



EU PESTICIDE RENEWAL MONITOR

August 31, 2023¹

In the European Union (EU), all pesticide active ingredients undergo periodic reevaluation, as laid out in Regulation (EC) No. 1107/2009². The reevaluation process typically follows the scheme indicated in the figure below.

This document provides an overview of active ingredients that are currently undergoing or are scheduled for the periodic active ingredient renewal in the European Union, and it is prepared based on publicly available information. It lists active ingredients that have expired or are expected to expire, as of **August 31, 2023**. The renewal process relates to the approval of active ingredients used in the EU market. It is lengthy and unpredictable. Only final, published Regulations are definitive. Pesticide Renewal is a separate process from MRL and Import Tolerance setting, which is governed by specific legislation. Change or removal of MRLs may take place after non-renewal has been finalized.

For additional information on the registration status and expiry dates for active ingredients that are not listed in this document, please refer to the <u>EU pesticide database</u>³.

For information on specific active ingredients, please consult the <u>OpenEFSA Portal</u>⁴ or contact the companies that are supporting the active ingredient through the renewal process by contacting <u>croplife@croplife.org</u>.

Application	Renewal Assessment Report	EFSA Peer Review	EC Draft Regulation (PAFF)	WTO/TBT Notification	Commission Regulation (EU)
13 months 11 months 6 months 3 months+ 4 months+					

Figure 1: Schematic overview of the EU reevaluation process for non-renewals or restricted renewals. Timelines are indicative as outlined in Regulation (EC) No. 1107/2009. Steps can take longer than indicated.

Disclaimer: The EU Pesticide Renewal Monitor is intended for information purposes only. Users are invited to verify the information obtained from the EU Pesticide Renewal Monitor with knowledgeable third parties prior to engaging in any business activities, such as the sale or shipment of any product. Users acknowledge that CropLife International and <u>BCI</u> are not responsible for the accuracy, reliability, and currency of the information and that the information provided may not be one hundred percent (100%) accurate, up-to-date, and free of omissions. CropLife International and BCI shall not be held liable for any losses or damages arising from any errors, omissions, or misrepresentations from the use of the information contained in the EU Pesticide Renewal Monitor.

¹ This EU Pesticide Renewal Monitor issue reflects substances listed as proposed non-renewal or restricted renewal on the PAFF agenda up to the September 15, 2023, meeting.

- ² https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&from=EN
- ³ <u>https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as</u>
- ⁴ <u>https://open.efsa.europa.eu/questions</u>





APPLICATION FOR RENEWAL - EXPIRED (September 2022 – August 2023)

Chemical companies must submit an application for renewal of approval of their active ingredient to EU authorities. If they do not, the active ingredient will automatically expire in the EU on a set date. Active ingredients below **have already expired** due to **no submission of application for renewal** or **withdrawal of application for renewal**. This list includes substances that have expired since September 2022.

- Adoxophyes orana GV strain BV-0001 (31/01/2023)
- Zucchini Yellow Mosaic Virus, weak strain (31/05/2023)
- Fatty acids C8-C10 methyl esters (CAS 85566-26-3) (Methyl octanoate (CAS 111-11-5); Methyl decanoate (CAS 110-42-9)) (31/08/2023)

APPLICATION FOR RENEWAL - EXPECTED TO EXPIRE (Up to August 2024)

For the active ingredients below, applications for **renewal of approval were not submitted** or **applications have been withdrawn**. The expiration date is outlined. Please note that the expiration of active ingredients in the EU is not notified to the World Trade Organization (WTO).

- Bacillus firmus I-1582 (30/09/2023)
- Spiromesifen (30/09/2023)
- Quizalofop-P (30/11/2023)
- Spirotetramat (30/04/2024)
- Ascorbic acid (or L-ascorbic acid) (30/06/2024)
- Spinetoram (30/06/2024)
- Flubendiamide (31/08/2024)

UP NEXT FOR REVIEW (Up to August 2024)

Under the EU pesticide review program, active ingredients need to reapply for renewal three years before its expiration date. Substances listed below have **upcoming deadlines** for the **submission of the renewal dossier** (submission date in parentheses). The list shows all active ingredients that are scheduled to go through the periodic renewal process. This does not imply that these active ingredients will have issues with renewal in the EU.

- Cyantraniliprole (14/09/2023)
- Isofetamid (15/09/2023)
- Bacillus amyloliquefaciens MBI 600
 (16/09/2023)
- Oxathiapiprolin (03/03/2024)
- Beauveria bassiana strain 147 (06/06/2024)
- Beauveria bassiana strain NPP111B005 (07/07/2024)





STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED (SCoPAFF)

Active ingredients below have been under discussion for **non-renewal** or **restricted renewal** and are now **under consideration** by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) as available in the July 11-12 and September 15, 2023 meeting agendas. A final decision may have not yet been made.

- Benthiavalicarb
- Captan
- Metiram

- Clofentezine
- Triflusulfuron-methyl
- S-metolachlor

WTO NOTIFICATION (September 2022 – August 2023)

Active ingredients below have been notified to the **WTO as proposed for non-renewal** or **restricted renewal**. Active ingredients that are renewed do not need to be notified to the WTO. These WTO Technical Barrier to Trade (TBT) notifications advise that the active ingredient is subject to a proposed non-renewal for use in the EU. This is not necessarily indicative of the final EU decision. Further Committee work is done by the Commission and EU Member States after notification, which can change the proposal. Definitive non-renewal regulation may take a significant period of time after the WTO consultation has completed. These notifications do not advise what will happen with EU MRLs. This information is provided in Sanitary and Phytosanitary (SPS) notifications via WTO, typically some years later. For full explanation on the justification for proposed restricted renewal or non-renewal of approval, please refer to the draft implementing regulation. Notification date is shown in parentheses.

Proposed non-renewal

Benthiavalicarb: proposed non-renewal based on concerns including classification as carcinogenic potential meets the criteria for endocrine disruption for humans for the T and EAS modalities were met. (20/07/2023)

Clofentezine: proposed non-renewal based on multiple concerns, including endocrine disrupting properties that may cause adverse effects in humans. Clofentezine is also seen as a high, long-term risk to birds and wild mammals. (14/07/2023)

Metiram: proposed non-renewal based on various concerns, including meeting the criteria for endocrine disruption for humans, exposure to the active ingredient exceeds the reference values, and is a high risk to aquatic organisms and non-target arthropods. (20/07/2023)

S-metolachlor: proposed non-renewal bases on concerns including groundwater contamination, and therefore human and animal consumption. (24/05/2023)

Triflusulfuron: proposed non-renewal based on multiple concerns, including groundwater metabolites and endocrine disrupting properties in humans. (13/07/2023)

Proposed restricted renewal

Captan: proposed restricted renewal of approval to permanent greenhouse use only. (28/09/2022)





COMMISSION IMPLEMENTING REGULATION (September 2022 – August 2023)

The Commission has published final decisions on non-renewal or restricted renewal in the EU for the active ingredients below. For full explanation on the justification for restricted or non-renewal of approval, please refer to the published implementing regulation. Publication date is shown in parentheses.

Non-renewal

Benfluralin: non-renewal based on a long-term health risk to birds, aquatic organisms, as well as the genotoxic potential of an impurity could not be excluded. (20/01/2023)

Oxamyl: non-renewal of approval due to a high risk for all the representative uses assessed to exceed the acceptable operator exposure level, exceedance of the acute reference dose, others. (05/04/2023)

Ipconazole: withdrawal of approval due to high long-term risk to birds and classification as toxic for reproduction category 1B. (10/05/2023)

Dimoxystrobin: non-renewal of approval due to a high risk for groundwater contamination in all geoclimatic conditions. (10/07/2023)

Restricted renewal

Abamectin: restricted renewal to greenhouse use based on a high risk identified to aquatic organisms, mammals, birds, and soil macroorganisms. (08/03/2023)

Penflufen: restricted renewal due to a classification in carcinogen category 2 and the presence of the metabolite M01 for groundwater. (05/09/2022)

MRL CHANGES (September 2022 – August 2023)

As a **result of non-renewal** or **expiration** of approval, restrictive MRLs have either been proposed (WTO notification) or implemented (Commission Regulation) for the substances below. Notifications of MRL changes usually appear as WTO SPS notifications. Please note that not all MRL changes are included here as MRLs may change even if the active ingredient is reapproved.

WTO Notification

- **Bifenazate**: WTO notification G/SPS/N/EU/609. (17/01/2023)
- Carbetamide: WTO notification G/SPS/N/EU/616. (23/02/2023)
- Carboxin: WTO notification G/SPS/N/EU/616. (23/02/2023)
- Triflumuron: WTO notification G/SPS/N/EU/616. (23/02/2023)
- **Denatonium benzoate**: WTO notification G/SPS/N/EU/617. (24/02/2023)
- **Diuron:** WTO notification G/SPS/N/EU/617. (24/02/2023)
- Etoxazole: WTO notification G/SPS/N/EU/617. (24/02/2023)
- Methomyl: WTO notification G/SPS/N/EU/617. (24/02/2023) some CXLs maintained
- Teflubenzuron: WTO notification G/SPS/N/EU/617. (24/02/2023) some ITs and CXLs maintained
- Acrinathrin: WTO notification G/SPS/N/EU/642. (13/06/2023)
- Azimsulfuron: WTO notification G/SPS/N/EU/642. (13/06/2023)





MRL CHANGES (Continued)

WTO Notification

- Famoxadone: WTO notification G/SPS/N/EU/642. (13/06/2023) some CXLs maintained
- Methyl nonyl ketone: WTO notification G/SPS/N/EU/642. (13/06/2023)
- Prochloraz: WTO notification G/SPS/N/EU/642. (13/06/2023)
- Sodium hypochlorite: WTO notification G/SPS/N/EU/642. (13/06/2023)
- Diethofencarb: WTO notification G/SPS/N/EU/649. (29/06/2023) some ITs maintained
- Fenoxycarb: WTO notification G/SPS/N/EU/649. (29/06/2023)
- Flutriafol: WTO notification G/SPS/N/EU/649. (29/06/2023) some CXLs and ITs maintained
- Pencycuron: WTO notification G/SPS/N/EU/649. (29/06/2023)
- Thiacloprid: WTO notification G/SPS/N/EU/651. (06/07/2023) some CXLs and ITs maintained
- Haloxyfop: WTO notification G/SPS/N/EU/652. (06/07/2023) some CXLs maintained
- Indoxacarb: WTO notification G/SPS/N/EU/653. (07/07/2023)
- **Desmedipham:** WTO notification G/SPS/N/EU/654. (07/07/2023)
- Difenacoum: WTO notification G/SPS/N/EU/654. (07/07/2023)
- Etridiazole: WTO notification G/SPS/N/EU/654. (07/07/2023)
- Flurtamone: WTO notification G/SPS/N/EU/654. (07/07/2023)
- Profoxydim: WTO notification G/SPS/N/EU/654. (07/07/2023)

Implementing Regulation

- **Benalaxyl**: Commission Regulation 2023/128 on 19/01/2023. *Effective date: 08/08/2023* CXLs maintained, MRLs to cover benalaxyl-M uses maintained.
- Bromoxynil: Commission Regulation 2023/128 on 19/01/2023. Effective date: 08/08/2023
- Chlorsulfuron: Commission Regulation 2023/128 on 19/01/2023. Effective date: 08/08/2023
- Epoxiconazole: Commission Regulation 2023/128 on 19/01/2023. Effective date: 08/08/2023
- Fenamiphos: Commission Regulation 2023/128 on 19/01/2023. Effective date: 08/08/2023
- Cyromazine: Commission Regulation 2023/147 on 23/01/2023. Effective date: 12/08/2023
- Topramezone: Commission Regulation 2023/147 on 23/01/2023. Effective date: 12/08/2023
- Triflumizole: Commission Regulation 2023/147 on 23/01/2023. Effective date: 12/08/2023
- Beta-cyfluthrin: Commission Regulation 2023/173 on 27/01/2023. Effective date: 16/08/2023
- Cyfluthrin: Commission Regulation 2023/173 on 27/01/2023. Effective date: 16/08/2023
- Clothianidin: Commission Regulation 2023/334 on 15/02/2023. Effective date: 07/03/2026
- Thiamethoxam: Commission Regulation 2023/334 on 15/02/2023. Effective date: 07/03/2026
- Sodium Aluminium Silicate: Commission Regulation 2023/377 on 22/02/2023. Effective date: 14/09/2023
- Triadimenol: Commission Regulation 2023/377 on 22/02/2023. Effective date: 14/09/2023
- Chloridazon: Commission Regulation 2023/710 on 31/03/2023. Effective date: 21/10/2023
- Imazaquin: Commission Regulation 2023/710 on 31/03/2023. Effective date: 21/10/2023
- Fenpropimorph: Commission Regulation 2023/710 on 31/03/2023. *Effective date: 21/10/2023 –* Import tolerances and CXLs maintained
- Tralkoxydim: Commission Regulation 2023/710 on 31/03/2023. Effective date: 21/10/2023
- Phosmet: Commission Regulation 2023/1029 on 26/05/2023. Effective date: 15/09/2023





Table I. EU Pesticide Renewal Monitor (PRM) in Numbers

Time scope / Review step	2019 (January-December)	2020 (January-December)	2021 (January-December)	2022 (January- December)	PRM 2023 (Year to Date)
	22	11	22	3	3
Expired Active Ingredients	<u>Fuberidazole, Bacillus</u> <u>thuringiensis subsp.</u> <u>Tenebrionis strain NB 176</u> (<u>TM 14 1),</u> <u>Fenpropimorph,</u> <u>Tralkoxydim, Trichoderma</u> <u>polysporum strain IMI</u> <u>206039, Ammonium</u> <u>acetate, Limestone,</u> Methomyl, <i>Pepper,</i> <u>Putrescine, Sea-algae</u> <u>extract, Sodium aluminium</u> silicate, Sodium hypochlorite, Triadimenol, <u>Trimethylamine</u> <u>hydrochloride, Quizalofop-P, Teflubenzuron,</u> <u>Difenacoum,</u> Chlorsulfuron, Cyromazine, <u>Lufenuron,</u> Propanil	Phlebiopsis gigantea multiple strains, Epoxiconazole, Triflumizole, Spirodiclofen, <u>FEN</u> <u>560</u> , Thiophanate methyl, <u>Calcium</u> phosphide, <u>Denatonium</u> benzoate, Imidacloprid, Zeta cypermethrin, Haloxyfop-P	Triflumuron, Fenbuconazole, Metosulam, Trichoderma IMI 206040, Bromadiolone, Carbetamide, Carboxin, Cyproconazole, Diethofencarb, Etridiazole, Fenoxycarb, Flutriafol, Myclobutanil, Oryzalin, <u>Pencycuron,</u> <u>Profoxydim, Fatty</u> <u>acids C8-C10 methyl</u> <u>esters, Triazoxide,</u> <u>Acrinathrin,</u> <u>Azimsulfuron,</u> <u>Fluquinconazole,</u> <u>Prochloraz</u>	Bispyribac, Plant oils/ Citronella oil, <u>Isopyrazam</u>	Adoxophyes orana GV strain BV-0001, Zucchini Yellow Mosaic Virus, weak strain, Fatty acids C8-C10 methyl esters
	5	6	7	1	5
Step 1: Proposed Restricted or Non-Renewal of Approval (WTO TBT)	Chlorpyrifos, Chlorpyrifos- methyl, Metalaxyl-M, Thiacloprid, Thiophanate- methyl	Beta-cyfluthrin, <u>Benalaxyl,</u> Benfluralin, Bromoxynil, Etoxazole, Fenpyrazamine	Abamectin, Alpha- cypermethrin, Cypermethrin, Famoxadone, Indoxacarb, Phosmet, Sulfoxaflor	Captan	S-metolachlor, <u>Benthiavalicarb,</u> Clofentezine, Metiram, Triflusulfuron





Table I. EU Pesticide Renewal Monitor (PRM) in Numbers

Time scope / Review step	2019 (January-December)	2020 (January-December)	2021 (January-December)	2022 (January- December)	PRM 2023 (Year to Date)
	11	11	6	4	6
Step 2: Restricted or Non-Renewal of Approval (Commission Regulation)	Alpha-Cypermethrin, Chlorothalonil, Chlorpropham, Cyflumetofen, Dimethoate, Desmedipham, Ethoprophos, Methiocarb, Methoxyfenozide, Thiacloprid, <u>Tolclofos-</u> <u>methyl</u>	Benalaxyl, Beta- cyfluthrin, Bromoxynil, Chlorpyrifos, Chlorpyrifos-methyl, Etoxazole, <u>Fenamiphos,</u> Mancozeb, Metalaxyl-M, <u>Thiacloprid,</u> Thiophanate-methyl	Alpha-cypermethrin, Cypermethrin, Famoxadone, Fenpyrazamine, Indoxacarb, Terbuthylazine	Phosmet, <u>Isopyrazam,</u> Sulfoxaflor, Bifenazate	Benfluralin, Oxamyl, Ipconazole, Abamectin, <u>Dimoxystrobin,</u> Penflufen
	3	8	7	14	27
Step 3: Active Ingredients with Proposed MRL Changes due to Non- Approval (WTO)	<u>Flufenoxuron,</u> Chlorpyrifos, Chlorpyrifos- methyl	Chlorothalonil, Chlorpropham, Dimethoate, Ethoprophos, Fenamidone, Methiocarb, Propiconazole, Pymetrozine	Bifenthrin, <u>Chloridazon,</u> Imazaquin, Fenpropimorph, <u>Tralkoxydim,</u> <u>Propoxur</u> , Thiram	Cyfluthrin, Beta cyfluthrin, Bromoxynil, Chlorsulfuron, <u>Epoxiconazole,</u> <u>Fenamiphos,</u> Sodium aluminium silicate, Triadimenol, Calcium phosphide, Cyromazine, Topramezone, Triflumizole, Clothianidin, Thiamethoxam	Bifenazate, <u>Carbetamide</u> , Carboxin, <u>Triflumuron,</u> <u>Denatonium benzoate</u> , Diuron, Etoxazole, Methomyl, <u>Teflubenzuron,</u> <u>Acrinathrin,</u> <u>Azimsulfuron,</u> Famoxadone, <u>Methyl nonyl ketone,</u> <u>Prochloraz,</u> <u>Sodium hypochlorite,</u> <u>Diethofencarb,</u> <u>Fenoxycarb,</u> <u>Flutriafol,</u> <u>Pencycuron,</u> <u>Thiacloprid,</u>



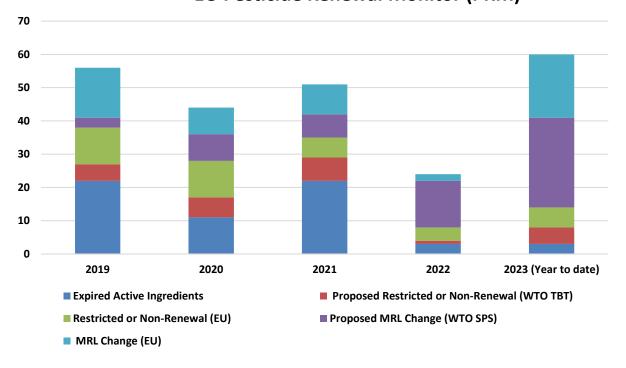


Table I. EU Pesticide Renewal Monitor (PRM) in Numbers

Time scope / Review step	2019 (January-December)	2020 (January-December)	2021 (January-December)	2022 (January- December)	PRM 2023 (Year to Date)	
					<u>Haloxyfop,</u> Indoxacarb, Desmedipham, <u>Difenacoum,</u> Etridiazole, <u>Flurtamone,</u> <u>Profoxydim</u>	
	15	8	9	2	19	
Step 4: Active Ingredients with MRL Changes due to Non- Approval (Commission Regulation)	Iprodione, Linuron, Buprofezin, <u>Diflubenzuron</u> , Picoxystrobin, <u>Tepraloxydim,</u> <u>Ethoxysulfuron, Ioxynil,</u> <u>Amitrole, Flupyrsulfuron- methyl, Isoproturon,</u> Triasulfuron, Fipronil, Imazosulfuron, Orthosulfamuron	Chlorpyrifos, Chlorpyrifos-methyl, <u>Azinphos-methyl,</u> <u>Flufenoxuron,</u> <u>Oxadiazon,</u> <u>Phosalone, Tall oil</u> <u>pitch, Tall oil crude</u>	Chlorothalonil, Chlorpropham, Dimethoate, Ethoprophos, Fenamidone, Methiocarb, Propiconazole, Pymetrozine, Propineb	<u>Propoxur</u> , Thiram	Cyfluthrin, Beta cyfluthrin, Bromoxynil, <u>Benalaxyl</u> , Chlorsulfuron, <u>Epoxiconazole,</u> <u>Fenamiphos, Sodium</u> <u>aluminum silicate,</u> Triadimenol, Clothianidin, Thiamethoxam, <u>Chloridazon,</u> Imazaquin, <u>Fenpropimorph,</u> <u>Tralkoxydim,</u> Phosmet, <u>Cyromazine,</u> Topramezone, Triflumizole	
Total Number of Decisions*	56	44	51	24	60	
Note: Active ingredients may repeat in table because pesticide review is a multi-step process.						
	Substances that are not included in the USDA's EU Early Alert – Pesticide Review are underlined.					
* Number of decisions reflects proposed and implemented decisions on restrictions to pesticide approval and corresponding MRLs.						

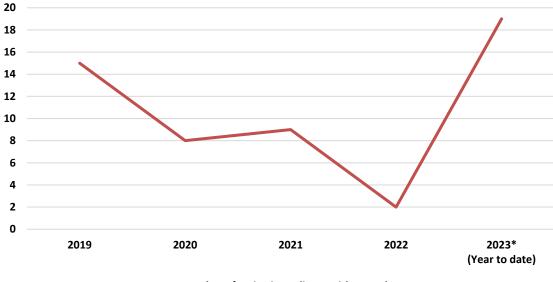






Total Active Ingredients per EU Pesticide Renewal Monitor (PRM)

MRL Changes Due to Non-approval



Number of active ingredients with MRL change

*Includes only established MRLs





EU PESTICIDE RENEWAL MONITOR Q&A

What is the EU Pesticide Renewal Monitor report?

- Provides an overview on the active ingredients that are scheduled for the periodic review or are currently undergoing the periodic review. The periodic review is a normal and regular procedure for all pesticides approved in the EU, according to Regulation 1107/2009 that regulates market access for pesticides in the EU.
- Active ingredients that have not been renewed, have a restricted renewal or are expired (with no renewal dossier submitted) are also listed.

Why was this report created?

- CropLife International commissioned the Pesticide Renewal Monitor report to support governments, farmers and the agri-food value chain to better understand which active ingredients are currently undergoing the pesticide renewal process in the European Union.
- The EU pesticide renewal procedure can be complex and challenging to track, and the status of active ingredients in the review process may be difficult to interpret.
- Information on review status of active ingredients is publicly available but spread over multiple websites and reports. Most information is not available in one place.
- The EU needs to notify WTO member states when an active ingredient approval is changed or not renewed (TBT notification). WTO notifications are only made late in the EU renewal process, consequently stakeholders are informed late in the process. A subsequent decision to lower or delete MRLs (potentially including ITs and MRLs corresponding to Codex) is done through an SPS notification but may be too late for stakeholders to influence the decision or adapt their crop protection strategies.

What is the difference between the USDA Early Alert and the CropLife International EU Pesticide Monitor?

- The USDA Early Alert covers active ingredients undergoing the EU renewal that have MRLs (tolerances) established in the United States.
- The CropLife International report covers all active ingredients undergoing the renewal in the EU, i.e., more substances than the USDA report.

Why was the report developed?

- To inform interested stakeholders on the process and timing of active ingredient renewal in the EU, to create awareness for non-EU stakeholders.
- In case of introduction of restrictions or non-renewal: alert stakeholders that/when MRLs may be lowered to the Limit of Quantification (LOQ).
- Provide timely information so stakeholders may engage in support of adequate transition periods or maintenance of MRLs that are important for trade with the EU.

Who is responsible for submitting a dossier for active ingredient renewal in the European Union?

- Normally, industry (individual companies, several companies jointly, or task forces) generates the data and compiles and submits the dossier. A list of dossier submitters is available on the OpenEFSA Portal: <u>https://open.efsa.europa.eu/questions</u>
- Data requirements for active ingredient approval are in place (Regulation EU 283/2013).





• All stakeholders are invited to provide information relevant for the renewal of the active ingredients.

What is the relationship between active ingredient renewal and MRL / IT?

- When an active ingredient is not renewed in the EU or if the conditions of use are amended, MRLs may be deleted or lowered.
- Deletion of MRLs following the revocation of pesticide authorizations in the EU does not apply to MRLs based on Codex MRLs and Import Tolerances established to facilitate global trade, provided that they are deemed acceptable with regard to consumer safety.

Whom can I contact for questions on a specific active ingredient?

- Companies that submitted a dossier for EU renewal can be identified through the OpenEFSA Portal: <u>https://open.efsa.europa.eu/questions</u>
- Individual companies will have the relevant information on the active ingredient, products they sell to farmers and the range of crops that the product is approved for use.
- In case of issues in identifying the relevant authorization holder for a specific active ingredient, please feel free to contact <u>CropLife International</u>.

Is this a complete list of substances registered in the EU?

- No. Active ingredients are listed here only if they will undergo or are currently undergoing the renewal process. Also, substances for which authorizations have expired, were not renewed or had a restricted renewal are mentioned.
- For more information and for information on the approval status and expiry dates for active ingredient that are not listed in this document, we refer to the EU pesticide database: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

When will this report be updated?

• This report will be updated on a quarterly basis or at the discretion of CropLife International.