Regulatory Update from CRD

Dr Christine Snaith – Head of Plant Protection Products
BCPC, 7 November 2023, Harrogate
What is Being Covered?

- 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

- 2020: 243 FTE
- Today: c.440 FTE
- 2024 Target: c.500 FTE

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

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

- **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

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- Improve services to UK businesses and the public
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Transformation
New Digital Systems

Biocides and Pesticides Transformation Programme (BPTP):
Aim: To deliver a transformed, modern digital service, harmonising the registration of biocides and pesticides

Phase 1
Service for plant protection products
Timing: April 2024

Phase 2
Service for biocidal products
Timing: later 2024

Later phases
Service for biocide and pesticide active substances
Timing: tbc

Invitations for user testing sent 30th October. To be involved contact b-pt_programme@hse.gov.uk
PPP New Active Substance Process

[Pre-Submission Meeting]  Admissibility check  Independent Scientific Advice (ISA) and Public Consultation (PC)  HSE Conclusion

Dossier Submission  Evaluation  Additional Information  Decision

45 days  12 months + 6 months additional information  60 days for PC  120 days + 90 days (for ISA)  6 months
New Active Substances in GB

• New re-patriated functions:
  
o  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)
  
o  HSE conclusion of the Authority document / Decision document
  
o  Decision making process with Ministers / devolved governments
  
o  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

• 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

• **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)

- 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

• Key elements of a new renewals process:
  o maintain levels of protection for people and the environment
  o incentivise low-risk pesticides on the GB market
  o enable regulatory effort to be focussed on the highest risks to people and the environment
  o deliverable (including providing a proportionate, transparent regime which engenders trust in the regulatory process)

• Predictability:
  o requirements of the process to be clearly set out
  o time to update supplementary dossiers
  o meaningful extensions where required
Communication and Engagement

- 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
Plant Protection Products

• Higher complexity of assessed applications, on average, compared with when in EU. New product applications on the increase.

• Performance
  o Continuing to grow capacity and capability, to return to former levels of delivery, but recognise many applications delayed for reasons of capacity/capability building
  o We actively manage and monitor delivery to meet deadlines, wherever possible
  o 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)
• Isoflucypram representative product issued within 7 days of the New Active Substance Approval
• Contact joint Acting head of PPT barry.neill@hse.gov.uk to discuss your prioritised applications; or novel product matters
Treated Seed and Parallel Trade Products

- 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

• 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](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
  
  o Applications required between 1 January and 1 April 2024
  o Re-instated permits to be issued by 30 June 2024
MRLs

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

• 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

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<tr>
<th>Recently Delivered</th>
<th>Upcoming</th>
<th>Longer Term</th>
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<tr>
<td>Decision making tool for fungicide mixtures</td>
<td>Additional risk mitigation options to protect surface and groundwater</td>
<td>Monitoring pests with high resistance in protected field crops</td>
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<td>Home and garden container recycling</td>
<td>Reviews of honeybee, biological and low-risk products, and aquatic</td>
<td>Worker exposures in protected cropping and with particular</td>
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<td>Monitoring pests with high resistance in protected crops</td>
<td>organisms risk assessment</td>
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<td>Status of pests in arable and horticultural cropping in Northern Ireland.</td>
<td>Effect of modern application methods on food residues</td>
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<td>Modelling variable rate spraying</td>
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<td>Review of soil microbial processes assessment</td>
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<td>Pesticide residues in nectar and honey</td>
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Strategic Objective:
Engage and influence global chemicals regulatory regimes
**International Work (Pesticides)**

- **United Nations**
  - SAICM (all)

- **Codex**
  - Pesticides residue/food

- **JMPR**
  - Pesticides residue/food

- **EPPO**
  - Pesticides

- **Other Intergovernmental Organisations**
  - OECD

**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

• 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?

- Any follow-up questions to: pppenquiries@hse.gov.uk
- chris.snaith@hse.gov.uk
- Volunteering for engagement with the digital development of B-PTP: b-pt_programme@hse.gov.uk
- HSE Pesticides website: https://www.hse.gov.uk/pesticides/

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