What you need to know about Agrochemical Regulations in EU and UK (Great Britain)

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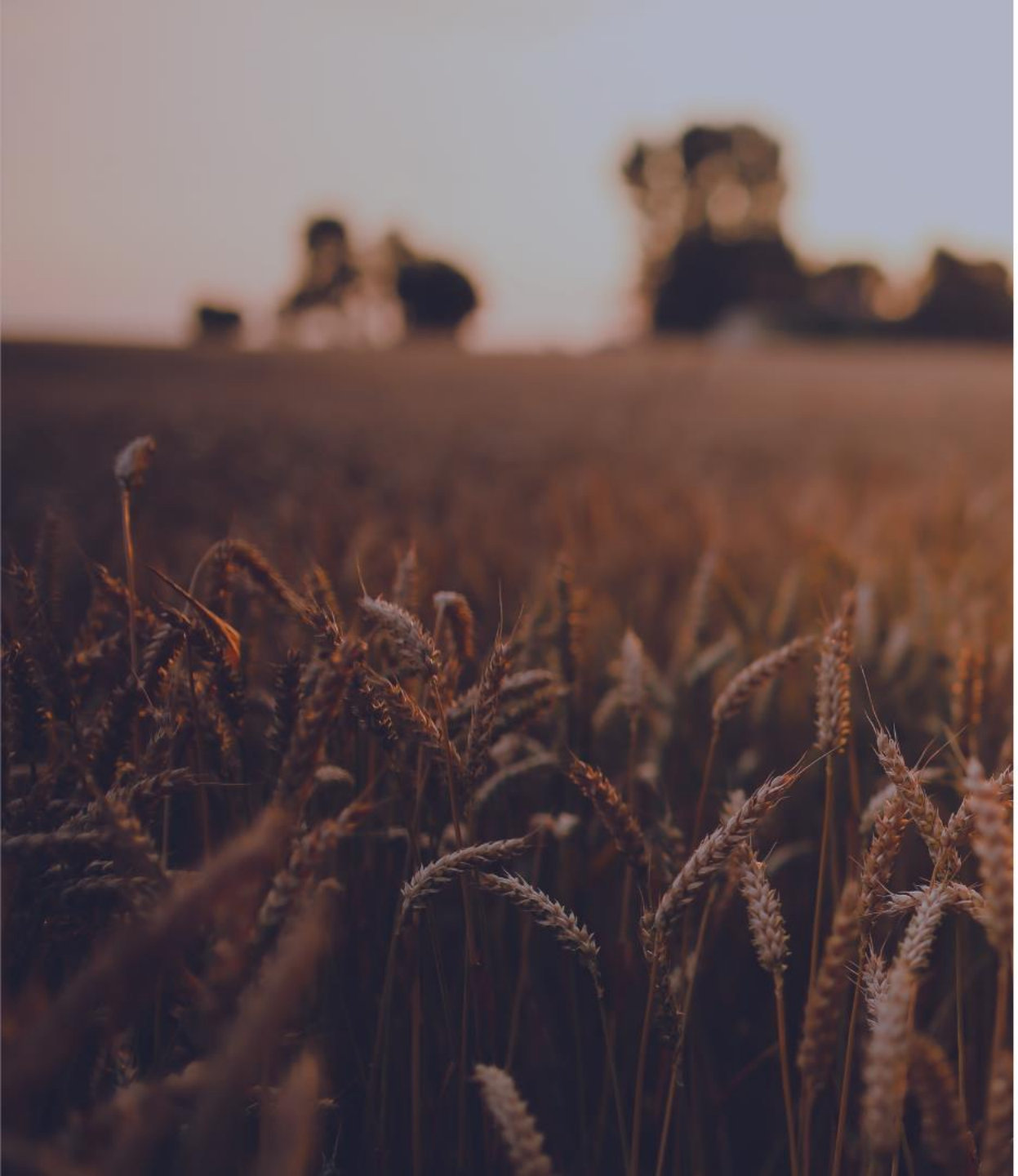

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What is Plant Protection Products (PPP)?

- Plant protection products are 'pesticides' that protect crops or desirable or useful plants. They are primarily used in the agricultural sector but also in forestry, horticulture, amenity areas and in home gardens.

- They contain at least one active substance and have one of the following functions:
  - protect plants or plant products against pests/diseases, before or after harvest
  - influence the life processes of plants (such as substances influencing their growth, excluding nutrients)
  - preserve plant products
  - destroy or prevent growth of undesired plants or parts of plants

- EU countries authorize plant protection products on their territory and ensure compliance with EU rules.

Regulation (EC) No 1107/2009

- Regulation (EC) No 1107/2009 of the European parliament and of the council of 21 October 2009 concerning the placing of plant protection products on the market.

- The process for plant product registration (PPP) entails two steps:
  1) Authorization of the active substance at EU level
  2) Authorization of the plant protection products by the Member States at National level

- The Regulation (EC)1107/2009 sets out comprehensive approval criteria for active substances at the EU level and procedures for product assessment within a zonal authorization framework.

Authorization of active substance in the EU

- Process of approval of new active substance
- Candidate for substitution (CfS)
- Low-risk active substance
- Data requirements
- Risk assessments
- Endocrine disruptors
- Process of renewal of approval of active substances
- Process of Technical Equivalency

Authorization of active substance in the EU

- **Active substance** is a chemical, microorganism or substance of plant origin that exerts an insecticidal, herbicidal, fungicidal or other action used in products meant for agriculture use.

- Active substance is the active ingredient(s) in a PPP that enables it to effectively protect crops.

- Type of authorization of active substances in EU
  1) Approval of active substances
  2) Renewal of approval of active substances
  3) Equivalency of technical material for active substances

Process of approval of active substance (1/3)

- A company submits an application for approval of an active substance to one EU Member State (**RMS: Rapporteur Member state**) including scientific studies and risk assessments

- The RMS' checks if the applicant has fulfilled all required pre-submission requirements and has provided all required tests and study reports before confirming that the application is admissible.

- The reporting EU Member State evaluates the application and scientific data and summarizes the conclusion in a draft assessment report (DAR).

- The RMS delivers DAR to the **European Food Safety Authority (EFSA)** for peer-review.
  - If necessary, the RMS can request the applicant to provide additional information during the evaluation.

Process of approval of active substance (2/3)

- EFSA distributes the DAR to the applicant(s), and the Member States for commenting. Public commenting is also possible (on the EFSA website).
- EFSA adopts and publishes a **peer review report** **Include a** list of endpoints, data gaps and areas of concern, etc.
- The relevant period is provided for adopting conclusion depending upon the additional information (stop the clock events) and consultation with experts are considered necessary.
- **EU Commission** drafts review report and draft regulation that proposes approval of renewal or non-approval. The Standing Committee on Pesticides, Animals, Feed and Food (SC PAFF) that consists of representatives of each Member State votes on this proposal.

Process of approval of active substance (3/3)

- Usually, a new active substance is approved for **10 years**.
  - All studies are protected for 10 years (data protection) and cannot accessed by another party without the study owner's consent.

- The timelines set out in Regulation for first approval of an active substance should take between **2.5 to 3.5 years.** However, experience has shown that the procedure can take longer time depending on the complexities.

- Currently, EFSA does not charge a fee for its scientific evaluations.

- RMS charges fee for administration and evaluation purpose

Cut-off (exclusion) criteria

- Annex II of Regulation (EC) 1107/2009 sets the criteria for the approval of active substances. Active substances that fulfil certain criteria won't be approved ('cut-off').

Criteria for active substance

- Carcinogens Cat. 1A or 1B
- Mutagens Cat. 1A or 1B
- Toxic for reproduction Cat. 1A or 1B
- Endocrine disrupting properties
- Persistent, bio accumulative, and toxic (PBT)
- Very persistent and very bio accumulative (vPvB)
- Fulfilling POP (persistent organic pollutant) criteria

Candidate for substitution (CfS) (1/2)

- An active substance shall be approved as a candidate for substitution where any of the following conditions are met listed in Annex II of Regulation (EC) 1107/2009.

  - if ADI, ARfD or AOEL is significantly lower than those of the majority of the approved active substances within groups of substances/use categories.
  - it meets two of the criteria to be considered as a PBT substance,
  - there are reasons for concern; Developmental neurotoxicity, immunotoxicity, risk to groundwater, very restrictive risk management measures (such as extensive personal protective equipment or very large buffer zones),
  - it contains a significant proportion of non-active isomers,
  - it is or is to be classified as carcinogen category 1A or 1B
  - it is or is to be classified as toxic for reproduction category 1A or 1B
  - if, on the basis of the assessment or internationally agreed test guidelines or other available data and information, reviewed by the Authority, it is considered to have endocrine disrupting properties

Candidate for substitution (CfS) (2/2)

- The objective of this provision is to:
  1. Identify substances of particular concern to public health or the environment
  2. to ensure that these substances are phased-out and replaced by more suitable alternatives over time.

- For plant protection products (PPPs) containing these active substances, Member States are required, when assessing an application for an authorization, to evaluate if they can be replaced (substituted) by other adequate solutions (chemical or non-chemical).

- Active substances which are candidates for substitution will not be approved for more than seven years, even in the case of renewal.

- Examples of CfS in EU: Prosulfuron, Lambda cyhalothrin, Metsulfuron-methyl etc.

Low-risk active substance

- An active substance, other than a micro-organism, shall not be considered as low-risk active if it corresponds to any of the following:

a) it is classified in accordance with Regulation (EC) No 1272/2008 as any of the following:

- carcinogenic category 1A, 1B or 2,
- mutagenic category 1A, 1B or 2,
- toxic to reproduction category 1A, 1B or 2,
- skin sensitizer category 1,
- serious damage to eye category 1,
- respiratory sensitizer category 1,
- acute toxicity category 1, 2 or 3,
- specific Target Organ Toxicant, category 1 or 2,
- toxic to aquatic life of acute and chronic category 1 on the basis of appropriate standard tests,
- explosive,
- skin corrosive, category 1A, 1B or 1C;

b) it has been identified as priority substance under Directive 2000/60/EC;

c) it is deemed to be an endocrine disruptor;

d) it has neurotoxic or immunotoxic effects.

e) An active substance, other than a micro-organism, shall not be considered as being of low-risk where it is persistent (half-life in soil is more than 60 days) or its bio-concentration factor is higher than 100.

- A major benefit for applicants is that the active substance will be included in the Annex for 15 years instead of 10 years.

Data requirements for active substance authorization

- The current data requirements for the EU dossier of an active substance are set out in Regulation (EU) 283/2013. These data facilitate an in-depth assessment of the active substance. The data are sub-divided into various sections:
  - Physical and chemical properties
  - Information regarding use
  - Methods of analysis
  - Efficacy
  - Toxicology and metabolism
  - Residues in food and feed
  - Fate and behavior in the environment and
  - Ecotoxicology
  - Endocrine disruption
- In addition, data of at least one representative formulation which contains the intended active substance is required. The data requirements are laid down in Regulation (EU) 284/2013.

Risk assessment of plant protection products

- The authorization of a plant protection product requires that, when the product is used correctly and in line with its intended purpose, the protection environment, animals and people who may come into contact with the pesticide, or its residues is ensured.

  - Non dietary exposure and risk assessment (of plant protection products)
  - Dietary exposure and risk assessment (of residues of plant protection products in food and feed commodities)
  - Ecological/Environmental exposure and risk assessment.

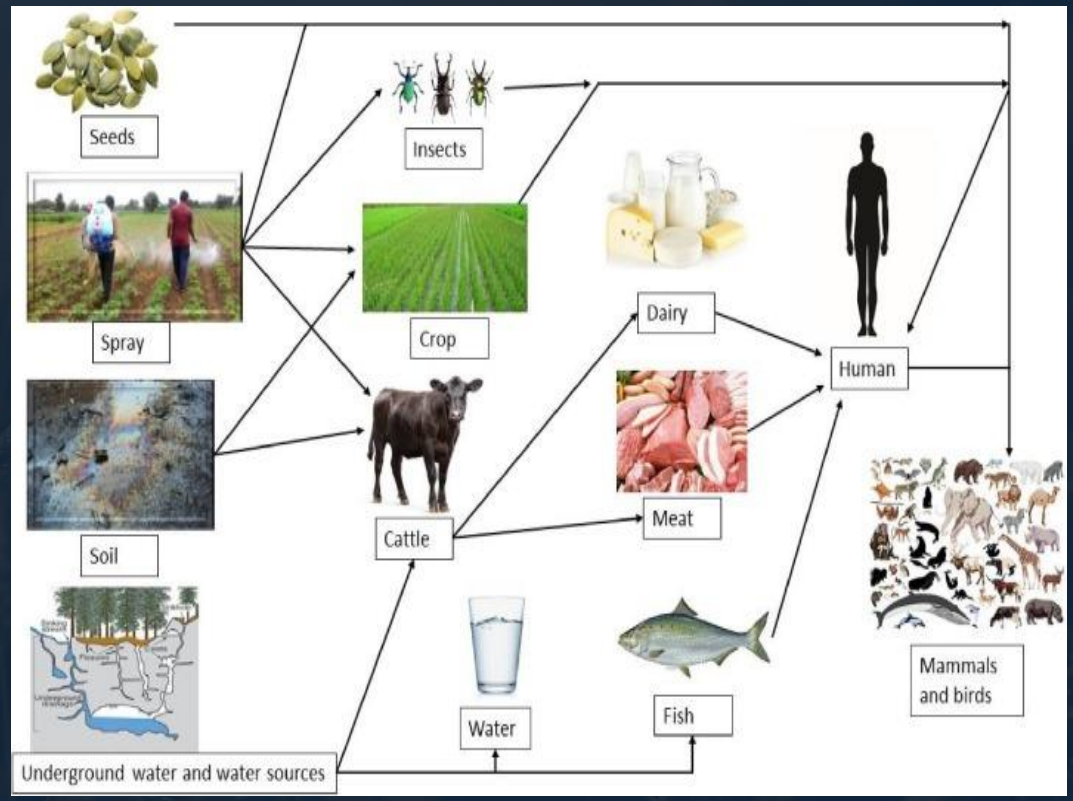


Fig. 1. Bio-concentration of residual pesticides in food chain

(source: https://doi.org/10.1016/j.enmm.2018.07.013)

Renewal of approval of active substances

- The initial approval of an active substance is valid for a limited period and the approval of an active substance needs to be reviewed periodically.

- Regulation (EU) 844/2012 lays down the renewal procedure for active substances whose approval period ends before March 27, 2024.

- Regulation (EU) No 2020/1740 applies to active substances whose approval period ends on or after March 27, 2024.
  - The 5th renewal programme: For active substances whose approval expires between 1 January 2022 and 31 December 2024
  - The 6th renewal programme and beyond: For active substances whose approval period ends between 31 March 2025 and 27 December 2028

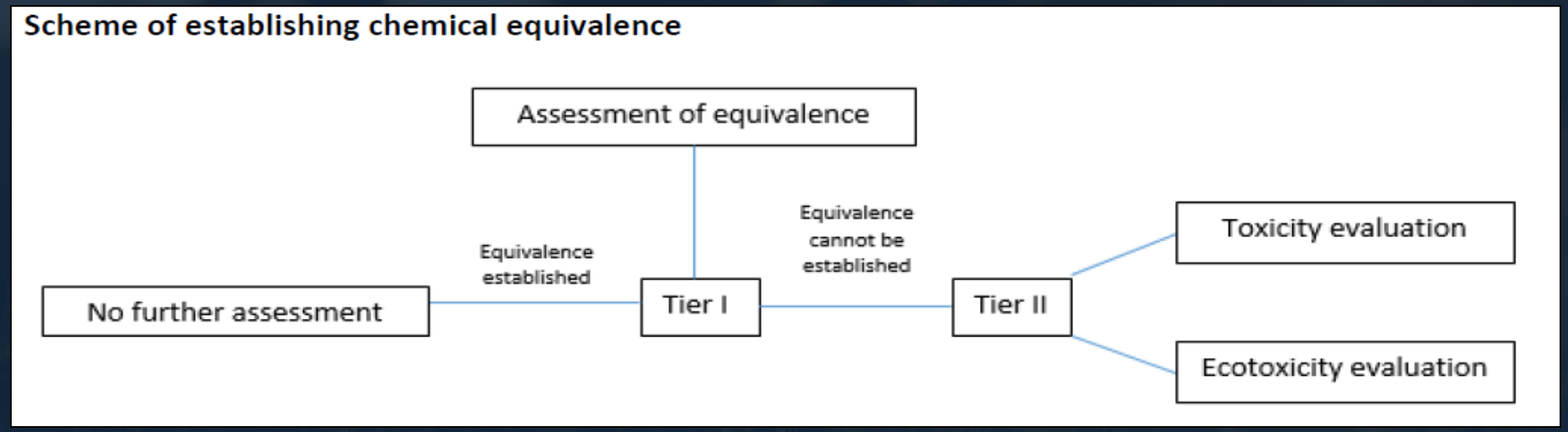
Process of renewal of approval of active substances

- Company that intend to renew the approval of active substance; make an application to the rapporteur and co-rapporteur Member State (3 years prior to expiry of the approval of active substance).

- The review of existing active substances is behind schedule because of limited resources in EU Member States and at EFSA. If the renewal of an active substance does not happen before the expiry date, the approval will be extended for 1 year.

- Following renewal of approval of an active substance, all plant protection products containing that active substance must also undergo a renewal assessment to make sure that products comply with the updated assessment of the active substance and with new scientific and technical knowledge.

Technical Equivalence



- Equivalence of the new source is established if:
  - a) it has a minimum purity not lower than the reference source,
  - b) It contains no new impurities,
  - c) the limits for (eco)toxicologically relevant impurities certified in the reference source are not exceeded, and
  - d) the limits for non-relevant impurities certified in the reference source are not in exceedance of well-defined threshold values.
- If equivalence cannot be established based upon the chemical comparison, then the assessment moves on the Tier II.

Authorization of Plant Protection Product in the EU

Authorization of PPP in the EU (1/2)

The EU has been divided into 3 regulatory zone for the registration of plant protection products.

- **Northern zone:** Denmark, Estonia, Finland, Latvia, Lithuania, Sweden.
- **Central zone:** Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia, ~~United Kingdom~~
- **Southern zone:** Bulgaria, Croatia, Cyprus, France, Greece, Italy, Malta, Portugal, Spain.

EU countries authorize plant protection products on their territory and ensure compliance with EU rules.

Authorization of PPP in the EU (2/2)

- Regulation (EU) 1107/2009 sets out the requirements, procedure and timeframes for authorization of Plant Protection Products (PPPs).

- A zonal system of authorization operates in the EU to enable a harmonized and efficient system to operate.

- Whilst the regulation derives from the EU, authorization of plant protection products is the responsibility of each EU Member State. Despite ongoing efforts at harmonization and mutual recognition procedures, some Member States maintain different administrative, regulatory and data requirements.

- There are different types of application that can be submitted depending on the intended use of the PPP, the intended Member State(s) and the existing authorizations of PPP.

Types of PPP authorization in the EU

- Zonal application
- Mutual recognition
- Product Renewals
- Change in product authorization
  - amendment of uses
  - extension of uses
  - change in restriction sentences
  - change in the legal instructions for use
  - major change in product composition
  - Minor or administrative changes
  - Minor uses and extension with minor uses

Process of authorization of PPP (1/3)

- Company applies to an EU Member State for the registration of a plant protection product that contains an approved active substance.

- The data provided is proposed in a draft Registration Report (dRR). This is a summary of the assessment and the results based on the data. The dRR also contains a proposal for the labelling of the product. dRR consist of core assessment and national addenda (as per MS requirement)

- The dRR contains 3 sections:
  - Part A – risk management
  - Part B – data evaluation and risk assessment (B0 to B10)
  - Part C – confidential information

Process of authorization of PPPs (2/3)

- The national authority (MS) that received the application assess the dRR for all proposed uses and provides the RR (Registration report) stating the approval or non-approval of PPP.

- It takes up to 1.5 years from the date of application to the granting, amendment or withdrawal of on authorization as per the regulation. However, this time frame varies depending on the MS capacity, application type and complexities.

- Within 3 months of the DoA (Date of Application) set in the renewal regulation of the approval of an active substance, authorization holders must apply to renew the authorizations of PPPs containing that active substance. The applicant has to submit applications in all the Member States in which they wishes to renew existing PPP authorizations.

Data requirements for PPP in EU

- The data requirements are set out in Regulation (EU) No. 283/2013 for the active substance and in Regulation (EU) No. 284/2013 for the product (formulation).

- In addition, there are also national requirements which are specific to each Member State.

- The technical requirements are divided into various areas which consist of required studies and risk assessments:
  - Physical and chemical properties,
  - Toxicology
  - Residues
  - Fate and behavior in the environment
  - Ecotoxicology
  - Efficacy

EPPO Climatic Zones

- The efficacy must be determined to prevent non-effective product from reaching the market and to ensure that the effective products have no undesirable effects on plants or plant products.

- The efficacy of the plant protection product must be tested in accordance with the guidelines of the European and Mediterranean Plant Protection Organization (EPPO).

- Efficacy trials need to be planned based on the countries of interest.

New GB (Great Britain) PPP regulation

Regulating pesticides in the UK after Brexit

- From 1 January 2021, an independent pesticides regulatory regime is in operation in Great Britain (England, Scotland and Wales).
- Under the terms of the Withdrawal Agreement and Northern Ireland Protocol, EU PPP legislation continues to apply in Northern Ireland (NI).
- New decisions taken under the EU regime is not apply in Great Britain. This includes active substance and maximum residue level (MRL) decisions and any new EU plant protection product (PPP) legislation.
- The **Health and Safety Executive (HSE)** is the national regulator for the whole of the UK, on behalf of the UK government and administrations.

Key aspects of the new GB PPP regulation (1/3)

- All active substances approved in the EU till 31 December 2020 will remain approved in Great Britain.
- All existing active substance approvals, plant protection product authorizations and MRLs (maximum residue levels) continue to be valid in GB.
- Active substance approvals due to expire before December 2023 have been extended for 3 years.
- Applications for new active substance approvals, PPP authorizations and MRLs should continue to be submitted to CRD/HSE in the existing format.

Key aspects of the new GB PPP regulation (2/3)

- All relevant EU PPP regulations have been retained in UK law, with certain operational amendments, and keep the same official titles, for example, Regulation (EC) 1107/2009. Whilst therefore the laws for Great Britain and Northern Ireland have similar titles, over time requirements for registrants are expected to diverge.

- No further mutual recognition applications can be accepted under the GB PPP regime. Any ongoing evaluations will be continued to a GB only decision. EU mutual recognition applications can continue to be considered for Northern Ireland.

- Great Britain sets MRLs based on our own assessments but all existing (EC) MRLs remain valid until they are amended. Applicants will need to continue to meet any existing conditions under the new GB pesticide regime.

Key aspects of the new GB PPP regulation (3/3)

- MRLs in Great Britain and the EU may start to diverge over time, so businesses producing food for export or trading in food produce should consider the requirements in their target market.

- Seed that has been treated with a product authorized for that purpose in an EU member state can continue to be traded and used in GB until 31 December 2023. After this date, treated seed can only be traded and used in GB if it has been treated with a PPP authorized for that purpose in GB.

- To gain access to Great Britain (GB), NI and EU markets, new authorizations or amendments under both the GB and EU pesticides regimes may be required.

Points to consider (1/3)

- The requirements and their constant evolution represent a challenge for companies wishing to place their plant protection products on the market.

- The Regulation (EC)1107/2009 sets out comprehensive approval criteria for active substances at the EU level and procedures for product assessment within a zonal authorization framework. It also provides the basis for a comprehensive renewal programme for existing approved active substances.

- The specific data requirements for applicants are contained in Commission Regulation EU 283/2013 and Commission Regulation EU 284/2013. The rules specify a comprehensive risk assessment and authorization procedure for active substances and products containing these substances

Points to consider (2/3)

- Each active substance has to be proven safe in terms of human health, including residues in the food chain, animal health and the environment.
- New procedures, criteria, and data requirements make this regulatory area more complex than it has ever been.
- Ensuring a high level of protection of bees and other pollinators is very important for the European Commission when deciding on the approval of active substances for use in plant protection products.
- Commission Regulation EU 2018/605 introduced new scientific criteria for the determination of endocrine disrupting (ED) properties, which have been applicable since 10 November 2018 to all applications for the approval of active substances.

Points to consider (3/3)

- From March 2021, EFSA require IUCLID to be used for active substance dossiers (for both chemicals and micro-organisms). For renewal dossiers, if the submission deadline is later than 27 March 2021 the mandatory format is IUCLID.

- Starting from 27 March 2021 the application (which includes the renewal dossier) for the renewal of the approval of active substance must be submitted in the IUCLID format as laid down in Commission Implementing Regulation (EU) No 2020/1740.

- Plant product products are regulated at MS level and applicant need to fulfill the national requirements and assessments.

- To gain access to Great Britain (GB), NI and EU markets, new authorizations or amendments under both the GB and EU pesticides regimes may be required.

Thank you for your attention!

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