Developments in regulating PPP active substances in GB

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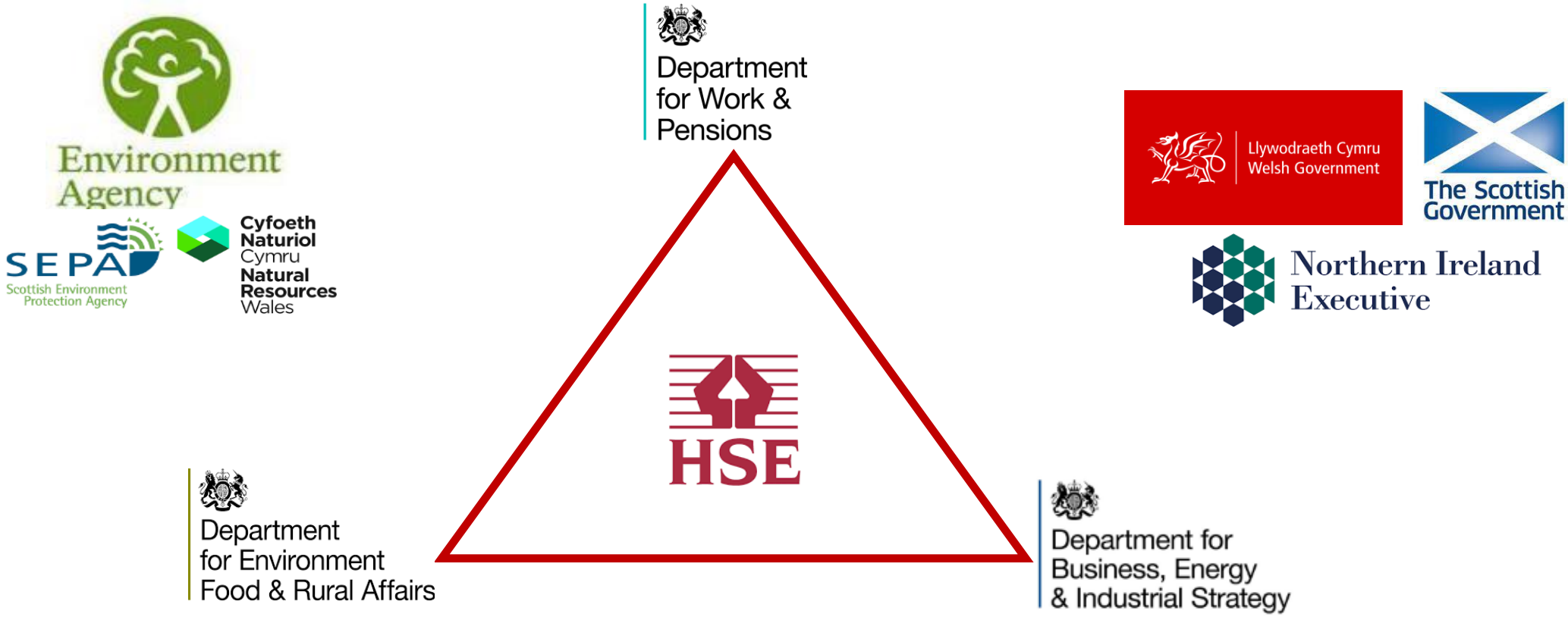
Content

- Chemicals Regulation – the national context and where CRD fits in
- CRD Vision and Strategic Objectives
- New active substances
- Biopesticides
- GB Active Substance Renewal Programme (ASRP)
- Reactive reviews

Chemicals Regulation in the UK

Post EU Exit:

‘Establish an **independent** regulatory framework that **maintains** the high standards of protection for human health and the environment.’



Chemicals Regulation : HSE / Defra Key Partnership

- Strategic governance arrangements between HSE, Defra, Devolved Administrations & Environment Agency

Policy & Operational Delivery

- Classification, Labelling, & Packaging (CLP)
- Biocides (BPR)
- Prior Informed Consent (PIC)

Operational Delivery

- Plant Protection Products (PPPs)
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- Detergents

Policy

Chemicals Regulation Division (CRD)

- HSE Operational division. CRD regulates the marketing and use of chemicals on the UK market
- Work across a range of disciplines and professions
- What do we do:
  - Scientific and technical assessments
  - granting 'permissions' of various types
  - advice
  - operational delivery & enforcement
  - supporting ministers

Unit 1: Enforcement

Unit 2: Biocides

Unit 3: Pesticides

Unit 4: REACH, CLP & PIC

Unit 5: Corporate Resources

Unit 6: Strategy, Evidence and Engagement

CRD Recruitment and training – key priority

- *Staffing* **–** since leaving the EU we have **increased CRD staff by nearly 50% (from 242 FTE in Sept 2020 to 354 FTE in March 2022**)…. (assorted grades and disciplines)

- Investing in **building capacity and capability** has been, and continues to be, an ***essential priority*** for CRD since leaving the EU.

- Further **recruitment took place earlier this year to fill a further 89 posts**; onboarding of these staff is currently underway.

- CRD recently secured HSE's **agreement to proceed with the next round of recruitment for a further 54 staff.** Recruitment for the majority of these posts is currently in progress**.**

- Ultimately, the plan is for CRD to have **over 500 staff by the end of 2024**
  (may be subject to change as plans are reviewed in current operating environment).

- *Locations* - York and Bootle – continue to be the principal locations, but intending to establish other hubs in Bedford, Bristol and Edinburgh (and more options for shortage disciplines)

CRD Vision, Mission and Strategic Objectives

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**

UK Aspirations for Working with Global Regulatory Authorities

- A CRD strategic objective is to: **Engage and influence global chemicals regulatory regimes**

CRD is already aiming to increase its participation in international fora, and to work with other regulators:

- In anticipation, CRD volunteered to establish and lead the OECD Drones Working Group in 2019 and is now a member of the OECD's Bureau for the Working Party on Pesticides.
- CRD participates in many of the OECD expert groups (e.g. Biopesticides, Residues Chemistry, Pollinators, Pesticide Effects on Insect Pollinators - Testing and Assessment Group, Electronic Exchange of Pesticide Data and OECD Network Illegal Pesticides)
- Despite resource challenges, CRD is maintaining engagement e.g. with JMPR and EPPO (Efficacy)

UK Aspirations for Working with Global Regulatory Authorities (.../continued)

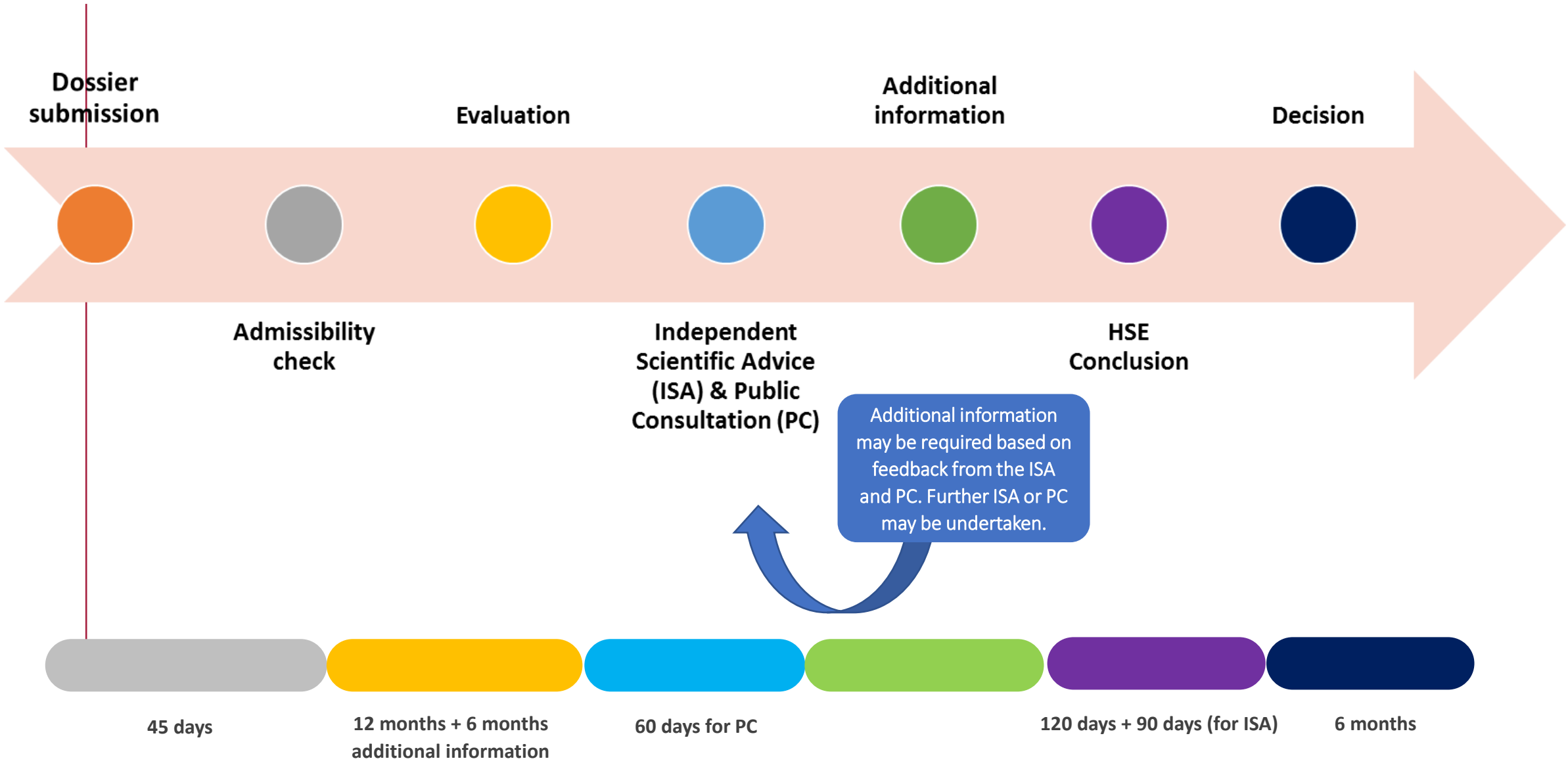
- A CRD strategic objective is to: **Engage and influence global chemicals regulatory regimes**

- Maintaining networks with other Regulators is crucial – CRD has hosted a session on international approaches to AS Renewals and is arranging another on sharing lessons on Transformational activities.

- Bilateral contacts with fellow regulators are also ongoing

- In the medium term, opportunities to work together on evaluations may be beneficial – previously focussed on new active substances, but now also looking at reviews/renewals

PPP New Active Substance Process



New Active Substances in GB

Process now established:

- Pre-submission meetings (lots of them which is encouraging)
- Admissibility check (45 days)
- Evaluation (18 months rather than the 12 months initially indicated)
- Expert Committee on Pesticides (ECP) for independent scientific advice (2 meetings, detailed discussion then advice at next meeting)

New Active Substances in GB

Process now established:

- New Re-patriated functions:
  - Publication and public consultation (functions repatriated from EFSA, processes now established, 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 / Admins

- Overall looking at 2 – 2.5 years (rather than 12-18 months for approval/authorisation suggested pre-Brexit)

GB New Actives - Cinmethylin

- System does allow for parallel processing of active substance, representative product, MRL and CLH
- First active approved under the new GB regulatory regime
- 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)
- Lots of pre-submission meetings booked – clearly will become 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

GB Active Substance Renewal Programme (ASRP)

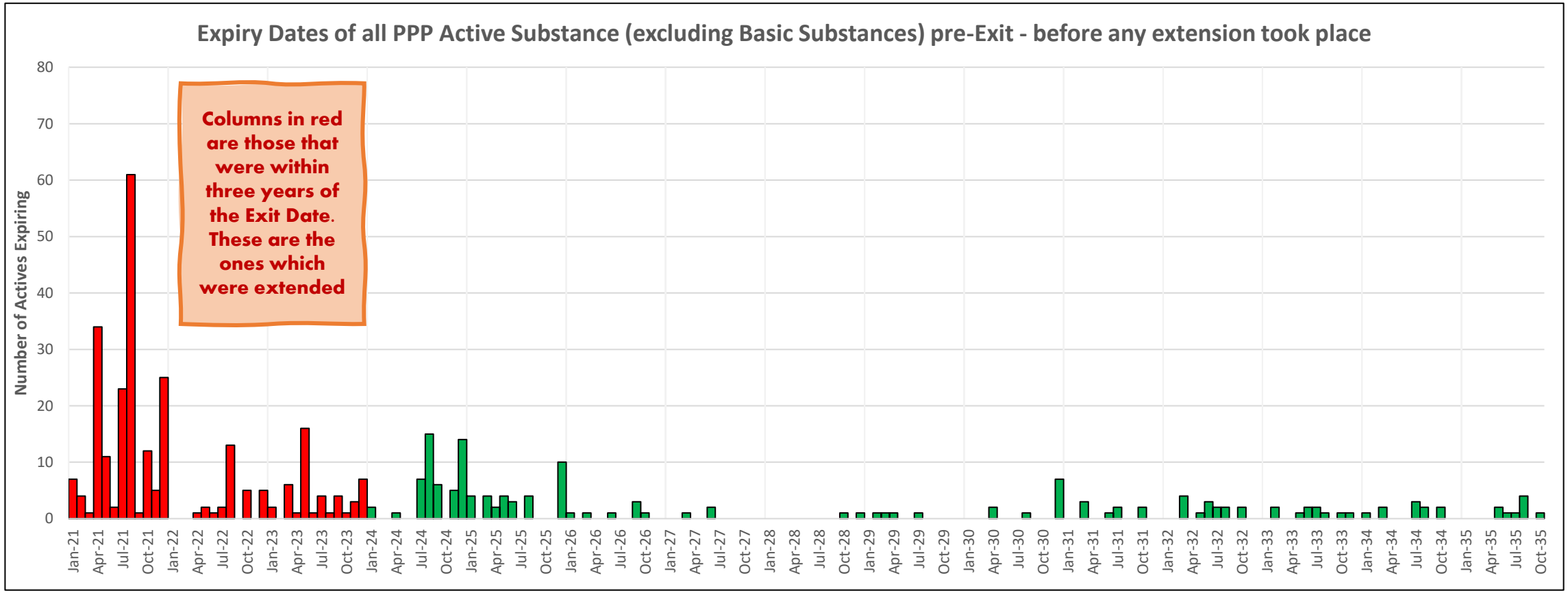
- Approval expiry dates originally extended for 3 years (to allow for the developments of the new GB renewal programme)
- Applications for renewal and supplementary dossiers have been submitted for renewal of actives in accordance with the timelines in the Regulation (3 years and 2.5 years before expiry)
- More complex than originally anticipated - working closely with Defra and Admins to consider various options / develop the future programme (for consultation with Ministers)
- HSE expanding resources to deal with the future renewal programme
- **Approvals will be maintained** in the meantime (expiry dates approaching, required to extend approvals where a decision has yet to be made under Art 17)

GB Active Substance Renewal Programme (ASRP)

Key requirements of the new renewal process:

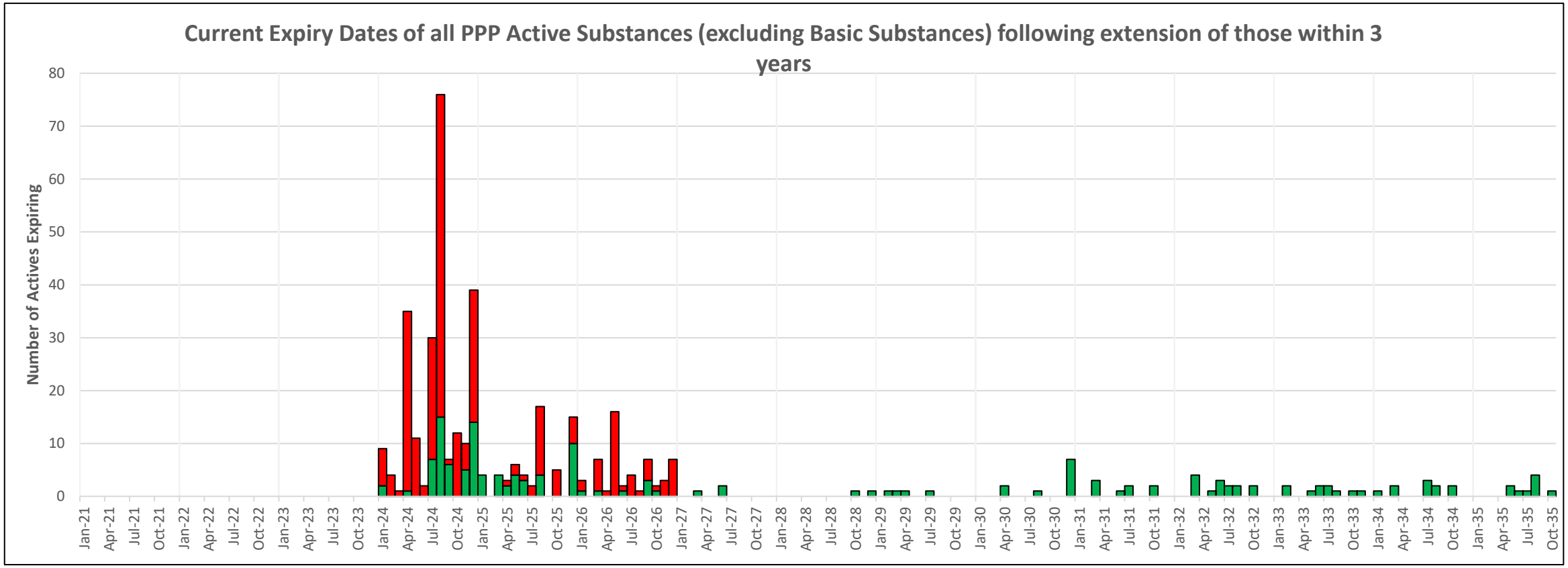
- Predictability
  - requirements of the process to be clearly set out
  - time to update supplementary dossiers
  - meaningful extensions where required
- Business planning
  - when will the programme begin
- Realistic programme
  - Need a challenging but achievable programme

The challenge - Active Substance Expiry dates



186
actives
(419 actives approved in GB)

Backlog of Active Substance Expiries – Post Extension



236
actives

(419 actives approved in GB)

GB Reactive Reviews

- Article 21 provides that we can review approvals at any time (where, in the light of new knowledge there are indications that the substance no longer satisfies the approval criteria)
- Until now have been focussing on EU decisions (resource, Requirements/guidance the same, need to consider for NI anyway) but will consider new knowledge/decisions from any comparable regulator
- Focus so far on Art 21 reviews of negative decisions – also looking into the possibility of using positive decisions from other jurisdictions to support similar decision in GB.

GB Reactive Reviews

Process now established:

- Seek agreement to initiate the review
- Initiate the review – contacting approval holders/producers informing of the reasons for the review and allowing for any additional info to be provided
- Review the decision from the other jurisdiction and any additional information provided - relevance of the decision to GB
- Reach a conclusion on the review, make a decision in accordance with governance arrangements with administrations
- Will be looking to complete process 6 months after initiation
- Website being updated to provide details of the new procedure

Thank you for listening – any questions ?