Net Zero, Energy and Transport Committee

8th Meeting, 2023 (Session 6)

Tuesday, 27 February 2023

UK subordinate legislation: consideration of consent notification

Introduction

1. This paper supports the Committee's consideration of a 'type 1' consent notification sent by the Scottish Government relating to the following proposed UK statutory instrument (SI)— Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024

Process for parliamentary scrutiny of consent notifications in relation to UK statutory instruments

2. The process for the Scottish Parliament's consideration of consent notifications is set out in a Protocol on scrutiny by the Scottish Parliament of consent by Scottish Ministers to UK secondary legislation in devolved areas arising from EU Exit.

3. The Protocol provides for the Scottish Parliament to scrutinise the Scottish Government's decisions to consent to certain subordinate legislation made by the UK Government: specifically, UK Government subordinate legislation on matters within devolved competence in areas formerly governed by EU law. It sets out a proportionate scrutiny approach and categorises SI notifications as 'type 1' or 'type 2'.

4. Type 2 applies where all aspects of the proposed instrument are clearly technical (e.g., they merely update references in legislation that are no longer appropriate following EU exit) or do not involve a policy decision. These are notified retrospectively, after the Scottish Government has given its consent.

5. All other proposals are type 1. In this case, the Scottish Parliament's agreement is sought *before* the Scottish Government gives consent to the UK Government making subordinate legislation in this way. Each type 1 notification must be considered by the relevant Committee.

6. **The Committee's role in relation to type 1 notifications is to decide whether it agrees with the Scottish Government's proposal to consent to the UK**

Government making Regulations within devolved competence, in the manner that the UK Government has indicated to the Scottish Government.

7. If Members are content for consent to be given, the Committee will write to the Scottish Government accordingly. The Committee may also wish to note any issues in its response or request that it be kept up to date on any relevant developments.

8. If the Committee is not content with the proposal, however, it may recommend that the Scottish Government should not give its consent (more detail on the options available to the Committee in relation to this particular notification is given below). In that event, the Scottish Ministers have 14 days under the Protocol to respond to the Committee's recommendation. They could—

- Agree. If so, the Scottish Ministers would then withhold their consent.
- Not agree. If so, Parliament will debate the issue.

9. If the Parliament agrees to the Committee's recommendation that the Scottish Ministers should not consent, the Protocol provides that the Scottish Ministers should "normally not consent" to the UKSI. However, the Protocol also provides that if the Scottish Ministers consider that the Committee's proposed alternative cannot be achieved, they may consent to the UK SI. If so, they must explain why they are doing so to the Scottish Parliament.

Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024

10. On 24 January, the Cabinet Secretary for Transport, Net Zero and Just Transition wrote to the Committee to notify the Scottish Government's proposal to consent to the UK SI. This correspondence is in **Annexe A**. The SI notification is available in **Annexe B** and the summary notification in **Annexe C**.

11. The proposed instrument is expected to be laid before the UK Parliament on 5 March. The Committee has therefore been asked to respond by **29 February**.

12. The proposed SI will amend Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products ("the GB BPR"), which replaced the equivalent "EU BPR" after EU exit.

13. The amendments relate to the information requirements in Annexes II and III to the GB BPR. These concern the relevant information required to be submitted as part of the dossier for an application, to seek approval for a biocidal active substance and to bring to market a biocidal product that contains one or more active substances.

14. The changes are to reflect advances in regulatory scientific understanding, techniques and methodology since the publication of the EU BPR in 2012. These advances mean that several information requirements can now be updated, allowing

the provision of better information and an overall reduction in the need for animal testing in the safety assessment of biocidal active substances and products. These updates will also align the GB BPR Annexes II and III with those of the (updated) EU BPR. The notification states that: "There are some minor differences between these updates that do not affect overall functional alignment with the EU BPR."

15. The proposed SI will be made under the powers in articles 85(1) and 83A(2) of the GB BPR. These powers are only exercisable by UK Ministers, and there is no power for provision to be made by joint procedure (that is, by an instrument laid in both the UK Parliament and Scottish Parliament). There is a statutory requirement that UK Ministers must obtain the consent of Scottish Ministers before making this instrument, as set out in Article 85(2) and 83(B). Accordingly, it cannot be made as proposed unless the Scottish Ministers consent.

16. The Health and Safety Executive (HSE) consulted on the proposed changes from 17 January to 14 March 2023. The notification states that "A summary report of the consultation's responses is in preparation". Scottish Parliament officials informally sought more information from Scottish Government officials regarding whether the Scottish Government had accessed consultation responses or had received any stakeholder feedback directly raising any concerns. Scottish Government officials confirmed that the consultation responses and draft consultation response report, had not been provided, although HSE have agreed to share a draft when ready, and its understanding was that the only thing of significance the consultation returned was on timings for requirements to be phased in (as a result of which the instrument was amended to extend the phase in period from 12 to 18 months).

17. SPICe has highlighted that in the absence of the consultation analysis, scrutiny of the instrument is more challenging. However, Scottish Government officials have provided reassurances that divergences from the EU BPR are minor and aimed at reducing animal testing requirements, and the available information indicates that there are no major stakeholder concerns.

Next steps

18. If the Committee wishes to approve the proposal to consent to the SI, it may, in doing so, set out any observations or concerns in its letter to the Scottish Government that it thinks are relevant.

19. If the Committee is not content with the proposal, however, it may make one of the following recommendations—

I. That the Scottish Government should not give its consent to the provision being made in a UK SI and that the Scottish Government should instead produce an alternative Scottish legislative solution (though, since the particular powers being used are available only to UK Ministers, Scottish Ministers would need to find a different way to make this provision); or

II. That the provision should not be made at all (that is, that the Scottish Government should not consent to the provision being included in a UK

SI, nor should the Scottish Government take forward an alternative Scottish legislative solution).

20. If the Committee recommends that the Scottish Government should not consent, it should write to the Scottish Government, setting out which of the options for non-consent (see above), reflects its view.

Clerks
Net Zero, Energy and Transport Committee

ANNEXE A: Correspondence from the Cabinet Secretary for Transport, Net Zero and Just Transition

Edward Mountain, MSP
Convener of the Net Zero, Energy and Transport Committee
Scottish Parliament
Edinburgh
EH99 1SP
Copied to UKSIs@parliament.scot

24 January 2024

Dear Edward,

THE BIOCIDAL PRODUCTS (HEALTH AND SAFETY) (AMENDMENT AND TRANSITIONAL PROVISION etc.) REGULATIONS 2024 – EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

I am writing in relation to the protocol on obtaining the approval of the Scottish Parliament to proposals by the Scottish Ministers to consent to the making of UK secondary legislation affecting devolved areas arising from EU Exit.

That protocol, as agreed between the Scottish Government and then Parliament, accompanied the letter from the then Cabinet Secretary for Government Business and Constitutional Relations, Michael Russell MSP, to the Conveners of the Finance & Constitution and Delegated Powers and Law Reform Committees on 4 November 2020 and replaced the previous protocol that was put in place in 2018.

I attach a Type 1 notification which sets out the details of the SI which the UK Government proposes to make and the reasons why I am content that Scottish devolved matters are to be included in this SI. The SI relates to the biocidal regulatory regime that operates in Great Britain (in Northern Ireland the equivalent EU legislation continues to apply). We have received a copy of the final draft of this SI and I am content that it is in keeping with the terms of this notification.

The UK Government consent request, received on 17 January 2024, requests a response from Scottish Ministers by 27 February 2024. As this timeline would not provide the Scottish Parliament with the full 28 days scrutiny, I have written to the UK Government to ask them to accommodate the necessary time for scrutiny ahead of the proposed laying date of the SI on 5 March. In the expectation that UK Government affords Scottish Ministers more time to respond, I look forward to hearing from you by 29 February 2024.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee.

Yours sincerely,

MAIRI MCALLAN

ANNEXE B: NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s)

The Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024

Is the notification Type 1 or Type 2

Type 1

Brief overview of the SI

The Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024 ("the 2024 regulations") amend the assimilated EU law Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ("the GB BPR");

Previous amendments to this instrument were made by the Biocidal Products (Health and Safety) (Amendment) Regulations 2022 ("the 2022 regulations").[1]

The UK Government Department for Work and Pensions intends to lay the 2024 regulations at Westminster under the negative procedure on 05 March 2024. The 2024 regulations will come into force on 06 April 2024.

Details of the provisions that Scottish Ministers are being asked to consent to.

The GB BPR regulates the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, such as pests or bacteria, by the action of the active substance contained in the biocidal product. It establishes a list of active substances that may be used in biocidal products. Only authorised biocidal products can be made available for use, following evaluation of a company's authorisation application. The GB BPR is now assimilated law; it was previously amended following Implementation Period ("IP") completion day to ensure that it operated effectively (as retained EU law) in GB.

Under the GB BPR, Scottish Ministers are designated as the competent authority for Scotland, but under an agency agreement, the Health and Safety Executive ("HSE") acts as the competent authority on behalf of Scottish Ministers. Through agency agreements which were updated post EU exit, HSE continues to undertake the functions of the competent authority throughout the UK. The GB BPR does not

[1] The 2022 regulations were notified to the Scottish Parliament on 23 September 2022: NZET_Committee_2022.10.04_SI_The_Biocial_Products_Notification.pdf (parliament.scot). The Scottish Parliament agreed with Scottish Ministers' intention to consent to the 2022 regulations on 04 October 2022 and these regulations were subsequently made on 31 December 2022.

apply to Northern Ireland which remains subject to the EU BPR as required by the Protocol on Northern Ireland.

The 2024 regulations will be made under articles 85(1) (and article 83A(2)) of the GB BPR. Article 85(1) that enables amendments which take account of current scientific and technical knowledge to be made to Annexes II (information requirements for active substances) and III (information requirements for biocidal products) of the GB BPR. These amendments are being made so that the GB BPR remains closely aligned with similar changes made to the equivalent EU law version of Regulation (EU) No 528/2012 by Commission Delegated Regulation (EU) 2021/525 of 19 October 2020 amending Annexes II and III to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products. Commission Delegated Regulation (EU) 2021/525 took effect from March 2022. The 2024 regulations do not amend the GB BPR retrospectively; only new or renewal applications under the GB BPR will be in scope of these changes. The requirements being inserted by the 2024 regulations will apply to applications made after 6 October 2025. The 2024 regulations will, however, include a transitional provision to allow applicants in the intervening period to choose whether to comply with Annexes II and III as amended by the 2024 regulations or as they are at present. A similar derogation allowing in effect voluntary compliance with the new requirements was provided for in Commission Delegated Regulation (EU) 2021/525.

Amendment to Annexes II and III of the GB BPR

Annexes II and III to the GB BPR set out the information requirements applicants seeking approval for a biocidal active substance (Annex II) and wishing to bring to market a biocidal product containing an active substance (Annex III) must prepare. This information has to be submitted as part of their application to the HSE. Information requirements include intrinsic substance properties and identification, methods of manufacture, substance hazards (toxicity to humans and effects in the environment), efficacy, and unintended impacts (e.g. impacts on “non-target organisms” or on the material being protected by the biocidal product). This information is essential for applicants to understand the properties of their active substances/products and for the HSE to carry out its evaluation of the active substance and products that contain it, to conclude if they meet the safety and efficacy criteria for approval and authorisation to the GB market.

Since 2012, when what is now the GB BPR was first published by the EU, there have been advances in scientific understanding and safety assessment, including the development of new testing techniques and methodologies. The 2024 regulations implement changes to Annexes II and III reflecting these advances. The main changes are to testing requirements, including on hierarchies of information, on hazards to humans (specifically, the toxicological “endpoints” skin irritation/corrosivity, skin sensitisation, eye damage and irritation, as well as tests used to identify potential longer term effects including neurological, reproductive and developmental toxicity, and carcinogenicity). Similar changes have been made to information requirements for the environment around effects on fish.

These changes are designed to reduce or remove the need for animal testing in many instances, whilst maintaining certainty and robustness in the information available for hazard and risk assessment. An information and testing hierarchy is also introduced to investigate endocrine (hormone) disrupting properties for humans and the environment. In Annex II, some information requirements have been amended to include active substance precursors and *in situ* generated active substances, as these were omitted in the original EU BPR in 2012 whilst being in scope of the provisions contained in the then EU BPR. In Annex III, additional requirements for any "non-active substance" constituents of potential concern have been added. Finally, various clarifications to existing information requirements have been included to provide clarity and remove ambiguity.

These updates will align the GB BPR Annexes II and III with those of the EU BPR, with minor differences that do not affect overall alignment and are briefly described below. Some of the differences reflect clarifications or corrections of minor oversights in the EU BPR amendment drafting. The more notable differences concern some toxicological endpoints (for the human health hazard assessment) where the GB approach is designed to reduce necessary animal testing beyond those in the equivalent EU regulations, while still providing information suitable for regulatory use. For example, the GB regulations stipulate that the information requirements for the hazard endpoint *in vivo genotoxicity* can be fulfilled by integrating this into repeated dose toxicity testing, should this study be required, thereby removing the need for an additional study. A related approach is taken for the endpoint *developmental neurotoxicity*, where the GB regulations allow the use of alternative information to conclude on this endpoint where this is possible, again avoiding the necessity of an additional animal test. Overall, the amendments to the EU and GB BPR should result in a reduction in the need for animal testing compared with the previous iteration of the GB BPR. The HSE's approach under GB BPR for some endpoints should take this further, whilst still allowing clear conclusions to be made for relevant hazard endpoints and not conflicting with EU requirements.

Summary of the proposals

The purpose of the 2024 regulations is to update the Annexes II (for active substances) and III (for biocidal products) of the BPR to take account of current scientific and technical knowledge. These Annexes set out the information required to be submitted as part of the application to approve an active substance for use in GB products and for bringing a biocidal product to the GB market.

The HSE undertake assessments of dossiers prepared by applicants. These highly technical submissions include information gathered by the applicant in accordance with the information requirements set out in Annexes II and III to the GB BPR. Consistency and scientific rigour in all such information is essential, with testing needing to be conducted according to internationally agreed standards. Since the publication of the then EU BPR in 2012, there have been various advances in the scientific understanding and assessment techniques and methodologies. These now allow for some properties, which could previously only be determined through testing on live animals, to be derived using alternative approaches.

The 2024 regulations update the requirements listed in Annexes II and III to include these more up to date test methods and approaches. These updates will align information requirements of the GB BPR with those of the EU BPR, except for some minor differences in drafting and minor divergence on specific human health hazard endpoints (where the difference is scientifically justified as described above).

Chemicals policy, including in relation to biocides, engages a complex mixture of reserved and devolved competence. Environmental protection, waste management and public health are devolved while product safety, animal testing as well as health and safety at work are reserved.

Does the SI relate to a common framework or other scheme?

Yes. The GB BPR forms part of the Chemicals and Pesticides Common Framework.

Summary of stakeholder engagement/consultation

UK Government previously undertook a UK-wide consultation on the changes. A summary report of the consultation's responses is in preparation. As a result of the consultation the "phase in" period for these changes was extended from 12 to 18 months.

A note of other impact assessments, (if available)

UK Government carried out an Impact Assessment on the impact of the changes the 2024 regulations represent for the GB biocides industry as a whole. This estimated one-off familiarisation costs of around £400,000, applying to around 2,950 businesses involved in the manufacture of biocidal products and active substances, equating to around £136 per business. In addition, businesses undertaking additional required tests for new and renewal biocidal active substance dossiers would incur ten-year present value costs of between around £150,000 and £550,000, depending on the amount of testing required. This cost equates to a single active substance application being made within a 10-year period. It should be noted that as the information requirements that are the subject of the 2024 regulations already apply in the EU, it is likely that for those GB-based companies that also trade in the EU these new and amended information requirements will already have been met (and so these costs will not apply under GB BPR as they will already have been incurred in relation to a parallel EU BPR application).

While the proposals introduce technical changes which relate to the information requirements applicants seeking approval for a biocidal active substance or wishing to bring to market a biocidal product containing an active substance, the proposals do not constitute an overall policy change in relation to biocides. The overall policy intention aims to ensure that the requirements on applicants seeking approvals take account of current scientific and technical knowledge.

Summary of reasons for Scottish Ministers' proposing to consent to UK Ministers legislation

Scottish Ministers consider that the 2024 regulations improve the information requirements for the HSE's evaluation of applicants' dossiers for biocidal active substances and products. These changes should result in an overall reduction in the need for animal testing, will allow the submission of additional important information, and will clarify other aspects of the process for applicants.

The 2024 regulations also update the data requirements for GB broadly aligning them with the EU. A few minor differences as described above mean that under GB BPR data will not be requested where it is not needed, but that it will still be possible to reach clear conclusions that are suitable for HSE's evaluation of applications.

Officials have worked with HSE to ensure the drafting delivers for our interests and respects devolved competence in Scotland, and so Scottish Ministers propose to agree to a GB approach for these amendments. This GB approach ensures that the requirements on applicants seeking approvals are broadly aligned with the requirements under the equivalent EU BPR. As set out above, the proposals contain very minor differences from the EU BPR provisions where the difference is scientifically justified, but this is not considered to negatively impact the Scottish Government's commitment to align with the European Union.

Intended laying date (if known) of instruments likely to arise

This instrument is subject to the negative procedure and will be laid for sifting at Westminster on 05 March 2024.

If the Scottish Parliament does not have 28 days to scrutinise Scottish Ministers' proposal to consent, why not?

Scottish Ministers request a response by 29 February, which should allow the Scottish Parliament 28 days to scrutinise this proposal.

Information about any time dependency associated with the proposal

None

Are there any broader governance issues in relation to this proposal, and how will these be regulated and monitored post-withdrawal?

None.

Any significant financial implications?

None.

Lead Official: Dan Merckel, Environmental Quality & Resilience
Lead SGLD Lawyer: Ailsa Heine

ANNEXE C: SI NOTIFICATION: SUMMARY

Title of Instrument The Biocidal Products (Health and Safety) (Amendment and Transitional Provision etc.) Regulations 2024
Proposed laying date at Westminster 05 March 2024
Date by which Committee has been asked to respond 29 February 2024
Power(s) under which SI is to be made Article 85(1) (and article 83A(2)) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.
Categorisation under SI Protocol Type 1
Purpose This instrument amends the following assimilated law: Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products ("the GB BPR"), which replaced the equivalent "EU BPR" after EU exit. This negative instrument makes amendments to the information requirements in Annexes II and III to the GB BPR. These concern the relevant information required to be submitted as part of the dossier for an application, to seek approval for a biocidal active substance and to bring to market a biocidal product that contains one or more active substances. The HSE evaluates these applications, acting as competent authority on behalf of Scottish Ministers. Since the publication of the then EU BPR in 2012, there have been advances in regulatory scientific understanding, techniques and methodology. These advances mean that several information requirements can now be updated, allowing the provision of better information and an overall reduction in the need for animal testing in the safety assessment of biocidal active substances and products. These updates will also align the GB BPR Annexes II and III with those of the (updated) EU BPR (as amended inter alia by Commission Delegated Regulation (EU) 2021/525). There are some minor differences between these updates that do not affect overall functional alignment with the EU BPR.
Other information No further information.
SG Policy contact: Dan Merckel [REDACTED] **SG Legal Dept contact:** SGLD lawyer: Ailsa Heine [REDACTED]