tick-borne diseases in animals.	
21	Control of pest problem(s) and benefit of proposed product
Please provide a reasoned case justifying how the proposed emergency authorisation will provide a sufficient level of benefit (pest control, reduction in damage etc.) to support an authorisation. Where applicable, please provide historical information.	
See the Supporting Information.	
22	Limitation and Control
Please provide details of how the use of the product will be limited and controlled. Include details of the decision process governing the use of the product (e.g. agronomic factors, pest thresholds); a reasoned case justifying the scale of use (% crop that may be required to be treated, including geographical location); or other limitations on use (e.g. period of use); bespoke product stewardship arrangements, and the rationale underlying these proposals.	
Control of bracken takes place on a wide range of different scales. In some areas control is limited to corners of fields and open land where bracken is encroaching. In other areas, the target is large bracken beds of many 10s of hectares. The decision about whether to spray or not will be made based on the control methods available and the risk to habitat, economic returns from the land and the health of livestock and humans. In addition to the 120-day Emergency Authorisation limiting the period of use, guidance is provided to users advising the optimum timings for application to maximise product effectiveness, this will further limit the period of use. Bracken is prevalent in all parts of the UK, but it is most likely to be a problem in the margins between upland and lowland areas, which have higher levels of fertility than other areas of unenclosed land.	
23	Additional risk(s)
Please provide details of any additional risk mitigation measures proposed and the rationale for these proposals.	
Guidance is available about the safe application of asulam.	



24	Safety assessment cases
<p>Please provide details how each risk assessment area will be addressed using supporting data and/or a robust case.</p> <p>You must detail whether there is likely to be any increase in risk/hazard posed by your proposed use.</p> <p>If data is being used to support any risk assessment area and has previously been submitted to HSE, please provide the product's name and COP number.</p>	
Operator, Worker, Bystander Exposure (Predictive operator exposure models can be submitted)	
<p>The GAP proposed for this Emergency Authorisation is the same as that previously authorised under COP 201602558 (Emergency Authorisation number 1000 of 2017). Risks to operators, bystanders and workers are the same as those evaluated and accepted for the previous authorisation.</p>	
Consumer exposure (supporting data or case must address UK specific requirement)	
<p>It is not proposed to use Asulox on edible crops. No consumer exposure assessment is necessary.</p>	
Environmental fate (supporting data or case must address UK specific requirement)	
<p>The GAP proposed for this Emergency Authorisation is the same as that previously authorised under COP 201602558 (Emergency Authorisation number 1000 of 2017). The environmental fate assessment is therefore anticipated to be the same as that evaluated and accepted for the previous authorisation.</p>	
Ecotoxicology (supporting data or case must address UK specific requirement)	
<p>The GAP proposed for this Emergency Authorisation is the same as that previously authorised under COP 201602558 (Emergency Authorisation number 1000 of 2017). The safety of the assessment for the safety of the product in the environment can therefore be expected to be the same as evaluated and accepted for the previous authorisation.</p>	

Part F – Permanent solution

25	Proposed permanent solution
<p>Please outline the steps that will be taken by you or the authorisation holder to transfer this emergency authorisation to an on label or extension of authorisation of minor use. (See guidance in Part G).</p>	
<p>An application for the registration of Asulam under Regulation (EC) 1107/2009 is being processed. The outcome is expected during 2018.</p>	



26	Alternative product(s)
Please provide details of ongoing work aimed at developing alternative products to address this pest problem. Include information on the active substance and anticipated timelines for availability of the data or application for the alternative solution.	
<p>Bracken treatment trials are ongoing. Alternative treatments on bracken on 19 sites across England and Scotland have been compared. The results will be available in 2018/19.</p> <p>Asulam was one of the treatments compared and early indications are that asulam is highly effective at treating bracken with limited impact on non-target species.</p> <p>GEP trials to support the registration of asulam for bracken control have been performed in 2016-17, in which asulam has been compared to another selective herbicide (amidosulfuron). Results show a lower level of control and potential for greater regrowth from amidosulfuron.</p>	
27	Non-chemical solutions
Please provide details of any alternative non-chemical methods of control that are under development and whether any of these measures have already been implemented.	
<p>Many non-chemical control methods are already available.</p>	
28	Progress from previous authorisation
Where this is a repeat application, please explain the progress towards a permanent solution that has been made since the previous application. Include timelines and projections for data/application for the permanent solution.	
<p>Additional data has been obtained and supplied to support the registration of Asulam under Regulation (EC) 1107/2009.</p>	
Where this is the 3rd or more repeat, please provide justification why no permanent solution has been sought.	
<p>A permanent solution is being sought, but the outcome of this will not be known until a decision is reached about the application for registration.</p>	



Part G – Comparison table proposed emergency use and current authorised uses

29 Please complete the proposed emergency use section of the below table. Please use the comparison section of the table when extrapolating from an authorised product or previous emergency authorisation.

30	Product	Proposed emergency use/situation	Comparison product
	On-label/Extension of Use/ Previous Emergency authorisation		Previous emergency authorisation
	Product	Asulam	Asulam
	MAPP number	13175	13175
	Active substance(s) and content	400 g/l asulam	400 g/l asulam
	Formulation type	Aqueous solution	Aqueous solution
	Estimated period of use (dates)	1 July – 15 September	1 July – 15 September
	Field of use	Rough grazing, moorland, amenity grassland and forestry.	Rough grazing, moorland, amenity grassland and forestry.
	User	Landowners and managers	Landowners and managers

31	Uses	Proposed emergency situation	Current authorised use or previous Emergency authorisation
Crop details	Identity of crop (Common name and EPPO code**)	Grassland (NNNFW) and Forestry	Grassland (NNNFW) and Forestry
	Situation of crop		
	Height of target		
Target pest	Name , type and EPPO code**	Bracken - PTEAQ	Bracken - PTEAQ
Max. individual dose		Rough Grazing, Moorland and Amenity Grassland – 11 lit/ha. Forestry – 10 lit/ha.	Rough Grazing, Moorland and Amenity Grassland – 11 lit/ha. Forestry – 10 lit/ha.



Chemicals Regulation Division
Application for Extension of authorisation of a plant protection product

Max. total dose		
Max. number of treatments	Only one application each year.	Only one application each year.
Earliest date of application and BBCH code***	1 July – BBCH 19 (PTEAQ)	1 July – BBCH 19 (PTEAQ)
Latest date of application and BBCH code***	15 September – BBCH 90 (PTEAQ)	15 September – BBCH 90 (PTEAQ)
Interval between applications	One application each year	One application each year
Proposed period of use (Dates)	1 July – 31 October 2018 (proposed emergency authorisation period allowing for brief storage and disposal after the latest expected date of application).	1 July – 31 October 2017

32	Application	Proposed emergency situation	Current authorised use or previous Emergency authorisation
Total amount of crop grown	Hectares	Bracken is not grown as a crop	
	Tonnage where applicable		
Total amount of crop treated	Hectares		
	Tonnage where applicable		
% Area of UK crop to be treated			
Geographical location of proposed uses		Throughout the UK	Throughout the UK
Method(s) of application		Aerial and vehicle sprayers, hand-held equipment.	Aerial and vehicle sprayers, hand-held equipment.

Throughou
Aerial and



Water volumes	Grassland & Amenity Vegetation: Aerial: 11 L/ha with an adjuvant (0.1%) in a total spray volume, including water, of 44 L/ha. Vehicle mounted: 11 L/ha in 400 - 500 L/ha of water as a MEDIUM or COARSE spray (BCPC category) Hand-held: 1 part Asulam with 100 parts of water. Forestry: Aerial: 5-10 L/ha in a total spray volume, including water, of 55 L/ha. Tractor sprayer: 5-10 L/ha in 200 - 300 L/ha of water as a MEDIUM or COARSE spray. Hand-held: 1 part Asulam with 100 parts water.	Grassland & Amenity Vegetation: Aerial: 11 L/ha with an adjuvant (0.1%) in a total spray volume, including water, of 44 L/ha. Vehicle mounted: 11 L/ha in 400 - 500 L/ha of water as a MEDIUM or COARSE spray (BCPC category) Hand-held: 1 part Asulam with 100 parts of water. Forestry: Aerial: 5-10 L/ha in a total spray volume, including water, of 55 L/ha. Tractor sprayer: 5-10 L/ha in 200 - 300 L/ha of water as a MEDIUM or COARSE spray. Hand-held: 1 part Asulam with 100 parts water.
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Chemicals Regulation Division
Application for Extension of authorisation of a plant protection product

33	Restrictions	Proposed emergency situation	Current authorised use or previous Emergency authorisation
	Operator protection	Aerial / vehicle mounted sprayers are the principal means of application. Applications made via hand-held equipment to be made in a maximum concentration of 1 part product to 100 parts water. Appropriate PPE to be worn.	Aerial / vehicle mounted sprayers are the principal means of application. Applications made via hand-held equipment to be made in a maximum concentration of 1 part product to 100 parts water. Appropriate PPE to be worn.
	Environmental protection	Buffer zones established for aerial and ground based control as specified in the label for previous years covered by an EA.	Buffer zones established for aerial and ground based control as specified in the label for previous years covered by an EA.
	Other specific restrictions	No chemical to be stored in the UK after 31 October 2018. The manufacturer will recover full containers of asulam through distributors.	No chemical to be stored in the UK after 31 October 2017. The manufacturer will recover full containers of asulam through distributors.

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 authorised 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. You must include the common name and EPPO code for the pest and crop; also the BBCH code for the first and last application as well as the timing in words. Full details must be given or worst-case assumptions will be made.

**Individual crops and pests are given an EPPO code for harmonised identification. Please use the following link to obtain the required EPPO code <https://gd.eppo.int/>

*** The growth stages of crops are categorised using a scale. The following link provides a PDF document containing the growth stages for multiple crops. [BBCH scale](#)



Part H – Guidance

An emergency authorisation is granted under Article 53 emergency situations in plant protection of Regulation EC 1107/2009.

The following link provides guidance on the process of how an emergency authorisation is granted. Emergency authorisation webpage - <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-emergen.htm>

The Expert Committee on Pesticides (ECP) review all applications submitted to HSE before an authorisation is granted. The following link provides guidance on the ECP process: <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/acp-guidance-on-emergency-a.htm>

There must be a permanent solution planned for the emergency situation. This can be achieved either by a submission of a new product, addition of use and/or pest to an existing product (Article 33) or applying for an extension of authorisation for minor uses (Article 53).

I confirm (please tick to confirm):

- I have read the above guidance and accept a permanent solution to the emergency situation is being sought.
- Failure to confirm and provide the correct or sufficient information will result in this application being rejected.

Using personal data

HSE is under a legal duty to protect any personal information we collect and we will only use that information in accordance with the law, including the Data Protection Act 1998, the Freedom of Information Act 2000 and the Environmental Information Regulations 2004. We meet our obligations as part of UK Government to safeguard data and prevent any unauthorised access to it through use of technical, personnel and procedural controls. More details on Government security may be found on the Gov.UK Web site [<https://www.gov.uk/government/collections/government-security>]. In order to carry out our functions and respond to enquiries effectively, we will sometimes need to share information with other government departments, the emergency services, law enforcement agencies, public authorities (such as local authorities and the Environment Agency) and organisations acting on our behalf. However, we will only do this where it is required or permitted by law.