

## EU PESTICIDE RENEWAL MONITOR

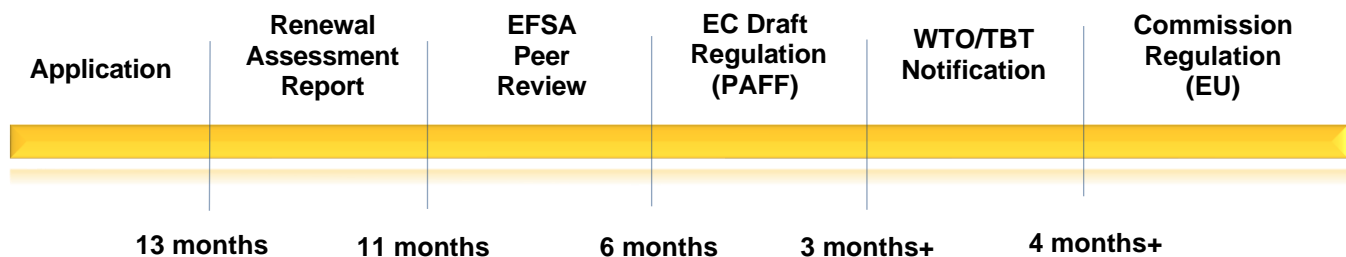
February 28, 2021<sup>1</sup>

In the European Union, all active ingredients undergo periodic reevaluation, as laid out in Regulation (EC) No. 1107/2009<sup>2</sup>. 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 expired or are expected to expire, as of **February 28, 2021**. Please note that 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 to the EU MRL and Import Tolerance setting, which is governed by specific legislation. MRL change or removal may happen 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 [EU pesticide database](#)<sup>3</sup>.

For information on specific active ingredients, please consult the [EFSA website](#)<sup>4</sup> (then click on the “Pesticide Dossier” tab) or contact the companies that are supporting the active ingredient through the renewal process by contacting [croplife@croplife.org](mailto:croplife@croplife.org).



**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.

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<sup>1</sup> This EU Pesticide Renewal Monitor issue reflects substances listed as proposed non-renewal or restricted renewal on the PAFF agenda up to the January 25-26, 2021 meeting.

<sup>2</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1107&from=EN>

<sup>3</sup> <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as>

<sup>4</sup> <http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin>

**APPLICATION FOR RENEWAL - EXPIRED (March 2020 – February 2021)**

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 March 2020.

<b>Phlebiopsis gigantea</b>		<b>Thiophanate methyl</b>	31/10/2020
<b>multiple strains</b>	30/04/2020	<b>Calcium phosphide</b>	01/12/2020
<b>Epoxiconazole</b>	30/04/2020	<b>Denatonium benzoate</b>	01/12/2020
<b>Triflumizole</b>	30/06/2020	<b>Imidacloprid</b>	01/12/2020
<b>Spirodiclofen</b>	31/07/2020	<b>Zeta cypermethrin</b>	01/12/2020
<b>FEN 560</b>	31/10/2020	<b>Haloxypop-P</b>	31/12/2020

**APPLICATION FOR RENEWAL - EXPECTED TO EXPIRE (Up to February 2022)**

Applications for **renewal of approval were not submitted** or **applications have been withdrawn** for the active ingredients below. 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).

<b>Triflumuron</b>	31/03/2021	<b>Fenoxycarb</b>	31/05/2021
<b>Fenbuconazole</b>	30/04/2021	<b>Myclobutanil</b>	31/05/2021
<b>Metosulam</b>	30/04/2021	<b>Oryzalin</b>	31/05/2021
<b>Trichoderma atroviride</b>		<b>Pencycuron</b>	31/05/2021
<b>strain IMI 206040</b>	30/04/2021	<b>Profoxydim</b>	31/07/2021
<b>Bromadiolone</b>	31/05/2021	<b>Fatty acids C8-C10</b>	
<b>Carbetamide</b>	31/05/2021	<b>methyl esters</b>	31/08/2021
<b>Cyproconazole</b>	31/05/2021	<b>Triazoxide</b>	30/09/2021
<b>Carboxin</b>	31/05/2021	<b>Azimsulfuron</b>	31/12/2021
<b>Diethofencarb</b>	31/05/2021	<b>Fluquinconazole</b>	31/12/2021
<b>Etridiazole</b>	31/05/2021		

### UP NEXT FOR REVIEW (Up to August 2021)

Under the EU pesticide review program, the active ingredients listed below have **upcoming deadlines** for the **submission of the application for renewal**. 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.

Orange oil	31/07/2021	Hexythiazox	31/08/2021
Prosulfuron	31/07/2021	Isoxaben	31/08/2021
Quinmerac	31/07/2021	Lime sulphur	31/08/2021
Sodium silver thiosulfate	31/07/2021	Margosa extract (azadirachtin source — Mitsui)	31/08/2021
Spirotetramat	31/07/2021	Margosa extract (azadirachtin source — SIPCAM)	31/08/2021
Tembotrione	31/07/2021	Margosa extract (azadirachtin source — Trifolio)	31/08/2021
Zinc phosphide	31/07/2021	Pendimethalin	31/08/2021
1-Decanol	31/08/2021	Sintofen	31/08/2021
6-Benzyladenine	31/08/2021	tau-Fluvalinate	31/08/2021
Aluminium sulfate	31/08/2021	Tebufenozide	31/08/2021
Bupirimate	31/08/2021		
Dithianon	31/08/2021		
Dodine	31/08/2021		
Fluometuron	31/08/2021		

### STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED (PAFF)

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 (PAFF) as available in the December 3-4, 2020, and January 25-26, 2021, meeting agendas. A final decision may have not yet been made.

- Abamectin
- Alpha-cypermethrin
- Benfluralin
- Fenpyrazamine
- Indoxacarb
- Prosulfuron
- Sulfoxaflor

## WTO NOTIFICATION (March 2020 – February 2021)

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 notifications via WTO Sanitary and Phytosanitary (SPS), typically some years later. For full explanation on the justification for proposed restricted or non-renewal of approval, please refer to the draft implementing regulation. Notification date is outlined in parentheses ( ).

**Benfluralin:** proposed non-renewal based on long-term risk to birds and mammals including the risk from secondary poisoning of earthworm eating birds and mammals, as well as the genotoxic potential of an impurity could not be excluded. (06/05/2020)

**Alpha-cypermethrin:** proposed to withdraw the approval as applicant did not submit required confirmatory data. (22/01/2021)

### Proposed restricted renewal

**Fenpyrazamine:** proposed to restrict products with concentration of hydrazine higher than 0.0001%. (08/09/2020)

## COMMISSION IMPLEMENTING REGULATION (March 2020 – February 2021)

**The Commission has published the final decision 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 outlined in parentheses ( ).

**Beta-cyfluthrin:** non-renewal based on unacceptable risk to workers, high risk to residents, to non-target arthropods and to aquatic organisms. (30/06/2020)

**Fenamiphos:** non-renewal based on incomplete data and acute risk for consumers identified for all the representative uses concerning fruiting vegetables. (02/09/2020)

**Benalaxyl:** non-renewal based on potential groundwater contamination, long term risk to birds and earthworm-eating birds from secondary poisoning as well as lack of data to assess the endocrine disrupting potential. (14/09/2020)

**Bromoxynil:** non-renewal based on suggested classification as toxic for reproduction category 1B. (14/09/2020)

**Thiophanate-methyl:** non-renewal due to the withdraw of application for the renewal of approval. (15/10/2020)

**Mancozeb:** non-renewal based on classification as toxic for reproduction category 1B. (15/12/2020)

**COMMISSION IMPLEMENTING REGULATION (Continued)**Restricted renewal

**Metalaxyl-M:** restricted renewal limits seeds treated with metalaxyl-M to only be grown in greenhouses. (05/05/2020)

**Etoxazole:** renewal as a candidate for substitution and restricted to use on ornamental plants in permanent greenhouses. (16/12/2020)

**MRL CHANGES (March 2020 – February 2021)**

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 will 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 SPS NotificationImplementing Regulation

- **Chlorpyrifos:** Commission Regulation 2020/1085 on 24/07/2020. *Effective date: 13/11/2020*
- **Chlorpyrifos-methyl:** Commission Regulation 2020/1085 on 24/07/2020. *Effective date: 13/11/2020*
- **Azinphos-methyl:** Commission Regulation 2020/1633 on 27/10/2020. *Effective date: 25/05/2021*
- **Flufenoxuron:** Commission Regulation 2020/1633 on 27/10/2020. *Effective date: 25/05/2021*
- **Oxadiazon:** Commission Regulation 2020/1633 on 27/10/2020. *Effective date: 25/05/2021*
- **Phosalone:** Commission Regulation 2020/1633 on 27/10/2020. *Effective date: 25/05/2021*
- **Tall oil pitch:** Commission Regulation 2020/1633 on 27/10/2020. *Effective date: 25/05/2021*
- **Tall oil crude:** Commission Regulation 2020/1633 on 27/10/2020. *Effective date: 25/05/2021*
- **Chlorothalonil:** Commission Regulation 2021/155 on 10/02/2021. *Effective date: 02/09/2021*
- **Chlorpropham:** Commission Regulation 2021/155 on 10/02/2021. *Effective date: 02/09/2021*
- **Dimethoate:** Commission Regulation 2021/155 on 10/02/2021. *Effective date: 02/09/2021*
- **Ethoprophos:** Commission Regulation 2021/155 on 10/02/2021. *Effective date: 02/09/2021*
- **Fenamidone:** Commission Regulation 2021/155 on 10/02/2021. *Effective date: 02/09/2021*
- **Methiocarb:** Commission Regulation 2021/155 on 10/02/2021. *Effective date: 02/09/2021*
- **Propiconazole:** Commission Regulation 2021/155 on 10/02/2021. *Effective date: 02/09/2021*
- **Pymetrozine:** Commission Regulation 2021/155 on 10/02/2021. *Effective date: 02/09/2021*

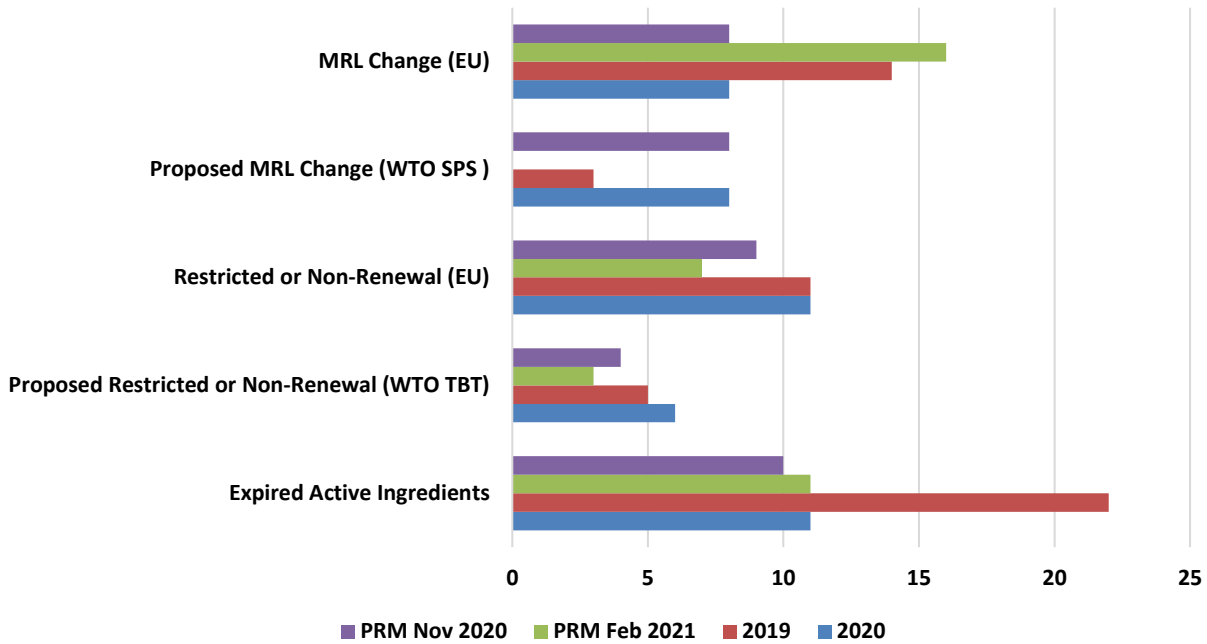
**Table I. EU Pesticide Renewal Monitor in Numbers**

<b>Time scope / Review step</b>	<b>2019</b> (January-December)	<b>2020</b> (January-December)	<b>PRM November 2020</b> (December 2019- November 2020)	<b>PRM February 2021</b> (March 2020- February 2021)
<b>Expired Active Ingredients</b>	<b>22</b>	<b>11</b>	<b>10</b>	<b>11</b>
	Fuberidazole, Bacillus thuringiensis subsp. Tenebrionis strain NB 176 (TM 14 1), Fenpropimorph, Tralkoxydim, Trichoderma polysporum strain IMI 206039, Ammonium acetate, Limestone, Methomyl, Pepper, Putrescine, Sea-algae extract, Sodium aluminium silicate, Sodium hypochlorite, Triadimenol, Trimethylamine hydrochloride, Quizalofop-P, Teflubenzuron, Difenacoum, Chlorsulfuron, Cyromazine, Lufenuron, Propanil	Phlebiopsis gigantea multiple strains, Epoxiconazole, Triflumizole, Spirodiclofen, FEN 560, Thiophanate methyl, Calcium phosphide, Denatonium benzoate, Imidacloprid, Zeta cypermethrin, Haloxyfop-P	Difenacoum, Chlorsulfuron, Cyromazine, Lufenuron, Phlebiopsis gigantea multiple strains, Epoxiconazole, Triflumizole, Spirodiclofen, FEN 560, Thiophanate-methyl	Phlebiopsis gigantea multiple strains, Epoxiconazole, Triflumizole, Spirodiclofen, FEN 560, Thiophanate methyl, Calcium phosphide, Denatonium benzoate, Imidacloprid, Zeta cypermethrin, Haloxyfop-P
<b>Proposed Restricted or Non-Renewal of Approval (WTO TBT)</b>	<b>5</b>	<b>6</b>	<b>4</b>	<b>3</b>
	Thiacloprid, Metalaxyl-M, Chlorpyrifos, Chlorpyrifos-methyl, Thiophanate-methyl	Benalaxyl, Benfluralin, Beta-cyfluthrin, Bromoxynil, Etoxazole, Fenpyrazamine	Mancozeb, Benfluralin, Etoxazole, Fenpyrazamine	Alpha-Cypermethrin, Benfluralin, Fenpyrazamine
<b>Restricted or Non-Renewal of Approval (Commission Regulation)</b>	<b>11</b>	<b>11</b>	<b>9</b>	<b>7</b>
	Ethoprophos, Chlorothalonil, Chlorpropham, Dimethoate, Desmedipham, Methiocarb, Thiacloprid, Methoxyfenozide, Cyflumetofen, Tolclofos-methyl, Alpha-Cypermethrin	Benalaxyl, Beta-cyfluthrin, Bromoxynil, Chlorpyrifos, Chlorpyrifos-methyl, Fenamiphos, Mancozeb, Thiacloprid, Thiophanate-methyl, Metalaxyl-M, Etoxazole	Chlorpyrifos, Chlorpyrifos-methyl, Thiacloprid, Beta-cyfluthrin, Fenamiphos, Benalaxyl, Bromoxynil, Thiophanate-methyl, Metalaxyl-M	Beta-cyfluthrin, Fenamiphos, Benalaxyl, Bromoxynil, Thiophanate-methyl, Mancozeb, Metalaxyl-M

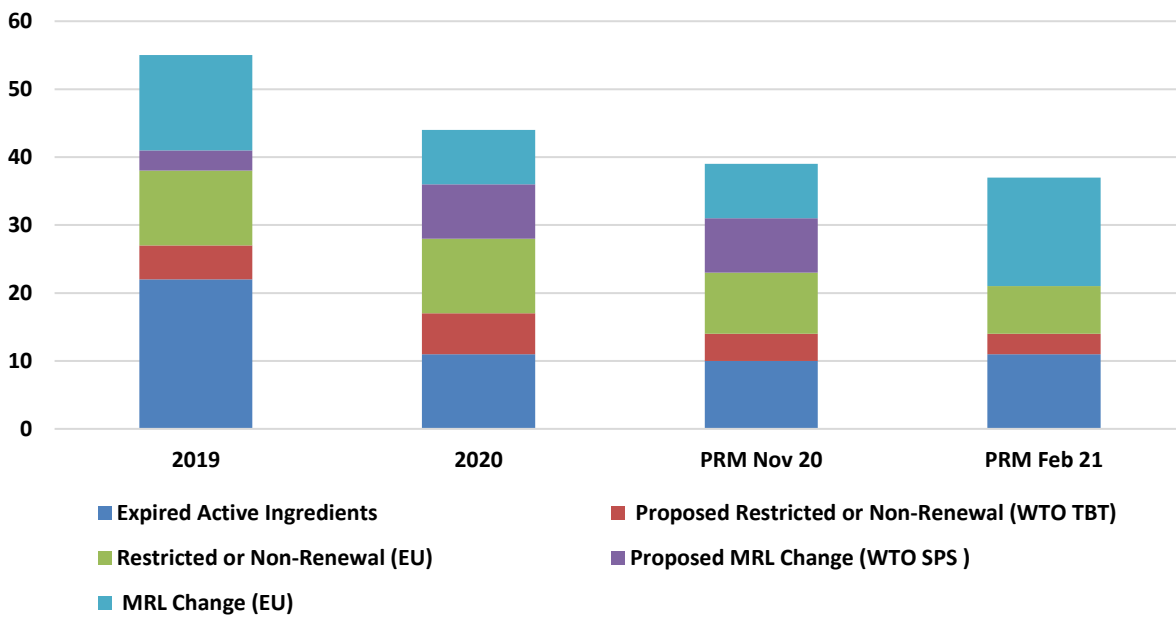
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<b>Active Ingredients with Proposed MRL Changes due to Non-Approval (WTO SPS)</b>	<b>3</b>	<b>8</b>	<b>8</b>	<b>0</b>
	Flufenoxuron, Chlorpyrifos, Chlorpyrifos-methyl	Chlorothalonil, Chlorpropham, Dimethoate, Ethoprophos, Fenamidone, Methiocarb, Propiconazole, Pymetrozine	Chlorothalonil, Chlorpropham, Dimethoate, Ethoprophos, Fenamidone, Methiocarb, Propiconazole, Pymetrozine	(None)
<b>Active Ingredients with MRL Changes due to Non-Approval (Commission Regulation)</b>	<b>14</b>	<b>8</b>	<b>8</b>	<b>16</b>
	Iprodione, Linuron Buprofezin, Diflubenzuron, Picoxystrobin, Tepraloxydim, Ethoxysulfuron, Ioxynil, Amitrole, Flupyrsulfuron-methyl, Isoproturon, Triasulfuron, Fipronil, Imazosulfuron, Orthosulfamuron	Chlorpyrifos, Chlorpyrifos-methyl, Azinphos-methyl, Flufenoxuron, Oxadiazon, Phosalone, Tall oil pitch, Tall oil crude	Chlorpyrifos, Chlorpyrifos-methyl, Azinphos-methyl, Flufenoxuron, Oxadiazon, Phosalone, Tall oil pitch, Tall oil crude	Chlorpyrifos, Chlorpyrifos-methyl, Azinphos-methyl, Flufenoxuron, Oxadiazon, Phosalone, Tall oil pitch, Tall oil crude, Chlorothalonil, Chlorpropham, Dimethoate, Ethoprophos, Fenamidone, Methiocarb, Propiconazole, Pymetrozine
<b>Total Number of Active Ingredients</b>	<b>55</b>	<b>44</b>	<b>39</b>	<b>37</b>

**Active Ingredients per Review Stage**



**Total Active Ingredients per EU Pesticide Renewal Monitor**





## 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 (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, challenging to track and the status of products 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), which is done through a SPS notification, may be too late for stakeholders to adapt their supply and/or to engage in the discussion.
- The US Department of Agriculture (USDA) has commissioned a similar report for US relevant active ingredients which has been valuable for US stakeholders.

### 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 established in the United States.
- The CropLife International report covers all active ingredients undergoing the renewal in the EU. i.e. the CropLife International report covers 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 restrictive or non-renewal: alert stakeholders that/when MRLs may be lowered to the Limit of Quantification (LOQ).
- Provide timely information so stakeholders could 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?

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

- Data requirements for active ingredient approval are in place (Regulation EU 283/2013).
- 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 EFSA website: <http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin> (then click on the “Pesticide Dossier” tab)

#### **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 were 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 retrieved through the EFSA website: <http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin> (then click on the “Pesticide Dossier” tab)
- 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 CropLife International.

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

- No. Only active ingredients are listed that will undergo or currently undergo the renewal process. Also, substances that 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.