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The regulatory landscape

The now and the not yet...



"I'm not too good at the hurdles."



Aims

- Promote common understanding
- Anticipate the coming changes
- Prepare for afternoon sessions





Who governs pesticides?

- All EU legislation comes from European Commission
- UK is split between
 - Food Standards Agency
 - Chemicals Regulation Directorate
 (formerly Pesticide Safety Directorate)





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'Thematic Strategy' on The Sustainable Use of Pesticides



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Placing of plant protection products on the market Regulation (EC) No 1107/2009

In order to approve a new pesticide:

Doesn't harm people's health Has no unacceptable effects on the environment Is effective against pests



Move to 'hazard-based' approval system - potential to cause harm

Risk -potential for harm from exposure to the hazard You need both hazard and exposure for there to be a risk. Can be mitigated by

- Elimination
- Substitution
- Engineering control
- Operational procedures
- PPE





Product authorisations

• The EC is divided into three zones- Northern, Central, Southern





Legislation relating to residues





Harmonised MRLs - Regulation 396/2005





Derivation of MRLs

Use of Good Agricultural Practice

- Maximum rate
- Maximum number of applications
- Minimum spray interval between applications
- Shortest Harvest/ Withholding Interval
 Defined number of residue trials (8 or 16)
 Use of statistical tools (eg OECD calculator)
 Consumption habits (all consumers- short & long term)



Consumer Safety Assessment Toxicological limits



Building in safety to the evaluations

- Risk assessment- it is assumed that:
 - -ALL of the crop has been treated
 - -ALL of the crop has a residue at the MRL
 - The person is a high consumer of the crop (97.5th percentile)
- No account is taken of peeling (eg banana) or cooking (eg potato) which will reduce the residue the exposure



Representative samples

Defined 2002/63/EC

'intended to be representative of the lot in respect of its pesticide residue content'

- To generate reliable residue information sampling must be representative
- Important that all samples- industry and statutory are truly representative



- Consist of a minimum of 12 tubers (EU guidance 10)
- For lots over 500kg, tubers must be obtained from at least ten different places.
- Weigh a minimum of 1.2 kg (EU guidance 1kg)
- All the potatoes that make up a sample must be from the same batch number/lot.
- The sample must be tubers of the same variety.



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sub-surface sampling port in store or duct wall



AND THE NOT YET...

Review of pesticides





Candidates for substitution

- Hazard criteria based on intrinsic properties
- Required to identify 'Candidates for substitution'
 Not Chlorpropham
- January 2015 Standing Committee agrees , ai's currently approved and considered safe
- Evaluate if they can be replaced (substituted) by other adequate solutions (chemical and non-chemical)



Endocrine disruption (1107/2009)

- Distinguish between
 - Endocrine active substances- interact with our endocrine system WITHOUT causing adverse effects, i.e. a benign interaction. These can be natural (eg coffee, soya)
 - Endocrine disruptors (ED)-S able to interact with our hor (66 ai) could be lost including resulting in adverse effects conditions of use).

At the most strict definition Chlorpropham. New data for re-registration supports the case it is not an ED.

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Public consultation to define of sciencing criteria with likely conclusion mid-end 2016



10 year review

- Evaluation by a rapporteur member State and peer review by EFSA
- Approval conditions are specified, including new hazard criteria based on substances' intrinsic properties. These are:
 - Mutagenic

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- Carcinogenic or have Reproductive Toxicity 'negligible')
- Persistent Organic Pollutants (PoPs)
- Persistent Bio-accumulative and Toxic (PBT)
- Very Persistent / very Bio-accumulative (vPvB)

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Chlorpropham review

in 2017

Water Framework Directive (2000/60/EC)

- Implemented in UK by Water Environment (WFD) Regulations 2003
- requires all rivers, lakes, ground and coastal water to reach good ecological and chemical status
- sets limits on the amount of pesticides and other chemicals that are allowed in drinking water

Priority Substances Directive- 45 chemicals are on the current list- Priority Hazardous Substances (PHS) and 'Priority Substances' (PS) eg chlorpyrifos, isoproturon, bifenox and cypermethrin



2009/128/EC Sustainable Use Directive



26 Nov 2015





26 Nov 2016

Immediately



Summary

- Fewer pesticides will be available
- Risk to hazard based approach for review
- CIPC will be reviewed in 2017 and data package is already submitted
- Legislation supports integrated approaches combining chemical and non-chemical methods





