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Speakers



Pooja Vishnoi
GM & Regulatory head

Ms. Pooja Vishnoi is working as GM and Head Regulatory in Auxilife Scientific Services Pvt. Ltd (a unit of GPC, Sweden). Pooja has over 9 years of Regulatory experience in areas of plant protection products, biocides, bio stimulant, and other chemicals. She holds a Master's degree in Environmental Engineering and in her career she has worked in areas of Environmental Impact Assessment, Environmental fate and behavior, EU and India regulatory and technical assessment.



Pritee Panicker
Senior Scientific Officer Regulatory

Pritee has hands-on experience working as a regulatory expert for plant protection product registration. She is working in this field from last 10 years and well versed in regulatory compliance and plant protection products' risk assessment. She possesses a keen understanding of plant protection products' regulatory compliance process in India and other countries.

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Content

India compliance

- ▶ Introduction
- ▶ Recent updates in regulation
- ▶ Updates in registration categories
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- ▶ Implications of Make in India
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Europe compliance

- ▶ Latest amendment in Microbial pesticides regulation
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Pesticide regulation updates and upcoming changes for registering pesticides in India

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Background: Insecticide Act

Insecticide Act

- Came into existence in 1968
- Enforced since 1 August 1971

Regulatory Authorities at the central level:

Central insecticide board	Registration committee
<ul style="list-style-type: none"> ▪ To advise the central government and state governments on technical matters arising out of the administration of this act ▪ To carry out the other functions assigned to the board by or under this act 	<ul style="list-style-type: none"> ▪ To register insecticide after scrutinizing their formulae and verifying claims made by the importer/manufacture: its efficacy and safety to human being and animals

- The import, manufacture, sale, transport, distribution and use of insecticides is regulated by these two bodies in India.

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Update (1): Changes in Regulation

- ▶ **Guidelines/Data** requirement for registration under various categories – 2022 (came into action as per the 442 RC meeting) replacing the existing “*GUIDELINES FOR REGISTRATION OF PESTICIDES OTHER THAN HERBICIDES) U/S 9(3)/ 9(3B) – 2012*”
- ▶ **Public notice** on Guidelines/data requirement for grant of registration under various categories – reg. (dated 9th December 2022)
- ▶ Updates in the data requirements as per the **Minutes of 443rd RC meeting held on 22.12.2022**
- ▶ **Proposal for revision of Registration fee for pesticides under various categories** –regarding (dated 4th January 2022)

The updates are applicable for all product categories:

- ▶ Plant protection products
- ▶ Plant growth regulator (PGR)
- ▶ Seed treatment
- ▶ Household pesticides
- ▶ Public use pesticide
- ▶ Bio pesticides

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Update (2): Key Changes in Data Requirements

- ▶ Registration of technical material under FI-WRT category is encouraged, registration of technical however, may get compulsory henceforth*.
- ▶ Acceptance of the position paper and published data for effects on beneficial insects under the efficacy section.
- ▶ Acceptability of **Internationally Peer reviewed published literature** for toxicological data requirements.
- ▶ The valid scientific justification/data waiver will be accepted to comply with toxicology data requirements
- ▶ Reduction in the data requirements for categories like 9(3) TI new source and addition of the toxicity data requirements under regular 9(3) registration category

Ref. Public notice on Guidelines/data requirement for grant of registration under various categories – reg. (dated 9th December 2022)

* Minutes of 443rd RC meeting held on 22.12.2022

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Update (3): Registration Categories

- ▶ The data requirements are streamlined under different registration categories.
- ▶ The registration categories as per the earlier guidelines remains same except “TI vs TIM” and “TIM vs TI”
- ▶ The registration guidelines and data requirements does not talk about the registration under previously present “TI vs TIM” and “TIM vs TI” categories applicability.
- ▶ The indigenous manufacturing of the technical and formulated product is encouraged.
- ▶ There are no changes in the guidelines/data requirements for export categories. It will remain same as per the 380th RC meeting.

Ref. Public notice on Guidelines/data requirement for grant of registration under various categories – reg. (dated 9th December 2022)

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Proposed new fees

Registration category	Timeline	Old fees (in INR)	New fees* (in INR)
9(3) registration categories	4+ years	5,000	500,000
9(3b) registration categories	3+ years	5,000	450,000
9(4) registrations	Max. 6 months	2,500	250,000
Endorsement cases	1-3 months	100	25,000

- ▶ Proposed new fee on 4 January 2022 and potentially come into force in 2023.

Ref. Proposal for revision of Registration fee for pesticides under various categories (published on 4 January 2022)

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Implications of Make in India

- ▶ The import of any new pesticides will be allowed on the valid registration certificate.
- ▶ For pesticides already registered under indigenous manufacture category, the import is allowed on case-by-case basis.
- ▶ The custom authority and CIB & RC work hand in hand to regulate the import of any insecticide (specific quantity) from the approved source having valid certificate of registration.
- ▶ The same condition of quantity import is applicable for already issued certificates of registration for import of technical/formulation.
- ▶ For the import of additional quantity of technical/formulation permission is granted on case-by-case basis.



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Important points to consider

- ▶ Most of the registration categories remained unaltered in the recent updated guidelines and data requirements.
- ▶ As per the discussion in RC meeting 443 the date of the applicability of guidelines will be notified in the upcoming RC meeting.
- ▶ Registration under the category FI WRT will need the compulsory registration of the technical substance. (RC 443 meeting)
- ▶ One should pay the attention to the revised fees under various categories of registration, which might be applicable soon in the future.
- ▶ As per the latest data requirements it is important to choose the right registration category to enter the Indian market.

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European Commission finalized the regulations on Microbials for Plant Protection Product

(Applicable from 21st November 2022)

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Farm To Fork strategy (1)



- ▶ An important part of the **European Green Deal (May 2020)**
- ▶ **Legally binding targets:** Under the Farm To Fork strategy, the EU had committed to reduce the use of chemical pesticides by 50% till 2030.
- ▶ **Strict new rules to enforce environmentally friendly pest control:** new enforcement framework to encourage farmers to practice Integrated Pest Management (IPM)
- ▶ The Farm to Fork Strategy concerns the increase in total farmland under organic farming in EU, with at least 25% of the EU's agricultural land to be under organic farming by 2030.
- ▶ The new Regulations will make new sustainable alternatives available to EU organic farmers for controlling plant pests.

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Farm To Fork strategy (2)



The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take actions to:

- ✓ **reduce by 50%** the use and risk of chemical pesticides by 2030.
- ✓ **reduce by 50%** the use of more hazardous pesticides by 2030.



The **excess of nutrients** in the environment is a major source of air, soil and water pollution, negatively impacting biodiversity and climate. The Commission will act to:

- ✓ **reduce nutrient losses by at least 50%**, while ensuring no deterioration on soil fertility.
- ✓ **reduce fertilizer use by at least 20%** by 2030.



Antimicrobial resistance linked to the use of antimicrobials in animal and human health leads to an estimated 33,000 human deaths in the EU each year. The Commission will **reduce by 50% the sales of antimicrobials for farmed animals and in aquaculture by 2030**.



Organic farming is an environmentally-friendly practice that needs to be further developed. The Commission will boost the development of EU organic farming area with the aim to achieve **25% of total farmland under organic farming by 2030**.

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Picture from Factsheet (From Farm to fork: our food, our health, our planet, our future) https://ec.europa.eu/commission/presscorner/detail/en/fs_20_908

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Implementing Regulation

Commission Regulation

- ▶ (EU) 2022/1438: amending Annex II to Regulation (EC) No 1107/2009:
 - Approval of micro-organisms containing a.s
- ▶ (EU) 2022/1439: amending Regulation (EU) No 283/2013:
 - Information to be submitted and data requirements for micro-organisms containing a.s
- ▶ (EU) 2022/1440: amending Regulation (EU) No 284/2013:
 - Information to be submitted for PPP and the specific data requirements for PPP containing micro-organisms
- ▶ (EU) 2022/1441: amending Regulation (EU) No 546/2011:
 - Specific uniform principles for evaluation and authorization of PPP containing micro-organisms

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Background (1): 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:
 - ▶ Authorization of the active substance at EU level
 - ▶ 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.

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Background (2): Implementing regulation



- ▶ **European Commission finalized the regulations on Microbials for Plant Protection Product and enforced since 21st November 2022**
- ▶ Micro-organisms such as bacteria, fungi, viruses, and protozoa can be used to protect plants, as some of them are parasites or pathogens of insects or other organisms that are pests or cause disease in plants.
- ▶ Micro-organisms are naturally occurring in the environment and the strains with the best properties are those used in biological control to fight pests and diseases in crop protection.
- ▶ However, before micro-organism are allowed to be used, it needs to be verified that their use is safe and has no negative consequences for human and animal health or towards other non-target organisms.

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Points to consider

- ▶ The requirements and their constant evolution represent a challenge for companies wishing to place their plant protection products on the market.
- ▶ The specific data requirements for applicants are contained in Commission Regulation EU 283/2013 and Commission Regulation EU 284/2013. Each pesticide has to be proven safe in terms of human health, including residues in the food chain, animal health and the environment.
- ▶ Dossier need to be submitted in IUCLID (International Uniform Chemical Information Database)
- ▶ **European Commission finalized the regulations on Microbials (Micro-organisms such as bacteria, fungi, viruses, and protozoa) for PPP. The regulatory requirements for micro-organisms are made more "fit-for-purpose" and flexible**

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Key facts

- ▶ The Commission **adopted four** legal acts which will **simplify** the process of approval and authorization of biological PPP which contain micro-organisms.
- ▶ The new requirements are expected to lead to a faster access to the EU market
- ▶ The regulatory requirements for micro-organisms are made more "fit-for-purpose" and flexible. In addition, only focusing on relevant data also means less animal testing, because fewer experiments on animals will be required.
- ▶ More straight forward risk assessment, and shorter timelines is expected to get access to the EU market.
- ▶ Micro-organisms used as biocontrol agents in PPP provide farmers with alternative tools to substitute chemical plant protection products.

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Webinar in Turkish!

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11:30 - 12:30 CET
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An introduction to UK REACH: Compliance strategies and obligations

February 23
11:30 - 12:30 CET
16:00 - 17:00 IST

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If you want to learn more about Agrochemical Compliance, contact us at: info@auxilife.com



📍 IDEON Science Park, Beta 5.
Scheelevägen 17,
223 63 Lund, Sweden

✉ compliance@gpcregulatory.com

☎ + 46 (0) 46 211 46 15

🌐 www.gpcgateway.com

