For information
Document Number/s FLC 336/24, PPTC 173/24
To: PPA/FCPPA/SNACMA members
From: Andrew Curtis

30 August 2024

Plant protection products and biocides log – August 2024

Not for external distribution. Please do not forward this document.

Actives and issues of particular interest to the sector are highlighted.

Any member wishing to raise a topic or issue, please contact a member of the secretariat.

WTO Technical Barriers to Trade (TBT) notifications

EU

Draft Commission Implementing Regulation concerning the non-renewal of approval of the active substance tritosulfuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (Issued: 21/08/24. Deadline: N/A).
LINK: https://eping.wto.org/en/Search/Index?countryIds=U918&distributionDateFrom=2024-08-01&distributionDateTo=2024-08-28&viewData=G%2FSPS%2FN%2FEU%2F790

Draft Commission Implementing Regulation concerning the non-renewal of the approval of the active substance metribuzin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 and Commission Implementing Regulation (EU) 2015/408 (Issued: 01/08/24. Deadline: N/A).
LINK: https://eping.wto.org/en/Search/Index?countryIds=U918&distributionDateFrom=2024-08-01&distributionDateTo=2024-08-12&viewData=G%2FSPS%2FN%2FEU%2F789

EU Standing Committee (PAFF) meetings

Pesticide Residues 11 July 2024
The agenda is available to view here. Minutes of the meeting are available here.

Section B Draft(s) presented for an opinion
B.01 *Exchange of views and possible opinion of the Committee on a draft Commission Regulation (EU) …/… amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for thiacloprid in or on certain products (PLAN/2023/961)*

The Committee discussed comments received from four third countries and one FBO following the WTO-SPS consultation. COM proposed to include transitional measures for products which have been placed on the EU market before the new MRLs become applicable, except for some commodities for which EFSA identified an acute health risk for consumers (pears, peaches, raspberries (red and yellow), sweet peppers/bell peppers, Chinese cabbages/pe-tsai and lettuces).

Vote taken: *Favourable opinion*

Legislation 10-11 July 2024
The agenda is available to view here. Minutes of the meeting are available here.

Section A Information and/or discussion
A.05 *Draft Review/Renewal Reports for discussion:*
New active substances / Amendment of conditions of approval
1. Pydiflumetofen

COM informed that the RMS finalised the evaluation of an additional study (inhalation, 28 days). In its evaluation, a new lower AOEL was calculated and moreover, based on CLP criteria (Regulation (EC) No 1272/2008), a classification for STOT RE (Category 1, H372 causes damage to organs (lungs) through prolonged or repeated exposure (inhalation route) was proposed.. MS were invited to comment by 30/08/24.

2. Clove oil

COM shared comments received from two MS and informed that it intends to check with the RMS for the renewal of approval if the missing data to amend the approval conditions was submitted within the renewal file.

Renewal of approval
4. Pelargonic acid

COM informed that it continues the discussions with EFSA on a possible mandate for an additional evaluation of the risks that the representative use in home gardens and allotments of the plant protection product MON 74134 poses on non-target arthropods. MS were invited to comment by 15/08/24.

5. Rape seed oil

COM informed that the RMS intends to submit additional calculations of the risk for non-target arthropods when exposed to low dosage applications. MS were invited to comment by 15/08/24.

6. Flutolanil

COM is still examining the details, however one of the metabolites of flutolanil and relevant for rotational crops is trifluoracetic acid (TFA). Since no information on the level of TFA was submitted and the consumer exposure could not be concluded, the renewal for this active substance seems unlikely. MS were invited to comment by 30/08/24.

7. Sulfur

COM and some MS reminded the importance of this substance. Some risk mitigation measures proposed by applicant to demonstrate a safe use for at least the representative use in cereals (i.e. 4 × 8.0 kg a.s./ha with a

7- day interval, BBCH 15-69) are uploaded on CIRCABC. One MS requested the possibility of submitting confirmatory information at authorisation stage. MS were invited to comment by 15/08/24.

Section C Draft(s) presented for discussion

***C.02** Exchange of views of the Committee on a draft Commission Implementing Regulation (EU) concerning the non-renewal of the approval of the active substance metribuzin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 and Commission Implementing Regulation (EU) 2015/408.*

COM presented the draft Renewal Report and draft Implementing Regulation for non-renewal of metribuzin. MS were invited to comment by 17/07/24.

EFSA opinions, reviews and other EU developments

EFSA reports

Review of the existing maximum residue levels for difenoconazole according to Article 12 of Regulation (EC) No 396/2005 (Issued: 29/08/24).
LINK: https://www.efsa.europa.eu/en/efsajournal/pub/8987

Peer review of the pesticide risk assessment of the active substance 1-methylcyclopropene (Issued: 16/08/24).
LINK: https://www.efsa.europa.eu/en/efsajournal/pub/8977

Peer review of the pesticide risk assessment of the active substance Phthorimaea operculella granulovirus (Issued: 13/08/24).
LINK: https://www.efsa.europa.eu/en/efsajournal/pub/8976

Peer review of the pesticide risk assessment of the active substance triclopyr (variant triclopyr-butotyl) (Issued: 12/08/24).
LINK: https://www.efsa.europa.eu/en/efsajournal/pub/8177

Use and underlying principles of the EFSA Pesticide Residue Intake Model (PRIMo), revision 4 (Issued: 09/08/24).
LINK: https://www.efsa.europa.eu/en/supporting/pub/en-8990

Update of the standard regulatory actions for prospective and retrospective cumulative dietary risk assessment of pesticides in MCRA (Issued: 09/08/24).
LINK: https://www.efsa.europa.eu/en/supporting/pub/en-8942

Peer review of the pesticide risk assessment of the active substance Pythium oligandrum strain B301 (Issued: 06/08/24).
LINK: https://www.efsa.europa.eu/en/efsajournal/pub/8975

Peer review of the pesticide risk assessment of the active substance paraffin oil (CAS 8042-47-5, chain lengths C17–C31) (Issued: 23/07/24. Accidentally omitted from July PPP Log)
LINK: https://www.efsa.europa.eu/en/efsajournal/pub/8913

Consultations launched this month, or which were launched previously but which are still live.

Assessment Report on the active substance Choline hydrogen phosphonate, in the scientific domain Pesticides Peer Review (NAS) (Issued: 26/08/24. Deadline: 25/10/24).

LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001zhIn/pc1109

Assessment Report on the active substance 8-methyldecan-2-yl propanoate, in the scientific domain Pesticides Peer Review (NAS) (Issued: 19/08/24. Deadline: 18/10/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001twqn/pc1093

Assessments following the clock stop on endocrine disruption properties for the active substance fluazinam in the context of pesticides peer review, in the scientific domain Pesticides Peer Review (AIR) (Issued 30/07/24. Deadline: 28/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001icx5/pc1067

Assessment Report on the active substance fluroxypyr-meptyl (Issued 29/07/24. Deadline: 27/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001jrxH/pc1072

Application for the approval of the New Active Substance PLEURAN Complex Cell Wall Extract (CCWE) (Issued: 21/08/24. Deadline: 11/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001wfBu/pc1103

Application for the renewal of approval of the active substance metobromuron (Issued: 12/07/24. Deadline: 10/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001XItd/pc1045

Application for the renewal of approval of the active substance thiencarbazone-methyl, in the scientific domain Pesticides Peer Review (AIR) (Issued: 11/07/24. Deadline: 09/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001WLLh/pc1043

Assessment Report on the active substance Trichoderma harzianum T78 (Issued: 10/07/24. Deadline: 08/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001Udg5/pc1035

Application dossier for the setting of a new maximum residue level (MRL) for acetamiprid in honey (Issued: 16/08/24. Deadline: 06/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001vkgg/pc1096

Application for the renewal of approval of the active substance terbuthylazine (Issued: 08/07/24. Deadline: 06/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001SvXR/pc1030

Application dossier for the setting of a new maximum residue level (MRL) for Cyazofamid - in artichoke, leek, chicory, root, tuber (Issued: 13/08/24. Deadline: 03/09/24).
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001t98X/pc1089

Assessments following the clock stop on endocrine disruption properties for the active substance Fluoxastrobin in the context of pesticides peer review (Issued: 03/07/24. Deadline: 01/09/24)
LINK: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000001ROQf/pc1026

UK pesticide/biocide issues

UK Expert Committee on pesticides (ECP)

- 14 March 2023 – Minutes
- 18 April 2023 – Minutes
- 18 July 2023 – Minutes
- 12 September 2023 – Minutes
- 21 November 2023 – Minutes
- 23 January 2024 – Minutes
- 23 July 2024
- 10 September 2024
- 26 November 2024

HSE Chemicals Regulation Division (CRD)

HSE Pesticides ebulletin
Date issued: 29 August 2024

This ebulletin includes details of an upcoming workshop focusing on the regulatory approach to ecotoxicological risk assessment under the Plant Protection Products (PPP) regulations in Great Britain (GB).

For more information visit our Chemicals Regulation Division (CRD) training and events webpage.

Online workshop: Introduction to ecotoxicological risk assessment for PPPs
22 and 23 October 2024
This live workshop will help develop an understanding of the regulatory approach to ecotoxicological risk assessment under GB PPP.

It will focus on helping attendees develop an understanding of how to conduct first-tier risk assessments for non-target organisms and how these are assessed by HSE as the regulator responsible for authorisations and approvals under GB PPP.

The training will be delivered by HSE regulatory specialists and will help attendees improve the quality of their submissions and understand how these will be reviewed by the GB regulator.

Who should attend?
This workshop is specifically designed for registration specialists involved in the preparation and submission of PPP dossiers.

Topics covered
The workshop will be delivered over 2 half-day sessions and will include a mixture of presentations and practical workshops and will be given by members of HSE's Ecotoxicological Regulatory Science Group directly involved in the registration process.

- *active substance and PPP data requirements*
- *first tier bird and mammal risk assessment according to EFSA Bird and Mammal Guidance Document (2009)*

- *UK aquatic risk assessment (via spray drift and drainflow exposure)*
- *first tier bee and other non-target arthropod risk assessments*
- *first tier earthworm and soil macro- and micro-organisms risk assessment*
- *first tier non-target terrestrial plants risk assessment*
- *UK risk mitigation options*

This workshop will not address the new updated EFSA bird and mammal guidance document (2023), nor the new EFSA bee guidance document (2023), as they are not currently used for applications under GB PPP.

Registration
Find out more and register for this fee paid workshop
The closing date for registration is 14 October 2024.

HSE Biocides ebulletin
Issued: 28 August 2024

This ebulletin contains information on regulating biocides in Great Britain (GB).

Upcoming GB active substance expiry dates
Biocidal products must be phased off the GB market
The active substance/product type combinations listed below are due to expire under the GB Biocidal Products Regulation (GB BPR) on the following dates:

- *Iodine (CAS 7553-56-2 EC 231-442-4) in product types 1, 4 and 22*
  31 August 2025
- *n-Decanoic acid (decanoic acid) (CAS 334-48-5 EC 206-376-4) in product types 18 and 19*
  31 August 2025
- *n-Octanoic acid (octanoic acid) (CAS 124-07-2 EC 204-677-5) in product type 18*
  31 August 2025
- *Polyvinylpyrrolidone iodine (CAS 25655-41-8 EC 607-771-8) in product types 1, 4 and 22*
  31 August 2025

Once the approvals expire, the active substances will no longer be able to be used in biocidal products of the relevant product types in GB. In addition, articles treated with such products will no longer be able to be placed on the market in GB.

Upcoming GB active substance open invitation deadlines
Submit a notification by the deadline to keep active substances in the GB Review Programme

HSE has published open invitations to provide an opportunity for a person, company or task force/consortium to notify an intention to take up or take over the role of participant in the GB Review Programme for the following active substance/product type combinations.

Anyone wishing to support one of the active substance/product type combinations listed below in GB will need to submit a notification to HSE by the following deadlines:

- *Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with bromine and chlorine (DCDMH) (CAS N/A EC N/A) in product type 11*
  15 February 2025
- *Reaction products of 5,5-dimethylhydantoin, 5-ethyl-5-methylhydantoin with chlorine (DCEMH) (CAS 89415-87-2 EC 401-570-7) in product type 11*
  15 February 2025

If a notification to take over the role of participant is not received, these active substance/product type combinations will be subject to a GB non-approval decision. This means the active substances will no longer be able to be used in biocidal products of the relevant product type in GB.

In addition, articles treated with such products will no longer be able to be placed on the market in GB. HSE will provide separate updates on these where relevant.

If you are aware of any disproportionate negative impacts that are likely to arise from the non-approval of any of the active substance/product type combinations listed above, please contact us

HSE Pesticides ebulletin
Date issued: 27 August 2024

This ebulletin includes details on an upcoming workshop focusing on technical equivalence tier 1 assessments for plant protection products (PPPs) in Great Britain (GB) and Northern Ireland (NI).

For more information visit our Chemicals Regulation Division (CRD) training and events webpage.

Online workshop: Technical equivalence tier 1 assessments for PPPs in GB and NI
16 to 17 October 2024
This live workshop will be delivered over 2 half-day sessions and it will focus on technical equivalence tier 1 assessments. The aim is to provide training via a series of presentations and practical sessions to support technical equivalence applications submitted to HSE (CRD).

The workshop will address chemistry (tier 1) only. It will not include the toxicology and ecotoxicological assessments (tier 2). The workshop will mainly focus on GB assessments but will also cover how to submit NI applications through reduced fee technical equivalences (RFTE).
The training will be delivered by HSE regulatory specialists and will help attendees improve the quality of their submissions and understand how these will be reviewed by the regulator.

Who should attend?
The event is specifically designed for registration specialists involved in the preparation and submission of technical equivalence applications to HSE.

Topics covered

- *introduction to technical equivalence assessments*
- *discussion of technical procedures and guidance*
- *the technical equivalence report (TER) – Section A: Identity and Section B: Methods of analysis*
- *common problems with applications*
- *overview of HSE's processes and procedures for handling GB and NI technical equivalence applications*

Registration
Find out more and register for this fee paid workshop

The closing date for registration is 7 October 2024.

HSE Biocides ebulletin
Issued: 20 August 2024

Reminder – upcoming EU active substance expiry dates

Biocidal products must be phased off the NI market

The active substance/product type combinations listed below are due to expire under the EU Biocidal Products Regulation (EU BPR) on the following dates. This affects NI:

- *Methyl-benzimidazol-2-ylcarbamate (carbendazim) (CAS 10605-21-7 EC 234-232-0) in product types 7 and 10*
  31 January 2025
- *Powdered corn cob (CAS n/a EC n/a) in product type 14*
  31 January 2025
- *Thiamethoxam (CAS 153719-23-4 EC 428-650-4) in product type 18*
  31 January 2025
- *Synthetic amorphous silicon dioxide (nano) (CAS 112926-00-8 EC 231-545-4) in product type 18*
  31 October 2025

Once the approvals expire, the active substances will no longer be able to be used in biocidal products of the relevant product types in NI. In addition articles treated with such products will no longer be able to be placed on the market in NI.

If you hold an affected EU BPR product authorisation or Control of Pesticides Regulations (COPR) product approval, we will contact you about cancelling or revoking your authorisation or approval. You will have an opportunity to submit comments or additional information and we will take account of these when finalising our decision.

If you are aware of any disproportionate negative impacts that are likely to arise from the expiry of any of the active substance/product type combinations listed above, please contact us.

Reminder – upcoming EU active substance open invitation deadlines

Submit a notification by the deadline to keep active substances in the EU Review Programme

The European Chemicals Agency (ECHA) has published open invitations to provide an opportunity for a person, company or task force/consortium to notify an intention to take up or take over the role of participant in the EU Review Programme for the following active substance/product type combinations.

This affects NI. Anyone wishing to support one of the active substance/product type combinations listed below in the EU will need to submit a notification to ECHA by the following deadlines:

- *Chlorine dioxide generated from tetrachlorodecaoxide complex (TCDO) by acidification (CAS n/a EC n/a) in product types 2 and 4*
  20 October 2024
- *Tetrahydro-1,3,4,6-tetrakis(hydroxymethyl)imidazo[4,5-d]imidazole-2,5 (1H,3H)-dione (TMAD) (CAS n/a EC n/a) in product type 12*
  31 January 2025

If a notification to take over the role of participant is not received, these active substance/product type combinations will be subject to an EU non-approval decision.

This means the active substances will no longer be able to be used in biocidal products of the relevant product types in NI. In addition articles treated with such products will no longer be able to be placed on the market in NI. HSE will provide separate updates on these where relevant.

If you are aware of any disproportionate negative impacts that are likely to arise from the non-approval of any of the active substance/product type combinations listed above, please contact us.

This ebulletin contains information on regulating biocides in Northern Ireland (NI).

HSE Biocides ebulletin

Date issued: 19 August 2024

This ebulletin includes details of a new live online event focusing on how to address toxicology information requirements for biocidal products without vertebrate testing under the Great Britain Biocidal Products Regulation (GB BPR).

For more information visit our Chemicals Regulation Division (CRD) training and events webpage.

How to address toxicology information requirements for biocidal products without vertebrate testing under GB BPR

3 October 2024

HSE will be holding a 2-hour bitesize event on how to address toxicology information requirements for biocidal products without vertebrate testing.

The aim of the event will be to raise awareness of the Great Britain (GB) stance on vertebrate toxicological testing for biocide products and the alternative options available to applicants to meet the information requirements of the GB BPR.

The session will be delivered by HSE regulatory specialists and will help attendees improve the quality of their submissions and understand how these will be reviewed by the GB regulator.

Who should attend?

The event will be targeted at technical and regulatory staff involved in the production and submission of data into the GB biocide product authorisation process.

Topics covered

- *Introduction to the biocidal products toxicology information requirements and Article 62 of the GB BPR*
- *How to address the toxicology information requirements for various human health endpoints whilst minimising unnecessary animal testing, including the use of alternative approaches (for example calculation method of the classification, labelling and packaging [CLP] regulation no. 1272/2008 as it applies in GB, bridging/read across, in vitro and in silico methods). The human health endpoints covered will include:*
    - *acute oral toxicity*
    - *acute dermal toxicity*
    - *acute inhalation toxicity*
    - *skin irritation*
    - *eye irritation*
    - *skin sensitisation*

Registration

Find out more and register for this fee paid workshop

*The closing date for registration is **25 September 2024.***

HSE Pesticides ebulletin

Issued: 15 August 2024

This ebulletin includes details of 2 upcoming events focusing on aspects of the Plant Protection Product (PPP) regime in Great Britain (GB) and Northern Ireland (NI).

For more information visit our Chemical Regulation Division (CRD) training and events webpage.

Online bitesize event: Ecotoxicological risk assessment for PPPs

24 September 2024

HSE will be holding a live 2-hour bitesize event on ecotoxicology requirements for plant protection products. The aim of the event will be to provide guidance for how to assess the risk from the formulated product including extrapolation between different formulations and dealing with products containing more than one active substance.

The session will be delivered by HSE regulatory specialists and will help attendees improve the quality of their submissions and understand how these will be reviewed by the GB regulator.

Who should attend?

The event will be targeted at technical and regulatory staff involved in the production and submission of data into the GB and NI pesticide product authorisation process.

Registration

Find out more and register for this fee paid workshop

*The closing date for registration is **17 September 2024.***

Online workshop: Efficacy requirements and assessment under PPP regimes

25, 26 and 27 September 2024

This workshop will be delivered live over 3 morning sessions and will provide an overview of the efficacy data requirements for pesticide active substances and plant protection products as specified by the Regulations in force in GB and NI.

Particular emphasis is given on generating and utilising regional data packages in supporting both GB & NI authorisations; and assessment and presentation within a draft Registration Report (dRR).

The training will be delivered by HSE regulatory specialists and will help attendees improve the quality of their submissions and understand how these will be reviewed by the GB regulator.

Who should attend?

This workshop is suitable for attendees with a range of efficacy related responsibilities. This includes generation of efficacy trials data, product registration managers, writers of Biological Assessment Dossier (BAD) and dRR, or more general regulatory backgrounds seeking an overview of efficacy.

The content is focused on efficacy related aspects of plant protection product Regulations in GB and NI and is suitable for people with differing levels of experience.

Registration

Find out more and register for this fee paid workshop

*The closing date for registration is **16 September 2024.***

HSE Biocides ebulletin

Issued: 14 August 2024

This ebulletin contains information on regulating biocides in Northern Ireland (NI).

Reminder – upcoming EU active substance approval dates

Apply for product authorisation by the deadlines to keep your products on the NI market

The following EU Biocidal Products Regulation (EU BPR) active substance approval dates are coming up:

- *Sulfur dioxide generated from sulfur by combustion (CAS n/a EC n/a) in product type 4*
  1 October 2024
- *Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16)) (CAS 68424-85-1 EC 270-325-2) in product type 2*
  1 July 2025
- *Trihydrogen pentapotassium di(peroxomonosulfate) di(sulfate) (CAS 70693-62-8 EC 274-778-7) in product types 2, 3, 4 and 5*
  1 July 2025
- *Thermally treated garlic juice (CAS 8008-99-9 EC 232-371-1) in product type 19*
  1 July 2025

If you supply biocidal products containing these active substances in the relevant product types, don't forget to apply for EU BPR product authorisation by the dates above to keep them on the NI market.

Reminder – upcoming EU active substance renewal submission deadlines

Apply for active substance renewal by the deadlines to keep products on the NI market

Under the EU BPR, active substance approvals will expire unless a renewal application is submitted to The European Chemicals Agency (ECHA) at least 550 days before their expiry date.

The 550-day deadlines are coming up for the following active substance/product type combinations under EU BPR. This affects NI:

- *3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (permethrin) (CAS 52645-53-1 EC 258-067-9) in product types 8 and 18*
  27 October 2024
- *Hydrogen peroxide (CAS 7722-84-1 EC 231-765-0) in product types 1, 2, 3, 4, 5 and 6*
  30 July 2025
- *N-((6-Chloro-3-pyridinyl)methyl)-N'-cyano-N-methylethanimidamide (acetamiprid) (CAS 135410-20-7 EC 603-921-1) in product type 18*
  30 July 2025

Any person, company or task force/consortium can support an active substance/product type combination for renewal – it doesn't have to be the original supporter. Check the EU Article 95 List to see who the original supporters were.

If any of these active substance/product type combinations are important to you, consider contacting your supplier to let them know.

If a renewal application is not submitted for the above active substance/product type combinations under EU BPR, the approvals will expire. This means the active substances will no longer be able to be used in biocidal products of the relevant product types in NI. In addition articles treated with such products will no longer be able to be placed on the market in NI.

HSE Pesticides ebulletin

Issued: 9 August 2024

An independent pesticides regulatory regime is in operation in Great Britain (England, Scotland and Wales). This ebulletin includes information relating to Plant Protection Products (PPP) in Great Britain (GB).

GB PPP new active substance: public consultation on Elemental iron

Call for comments on the first GB approval of the new active substance Elemental iron.
HSE has received a dossier from ADAMA Agriculture B.V. for the following active substance/uses:

Substance: *Elemental iron – a molluscicidal active substance for the control of slugs and snails in edible and non-edible crops (outdoor and protected).*

The dossier is for the first approval of this substance in GB under assimilated Regulation No 1107/2009. The assessment was performed by HSE's Chemicals Regulation Division. Any interested third parties are invited to comment on the content and conclusions of the Draft Assessment Report (DAR) or share any relevant information. Comments can be submitted by any member of the public or interested party.

View the consultation details
HSE published the DAR in mid-June during the general election period, when government communications are kept to a minimum. So the 60-day consultation period has since been extended to provide more time for responses. The deadline for receiving comments is ***1 September 2024***

HSE Pesticides ebulletin
Issued: 7 August 2024
An independent pesticides regulatory regime is in operation in Great Britain (England, Scotland and Wales). This ebulletin includes information relating to Plant Protection Products in Great Britain (GB).

Expiry of the approval of the active substance famoxadone
Following a review of its approval as an active substance for use in plant protection products in GB, HSE has decided that famoxadone no longer meets the approval criteria set out in assimilated Regulation 1107/2009 (the Regulation).

On 10 January 2024 HSE issued an ebulletin that proposed withdrawal of the GB approval of famoxadone following a review that indicated it no longer met the approval criteria, required under the Regulation. The ebulletin referred to the next stage of the withdrawal process being consultation with trading partners via the World Trade Organisation (WTO).

This consultation has now concluded. The GB Administrations have given consent for HSE to carry out the decision-making function arising from this review.

In addition to the new knowledge that triggered the review, the comments that were made under the WTO process were also taken into account. HSE has concluded that an acceptable risk to birds cannot be demonstrated and therefore the approval criteria required under the Regulation are no longer met (Section 3.8.1. of Annex II of the Regulation).

The approval for famoxadone ended at its expiry date of ***30 June 2024.*** *Further details can be found by viewing the GB approval register on the HSE website. To allow existing stocks to be removed from the supply chain safely, HSE has agreed a phased withdrawal programme:*

- *producers will be permitted 6 months from the expiry date to sell and distribute authorised famoxadone products until 31 December 2024*
- *users will be permitted a further 1 year to dispose of, store, and use existing stocks of authorised famoxadone products until 31 December 2025*

Expiry of the approval of the active substance indoxacarb

Following a review of its approval as an active substance for use in plant protection products in GB, HSE has decided that indoxacarb no longer meets the approval criteria set out in assimilated Regulation 1107/2009 (the Regulation).

On 10 January 2024 HSE issued an ebulletin that proposed withdrawal of the GB approval of indoxacarb following a review that indicated it no longer met the approval criteria, required under the Regulation. The bulletin referred to the next stage of the withdrawal process being consultation with trading partners via the WTO.

This consultation has now concluded. The GB Administrations have given consent for HSE to carry out the decision-making function arising from this review.

In addition to the new knowledge that triggered the review and information provided by the producers, the comments that were made under the WTO process, were also taken into account. HSE has concluded that non-dietary exposure was above the toxicological reference value (AOEL/AAOEL) for operators, workers, residents, and bystanders for the uses of indoxacarb and therefore the approval criteria required under the Regulation are no longer met (Article 4 (3) (b) the Regulation).

*The expiry date of indoxacarb has been brought forward to **31 August 2024** when approval will end. Further details can be found by viewing the GB approval register on the HSE website.*

To allow existing stocks to be removed from the supply chain safely, HSE has agreed a phased withdrawal programme:

- *producers will be permitted 6 months from the expiry date to sell and distribute authorised indoxacarb products until 28 February 2025*
  users will be permitted a further 1 year to dispose of, store, and use existing stocks of authorised indoxacarb products until 28 February 2026

HSE Biocides ebulletin
Issued: 6 August 2024
This ebulletin contains information on regulating biocides in Northern Ireland (NI).

Reminder – upcoming EU active substance open invitation deadline
Submit a notification by the deadline to keep active substances in the EU Review Programme
The European Chemicals Agency (ECHA) has published an open invitation to provide an opportunity for a person, company or task force/consortium to notify an intention to take up or take over the role of participant in the EU Review Programme for the following active substance/product type combinations.

This affects NI. Anyone wishing to support one of the active substance/product type combinations listed below in the EU will need to submit a notification to ECHA by the following deadline:

- *Pyrithione zinc (zinc pyrithione) (CAS 236-671-3 EC 13463-41-7) in product types 2 and 10*
  21 December 2024

If a notification to take over the role of participant is not received, these active substance/product type combinations will be subject to an EU non-approval decision. This means the active substance will no longer be able to be used in biocidal products of the relevant product types in NI.

In addition articles treated with such products will no longer be able to be placed on the market in NI. HSE will provide separate updates on these where relevant. If you are aware of any disproportionate negative impacts that are likely to arise from the non-approval of any of the active substance/product type combinations listed above, please contact us

EU active substance expiry dates postponed

Active substance expiry dates postponed whilst the renewal evaluation is completed in the EU

For reasons beyond the control of the applicants, the approvals of the active substance/product type combinations listed below were likely to expire before a decision could be taken on their renewal under the EU Biocidal Products Regulation (EU BPR).

To allow sufficient time for the renewal evaluation to be completed, a decision has been taken to postpone the expiry dates of the following approvals. This affects NI:

- *Cis-tricos-9-ene, (Z)-Tricos-9-ene (muscalure) (CAS 27519-02-4 EC 248-505-7) in product type 19*
  30 September 2024 to 31 March 2027
- *1-(3,5-dichloro-4-(1,1,2,2-tetrafluoroethoxy)phenyl)-3-(2,6-difluorobenzoyl)urea (hexaflumuron) (CAS 86479-06-3 EC 401-400-1) in product type 18*
  30 September 2024 to 31 March 2027
- *Hydrogen cyanide (CAS 74-90-8 EC 200-821-6) in product types 8, 14 and 18*
  30 September 2024 to 31 March 2027

If you want to supply new biocidal products containing these active substances, you can still apply for EU BPR product authorisation. New products (including new trade names) must not be supplied in NI until product authorisation is granted. HSE will provide separate updates on the renewal decisions when relevant.

HSE ebulletin

Issued: 5 August 2024

This ebulletin includes details of an upcoming workshop focusing on submitting the efficacy section of application dossiers under the Great Britain Biocidal Products Regulation (GB BPR). For more information visit our Chemicals Regulation Division (CRD) training and events webpage

Live online workshop: biocides efficacy under the GB BPR

17, 18 and 19 September 2024

This workshop will be delivered online over 3 morning sessions and will help develop an understanding of the regulatory approach to efficacy assessment under the GB BPR.

The training will be delivered by HSE regulatory specialists and will help attendees improve the quality of their submissions and understand how these will be reviewed by the GB regulator.

We will share our experience and worked examples to demonstrate best practice and common issues and data gaps that we encounter during assessments.

Who should attend?

The course is suitable for all those involved in the creation and submission of an efficacy data package for GB BPR applications, including test houses, applicants, consultants, etc.

No prior experience is assumed; the course will provide both a good starting point for beginners and an opportunity to develop and update the knowledge of those experienced in producing dossiers.

Topics covered

- *identifying the label claims for a product and using the guidance to find the correct data requirements for these claims*
- *generating and presenting data to meet these requirements*
- *options when guidance is limited or unavailable*
- *product type (PT) specific considerations and requirements for: PT 1 – 5 (Disinfectants), PT 18 (Insecticides) and PT 19 (Repellents and Attractants)*

- *specific common issues for other product types*
- *efficacy data requirements for product families*
- *efficacy data requirements to demonstrate that a co-formulant is not an active substance in a product*
- *question and answer sessions*

Registration
The closing date for registration is 9 September 2024.
Find out more and register for this fee paid workshop.

HSE Biocides ebulletin
Issued: 2 August 2024
This ebulletin contains information on regulating biocides in Northern Ireland (NI).

Reminder – upcoming EU active substance renewal submission deadlines
Apply for active substance renewal by the deadlines to keep products on the NI market
Under the EU Biocidal Products Regulation (EU BPR), active substance approvals will expire unless a renewal application is submitted to European Chemicals Agency (ECHA) at least 550 days before their expiry date.

The 550-day deadlines are coming up for the following active substance/product type combinations under EU BPR. This affects NI:

- *[1α(S*),3α]-(α)-cyano-(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2.2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (alpha-cypermethrin) (CAS 67375-30-8 EC 614-054-3) in product type 18*
  27 December 2024
- *Bacillus sphaericus 2362, strain ABTS-1743 (CAS 143447-72-7 EC n/a) in product type 18*
  27 December 2024
- *Bacillus thuringiensis subsp. israelensis, strain SA3A (CAS n/a EC n/a) in product type 18*
  27 December 2024
- *Propan-2-ol (CAS 67-63-0 EC 200-661-7) in product types 1, 2 and 4*
  27 December 2024
- *Copper, granulated (CAS 7440-50-8 EC 231-159-6) in product type 8*
  29 June 2025
- *Biphenyl-2-ol (CAS 90-43-7 EC 201-993-5) in product types 1, 2, 4, 6 and 13*
  27 December 2025
- *Epsilon-momfluorothrin (CAS 1065124-65-3 EC n/a) in product type 18*
  27 December 2025
- *L-(+)-lactic acid (CAS 79-33-4 EC 201-196-2) in product type 1*
  27 December 2025
- *Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (mixture of CMIT/MIT) (CAS 55965-84-9 EC n/a) in product types 2, 4, 6, 11, 12 and 13*
  27 December 2025
- *Polyhexamethylene biguanide hydrochloride with a mean number-average molecular weight (Mn) of 1600 and a mean polydispersity (PDI) of 1.8 (PHMB (1600;1.8)) (CAS 27083-27-8 / 32289-58-0 EC 608-042-10) in product type 4*
  27 December 2025

Any person, company or task force/consortium can support an active substance/product type combination for renewal – it doesn't have to be the original supporter. Check the EU Article 95 List to see who the original supporters were.

If any of these active substance/product type combinations are important to you, consider contacting your supplier to let them know.

If a renewal application is not submitted for the above active substance/product type combinations under EU BPR, the approvals will expire. This means the active substances will no longer be able to be used in biocidal products of the relevant product types in NI. In addition articles treated with such products will no longer be able to be placed on the market in NI.

Reminder - upcoming EU active substance expiry date

Biocidal products must be phased off the NI market

The active substance/product type combinations listed below are due to expire under the EU BPR on the following date. This affects NI:

- *1-(4-chlorophenyl)-4,4-dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol (tebuconazole) (CAS 107534-96-3 EC 403-640-2) in product types 7 and 10*
  30 June 2025

Once the approval expires, the active substance/product type combinations will no longer be able to be used in biocidal products of the relevant product types in NI. In addition articles treated with such products will no longer be able to be placed on the market in NI.

If you hold an affected EU BPR product authorisation or Control of Pesticides Regulations (COPR) product approval, we will contact you about cancelling or revoking your authorisation or approval. You will have an opportunity to submit comments or additional information and we will take account of these when finalising our decision.

If you are aware of any disproportionate negative impacts that are likely to arise from the expiry of any of the active substance/product type combinations listed above, please contact us

HSE ebulletin

Date issued: 1 August 2024

This ebulletin contains details of an upcoming workshop focusing on dermal absorption for both plant protection products and biocidal products. For more information visit our Chemicals Regulation Division (CRD) training and events webpage.

Live online workshop: Dermal absorption for plant protection and biocidal products

11 and 12 September 2024

This workshop will be delivered over 2 online sessions.

It will present and explain the European Food Safety Authority (EFSA) 2017 guidance on dermal absorption (applicable in Great Britain), which replaced the previous EFSA guidance document (2012). The workshop will also address dermal absorption issues for both plant protection and biocidal products.

Who should attend?

The workshop is aimed at technical and registration specialists involved in the design of dermal absorption studies and in the preparation and submission to HSE of plant protection and biocidal product applications for authorisation.

Topics covered

- *overview of the 2017 guidance document*
- *critical aspects of dermal absorption studies and their interpretation*

- *key information frequently absent from, or not clearly presented in, dermal absorption study reports and / or regulatory submissions*
- *worked examples highlighting critical areas of the 2017 guidance*
- *common problems found in dermal absorption evaluations*
- *application of the guidance to biocidal products*
- *special cases for biocidal products including antifouling products and anticoagulant rodenticides*

Registration
The closing date for registration is 3 September 2024.
Find out more and register for this fee paid workshop

LINKS
GB Pesticides Approvals Register
LINK: https://www.hse.gov.uk/pesticides/pesticides-registration/active-substances/register.htm
Active substance renewals
LINK: https://www.hse.gov.uk/pesticides/pesticides-registration/active-substances-renewals.htm
New active substances
LINK: https://www.hse.gov.uk/pesticides/pesticides-registration/active-substances-new.htm
Pesticides news
LINK: https://www.hse.gov.uk/pesticides/news/index.htm

Expert Committee on Pesticide Residues in Food (PRiF)
The next meeting of the PRiF will be held on 16 October 2024.

29 January 2025
16 October 2024
24 January 2024 (agenda)
18 October 2023 (minutes)
19 July 2023 (minutes)
24 May 2023 (minutes)
25 January 2023 (minutes)

Pesticide residues in food monitoring results
May 2024 GB and NI Rolling Reporting, Format: ODS, Dataset: Pesticide Residues in Food
Quarter 1 2023 PRiF Report Quarterly Data (Northern Ireland), Format: ODS, Dataset: Pesticide Residues in Food
April 2024 GB and NI Rolling Reporting, Format: ODS, Dataset: Pesticide Residues in Food
March 2024 GB and NI Rolling Reporting, Format: ODS, Dataset: Pesticide Residues in Food
January and February 2024 GB and NI Rolling Reporting, Format: ODS, Dataset: Pesticide Residues in Food

FERA
Pesticide Usage Surveys release dates (see here.)
2021 Edible protected crops in the UK (28 February 2023)
2021 Grassland & Fodder crops in the UK (31 January 2023)
2022 Arable crops in the UK (21 November 2023)
2022 Soft Fruit in the UK (14 December 2023)
2022 Orchard crops in the UK (11 January 2024)
2022 Potato Storage in the UK (29 January 2024)

Scotland (SASA) Pesticide Usage Survey Reports
LINK: https://www.sasa.gov.uk/pesticides/pesticide-usage/pesticide-usage-survey-reports

Pesticide Usage in Scotland: Rodenticide Use on Grassland & Fodder Farms 2021 (22 February 2023)
Pesticide Usage in Scotland: Rodenticide Use on Grassland & Fodder Farms 2021 (February 2023, Biennial).
Soft Fruit Crops 2022 (13 December 2023, Biennial)
Arable crops and Potato stores 2022 (13 December 2023, Biennial)
Pesticide Usage in Scotland: Rodenticides on Arable Farms 2022 (7 March 2024, Biennial)
Pesticide Usage in Scotland: Outdoor Vegetable Crops 2023 (Expected October 2024, Biennial)

Northern Ireland (AFBI) Pesticide Usage Survey Reports
Soft Fruit Crops 2022
Top Fruit Crops 2022
Arable crops 2022

CABI bio-control and biopesticide database
Biocontrol and biopesticide products in the UK – BioProtection Portal

GB Potato Plant Protection Products and Biocides Issues Risk Matrix (August 2024)

Level of risk, imminent, medium-term to longer-term →

Decreasing impact on business ↓

Risk Analysis	PPP authorisation expires or related issues to be reviewed in the next 12 months (Before end August 2025) [Actions in hand] Dynamic situation	PPP authorisation in 12-36 months out (September 2025 – August 2027) Future Issue [Plans in preparation]	>36 months (after end August 2027) before PPP comes up for reauthorisation
Big Company Impact **Cost** **Reputation** **Media**	Mancozeb* (F) [GB expiry of authorisation 31/05/24. Sale and supply 30/11/24. Storage, disposal and use 30/11/25]. Criteria for defining EDs Candidates for substitution	Lambda-cyhalothrin* (I) [GB expiry 31/03/26] Mandipropamid* (F) [GB 31/07/26]	Metribuzin* (H) [GB 31/07/28] Cymoxanil (F) [GB 31/08/29] Fosthiazate (N) [GB expiry 31/10/29] Maleic Hydrazide (GR) [GB 31/10/32] Carfentrazone-ethyl (H) [GB 31/07/33]
Moderate Impact **Cost** **Material availability** **Working practice**		Glyphosate (H) [GB 15/12/25] Flonicamid (I) [GB 31/08/26]	Flutolanil (ST) [GB 28/02/29] Azoxystrobin (F) [GB 31/12/29] Imazalil (ST) [GB 31/12/29] Ferric phosphate (M) [GB 31/12/30] Thiabendazole* (ST) [GB 31/03/32]
Small Impact **Cost** **Materials** **Change**		Esfenvalerate (I) [GB 31/12/25] Fluopicolide (F) [GB 31/05/26] Benthiavalicarb (F) [GB 31/07/27] Dimethomorph (F) [GB 31/07/27]	Flufenacet (H) [GB 31/10/27] Difenoconazole* (F) [GB 31/12/28] Fluazinam* (F) [GB 29/02/29] Rimsulfuron (H) [GB 30/04/29] Propamocarb (F) [GB 31/07/29] Prosulfocarb (H) [GB 31/10/29]

NB: All GB authorisations that were still in place as of 01/01/2021 were automatically extended for a 3-year period. A further extension was granted for some actives as of 12/04/2023

Current issue Changed priority Identified as a potential high profile media issue *Potential Endocrine disruptor

H – Herbicide, F – Fungicide, GR- Growth Regulator, I – Insecticide, ST – Seed Treatment, N – Nematicide, D – Desiccant, M – Molluscicides

EU Potato Plant Protection Products and Biocides Issues Risk Matrix (August 2024)

Level of risk, imminent, medium-term to longer-term →

Decreasing impact on business ↓

Risk Analysis	PPP authorisation expires or related issues to be reviewed in the next 12 months (Before end August 2025) [Actions in hand] Dynamic situation	PPP authorisation in 12-36 months out (September 2025 – August 2027) Future Issue [Plans in preparation]	>36 months (after end August 2027) before PPP comes up for reauthorisation
Big Company Impact **Cost** **Reputation** **Media**	Criteria for defining EDs Candidates for substitution Metribuzin* (H) [EU expiry 15/02/25]	Mandipropamid* (F) [EU expiry 31/12/25] Lambda-cyhalothrin* (I) [EU expiry 31/08/26] Metaldehyde (M) [EU expiry 31/08/26] Cymoxanil (F) [EU expiry 31/08/26] Fosthiazate (N) [EU expiry 31/01/27]	Maleic Hydrazide (GR) [EU expiry 31/10/32] Carfentrazone-ethyl (H) [EU expiry 31/07/33]
Moderate Impact **Cost** **Material availability** **Working practice**	Azoxystrobin (F) [EU expiry 31/12/24] Imazalil (ST) [EU expiry 31/12/24] Flutolanil (ST) [EU expiry 15/06/25]	Plant oils/clove oil [EU Expiry 31/01/26] Plant oils/spear mint oil [EU Expiry 31/01/26] Ethylene (GR) [EU expiry 30/11/26] Flonicamid (I) [EU expiry 30/11/26]	Ferric phosphate (M) [EU expiry 31/12/30] Thiabendazole* (ST) [EU expiry 31/03/32] Glyphosate (H) [EU Expiry 15/12/33]
Small Impact **Cost** **Materials** **Change**	Benthiavalicarb (F) [EU authorisation expiry 13/06/24. Grace period 13/12/24] Dimethomorph (F) [EU expiry 15/02/25] Propamocarb (F) [EU expiry 15/06/25] Flufenacet (H) [EU expiry 15/06/25]	Difenoconazole* (F) [EU expiry 15/03/26] Fluazinam* (F) [EU expiry 15/04/26] Esfenvalerate (I) [EU expiry 31/05/26] Fluopicolide (F) [EU expiry 31/08/26] Prosulfocarb (H) [EU expiry 31/01/27]	Rimsulfuron (H) [EU expiry 15/08/28]

Current issue Changed priority Identified as a potential high profile media issue *Potential Endocrine disruptor

H – Herbicide, F – Fungicide, GR- Growth Regulator, I – Insecticide, ST – Seed Treatment, N – Nematicide, D – Desiccant, M – Molluscicides

Secondary Actives List: Actives which may become important if there are loses from priority list

Secondary List of Actives	EU Authorisation Expiry Date	GB Authorisation Expiry Date	MRL mg/kg
Acetamiprid (I)	28/02/2033	28/02/2033	0.01* (Limit of Determination)
Boscalid (F)	15/04/2026	31/07/2029	2.0
Clomazone (H)	15/06/2025	31/10/2029	0.01* (Limit of Determination)
Fludioxonil (F)	15/06/2025	31/10/2028	5.0
Pyraclostrobin (F) (with boscalid)	Pyraclostrobin 15/09/2025	Pyraclostrobin 31/10/2029	Pyraclostrobin - 0.02* (Limit of Determination)
	Boscalid 15/04/2026	Boscalid 31/07/2029	Boscalid - 2.0
Pyraflufen-ethyl (H)	31/03/2031	31/03/2031	0.02 * (Limit of Determination)
Cycloxydim (H)	31/08/2026	31/05/2026	3.0
Aclonifen (H)	31/10/2026	31/07/2025	0.02 * (Limit of Determination)
Ametoctradin (F)	31/12/2025	31/07/2026	0.05
Amisulbrom (F)	30/09/2024	30/09/2029	0.01
Bentazone (H)	31/05/2025	31/05/2025	0.2
Cyazofamid (F)	31/07/2036	31/07/2029	0.01
Fluxapyroxad (F)	31/05/2025	31/05/2025	0.1

Metobromuron (H)	31/12/2024	31/12/24	0.01* (Limit of determination, possibility this may be raised to 0.03 following EFSA review)
Oxathiapiprolin (F)	03/03/2027	03/03/2027	0.1
Pendimethalin (H)	30/11/2024	30/11/2028	0.05* (Limit Of Determination)
Propaquizafop (H)	28/02/2027	30/11/2029	0.1
Quizalofop-P-tefuryl (H)	28/02/2027	30/11/2028	0.1
Zoxamide (F)	31/06/2033	31/06/2033	0.02* (Limit of Determination)

H – Herbicide, F – Fungicide, GR- Growth Regulator, I – Insecticide,
ST – Seed Treatment, N – Nematicide, D – Desiccant, M – Molluscicide