PROTECTING PEOPLE AND PLACES HSE

Regulatory perspectives

Ingrid den Hoed

Efficacy team (Chemicals Regulation Division, GB Health and Safety Executive)

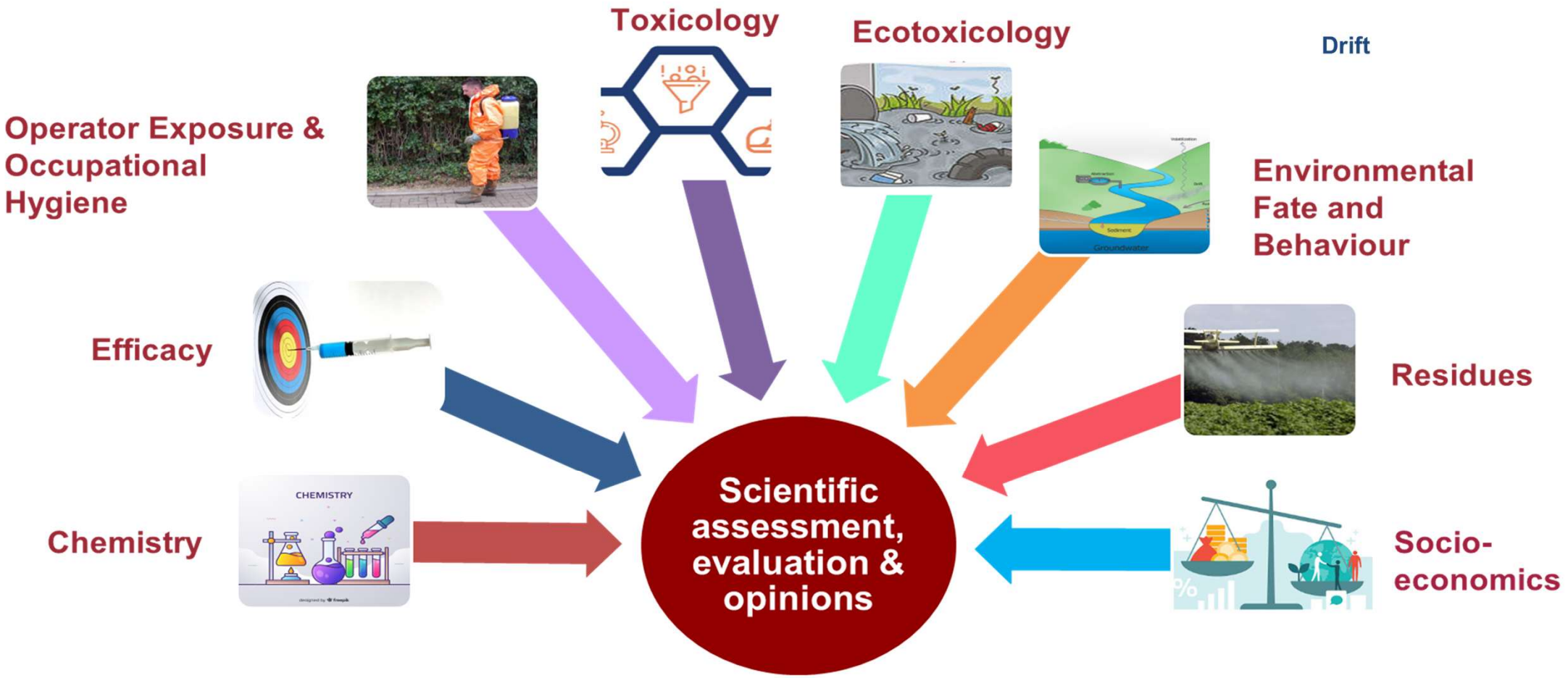
Regulatory perspectives

- Background
- Look back
- Regulatory process
- Capacity & capability
- Regulatory Landscape
- Questions

Background

PROTECTING PEOPLE AND PLACES HSE

- Chemicals Regulation Division (CRD) is a Division of the Health and Safety Executive (HSE)
- There are around 450 scientific, policy, and support staff based in York, Bootle, Bristol, Edinburgh and Milton Keynes.
- CRD is responsible for the regulation of:
  - Plant Protection Products (PPPs)
  - Biocides
  - Industrial Chemicals
  - Detergents


Toxicology
Ecotoxicology
Drift
Operator Exposure & Occupational Hygiene
Environmental Fate and Behaviour
Efficacy
Residues
Chemistry
CHEMISTRY
Scientific assessment, evaluation & opinions
Socio-economics

Look Back

- ~**5 calendar years** of HSE operating as the independent GB chemicals & pesticides regulator plus supporting Northern Ireland under different rules
- EU Exit has been the biggest development we've had to **respond** and **adapt** to
- Subject of significant industry, press and **Parliamentary** interest

PROTECTING PEOPLE AND PLACES HSE

NAO National Audit Office

Active Substance Approval

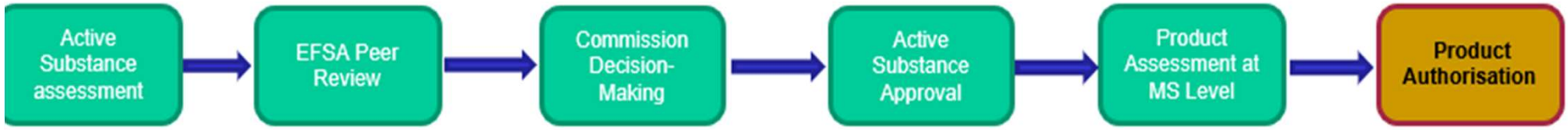
PROTECTING PEOPLE AND PLACES HSE

- Since EU Exit NI and GB approvals have been split.
- NI active substance approvals go through the EU process.
- GB has its own process under PPP Regulation EC 1107/2009, transposed into GB Regulation with effect from 1 January 2021.
- This is currently the same as the EU reg.
- A plant protection product (PPP) cannot be authorised in GB unless the active substance is currently approved in GB.

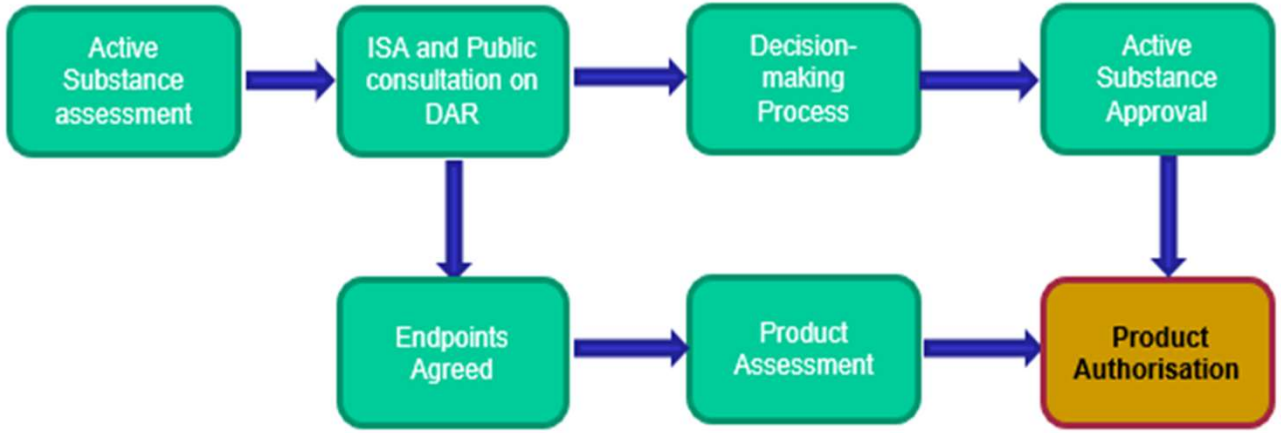
New Active Substances

PROTECTING PEOPLE AND PLACES HSE

EU Process



New GB Process



Active Substance Approvals

PROTECTING PEOPLE AND PLACES HSE

- Active substance approval generally 10 years
- For NI expiry dates in line with EU. In GB expiry dates of many supported active substances extended (since 2021) pending implementation of GB renewal programme. GB renewal assessment of glyphosate active substance started
- In the EU approval period may be extended for many active substances as part of EU simplification package. However, review may be triggered if safety concerns.
- GB regulatory process already monitors decisions taken under other jurisdictions, including EU
- HSE may review the approval of a pesticide active substance at any point if new scientific or technical knowledge indicates that it may no longer meet the approval criteria. Reviews undertaken under Article 21

Non-approval criteria

PROTECTING PEOPLE AND PLACES HSE

- **Human Health Exclusion Criteria**
  - Mutagenic - capable of inducing chemical mutation
  - Carcinogenic * - an agent capable of causing cancer
  - Toxic for reproduction * toxic to fertility or reproduction
  - Defined as category 1A or 1B classification

  * Unless exposure is negligible.
- **Environmental exclusion criteria**
  - POP
    - Persistent Organic Pollutants
    - Persistent, bioaccumulative and potential for long range transport.
  - PBT - Persistent, bioaccumulative and toxic.
  - vPvB - Very persistent and very bioaccumulative.

Category	Resistance class	RAC MoA	UK Authorised	Approval status	Date of approval/renewal	Date of expiry/revokation	Highest RF	C or R Cat 1 (1.0)	vPvB (1.0)	All 3 PBT (1.0)	ED (0.8)	Neonic (0.8)	CFS (0.6)	C2 (0.6)	M2 (0.6)	R2 (0.6)	P (0.4)	B (0.4)	T (0.4)	Scale of use (0.2 or 0.4)
RE				Not Approved			0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
IN			YES	Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
IN, HB				Not Approved		2004	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
IN	I	3A	YES	Approved	2011	2024	0.4	0	0	0	0	0	0	0	0	0	0	0	0.4	0.2
HB			YES	Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
FU				Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
FU	F	3	YES	Approved	2009	2019	0.8	0	0	0	0.8	0	0.4	0	0	0.8	0.4	0	0.4	0.2
IN	I	18		Approved	2011	2024	0.4	0	0	0	0	0	0	0	0	0	0.4	0	0	0.2
AC	I	21A	YES	Approved	2009	2022	0.4	0	0	0	0	0	0.4	0	0	0	0.4	0	0.4	0.4
HB	H	K1		Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
HB				Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
FU, PG	F	14	YES	Not Approved		2000	0.4	0	0	0	0	0	0	0	0	0	0	0	0	0.4
IN	I	15		Approved	2009	2019	0.4	0	0	0	0	0	0	0	0	0	0	0	0.4	0.2
IN	I	3A	YES	Approved	2012	2024	0.4	0	0	0	0	0	0	0	0	0	0	0	0.4	0.2
HB			YES	Approved	2014	2024	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
IN	I	1B		Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
HB	H	A	YES	Not Approved	2005	2015	0.8	0	0	0	0.8	0	0.4	0.8	0	0.8	0.4	0	0.4	0.2
HB				Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
IN	I	1B	YES	Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
HB				Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
HB			YES	Approved	2012	2024	0.8	0	0	0	0.8	0	0	0	0	0	0	0	0.4	0.2
HB	H	C1		Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
AC, IN			YES	Approved	2015	2025	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
IN	I	1B		Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
FU	F	3	YES	Approved	2010	2021	0.8	0	0	0	0.8	0	0	0	0	0	0.4	0	0	0.2
AT				Approved	2009	2019	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
AC, IN	I	12D		Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
IN				Never Notified			0	0	0	0	0	0	0	0	0	0	0	0	0	0
IN	I	3A		Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
AC	I	3A	YES	Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
RO			YES	Not Approved		2004	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
FU	F	1	YES	Approved	2002	2017	0.4	0	0	0	0	0	0	0	0	0	0.4	0	0	0.4
IN	I	4A	YES	Approved	2005	2018	0.8	0	0	0	0.8	0.8	0.4	0	0	0	0	0	0	0.2
IN	I	4A	YES	Approved	2007	2018	0.8	0	0	0	0	0.8	0	0	0	0	0	0	0	0.2
HB				Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2
HB				Not Approved		2002	0.2	0	0	0	0	0	0	0	0	0	0	0	0	0.2

Sugar Beet

PROTECTING PEOPLE AND PLACES HSE

- Most significant losses were desmedipham and chloridazon
- Other active substances commonly used include;
    - Metamitron – GB new expiry date 31/08/2031
        - **EU expiry – 30/11/2026**
    - Phenmedipham – GB expiry 31/7/2029
        - **EU expiry - 30/09/2026 – due to be discussed Jan 2026**
    - Ethofumesate – GB expiry 31/10/2031
        - EU expiry – 31/10/2031
    - Triflusulfuron – GB expiry 31/12/2028
        - **EU non-renewal decision - GB review?**
    - Lenacil – GB expiry 31/12/2027
        - EU expiry – 30/06/2040
    - Clopyralid – GB expiry 30/04/2029
        - EU expiry – 30/09/2036

PROTECTING PEOPLE AND PLACES HSE

Product Authorisations

- Authorisation (or renewal of an authorisation) based on a risk assessment
- New GB authorisations based on a GB decision process and HSE cannot rely on EU Member State assessments. HSE does welcome the provision of any competent authority assessments (from the EU or wider) which may help to inform the GB decision making.
- All EU guidance in place at the end of the transition period applies in GB unless HSE decides to remove or replace it.
- Any guidance implemented in the EU after the end of the transition period does not apply in GB unless HSE takes an active decision to use it
- At renewal of an authorisation acceptable risk may only be possible with changes to uses - e.g. reductions in dose, changes to numbers of application, application timing & frequency
- Restrictions such as application 1 in 3/4 years becoming more common.
- For Northern Ireland scope still remains to base on an assessment/authorisation from an EU Member State

CRD Capacity (all regimes)

PROTECTING PEOPLE AND PLACES HSE

Jan 2021 262

Today ~450

Net expansion of 188

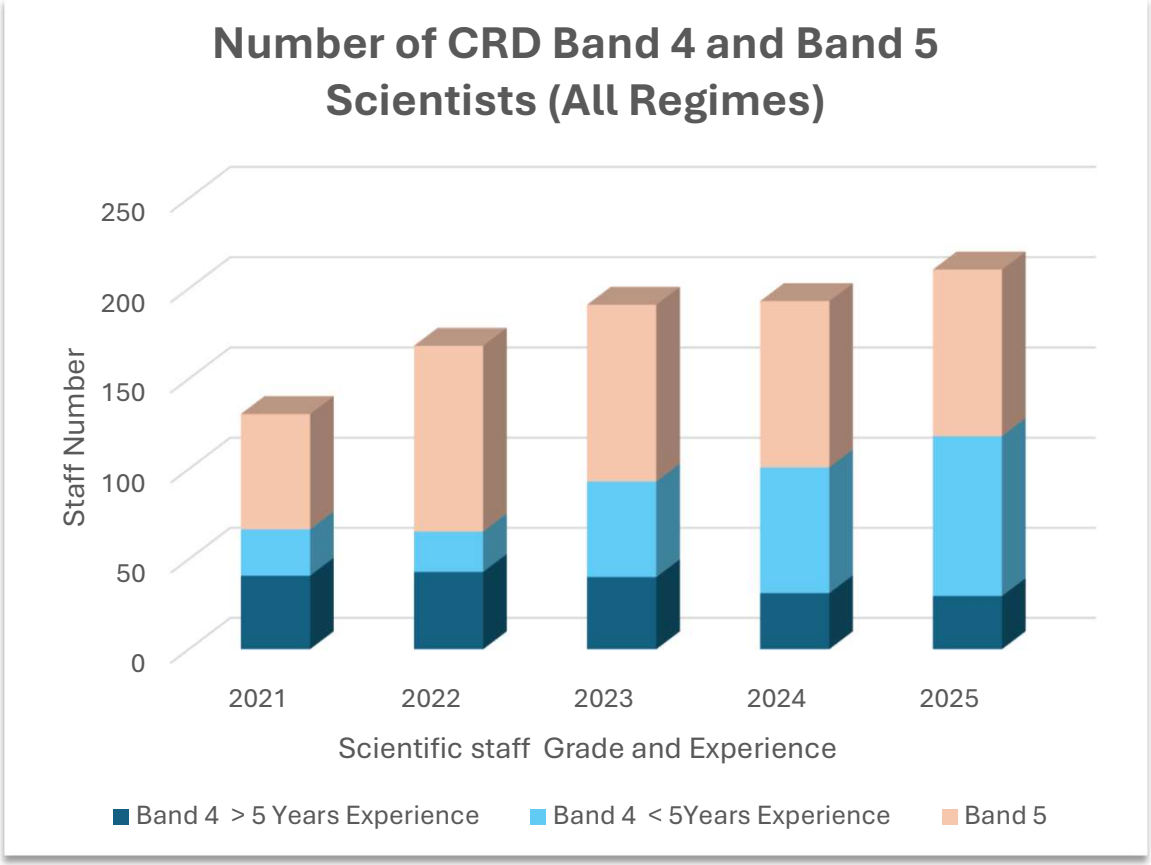
(inc. losses + vacancies filled internally)

= Total vacancies filled ~566

CRD Capability (all regimes)

PROTECTING PEOPLE AND PLACES HSE

- **Achieved** staff level of 450
- Focused on recruitment of graduate scientists, and particular specialisms
- Working towards increasing **skillsets** and levels of **experience**
- Getting the right **balance** of work for our most experienced staff
- Training 18-24 months typically



Regulatory landscape

PROTECTING PEOPLE AND PLACES HSE

- Challenges to active substance approval and product authorisations
- Different processes naturally lead to divergence between EU/NI and GB.
- Sugar beet
  - More limited in area than cereals – new active substances often focussed on cereals
  - Challenges to developing crop safe herbicides in sugar beet, without breeding for herbicide tolerance
  - Some positive benefits of spring sown crops which reduces risks to groundwater for example
  - Challenges of controlling diverse weed populations e.g., mugwort, barnyard/cockspur grass, nutsedge, amaranths

Sugar Beet as a Minor Use

- Increasing challenges to availability of chemical options in many crops, not only those generally recognised as minor crops.
- However, there is a specific authorisation for minor uses
- In GB/NI minor use is defined as:
  - Use in any crop other than a major crop (such as cereals (other than rye and triticale), oilseed rape, grassland, sugar beet, potato (other than seed), forage maize and beans dry harvested
  - Use in a major crop against a minor pest for which no practicable control measures are available
- No standard definition across Europe; area ranges from 2,500- 20,000ha
- UK sugar beet production around 102,000 ha
- Therefore, minor crop definition unlikely to include sugar beet

UK Pesticides National Action Plan 2025

Working for a more sustainable future

Three key objectives:

1. Encouraging the development and uptake of integrated pest management (IPM) and alternative approaches or techniques to reduce dependency on the use of pesticides
2. Establishing timetables and targets for the reduction of the risks and impacts of pesticide use, including monitoring and setting targets for the reduction of use of pesticides containing active substances of particular concern
3. Ensuring storage, handling, cleaning and disposal operations do not endanger human health or the environment through effective inspection, enforcement and other official control activities

PROTECTING PEOPLE AND PLACES HSE

UK Pesticides National Action Plan 2025 HSE Support

- **Action 6: Review regulatory barriers to innovation, particularly around precision application technologies: explore the potential benefits and drawbacks of pesticide application by drones and consider whether rules and guidance need to be amended.**
- Action 8: Continue to provide additional support to biopesticide applications.
- Action 9: Consider how we can make improvements to the arrangements for GB biopesticides to reduce burdens without compromising environmental and human health standards.
- Action 16: Review how membership of industry / assurance schemes might be taken into account as part of assessing users risk profiles, so inspections are better targeted.
- Action 17: Ensure guidance on the use of PPPs in particularly the 'Codes of Practice for using plant protection products' (and the Code of Practice for suppliers of pesticides to agriculture, horticulture and forestry), are updated to be current, remain clear and easily accessible, support compliance and embed IPM as a key part of our long-term approach to pest control.
- Action 18: Engage with online marketplaces to discuss findings of research regarding online sales of professional PPPs, and approaches to increasing visibility of the legal requirements of their use for the general public.

PROTECTING PEOPLE AND PLACES HSE

Review regulatory barriers to precision application technologies

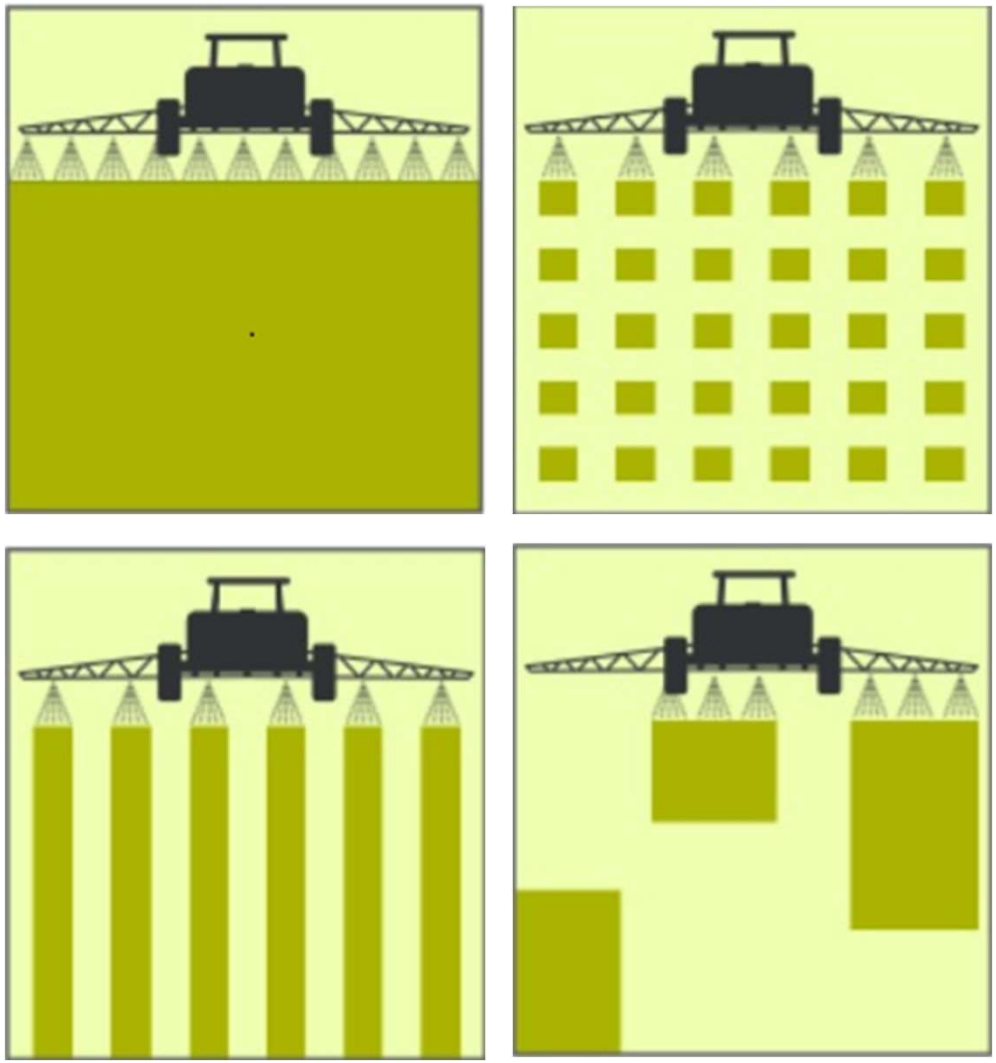
- Attractive to politicians and policy makers (Innovation and precision agriculture agenda);
  - Pesticide reduction/minimisation through ‘hyper-precise’ application.
  - Development of new skills and industries – exportable products and knowledge, adds value to the national economy.
  - Scope in sugar beet for ‘new’ technology and approaches
    - Non-chemical approaches
    - Low drift nozzles
    - Precision application
    - Unmanned aerial vehicles (UAVs)
  - But some technologies present challenges to risk assessment which need to be addressed.

National drone work

- Drone Stakeholder Group (industries, researchers and government)
- Working with key drone operating companies looking at interesting/challenging usage scenarios (bracken and amenity scenarios).
- Current ‘route to market’: Experimental Permits; EAMUs (only for minor uses); and Standard/Commercial-level Authorisations.
- Building an **evidence base** to inform future policy and regulatory considerations

Precision Application

- Current risk assessment relates to representative uses and generally aims to cover worst case uses.
- Precision application different to the standard technology currently evaluated and considered for risk assessment, although band application more commonly encountered.
- Activities include adapted risk assessments, including precision application as part of the product authorisation and potentially use recording and recognition



Sanitary and Phytosanitary Agreement

- Outcomes of SPS not yet not defined but target of 2027
- Concept of ‘dynamic alignment’ with EU.
- EU legislative changes, including EU simplification agenda (impact dependent on ability to shape)
- Mutual recognition – greater access to products but important to reflect GB conditions
- Access to active substances approved in the EU and not GB.
- Status of new & existing active substances approved in GB but not EU
- Wider market may increase numbers of product applications
- Treated seed/parallel products & wider trade implications
- Transitional arrangements important

Questions?