Net Zero, Energy and Transport Committee

26th Meeting, 2022 (Session 6), Tuesday 4 October 2022

UK statutory instruments - consideration of consent notification

Note by the Clerk

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)—

   The Biocidal Products (Health and Safety) (Amendment) Regulations 2022

Process for parliamentary scrutiny of consent notifications for 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 secondary legislation made by the UK Government. Specifically, this relates to UK Government secondary legislation on matters which are within devolved competence and are in areas formerly governed by EU law.

4. The protocol establishes a proportionate scrutiny approach and categorises SIs as type 1 or type 2.

5. 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. For type 2 SI notifications, the Scottish Government will notify the Scottish Parliament within five days *after* giving consent. The relevant Committee will be notified of the legislative proposal. But they do not need to formally consider it at a committee meeting. The protocol includes a number of review mechanisms and the categorisation of type 2 notifications will be monitored in this way.

6. 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 secondary legislation in this way. Unless they are classed as urgent, the Scottish Parliament has 28 days to consider them. Each type 1 notification must be considered by the relevant Committee

7. **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.**

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

9. If the Committee is not content with the proposal, however, it may make one of three 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;
    II. That the Scottish Government should not consent to the provision being made in a UK SI laid solely in the UK Parliament and should instead request that the provision be included in a UK SI laid in both Parliaments under the joint procedure; or
    III. 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).

The Biocidal Products (Health and Safety) (Amendment) Regulations 2022

10. On 23 September 2022, the Minister for Environment and Land Reform wrote to the Committee to inform them of this forthcoming UK instrument. A copy of this correspondence can be found in **Annexe A**. The SI Notification is available in **Annexe B** and the Summary Notification in **Annexe C.**

11. The UK Government intends to lay this SI before Parliament on **17 October 2022.** The date by which the Committee has been asked to respond on the notification is **11 October 2022.** The reasons for the short reporting deadline for this instrument was described as—

    "A final draft SI was received on 7 September 2022. Following the announcement of Her Majesty's death, Parliament was suspended before this notification could be made. The laying date of 17 October 2022 has not changed, so in these exceptional circumstances there are fewer than 28 days

available for scrutiny. Should a change be made to the laying date, the committee will be informed immediately."

12. The new instrument seeks to amend the GB Biocidal Products Regulation (the GB BPR), which is the regime imported from EU law into domestic law following EU withdrawal that regulates the use of biocidal products. The amendments change the evaluation deadlines set for the Competent Authority, the Health and Safety Executive, to complete its assessment of certain types of applications for biocidal products.

13. According to the notification, the instrument will amend the GB BPR in three ways—

- for relevant authorisation applications, postpone the deadline for notification of appropriate fees and evaluation deadline until 31 December 2027;
- extend the period in which certain biocidal products authorised under domestic law may continue to be used and made available on the GB market without authorisation under the GB BPR;
- introduce a new transitional provision for applications to change or modify an authorisation made under the EU BPR before IP completion day to be transferred to the GB BPR.

14. In order to make these changes to evaluation deadlines, the instrument will amend the following retained 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");
- Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ("Implementing Regulation 354/2013"); and,
- Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ("Implementing Regulation 414/2013").

15. The Scottish Government has been asked to consent to this instrument as Scottish Ministers are delegated as the Competent Authority in relation to the use of biocidal products in Scotland, however under an agency agreement HSE currently acts as the Competent Authority on behalf of Scottish Ministers.

16. Scottish Ministers intend to provide consent to the SI on the grounds that "the extension of evaluation deadlines will mean the protection of the environment and human health for the use of affected products currently on the GB market will rely on existing conditions of use, set in previous evaluations". The Scottish Government also say they are satisfied that potential changes in scientific knowledge in relation to active substances contained in biocidal products which could affect these solutions are unlikely to be a major issue.

Evidence session on Tuesday, 4 October 2022

17. Given the lack the time to consider the notification, the Convener has invited the Scottish Government to attend the 4 October meeting, for a short evidence session on it. The Committee will discuss the notification and any potential policy implications the proposal may have on environmental regulations in Scotland with Màiri McAllan, Minister for Environment and Land Reform, and Scottish Government officials.

For decision

18. Following the evidence session, the Committee will be formally invited, under the next agenda item, to consider whether it agrees with the Scottish Government that the proposals set out in the notification should be included in the UK SI.

ANNEXE A

Letter from the Minister for Environment and Land Reform to the Convener, 23 September 2022

Dear Edward,

THE BIOCIDAL PRODUCTS (HEALTH AND SAFETY) (AMENDMENT) REGULATION 2022 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 use of biocidal products available on the open market in Great Britain. We received a finalised draft SI on 7 September 2022 and the notification reflects this latest version. We will, in accordance with the protocol, advise you when the final SI is laid and advise you as to whether the final SI is in keeping with the terms of this notification.

As the final draft SI was received the day before the death of Her Majesty and start of the official mourning period, unfortunately the minimum period of 28 days' scrutiny are not available before the proposed laying date of 17 October 2022, which I understand has not been changed (should a change be made to the laying date, I will inform you immediately). Given these exceptional circumstances I hope you can understand my request for consideration of the SI to a faster timescale, if at all possible.

I am, as ever, grateful for your consideration of the attached notification and look forward to hearing from you by 11 October 2022. I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee.

Yours sincerely,

MÀIRI MCALLAN

ANNEXE B

NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s)

The Biocidal Products (Health and Safety) (Amendment) Regulations 2022

Is the notification Type 1 or Type 2

Type 1

Brief overview of the SI

The Biocidal Products (Health and Safety) (Amendment) Regulations 2022 ("the 2022 regulations") amend the following retained EU law:

1. 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");
2. Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ("Implementing Regulation 354/2013"); and,
3. Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council ("Implementing Regulation 414/2013").

Previous amendments to these instruments were made by the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 ("the 2019 regulations").[1]

The UK Government Department for Work and Pensions intends to lay the 2022 regulations at Westminster under the affirmative procedure on 17 October 2022. The 2022 regulations will come into force on 31 December 2022.

[1] The 2019 regulations were notified to the Scottish Parliament on 7 December 2018: ECCLR_2018.12.07_SI_GMO_Notification.pdf (parliament.scot). The Scottish Parliament agreed with Scottish Ministers' intention to consent to the 2019 regulations on 16 January 2019 and these regulations were subsequently made on 27 March 2019. The 2019 regulations were amended by the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020 ("the 2020 regulations"). The 2020 regulations were notified to the Scottish Parliament on 28 September: Chemicals_and_Genetically_Modified_Organisms_2020_2nd_SI_-_Notification.pdf (parliament.scot). The Scottish Parliament agreed with Scottish Ministers' intention to consent to the 2020 regulations on 3 November 2020 and these regulations were subsequently made on 16 December 2020.

Details of the provisions that Scottish Ministers are being asked to consent to.
The GB BPR concerns 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 2019 regulations amended the GB BPR on Implementation Period ("IP") completion day to ensure that it could operate as retained EU law.

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

The GB BPR contains transitional provisions for two categories of authorisation application:

- Resubmitted applications

These are applications made prior to the end of the transition period under the EU BPR, but for which no decision on authorisation had been made before IP completion day. The 2019 regulations amended the GB BPR to include transitional provisions that allow applications in this category to be transferred to the GB BPR, provided the applicant has resubmitted its application.

- Applications for biocidal products authorised under UK law

These are applications for biocidal products that were authorised under UK domestic law before the EU BPR came into force in 2012. These transitional provisions were in existence prior to EU exit as part of the EU BPR. Article 89 of the GB BPR allows these biocidal products to remain on the Great Britain ("GB") market (without authorisation under GB BPR) for three years following the approval of the last active substance in the biocidal product under the GB BPR.

Following EU Exit, HSE is considering applications across both categories. It needs further time to complete the evaluation of those applications and therefore it is necessary to extend the current deadlines of the GB BPR. This is due to a loss of access to EU data following the UK's exit from the EU BPR regime and delays associated with the evaluation of resubmitted applications to HSE. Failure by HSE to grant authorisation for an application within the evaluation deadlines set by the GB BPR will mean that the application will not be dealt with by the competent authority in accordance with the GB BPR.

Amendment of deadlines for resubmitted applications

Once a resubmitted application is received by HSE, the application is subject to the evaluation deadlines of the GB BPR. Depending on the type of authorisation

application, the relevant deadlines for evaluation by HSE are set out in Articles 26, 29 and 30 of the GB BPR or Articles 7 and 8 of Implementing Regulation 354/2013 (which sets out the procedure for applications to amend a GB BPR authorisation). The EU BPR requires that an evaluation is completed within a certain period after the applicant has paid the required fee. The 2022 regulations amend the deadlines set out in those articles. The date by which HSE must inform the applicant of the appropriate fees is postponed until 31 December 2027. This will delay the beginning of the evaluation process until that date, at the latest. The 2022 regulations also postpone, until 31 December 2027, the deadline for HSE to complete its evaluation of applications where the authorisation application has been validated sufficiently in advance of that date so that the evaluation can be completed within the deadlines of the GB BPR. The extended deadlines will apply to applications that may have already expired which will mean that the evaluation of such applications can be completed. The 2022 regulations amend three of the transitional provisions inserted by the 2019 regulations (Articles 95B, 95C and 95H) to ensure the provisions continue to operate effectively. The 2022 regulations amend Implementing Regulation 354/2013 to incorporate the postponed notification and evaluation deadlines of 31 December 2027.

Amendment of deadlines for biocidal products authorised under UK law

Following the approval of an active substance in biocidal products already on the GB market, HSE has three years to complete its evaluation and decide whether to grant authorisation under the GB BPR. The 2022 regulations amend Article 89 of the GB BPR to extend (beyond three years) the period that certain biocidal products can remain on the GB market following approval of the active substance(s) they contain. During this time, relevant biocidal products can remain on the GB market without authorisation under the GB BPR. This will apply to biocidal products that: (i) contain an existing active substance approved before IP completion day and for which an application made under EU BPR has been resubmitted; or, (ii) contain an active substance approved under the EU BPR and for which an authorisation application has been made after IP completion day. The period is extended until 31 December 2027 for applications that have been validated sufficiently in advance of that date so that evaluation by HSE can be completed. For applications not validated sufficiently in advance of 31 December 2027, the period is extended beyond that date to allow HSE to complete its evaluation. The extended period of authorisation under domestic law will apply to biocidal products meeting the relevant criteria regardless of whether the three-year period has already expired.

Transitional provision for applications under Implementing Regulation 414/2013

The 2022 regulations insert a new transitional provision into the GB BPR for authorisation applications under Implementing Regulation 414/2013. This new transitional provision will allow applications to change or modify an authorisation made under the EU BPR before IP completion day to be transferred to the GB BPR, provided the application and relevant information have been resubmitted.

Amendment of Implementing Regulation 414/2013

Implementing Regulation 414/2013 outlines the procedure applying to authorisation applications for products that are identical to other biocidal products which have been authorised or registered under the GB BPR. This requires the evaluation of applications to be completed within 60 days of validation. The 2022 regulations amend this Implementing Regulation to postpone the evaluation deadline for this type of authorisation application until 31 December 2027.

Summary of the proposals

The purpose of the 2022 regulations is to postpone the deadlines by which HSE must complete its evaluation of certain types of applications for authorisation. It is necessary to extend the current deadlines of the GB BPR to give HSE sufficient time to evaluate authorisation applications made under GB BPR transitional provisions. Failure by HSE to grant authorisation for an application within the evaluation deadlines set by the GB BPR will mean that the application will not be dealt with in accordance with the GB BPR. This will hold up access to market for new products and may mean that products already on the GB market will need to be phased off the market once their current evaluation deadline passes.

The 2022 regulations therefore amend the GB BPR to postpone the deadlines for authorisation applications related to such biocidal products, which will allow HSE to complete the evaluation of those applications. The 2022 regulations make the following amendments to the GB BPR: (a) for relevant authorisation applications, postpone the deadline for notification of appropriate fees and evaluation deadline until 31 December 2027; (b) extend the period in which certain biocidal products authorised under domestic law may continue to be used and made available on the GB market without authorisation under the GB BPR; (c) introduce a new transitional provision for applications to change or modify an authorisation made under the EU BPR before IP completion day to be transferred to the GB BPR. The 2022 regulations also amend Implementing Regulations 354/2013 and 414/2013 to incorporate, where relevant, the postponed deadlines.

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

Our stakeholders were previously made aware of the general approach we took to correcting deficiencies in environmental legislation. However, these new measures are aimed solely at ensuring the functioning of the GB BPR and, therefore, we have not undertaken any engagement, or any formal consultation, about these specific amendments.

A note of other impact assessments, (if available)

No additional impact assessment has been prepared. The proposals do not constitute a policy change and are aimed at ensuring effective operation of the GB BPR.

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

Scottish Ministers consider that the situation the 2022 regulations seek to address should have been foreseeable, but that the risk of disabling the operability of this GB regime by not agreeing to this extension is greater than the risk to the environment from consenting to it. 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.

The extension of evaluation deadlines will mean the protection of the environment and human health for the use of affected products currently on the GB market will rely on existing conditions of use, set in previous evaluations. In some cases, changes in scientific knowledge for the active substance contained in the product that could affect these conditions will not be considered until such time as the delayed evaluation is undertaken. Our understanding is that this is unlikely to be a major issue in many cases. Suppliers and users of existing biocidal products are likely to welcome these changes, which will add certainty to continuing access to biocidal products on the GB market. A minority of companies looking to market new products may be concerned about HSE resources and their implications for the time taken to process new applications; however, as part of ongoing work on the GB BPR Competent Authority assessment programme such products will be among those prioritised for evaluation.

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

This instrument is subject to the affirmative procedure and will be laid for sifting at Westminster on 17 October 2022.

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

A final draft SI was received on 7 September 2022. Following the announcement of Her Majesty's death, Parliament was suspended before this notification could be made. The laying date of 17 October 2022 has not changed, so in these exceptional circumstances there are fewer than 28 days available for scrutiny. Should a change be made to the laying date, the committee will be informed immediately.

Information about any time dependency associated with the proposal

The 2022 regulations are made using powers in the European Union (Withdrawal) Act 2018 which expire after two years of IP completion day (i.e. by 31 December 2022). The 2022 regulations will therefore need to be made before the end of this year.

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.

ANNEXE C

SI NOTIFICATION: SUMMARY

Title of Instrument

The Biocidal Products (Health and Safety) (Amendment) Regulations 2022

Proposed laying date at Westminster

17 October 2022

Date by which Committee has been asked to respond

11 October 2022

Power(s) under which SI is to be made

Section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018.

Categorisation under SI Protocol

Type 1

Purpose

This instrument amends the following retained EU 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"); Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council; and, Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council.

This instrument makes amendments to the GB BPR to postpone the deadlines by which the Competent Authority (the Health and Safety Executive ("the HSE")) must complete its evaluation of certain types of applications for product authorisation. To this end, the instrument amends the GB BPR:

(a) for relevant authorisation applications, to postpone the deadline under the GB BPR for notification by the HSE of appropriate fees and evaluation deadline until 31 December 2027;
(b) to extend until the period in which certain biocidal products authorised under domestic law may continue to be used and made available on the Great Britain market without authorisation under the GB BPR;

(c) to introduce a new transitional provision for applications to change or modify an authorisation made to the HSE under the EU BPR before Implementation Period (IP) completion day to be transferred to the GB BPR.

The instrument also amends: Implementing Regulation 354/2013 to incorporate the postponed notification and evaluation deadlines; and, Implementing Regulation 414/2013 to postpone until 31 December 2027 the evaluation deadline for applications for products that are identical to other biocidal products that have been authorised or registered under the GB BPR that have been accepted or validated before 1 November 2027.

Other information

A final draft SI was received on 7 September 2022. Following the announcement of Her Majesty's death, Parliament was suspended before this notification could be made. The laying date of 17 October 2022 has not changed, so in these exceptional circumstances there are fewer than 28 days available for scrutiny. Should a change be made to the laying date, the committee will be informed immediately.