

Introduction of AI at knoell – Insights, Successes, and Challenges

22-10-2025, ABIM, Dr. Milena Stephan

Who is knoell and where can AI support us?

Regulatory solutions for your key market

We assist you in obtaining and maintaining market access for your portfolio – globally.



ANIMAL HEALTH



BIOCIDES



CHEMICALS



CROP PROTECTION & BIOCONTROL



CROP NUTRITION



COSMETICS

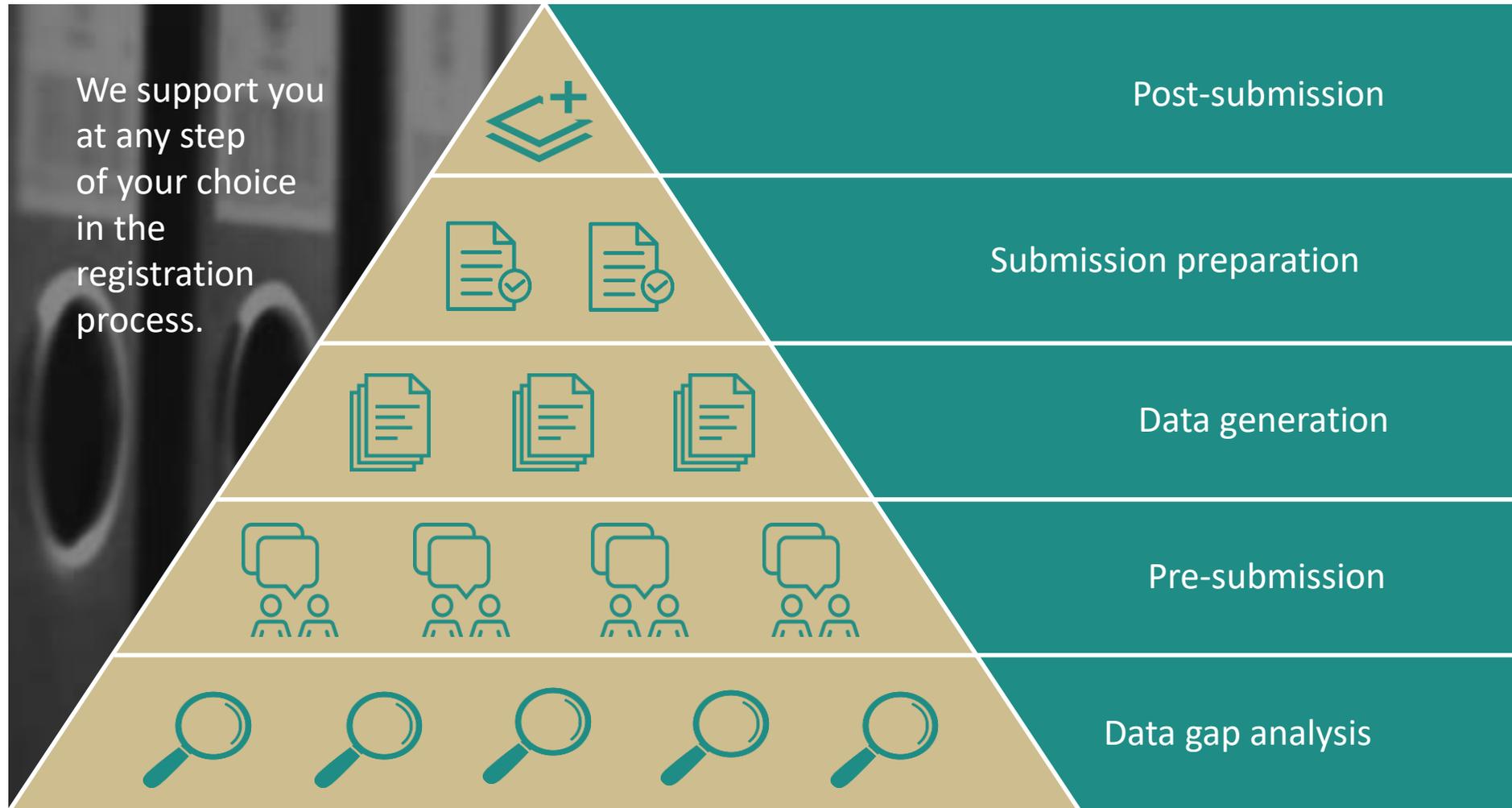


FOOD & FOOD CONTACT MATERIALS

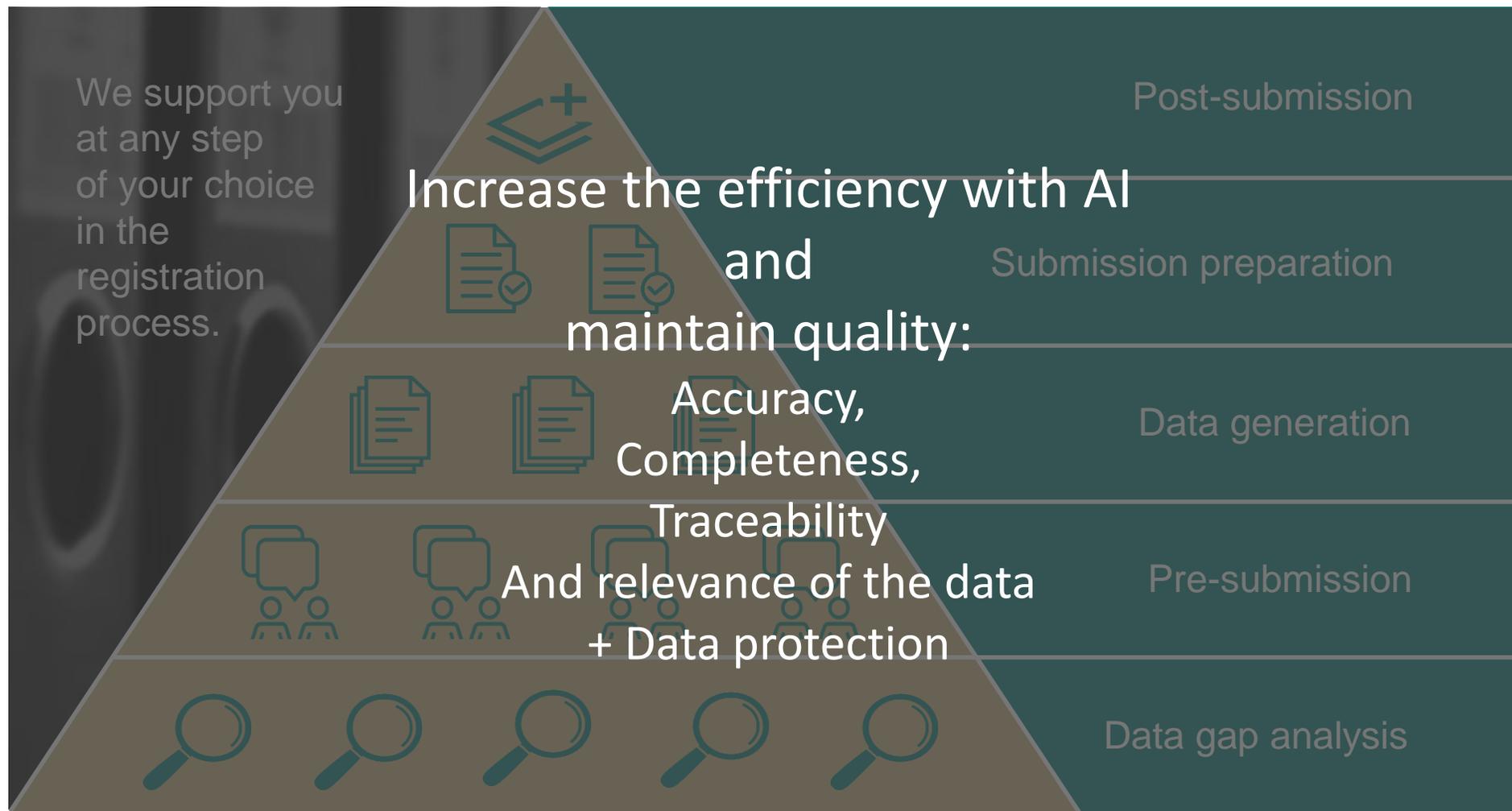


MEDICAL DEVICES

Where AI can support us



Where AI can support us



Legal Requirements

- EU AI Act
- Other AI laws and frameworks
- Data protection laws
- Copyright

Client Requirements

- Client contracts
- NDAs

Standards/ Certifications

- ISO 27001 (certified since 2024)
- ISO 9001 (certified since 2025)
- Sustainability rating (EcoVadis)

Internal Standards

- Internal quality requirements

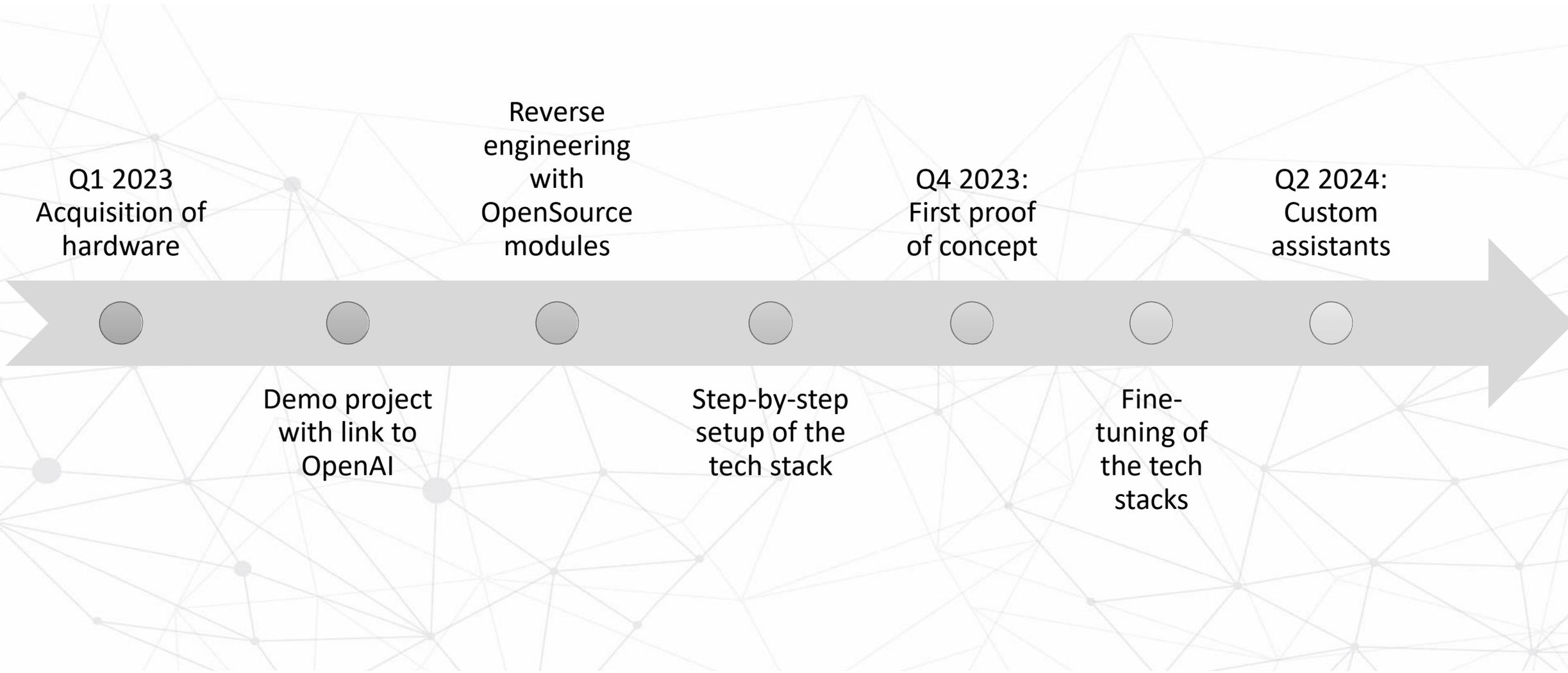
Development of a knoell AI solution – Why?

- Data protection and sovereignty
- Copyright
- Uniform quality
- Finetuning to our use case – Customized assistants
- Global political situation
 - Independence

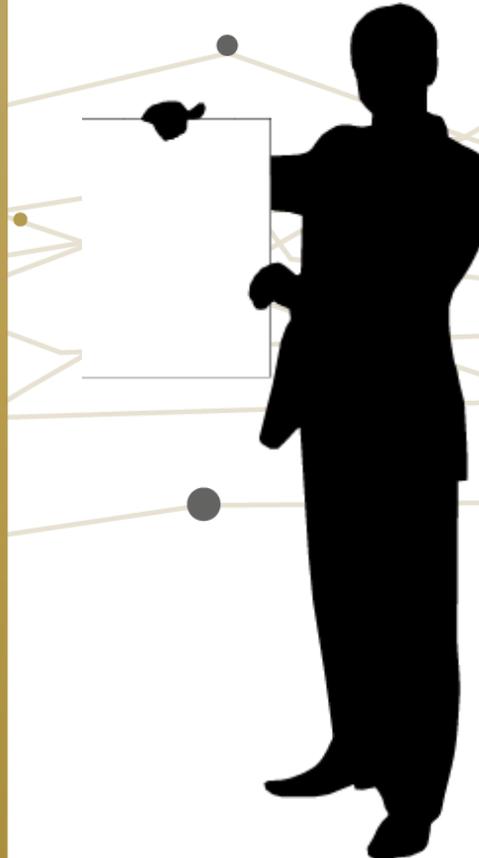


Development of knoell AI

knoell AI – Development Process and Technology



- Input of internal and confidential data such as:
 - Customer data
 - Personal dataonly into the knoell internal chatbot.
- Use of external AI tools such as Perplexity / ChatGPT only for publicly accessible information.
- Information from AI solutions must be verified by reliable sources.





knoell AI

Regulatory Assistant Biocontrol

Your friendly helper for all questions on the content of Biocontrol regulatory documents

What triggers a technical equivalence assessment for a microorganism and how does it work in the EU?

20 of 20000 tokens used





> Thinking done.

Technical Equivalence Assessment for Microorganisms in the EU

This structured summary outlines the triggers and processes for technical equivalence assessments of microorganisms under EU regulations, based on the provided documentation.

1. Triggers for Technical Equivalence Assessment

A technical equivalence assessment is required when changes to the production of a microorganism-based plant protection product (PPP) occur. These changes may affect the properties of the microorganism, necessitating regulatory evaluation. Key triggers include:

- **Change in Manufacturing Location:**
 - Relocating production to a new facility (e.g., moving from a pilot plant to an industrial-scale site).
 - Example: *SANCO/12823/2012 –rev. 4* (Documentation, p. 2–3).
- **Scale-Up of Production:**
 - Increasing the size of fermentation vessels (e.g., from lab-scale to commercial-scale production).
 - Example: *ENV/JM/MONO(2014)2* (Documentation, p. 21, 61).
- **Modification of Manufacturing Process:**
 - Altering production methods, equipment, or propagation conditions (e.g., temperature, media composition).
 - Example: *Commission Regulation (EU) No 546/2011* (Documentation, p. 28).

What triggers a technical equivalence assessment for a microorganism and how does it work in the EU?

In the EU regulatory framework, a technical equivalence assessment for a microorganism (such as a microbial pesticide or biocontrol agent) is triggered when:

✓ Trigger Points for Technical Equivalence Assessment

1. Change of source:

A different production strain or manufacturing process is proposed (e.g. new fermentation facility, change in medium components, etc.).

2. New manufacturer:

The microorganism is produced by a different company than originally approved.

3. Change in production method:

Changes in the formulation or fermentation method that could affect the microorganism's properties.

4. Renewal of approval:

During active substance renewal (under **Regulation (EC) No 1107/2009**), technical equivalence to the originally approved strain must be demonstrated.

- Same prompt
- No sources named
- Less detailed answer
(None expert audience)

What triggers a technical equivalence assessment for a microorganism and how does it work in the EU?

Answer Sources · 9 Steps

europa guidance document for the assessment of the - Food...	en.reach24h.com Technical Equivalence Assessment Under EU PP...	europa https://food.ec.europa.eu/di	hse.gov.uk Technical equivalence of an active substance: biocides
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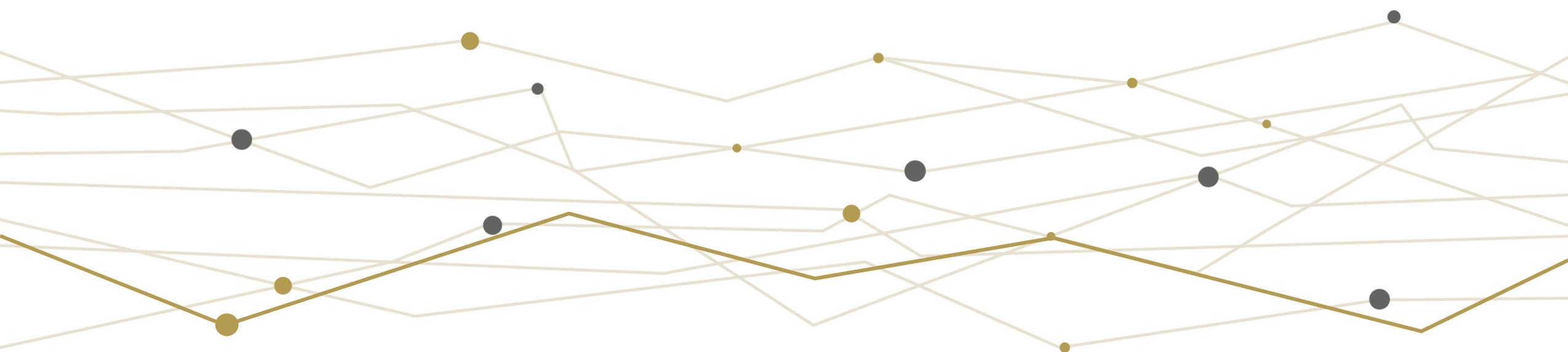
A technical equivalence assessment for a microorganism in the EU is triggered by specific changes in the source or manufacturing process of the microorganism used in products such as plant protection agents or biocides. This process ensures the new source is as safe and effective as the previously approved source and does not pose additional risks to human health or the environment. [food.europa +2](#)

Triggers for Technical Equivalence Assessment

- A change in the manufacturing plant location. [food.europa +1](#)
- Production scaling, such as moving from pilot-scale to industrial-scale fermentation. [cirs-group +2](#)
- Modifications in the manufacturing process (e.g., equipment, propagation conditions, or raw material). [food.europa +2](#)
- Use of a different manufacturer or production site than the original reference source. [cirs-group](#)

Any of these changes can potentially alter the properties or safety profile of the microorganism and thus require assessment. [cirs-group](#)

- Same prompt
- Sources named but these include online articles (Opinion not law)
- Less detailed answer (None expert audience)



Roll-out knoell AI - Insights, successes and challenges

Result from a knoell internal survey at the beginning of roll-out:
AI competence is inhomogeneous

Measures:

- AI Tool Manuals
- AI Training Courses for different levels of expertise
- Application Workshops for Specialist Departments



Improved communication

Digital competence improved through user-friendly chatbots

Successes

Increased speed and efficiency in research (on specific topics)

Increased speed and efficiency in generating texts and documents

Many ideas for specialized chatbot workflows

Current results only with internet connection

By using AI, also delays and extra effort – many new options, but not everyone is suitable

Know the limits of AI - **Hallucinations**



Prompt engineering needs to be practiced more

Resource requirements and costs

- Leveraging AI can help streamline operations and improve communication.
- Establishing specialized workflows is crucial for several key reasons:
 - Quality Assurance
 - Optimizing resource efficiency across humans and AI
- Human-Centric Roles: By automating routine tasks, workflows free up human resources to focus on higher-level analysis, strategic thinking, and quality control
 - Comprehensive training in AI fundamentals and prompt engineering is essential to empower employees to effectively collaborate with AI systems
- Provider Independence: Utilizing custom developed and on-premise tools minimizes dependency on a single AI provider and supports long-term sustainability.

→ Human interaction is necessary to ensure the correctness, completeness, and traceability of results.

→ The AI landscape is evolving rapidly, but it is essential to carefully evaluate both the costs and the benefits.



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