



Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT BY THE WELSH GOVERNMENT

TITLE	The Biocidal Products (Health and Safety) (Amendment and Transitional Provisions etc.) Regulations 2024
DATE	14 March 2024
BY	Lesley Griffiths MS, Minister for Rural Affairs and North Wales, and Trefnydd

Members of the Senedd will wish to be aware that we are giving consent to the Secretary of State exercising a subordinate legislation-making power in a devolved area in relation to Wales.

Agreement was sought by Viscount Younger of Leckie, Parliamentary Under Secretary of State for Work and Pensions to make a Statutory Instrument (SI) titled the Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024 to apply in relation to Great Britain.

The above titled SI will be made by the Secretary of State in exercise of powers delegated to them in Article 85 and Article 83A(2) of Great Britain Biocidal Products Regulation (EU) No 528/2012 (GB BPR) (adaptation to scientific and technical progress).

Statutory Instrument (SI) to modify Annexes II and III of the Great Britain Biocidal Products Regulation (EU) No 528/2012 (GB BPR), concerning making available on the market and use of biocidal products to introduce technical updates to Annexes II and III of the regulations which will enable:

- A reduction in the need for animal testing
- Alignment with current guidance and Organisation for Economic Co-operation and Development validated tests
- HSE to ensure scientific progress is monitored and developments are reflected.

The regulations were laid before Parliament on 13 March 2024 and come into force on 6 April 2024.

Any impact the SI may have on the Senedd's legislative competence and/or the Welsh Ministers' executive competence

Members will wish to note that the Regulations do not transfer any functions to the Secretary of State.

The purpose of the amendments

Biocidal products are used to protect people and animals, preserve goods, stop pests like insects or rodents and control viruses, bacteria and fungi through a chemical or biological action. The Health and Safety Executive (HSE) carries out the role of competent authority for GB BPR on behalf of the Secretary of State and Ministers in Scotland and Wales which includes authorising biocidal products for supply and use in Great Britain.

Under GB BPR, both biocidal active substances (the substances which produce the biocidal effect) and the products which contain them are subject to rigorous scientific assessment for the potential risks to humans, animals and the environment, and of their effectiveness before they can be made available on the market. Regulatory scientists in HSE's Chemicals Regulation Division undertake the assessments following an application made by a business or businesses who wish to approve a biocidal product or active substance. To allow assessments to take place, applicants must submit dossiers of information covering matters such as toxicity, effects on the environment, effectiveness, etc. The requirements for the information which must be submitted are set out in Annexes II (for active substances) and III (for biocidal products) of GB BPR.

Since the Regulation was published in 2012, scientific and technological advances have been made in testing, which allow some properties which could previously only be determined through testing using live animals to be tested using alternative approaches, as well as new test methods becoming available to reliably determine effects which could previously not be tested for (such as those to determine effects on developing nervous systems in fetuses).

The purpose of the current statutory instrument (SI) is to update the requirements listed in Annexes II and III to include these more up to date test methods. This is purely a technical update and will bring the GB system into line with the technical guidance that is currently used and with the EU's BPR, where such changes have already been implemented.

The Regulations and accompanying Explanatory Memorandum, setting out the detail of the provenance, purpose and effect of the amendments is available here:

<https://www.legislation.gov.uk/ukxi/2024/352/contents/made>

Why consent has been given

Consent has been given for the UK Government to make these changes in relation to, and on behalf of, Wales to ensure scientific and technological advances which extend our ability test for potentially harmful effects of biocides are incorporated into the regulations and to

enable a reduction in the necessity for animal testing, as well as to preserve the interconnected nature of the GB biocidal regime.