Changes to Chemical Regimes
BPR / PPP

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In partnership with Department for the Economy www.economy-ni.gov.uk

Biocidal Products Regulation (BPR)

- from 1/1/21

- Future for NI Businesses

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BPR > 1 January 2021
Future for NI Businesses

- Policy / Legal position
- Northern Ireland Protocol
- Biocidal Products for NI market
- Biocidal Products for GB market
    - Unfettered Access
- Biocidal Products for GB market
    - Not via unfettered access
    - GB BPR Transitional arrangements

UK's departure from the EU

- UK formally left the EU 31 January 2020
- Now in Transition Period until 31 December 2020
- Negotiations on-going on future trading relationship with EU
- Arrangements for biocides regulation largely unaffected by negotiation outcome
- Government has made clear it will maintain regulatory and legal autonomy in GB
  - But NI continues to follow EU

Legal Framework

- BPR ‘lifted and shifted’ into UK law via EU Withdrawal Act.
- 2019 Regulations amended BPR to work in UK for ‘no deal’
  - ECHA functions transferred to UK bodies (where still relevant)
  - COM decision making transferred to SoS with Devolved consent
  - Some aspects removed (eg mutual recognition, Union authorisation)
- 2020 Regulations:
  - Date to take effect shifted to ‘IP end day’
  - Changes to reflect Northern Ireland Protocol (becomes GB regime)
  - Includes full GB BPR transitional arrangements

Northern Ireland Protocol (NIP)

- Northern Ireland Protocol (NIP) is part of Withdrawal Agreement between the UK and the EU.
- Designed as a practical solution to avoiding a hard border on the island of Ireland, whilst ensuring that the UK, including Northern Ireland, could leave the EU as a whole.
- The NIP includes a number of special provisions which apply only in Northern Ireland from 1 January 2021.
  - One is that NI follows EU rules in a number of areas, including chemicals.
- NB. The NIP is not permanent, it is subject to ongoing consent by the people of NI.
  - First vote takes place in 2024.

Northern Ireland Protocol (NIP)
Biocidal Products for NI market

Due to the Withdrawal Agreement :

- NI will be subject to EU regulations for chemicals
- Biocidal products supplied in NI will be subject to EU BPR
- Applications for biocidal product authorisation to be submitted under EU BPR
- HSE will act on behalf of NI in processing product applications

Northern Ireland Protocol (NIP)

- Active Substance (Non)Approvals remain valid in NI (& GB)
- Biocidal product authorisations currently valid in UK remain valid in NI (& GB)
  - for NI products, Authorisation Holder must be established in EU or NI *
- EU Article 95 List becomes the GB Article 95 List
  - But will change over time

Northern Ireland Protocol (NIP)

- EU BPR requires authorisation holder to be established in EU
- GB BPR requires authorisation holder to be established in UK

This means from 1 Jan 2021:

- A company established in NI can hold an authorisation in:
  - NI (NB. the authorisation cannot be mutually recognised in EU)
  - EU
  - GB
- An EU established company can hold an authorisation in NI
- A company established in GB cannot hold an authorisation in NI unless also established in NI or EU

Northern Ireland Protocol (NIP)

Unfettered Access from NI to GB

- UK Government committed to 'unfettered access' for NI goods moving to the rest of the UK
- NB. Biocides = 'Highly Regulated Goods'
  - Notification procedure will apply
- Biocidal products with NI authorisation can automatically be made available in GB provided certain conditions are met. eg
  - Notification submitted to HSE
  - Company must be established in NI
  - Active substance must be approved in GB and supplier on GB Art 95 list

Unfettered Access from NI to GB

Notification procedure

- Share information with HSE
  - Same information as provided to ECHA for EU authorisation or to NI for NI authorisation
- Biocidal product can then be supplied 90 days after notifying HSE
- HSE may raise concerns (clock stops), amend or prohibit the product
- Renewals/changes also to be notified 90 days in advance
- No charge

Northern Ireland Protocol (NIP)

- The SI implementing the NIP and Unfettered Access was laid in parliament on 15th October.

  - This SI is available to view on gov.uk.

➢ Please visit the HSE transition pages for the latest information.

➢ Please also visit EHCA's website

Products for GB market

- The GB regime will reflect the EU framework, but they will operate independently ('Lift & shift' = no policy changes)
- HSE will act as competent authority for GB
- HSE loses access to ECHA IT tools
- HSE loses access to data stored in ECHA systems
- Existing active substance (non)approvals and biocidal product authorisations remain valid until normal expiry date

Products for GB market

Applications & data have to be resubmitted to HSE :

- For on-going applications :
  - within 90 days (UK=refMS/eCA) or 180 days (UK≠refMS/eCA) of the end of the TP
- For GB Art 95 listing
  - within 2 years from the end of the TP
- For already authorised products
  - at time of applying for renewal / change or when requested by HSE

Products for GB market

Companies have to be established in UK :

- For product authorisations :
  - within 1 year of the end of the TP
- GB Art 95 listing
  - within 2 years from the end of the TP
- For new applications :
  - at the time of submission of the application

Further Information

- Biocides section of the HSE website:
  http://www.hse.gov.uk/biocides/index.htm

- Biocides section of the HSE Transition pages:
  https://www.hse.gov.uk/brexit/biocides.htm

- Biocides e-bulletin:
  Sign up for free from our website (links above)

Thank you for listening

Plant Protection Product (PPP) regulation after the Transition Period

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Pesticides: Post 2020 Transition project , Defra
Rachel Brown
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What will we cover?

- Setting the scene – the current PPP regulatory regime
- UK's departure from the EU and the Northern Ireland Protocol
- Headlines on arrangements in GB
- Detailed arrangements in Northern Ireland
- Things for businesses to consider

PPPs – what is the current regulatory regime?

Main pieces of EU Plant Protection Product (PPPs) legislation:

- Regulation 1107/2009 – regulates the placing of PPPs on the market
- Regulation 396/2005 – regulates maximum residue levels (MRLs) of pesticides in food and feed
- Directive 2009/128/EC – a framework to encourage sustainable use of PPPs

HSE is the regulator on behalf of all 4 UK administrations

UK's departure from the EU

- UK formally left the EU 31 January 2020

- Withdrawal Agreement
  - Transition Period until 31 December 2020
  - Northern Ireland Protocol
  - Annex 2 of the Protocol includes 1107/2009 and 396/2005 (but not Directive 2009/128/EC)

What happens after the Transition Period?

From 1 January 2021:

- in GB (England, Scotland and Wales) Regs 1107/2009 and 396/2005 converted into national law.
- In NI, EU Regs 1107/2009 and 396/2005 continue to apply directly
- The Plant Protection Products (Sustainable Use) Regulations 2012 (which implemented the Directive) continue to apply in whole UK

Headlines on arrangements in Great Britain

- Independent pesticides regulatory regime
- Responsibility for active substance and maximum residue levels decisions repatriated
- All regulatory standards and technical requirements retained
- HSE acts as regulator on behalf of Defra and Devolved Administrations
- Inevitably some divergence from EU

Trade between GB and NI

- PPP regime and MRL regime place controls on placing of goods on the market, rather than movement of goods
- PPPs must be authorised for use and sale in each part of the UK (as now)
- UK Internal Market Bill
  - treated produce from NI will be able to be placed on GB market even if MRLs diverge

PPP Operational headlines – Active Substances

- Existing active substance approvals will continue to be valid in NI and GB.
- Applications for new active substance approvals will be submitted in the same format to HSE.
- To gain access to both GB and NI markets, the application needs to be considered under both regimes.
- When an active substance is approved in GB, it will be included in a statutory active substance register which will be published on the HSE website from 1 January 2021.
- The EU list of approved active substances published under Commission Implementing Regulation (EU) No 540/2011 will continue to apply in NI.
- The two active substance registers may diverge over time.

PPP Operational headlines – Active Substances

- A GB programme for the review of the safety of active substances is being developed. HSE retain the power to review active substance approvals, should new evidence identify any concerns to human health or the environment.
- Active substance approvals due to expire before December 2023 will be extended for 3 years to allow time to implement the GB review programme.
- Need to establish national renewals programme in a way which maintains effective protection and is manageable and proportionate.

PPP Operational headlines - MRLs

- Existing MRLs will continue to be valid in NI and GB.
- After the transition period, EU MRLs will continue to apply in NI.
- GB will set MRLs based on GB assessments, and publish them in a statutory register.
- New GB MRL applications will be submitted in a similar format, with no change in data requirements
- MRLs may begin to diverge in GB and EU therefore businesses should check requirements of target market.
- UK Internal Market Bill going through parliament allows a principle of mutual recognition which will apply to MRLs, to avoid trade barriers for food in the UK.

PPP Operational headlines – Products (1)

- Existing authorisations will continue to be valid in GB and NI.
- HSE will process PPP applications for both GB and NI.
- After the end of the transition period, applicants will require authorisation under both the GB and NI regimes to gain access to GB and NI markets.
- New applications - no changes in data requirements or format.
- We will continue to use evaluations from other jurisdictions where appropriate.

PPP Operational headlines – Products (2)

- Applications will be processed as usual, with some exceptions:
  - Mutual Recognition applications cannot be accepted for authorisation in GB, but can be accepted for authorisation in NI.
  - Parallel import application cannot be accepted for GB, and existing permits continue until their current expiry date or until 31 December 2022, whichever is the sooner. PI's will continue to be authorised in NI.
- Authorisations issued after the end of the Transition Period will specify whether they are valid in GB or NI only or both.
- New Application forms will include an option to select authorisation in GB or NI only or both.

PPP Operational headlines – Products (3)

- Where possible, HSE will maintain a common MAPP Number for products marketed in NI and GB.
- Similarly we aim to allow common labelling.
- Divergence may occur:
  - As a result of changes to expiry dates in active substances,
  - If GB takes a different decision to the EU,
  - If GB makes a decision at a different time to the EU.
- Divergence will impact on conditions of authorisations, data protection periods and MAPP numbers.

What should NI businesses do?

- Approval holders/ manufacturers operating in NI – consider pipeline of applications for both GB and NI. Talk to HSE!

- Food businesses in NI – no major change. EU MRLs continue to apply in NI and compliance with these will also enable sale of treated produce in GB.

- Pesticide users – no major change. Follow instructions on label. Engage in action to use pesticides responsibly, minimise use and make use of non-chemical methods where possible.

Further Guidance

HSE will continue to publish information on the HSE ‘Brexit’ webpage

http://www.hse.gov.uk/Brexit/

If you require further assistance or guidance, please contact

EU-Exitchemicals@hse.gov.uk

Questions

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Useful links

BIOCIDES

ECHA – understanding the Biocidal Products Regulations (BPR)
https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

HSE – biocides – FAQ
https://www.hse.gov.uk/biocides/faq.htm

ECHA – information on biocides
https://www.echa.europa.eu/information-on-chemicals/biocidal-products

PLANT PROTECTION PRODUCTS

HSE – Pesticides
https://www.hse.gov.uk/pesticides/

HSE – Regulating pesticides after the transition period
https://www.hse.gov.uk/brexit/regulating-pesticides.htm

DAERA – UK Government guidance to the pesticide industry
https://www.daera-ni.gov.uk/articles/uk-government-issues-guidance-pesticide-industry

DAERA website
https://www.daera-ni.gov.uk/topics/plant-and-tree-health/pesticides-use-and-regulations

European Commission – guidelines on active substances & plant protection products (PPP)
https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en