

# Regulatory Update from CRD



## Dr Christine Snaith – Head of Plant Protection Products

BCPC, 7 November 2023, Harrogate



# What is Being Covered?

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- Chemicals Regulation Division – Mission, Vision, Strategic Objectives
- Building Capacity and Capability
- Regulatory Services (across the Main Workstreams)
- International Involvement

# CRD Mission, Vision, Strategic Objectives – Agreed 2021

## Chemicals Regulation Division

### Mission

Protect people and places through the safe and effective use of chemicals to support a sustainable future.

### Vision

As a globally respected Competent Authority, support the UK to prosper through science-led regulation of the effective and safe use of chemicals and associated technology

### Strategic objectives

- Deliver chemicals regulation effectively in an independent UK environment
- Improve services to UK businesses and the public
- Reduce the cost of regulatory service delivery
- Improve quality and timeliness of 'permissions' issued to businesses
- Deliver world-class scientific and regulatory chemicals expertise
- Engage and influence global chemicals regulatory regimes

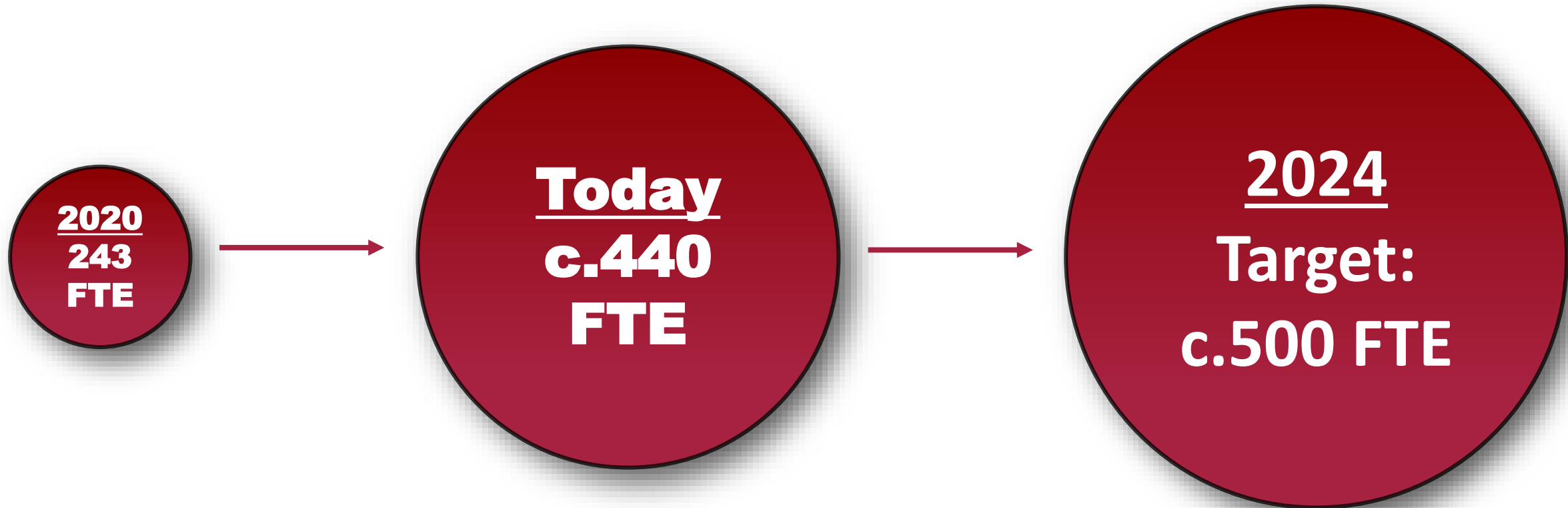
# Strategic Objective:

Deliver world-class scientific and regulatory chemicals expertise



# Expansion Since UK Left EU

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- 400 vacancies filled by October 2023
- Of which 300 people brought in from outside HSE

# Capacity – Disciplines Recruited

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- Regulatory scientists
- Policy advisors
- Operational support
- Enforcement – Pesticide Enforcement Officers and Regulatory Inspectors
- Economists
- Occupational hygienists
- Learning and development professionals



# Capability - Shape of CRD

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- **CAPABILITY** building now we are near **capacity** remains an essential priority, so sustained investment over a number of years to consolidate early years knowledge and skills
- Whilst we retained a **core of experienced staff**, necessarily the proportion with significant experience has reduced – and there is a lower level of experience overall
- To date, our capacity and capability **is not in the required balance across all the teams**, for optimised delivery – so some pinch points
- Some **shortage/ scarce disciplines**, where vacancies remain; alternative approaches to recruitment being explored and professional body interventions eg. British Toxicology Society
- **Retention remains a challenge** - it is a highly competitive market and even very junior staff have been approached or attracted to other opportunities – both industry and OGDs
- **Locations:** To diversify risks, we now recruit to other HSE offices, particularly Bristol, Bedford and Edinburgh, and others too for shortage disciplines



# Strategic Objectives

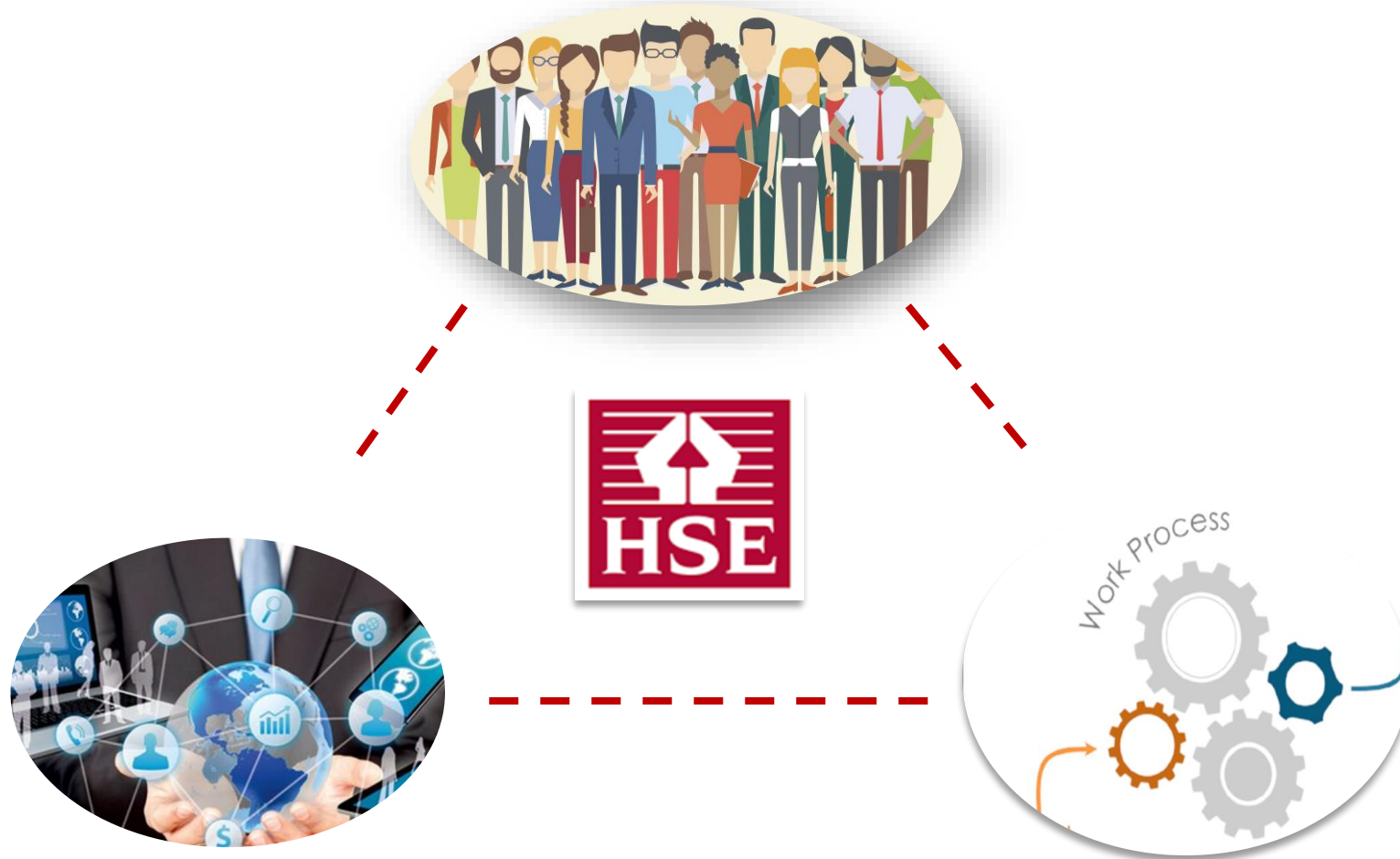
- **Deliver chemicals regulation effectively in an independent UK environment**
- **Improve services to UK businesses and the public**
- **Reduce cost of regulatory service delivery**
- **Improve quality and timeliness of 'permissions' issued to businesses**





# Transformation

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# New Digital Systems

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## Biocides and Pesticides Transformation Programme (BPTP):

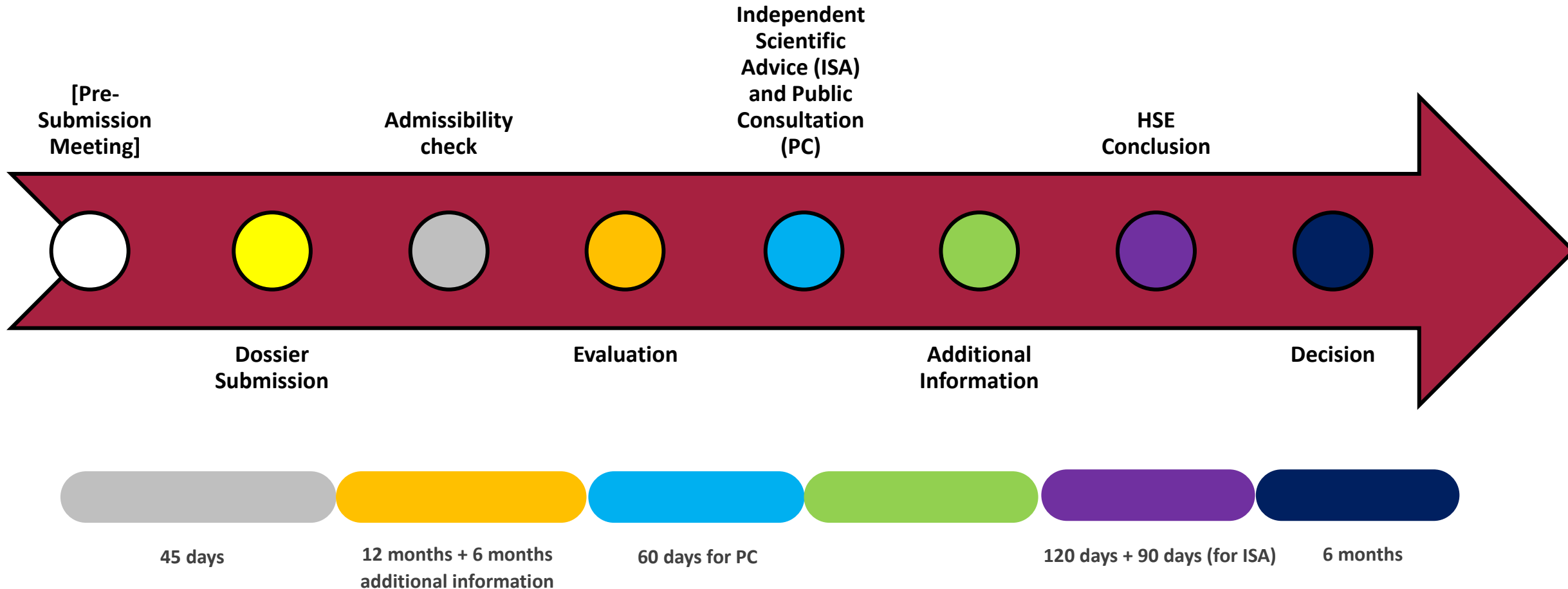
Aim: To deliver a transformed, modern digital service, harmonising the registration of biocides and pesticides



Invitations for user testing sent 30<sup>th</sup> October. To be involved contact

[b-pt\\_programme@hse.gov.uk](mailto:b-pt_programme@hse.gov.uk)

# PPP New Active Substance Process



# New Active Substances in GB

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- New re-patriated functions:
  - Publication and public consultation (functions repatriated from EFSA, processes now established including consultation platform, not without some difficulties eg accessibility of docs in relation to publication)
  - HSE conclusion of the Authority document / Decision document
  - Decision making process with Ministers / devolved governments
  - WTO notifications – Defra considers case by case
- Overall process looking more like 2.5 – 3 years (rather than 12-18 months for approval/authorisation suggested pre-Brexit)

# GB New Actives

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- System does allow for **parallel processing** of active substance, representative product, MRL and hazard classification and labelling
- Following on from the first active approved under the new GB regulatory regime, **Cinmethylin** (June 2022), **Isoflucypram** now also approved in GB (October 2023)
- Representative products authorised in the following week
- Additional products can be started towards the end of the active substance approval process (don't have to wait for approval of the active before applying)
- Significant time benefits under the new GB process

# Biopesticides

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- **2006 Biopesticides scheme** currently still in operation - covers three classes of pesticide products: semiochemicals (such as pheromones), micro-organisms and botanicals (such as plant extracts)
- **Greatest proportion of pre-submission meetings booked** – an increasingly important element of crop protection and Integrated Pest Management
- Part of the Government review of the regulatory regime for pesticides
- Continue to proactively engage with OECD and other regulators regarding Biopesticide initiatives and guidance development
- ECP now extended to include experts in the field of biopesticides (the '**biopesticide cloud**')

# GB Active Substance Renewal Programme (ASRP)

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- Approval expiry dates originally extended for 3 years (to allow for the development of the new GB renewal programme)
- Applications for renewal and supplementary dossiers have been submitted for renewal of actives in accordance with the timelines in the Regulation ( 33/30 months before expiry)
- Developing GB programme has proved more complex than originally anticipated - working closely with Defra and Devolved Govts to consider various options / develop the future programme
- Will soon be notifying/reminding about renewal dates (as for biocides)
- **Approvals are being maintained in the meantime**
  - First extension exercise in April 2023 – approvals expiring before end of March 2025 extended for up to 5 years
  - Next batch of extensions in preparation, as required by Article 17 (1)



# GB ASRP - Key Requirements

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- Key elements of a new renewals process:
  - maintain levels of protection for people and the environment
  - incentivise low-risk pesticides on the GB market
  - enable regulatory effort to be focussed on the highest risks to people and the environment
  - deliverable (including providing a proportionate, transparent regime which engenders trust in the regulatory process)
- Predictability:
  - requirements of the process to be clearly set out
  - time to update supplementary dossiers
  - meaningful extensions where required

# Communication and Engagement

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- New landing page created for active substances
- Active substance webpages updated with GB process guidance eg. Reactive Reviews, Art 21
- Statutory active substance documents published in specific spreadsheets
- Citizen Space platform for public consultations
- eBulletins for communicating decisions and publications

 Health and Safety Executive HSE ebulletin

**HSE Pesticides ebulletin**  
**Issued: 13 September 2023**

An independent pesticides regulatory regime is in operation in Great Britain (England, Scotland and Wales).

This ebulletin includes information on the [Plant Protection Products \(PPP\)](#) regulations in Great Britain (GB).

## **GB PPP new active substance: publication of HSE conclusion**

**New PPP active substances in GB are regulated under retained Regulation (EC) No 1107/2009.**

**Applicant:** Bayer AG

**Substance:** **Isoflucypram** – fungicidal active substance the control of stem-base, foliar and ear diseases in wheat (including Durum wheat and spelt), triticale, rye, barley and oats.

**Conclusion:** HSE's conclusion is that the active substance is expected to meet the approval criteria.

The risk assessment which underpins the Conclusion has been subject to public consultation and independent scientific advice from the Expert Committee on Pesticides. The input provided through these processes was considered by HSE when finalising the Conclusion on this new active substance.

[View the published conclusion \(.pdf\)](#)

# Plant Protection Products

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- Higher complexity of assessed applications, on average, compared with when in EU. New product applications on the increase.
- Performance
  - Continuing to grow capacity and capability, to return to former levels of delivery, but recognise many applications delayed for reasons of capacity/capability building
  - We actively manage and monitor delivery to meet deadlines, wherever possible
  - Increasingly look for synergies, to optimise efficiency
- Applications for Emergency Authorisation (A53s) remain high – our Guidance issued in 2022 has been helpful in clarifying requirements and process
- [Emergency authorisation to use, sell, supply or store a plant protection product \(hse.gov.uk\)](https://www.hse.gov.uk/plant-protection-products/emergency-authorisation)
- Isoflucypram representative product issued within 7 days of the New Active Substance Approval
- **Contact joint Acting head of PPT [barry.neill@hse.gov.uk](mailto:barry.neill@hse.gov.uk) to discuss your prioritised applications;** or novel product matters

# Treated Seed and Parallel Trade Products

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- On EU Exit permission to import, place on the market and use seed treated with Plant Protection Products not authorised in GB allowed **until 31 December 2023**
- Permits for parallel trade products withdrawn with **final sale date of 30 June 2023** and use date of 30 June 2024
- Concerns raised by industry regarding
  - the impact on particularly maize which is mostly imported as treated seed and
  - growers not having access to cheaper parallel trade products
- New SI laid in parliament on 24 October 2023 and to come into force 31 December 2023

# Treated Seed and Parallel Trade Products

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- New SI will allow treated seed to be imported, marketed and used until 1 July 2027, to allow time for manufacturers to obtain GB authorisations of PPPs for use as seed treatments
- Unrelated to the SI, HSE has developed new guidance on seed treatments <https://www.hse.gov.uk/pesticides/pesticides-registration/applicant-guide/treated-seed/requirements.htm> (regarding sowing rate and risk mitigations)
- Holders of parallel trade permits valid as of 31 December 2022 will be able to apply to have their permits re-instated for two years, to allow time for applicants to seek product authorisations
  - Applications required between 1 January and 1 April 2024
  - Re-instated permits to be issued by 30 June 2024

# MRLs

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## New/ Raised MRLs

- 2022 – published 11 ER/RO covering 79 new/raised MRLs
- 2023 (Jan – Oct) – published 13 ER/RO covering 152 MRLs
- 2023 also adopted MRLs for the new active substance Isoflucypram

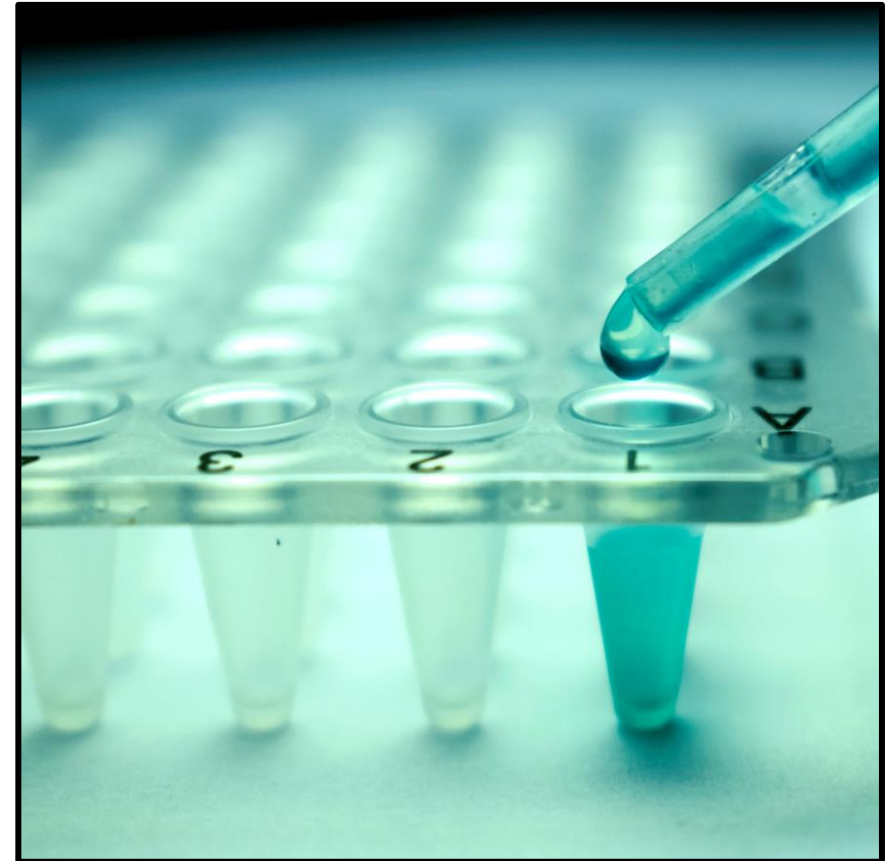
## MRL Reactive Reviews

- 2022 – MRL reviews completed for 6 non-approved active substances
- 2023 (Jan – Oct) – MRL reviews completed for 2 non-approved active substances, 1 MRL review of the specific MRL for spinetoram/ lettuce and the WTO/SPS notification in progress for one non-approved active substance

# Residue Monitoring Programme

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- Annual sample approx. 3300 samples foodstuffs. Testing for up to 400 pesticides. Reassuring findings – consistent with broader indicator picture
- Helps us check/determine that pesticides behaving as predicted by risk assessment/label instructions being followed; MRL compliance; dietary burdens, etc
- Commercial and legal consequences can be associated with findings so work carefully managed/controlled and programme continually evolving





# Research and Development Activity

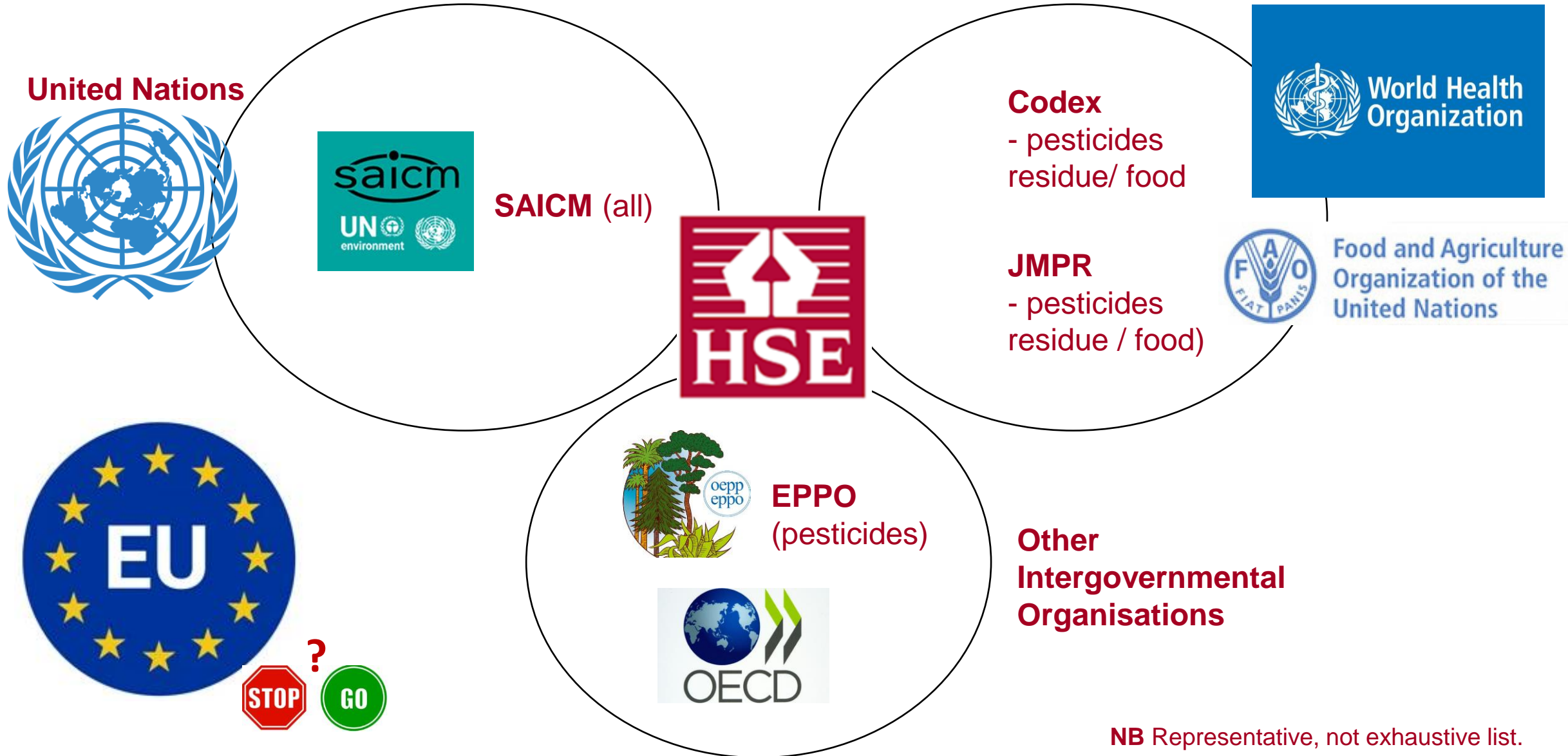
Recently Delivered	Upcoming	Longer Term
Decision making tool for fungicide mixtures	Additional risk mitigation options to protect surface and groundwater	Monitoring pests with high resistance in protected field crops
Home and garden container recycling	Reviews of honeybee, biological and low-risk products, and aquatic organisms risk assessment	Worker exposures in protected cropping and with particular application technologies
Monitoring pests with high resistance in protected crops	Status of pests in arable and horticultural cropping in Northern Ireland.	Effect of modern application methods on food residues
		Modelling variable rate spraying
		Review of soil microbial processes assessment
		Pesticide residues in nectar and honey

# Strategic Objective:

Engage and influence global chemicals regulatory regimes



# International Work (Pesticides)



NB Representative, not exhaustive list.

# UK Working with Global Regulatory Authorities



## JMPR

- Re-engaged since 2017 – Toxicology and Residue specialists attend
- Learning of approaches of other jurisdictions
- Influences on how risk assessments are done at international level, as well as specific substances
- Review of chronic risk assessment methodology discussed

## CODEX

- Electronic working groups on priority of periodic reviews – influencing priority
- Where appropriate, adopt CXLs based on safety for UK consumers

## OECD / EPPO

- Bureau and Working Party on Pesticides

Many different WG and work on guidelines

- OECD Drones Working Group
- Expert group on Biopesticides
- EPPO: Expert Working Group on Digital Technologies
- EPPO: Expert Working Group on Resistance

# Applying Pesticides By Drone

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- Result of HSEs prominent role in OECD Working Party for Pesticides drone sub-group
- Sponsored by OECD Co-operative Research Programme
- 130 speakers and delegates from the across the world
- Shared understanding of obligations, issues and approaches



# Thank You and Any Questions?

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- Any follow-up questions to:  
[pppenquiries@hse.gov.uk](mailto:pppenquiries@hse.gov.uk)
- [chris.snaith@hse.gov.uk](mailto:chris.snaith@hse.gov.uk)
- Volunteering for engagement with the digital development of B-PTP:  
[b-pt\\_programme@hse.gov.uk](mailto:b-pt_programme@hse.gov.uk)
- HSE Pesticides website:  
<https://www.hse.gov.uk/pesticides/>



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