10 January 2019

Dear Gillian,

I am writing in response to your correspondence of 19 December concerning the Chemicals (Health and Safety) and Genetically Modified Organisms (Amendment of Retained EU Law) (EU Exit) Regulations 2018. Your letter posed a number of questions on a variety of themes for which I have provided responses in the annex below. For ease of reference, the answers are provided alongside the text of the relevant question from the Committee.

Yours,

ROSEANNA CUNNINGHAM
Scottish Parliament - Environment Climate Change and Land Reform Committee

Questions following the notification of the intention to consent to the Chemicals (Health and Safety) and Genetically Modified Organisms (Amendment of Retained EU Law) (EU Exit) Regulations 2018 (The CGMO Regulations)

Posed 19 December 2018
Response requested by 9 January 2019

Section One - Name of instrument and summary of proposal.

The notification states “the European Chemicals Agency (ECHA) currently plays a number of key roles in various EU Chemicals regulations. In a no deal scenario, the UK will no longer have access to ECHA. The proposal is for the Health and Safety Executive (HSE) to carry out, in the UK, a number of the roles and functions that ECHA currently perform within the EU.

1. Which functions will HSE take on from ECHA?
2. And which will it not? Who will carry out those functions in the UK?

Taking these questions together, HSE will take on all functions listed by ECHA in the relevant EU regulations except where the function relates to co-ordinating activity on behalf of or for Member States and their representatives as this will no longer be appropriate. The UK Government Technical Notice ‘Regulating Biocidal Products if there’s no Brexit deal’ gives some examples of the functions HSE examples of functions that HSE would carry out. Link as follows: https://www.gov.uk/government/publications/regulating-biocidal-products-if-theres-no-brexit-deal

Section Two - Explanation of law that the proposals amend and summary of the proposals.

BPR

The notification states “Under the BPR, biocidal products can be approved in individual Member States, for use in their own territory, and then approved in other Member States by a process of mutual recognition, or, in a process known as Union authorisation, by the Commission for use throughout the EU”.

3. How will the system of ‘mutual recognition’ be replicated between the UK and the EU in the event of no deal?

In a no deal scenario, we do not expect any mutual recognition procedures to be available as this is only available between Member States and EEA countries. Applicants wishing to seek biocidal authorisations in the UK would have to apply to the UK for UK-specific authorisations. The UK will have its own Biocidal Active substance review programme and active substance approvals and non-approvals would also be UK-specific. The UK would be able to take account of active substance evaluations undertaken in other countries, including...
the EU, but would be responsible for taking its own decisions nationally. The various administrations would have the appropriate oversight of whether substances are approved or otherwise.

4. How will consistency be applied between the UK and the EU where derogations are made “because of a danger to public or animal health or the environment”?

Derogations are applied on a nation-specific level. Any derogation in the UK would need to be based on the specific circumstances within the UK. Examples of recent derogations include:

- a derogation for products used to control the pine processionary caterpillar/moth which was found to be widespread in municipalities in France; and
- a product to control mosquitos in Belgium after exotic species of mosquito which can be vectors for tropical diseases were found in specific locations in Belgium.

The notification states “In practice, Ministers in all of the administrations have delegated their functions as a competent authority to the HSE by Agency Agreement”.

5. Could the committee see a copy of this agreement?

Yes. The agency agreement between the Scottish Ministers and HSE is published on HSE’s website. Link as follows: http://www.hse.gov.uk/aboutus/howwework/framework/aa/scottish-biocides.pdf

It is possible that existing agency agreements will be updated to reflect any future common framework.

The notification states “The EU list of active substances will be replaced with a UK List of approved substances. There will also be a Simplified Active Substance List for the UK and a simplified authorisation procedure. Union authorisation and mutual recognition would no longer be available upon exit. The HSE would instead evaluate applications for national authorisations, having had sight of the supporting data, and make recommendations for the approval of active substances in the UK”.

6. What is the “supporting data” which HSE would need to see to make a decision on whether a substance was to be added to the UK approved substance list? Would access be required to data held by the ECHA?

The technical scientific information required to support an active substance approval is set out in annex II 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 and this will become retained EU law.

This data would already be held by companies who have applied to ECHA. Those companies would now have to resubmit it to HSE as part any application for approval in the UK regime. Therefore, advice from HSE is that they have no requirement access to data held exclusively by ECHA.
7. Decisions on the list are to be made by the Secretary of State with the consent of the Devolved Administrations. What happens if this consent is not forthcoming?

This is not a situation we envisage, however the ongoing framework discussions on Chemicals and Pesticides, which the Committee is already aware of, will include a mechanism for dispute resolving disputes such as this. The legislation provides that the UK Government would not be able to act without consent in relation to devolved matters.

8. Who advises Scottish and UK Ministers as to whether a derogation from the “usual requirements of the regulation”, where devolved and reserved competency and interests lie, and how such derogations are legally enforceable?

The Scottish Government would seek legal advice from the Scottish Government Legal Directorate, the UK Government would seek advice from its own legal officers, including the Office of the Advocate General in relation to the devolution settlement in Scotland.

The requirements of the Biocidal Products Regulation is already enforced through the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.

The notification states that “references to the UK using ECHA IT systems are amended with a provision to follow a UK system.”

9. What IT or database systems need to be developed and in place in order to replicate the ECHA IT systems mentioned, and what progress is being made? Will the systems be in place in time in the event of no deal?

The development of IT systems is being led by the UK Government and HSE. HSE are not intending to replicate any ECHA-owned IT systems in time for day 1 in a no-deal scenario. ECHA’s IT system for handling biocidal product applications is the Register for Biocidal Products (R4BP3), however this is designed for the EU regime and HSE has advised that much of its functionality is not needed in the UK-only context. In the longer term, HSE has advised that it intends to build an IT system for handling applications, however interim arrangements for receiving and processing applications will be put in place from exit day while it is developed. These are currently under development and further information will be provided to businesses on how to submit data and applications to HSE from exit day in the coming weeks.

The notification states “reference to using EU Scientific Committees and advisory bodies are deleted”.

10. How will the expertise on such committees and advisory bodies be adequately replaced, and who will pay for this?

11. What formal opportunities and mechanisms will there be for stakeholder engagement in HSE decisions, which are currently provided through ECHA Committees and other practices?
Taking questions 10 and 11 together, the EU committees referred to in BPR are the Biocidal Products Committee (BPC) at ECHA and the Commission’s Standing Committee on Biocidal Products. Membership of both committees is restricted to Member State representatives and alternates. Although accredited stakeholder organisations and applicants can attend BPC meetings as observers (no stakeholders attend the Standing Committee), they are not formally involved in decision making and the Committee is not primarily intended as a means to engage stakeholders in decision-making. Neither of these structures is considered relevant in a UK-only context.

HSE has obligations under the regulators code, the Aarhus convention and the Health and Safety at Work Act 1974 to allow for public participation and stakeholder interaction, supplemented by the consultation requirements in the EU BPR which will form part of retained EU law. Such arrangements will be kept under review in line with the commitments by all governments to maintain the highest possible environmental standards.

The CLP regulation

The notification states “the HSE will undertake the role of the [ECHA] and carry out the relevant Agency functions for the whole of the UK”.

12. What is meant by the HSE ‘must have regard to’ opinions published by the ECHA on or after exit day?

This means that HSE will actively monitor the opinions of ECHA’s Risk Assessment Committee (RAC) on harmonised (legally binding) classification and labelling published by ECHA. Harmonised classification and labelling apply across all EU Member States in the same way creating a level playing field for suppliers while maintaining a high level of protection of both people and the environment. After exit, the UK will retain the arrangements for legally binding classification and labelling although the term ‘mandatory classification and labelling’ (MCL) will be used. MCLs will apply across the UK.

HSE will independently consider the published RAC opinions and decide whether to recommend that the UK should align future new and revised UK mandatory classification and labelling to the proposed changes in the EU. Given the close relationship between hazard classification and the regimes governing active substances (pesticides and biocides), and the priority CLP gives to active substances, both in the EU and in the UK, it is anticipated that the UK will stay as closely aligned with EU harmonised classification and labelling decisions as possible. This aligns with the position of the Scottish Government.

The function of whether or not to accept a recommendation of the HSE is subject to the consent of the devolved administrations in line with their devolved competence.

13. Why is there no similar provision for HSE to ‘have regard to’ opinions of the ECHA in the REACH Regulation?

Although the REACH Regulation and the CLP Regulation are aligned, they are separate regimes and operate in different ways. Our understanding is that, while REACH essentially considers risk, the CLP Regulation deals with the fundamental intrinsic hazardous properties
of substances and mixtures. Intrinsic hazards are identified through an evaluation of available scientific data against set classification criteria.

14. Is there an agreement in place for this to take place, otherwise why would it be necessary after exit day?

HSE has been designated the Agency for the purposes of CLP with the agreement of the devolved administrations. Existing Agency Agreements between HSE, and the various administrations will be revised to take account of the new UK regulatory landscape.

The notification states “Other functions that the HSE will perform include the consideration of request for the use of an alternative chemical name, preparing draft exemptions from labelling and packaging requirements, preparing proposals for a new or revised mandatory classification and labelling requirement and the establishment of the UK mandatory CLP list, the UK notification database and a national helpdesk”.

15. What will delivery of these functions cost, and who will pay for them?

We are not aware of a costing having been undertaken for these functions but costs are expected to be met through established UK funding arrangements.

There will be arrangements for HSE to charge a fee for the consideration of proposals for new or revised mandatory classification and labelling which fall outside the priority hazard classes or are not related to active substances (see 12 above). This fee has been calculated using HSE’s current cost recovery arrangements. The fee will be an initial £5,000 for a proposal with the possibility of top up fees and refunds as required. The number of affected proposals is likely to be small – there have been only three proposals from industry submitted to HSE since 2008. The current ECHA standard fee of EUR12,000 for similar proposals submitted under the current arrangements.

The level of the fee above has been approved by the UK Treasury.

ECHA currently charge a fee for processing requests for the use of an alternative chemical name. This fees ranges for EUR100 to EUR4000 depending on the size of the business and the number of mixtures affected. HSE will not be charging a fee once this function is transferred although this policy will be kept under review.

16. Will businesses now be required to adhere to, and pay to access, a UK system as well as an EU system?

No. Unlike other chemical regimes, CLP does not require the storing of data therefore there are no ‘pay to access’ requirements. For the purposes of CLP, a great deal of information is published on ECHA’s web site and is publicly available i.e. the Classification and Labelling Inventory (a list of all the substances placed on the EU market including their hazard classification and labelling both harmonised and self-classified by the suppliers themselves). RAC Opinions, together with responses to public consultations on proposals (omitting responses the respondent has asked to remain confidential) are also publicly available and free of charge.

Scottish Ministers, special advisers and the Permanent Secretary are covered by the terms of the Lobbying (Scotland) Act 2016. See www.lobbying.scot

St Andrew’s House, Regent Road, Edinburgh EH1 3DG
www.gov.scot
The new UK CLP arrangements will also be free to access with the exception of the fee described at 15 above.

The notification states “The Devolved Administrations must appoint, or consent to the Secretary of State appointing on their behalf, a body or bodies responsible for receiving information for formulating preventative and curative measures in the event of an emergency health response, from importers and downstream users placing mixtures on the market”.

17. What happens if the Devolved Administrations appoint different bodies on their behalf “for receiving information for formulating preventative and curative measures in the event of an emergency health response, from importers and downstream users placing mixtures on the market”?

Scottish Ministers are able to appoint a separate body in Scotland if desired in a way that respects the position that public health is fully devolved.

In the event that there are different bodies appointed then those bodies would be expected to work together to share information as is current practice between Public Health England and Health Protection Scotland for example.

18. The decision for making such measures permanent “will be made by the Secretary of State, subject to the consent of the Devolved Administrations”. Please provide more information about how this consent process would work.

This is subject to ongoing framework discussions between the 4 administrations and regulators. It is not possible to provide an exact process at this time but there will likely be regular engagement between officials to clarify understanding and issues. The Scottish Ministers will be held to account by Parliament for any decisions they take.

19. Does the Scottish Government anticipate that SEPA’s functions will increase or change under this requirement?

SEPA currently has no role in relation to CLP and no change is expected.

The PIC regulation

The notification states “the PIC Regulation concerns import and export control, which is subject to a specific reservation”.

20. What reservation is the PIC Regulation subject to?

PIC concerns the import and export of Chemicals, including Pesticides. Import and export control is subject to reservation C5 in the Scotland Act.
21. The notification states that “the movement into and out of Scotland of pesticides is an exception to the reservation”. How is this exception legislated for?

Functions of the Secretary of State in relation to import decisions and the placing of a chemical on the UK PIC list will be made subject to the consent of the Scottish Ministers if, or to the extent that, the exercise of the function is within devolved competence. The consent of the Scottish Ministers would be required before the Secretary of State could exercise such functions in relation to pesticides.

22. Mention is made in this section of the Health and Safety Executive for Northern Ireland. In the event of no deal, how will there be interplay between HSE and HSE Northern Ireland as regards all of the matters in this notification?

There is an MoU in place between HSE and HSENI under which HSE agrees to carry out the administrative functions of the PIC Designated National Authorities for both Great Britain and Northern Ireland where HSENI retains responsibility for enforcement in Northern Ireland. Our understanding is that this arrangement will continue, and the MoU will be updated.

23. The Secretary of State is to be “responsible for participation in the Convention, and communication with the Secretariat of the Convention”. Will the Secretary of State also have a duty to keep Devolved Administrations aware of such communication?

The secretariat of the Rotterdam Convention makes the majority of its material publicly available on its website and we expect that appropriate updates would be provided through arrangements established under the proposed framework agreement and through established lines of communication between ministers and officials. We do not see a need for a statutory duty in this area.

24. The notification states “the Secretary of State must also evaluate, in close cooperation with the Designated National Authorities and the Devolved Administrations, the need to take measures to prevent unacceptable risks to human health or the environment...”. What does ‘in close cooperation with’ mean?

This is the wording used in the EU PIC Regulation being carried over into retained EU law. At a high level, the Scottish Government interprets this as meaning through regular and consistent dialogue to ensure that information is shared and available and decisions taken are as well informed as is possible at any given time. However, this may be more formalised through the ongoing framework discussions.

25. The notification states “the Secretary of State’s function of including a chemical in the UK PIC list or adopting or revising an import decision is subject to the consent of Scottish Ministers, to the extent that it is within their devolved competence”. Could the committee see a worked through example of what this might actually look like in practice?

The underpinning administrative arrangements to support Ministerial decisions requiring consent are still being developed as part of the framework discussions, so it is not possible...
to produce a worked example at the present time. We understand that the Committee will want to be kept informed as those framework discussions progress.

GMO CU Regulations

The notification states:

“In addition, regulation 3(2)(a)(iii) of the 2014 Regulations, which disappplies the Regulations where a written consent is given by a competence authority of an EEA state (pursuant to Directive (EC) No 2001/18) in relation to the deliberate release of GMOs into the environment, will be deleted as post EU exit there will be a fully devolved approach to GMO deliberate releases, including marketing releases. However, transitional provisions will ensure that written pre-exit consents, granted by the competent authority of an EEA State, under Articles 15(3), 17(6) or 18(2) of Directive EC No 2001/18 remain exempt from the scope of the GMO Contained Use Regulations 2014. Existing domestic provisions contained in Section 111(1) of the Environmental Protection Act 1990 will continue to apply. Our domestic deliberate release SSI will be separately amended to ensure GMOs that have a written consent from an EEA state will remain exempt from the scope of the GMO (CU) regulations”.

The committee would value some clarity as to the changes which will be made under this section. In particular:

26. What is meant by “post EU exit there will be a fully devolved approach to GMO deliberate releases, including marketing releases”? What will this fully devolved approach look like, how will it differ from what happens at the moment, who will deliver it, and how will it be resourced? What are “marketing releases”? What scope is there for policy divergence across the UK post EU exit?

Article 3 of the GMO contained use regulations is all about exclusions from the scope of the regulations. It mentions, in this regard, consents granted under the EU’s GMO deliberate release Directive 2001/18/EC. This Directive is transposed into domestic legislation – the GMO Deliberate Release (Scotland) Regulations 2002 (as amended). The Directive and our domestic SSI cover procedures and requirements for both GM research releases and GM marketing releases (primarily commercial cultivation of GM crops but also includes some non-food/feed imports such as cut flowers). Scottish Ministers are responsible for considering applications for research releases and granting consents. However marketing releases are considered at EU level - consents are granted after being approved by the European Commission following a lengthy approvals process involving a scientific assessment of the application by the European Food Safety Authority and views of Member States. Marketing consents are EU-wide, although provisions to opt out of GM cultivation were brought in in 2015. As agriculture is devolved, we have agreed with Defra and the devolved administrations that, post EU exit, our respective Ministers will be responsible considering and granting marketing consents in future, using the Advisory Committee on Releases to the Environment as a joint resource for providing scientific advice. However, the amendments to the GMO contained use regulations are purely to ensure the current exemptions remain operable after EU exit.

27. Can more clarification be given on the statement that “our domestic deliberate release SSI will be separately amended to ensure GMOs that have a written
consent from an EEA state will remain exempt from the scope of the GMO (CU) regulations”? Can you provide a worked through example, so it is clear what this would look like in practice for a particular product or material?

There are currently provisions in our domestic deliberate release SSI regarding exemptions that will have to be fixed to ensure they remain operable post EU exit. This statement was only added to show that we are aware of the interplay between different GMO legislation and will take appropriate measures regarding cross-references. We apologise if the inclusion of this statement has caused confusion but it has no bearing on the amendments being made to the GMO contained use regulations.

Section Four - Scottish Government categorisation of significance of proposals.

We think that the GMO CU Regulations should also be Category B – there are significant changes proposed for post EU Exit.

The view of the Scottish Government is that there are no significant changes to the GMO contained use regulations post EU exit. The changes to the GMO contained use regulations are, as stated in the notification, limited to ensuring continued operability after EU exit.

Section Five - Impact on Devolved Areas.

28. Could the committee have an explanation how it can be that the notification states “the amendments to the GMO (CU) Regulations respect the devolved competence of the Scottish Ministers, have no impact on devolved powers exercised under the regulations, or on future devolved discretion over future changes to the regulations”, but the notification also seems to set out a number of areas where there will be changes required to be delivered using devolved powers?

As per the answers to 26 and 27 above. Scottish Ministers currently have joint competent authority responsibility with the Health and Safety Executive for considering GMO contained use applications and granting consents. Scottish Ministers are responsible for environmental aspects (devolved), while HSE is responsible for health and safety (reserved). This will not change after EU Exit.

29. For the “BPR”, the “CLP Regulation”, and the “PIC Regulation” in relation to pesticides, in particular, could an explanation be provided as to the scope of the devolved powers impacted by the proposals, and therefore the extent of possible divergence going forward, as between Scotland and the rest of the UK?

The PIC Regulation relates to the import and export of chemicals, which is a reserved matter, with an exception to this being the movement to and from Scotland of pesticides. Functions exercised under PIC are made on a UK wide basis. The consent of the Scottish Ministers is required where the provisions extend to the import or export of pesticides. The PIC Regulations, including those provisions relating to pesticides, will be consistent throughout the UK.

The CLP Regulation concerns the protection of human health and the environment, which are devolved, but reservations which are impacted include health and safety and product standards, safety and liability - including product labelling. Pesticides is an exemption to the
product standards, safety and liability specific reservation. The Devolved Administrations may take appropriate separate provisional measures, within their devolved competence, if they have justifiable grounds for believing that a substance or mixture constitutes a serious risk to human health or the environment due to reasons of classification, labelling or packaging. Within a specified time, the taker of the measure must revoke the measure or begin the process to make the measure permanent on a UK-wide basis. The decision of whether to make the measure permanent will be made by the Secretary of State, subject to the consent of the Devolved Administrations.

The BPR relates the protection of public health and the environment, which are devolved, but also concerns reserved matters such as health and safety. These functions are exercised on a UK-wide basis under the BPR. The consent of the Scottish Ministers will be necessary if and to the extent that the function is within devolved competence. Under the BPR the Scottish Ministers are able to derogate from the usual requirements of the regulation, for a limited time, when such a measure is necessary due to danger to public or animal health or the environment. The power to extend such a measure is conferred on the Scottish Ministers, if the danger relates to Scotland and it is within their devolved competence to take such a measure. Similarly, where the decision relates to Scotland and is within devolved competence, the Scottish Ministers may issue a decision allowing the competent authority to authorise a biocidal product containing a non-approved active substance, if it is essential for the protection of cultural heritage. The Secretary of State may take such action for whole of the UK but will require the consent of the Scottish Ministers where their devolved interests are impacted.

Section Six - Stakeholder engagement/consultation

The notification states that “we are in regular contact with all our stakeholders” and “HSE have been in regular contact with stakeholders”.

30. Which “stakeholders “has the Scottish Government been in “regular contact” with about the matters in this notification?

The Scottish Government has undertaken informal liaison with the Chemical Industries Association and attended the HSE event in August in order to hear concerns first hand. We have not been made aware of any Scottish specific concerns as yet but appreciate there is a high level of concern amongst all stakeholders in this area.

31. Of those who attended the HSE event in August 2018, which were from Scotland?

Three Scottish Companies were represented at two stakeholder events held by HSE in August and October. HSE has advised that trade associations representing a further 19 Scottish companies were in attendance, or form part of their regular ongoing engagement work.
Section Nine - Have Scottish Ministers had regard to the guiding principles on animal welfare and the environment?

Stakeholders have raised concerns with regard to the process of transferring various chemicals registrations into new UK systems in the event of no deal, that animal testing may have to be repeated in order to provide the required evidence and data.

32. Has Scottish Government assessed whether these Regulations will result in requirements for any new or repeated animal testing, in order to satisfy new data requirements or due to lack of access to data in EU systems?

As for question 6, our understanding based on advice from HSE is that for the matters covered by this notification the data required would already be held by companies applying to HSE for any new UK equivalent of a current ECHA decision. Therefore, no new or repeated animal testing, or need to access to ECHA systems or data is expected.

33. Will the same environmental information be available to the public under these Regulations (having regard to the principle of public access to environmental information), and will there be any gaps in availability of information?

We do not envisage any gaps in availability of information to the public, this will be provided through information on substances remaining available on ECHAs website, which may be replicated on HSE’s website, as well as the requirements of the Aarhus convention.

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

34. A Memorandum of Understanding is mentioned. Is this available?

No. This has not been drafted yet, it is one of the possible outcomes of the ongoing framework discussions. As above, we are aware of the Committee’s interest in being kept informed of progress in relation to framework discussions.

Section Fourteen - Any significant financial implication?

35. What assessment has been made of financial implications for industry, especially as it seems operators will have little choice but to have to adhere to the UK and EU systems?

An assessment of the financial implications has been undertaken by HSE. The amendments in these Regulations relate to the maintenance of existing regulatory standards. Therefore it has been calculated to have a net direct impact on business or civil society organisations of less than £5 million annually.
Section Fifteen - Additional Information to Note

36. Why was this notification not introduced at the same time as the REACH notification if they are so interrelated?

This is a separate SI being laid by a separate department of the UK Government. The timing of the notifications is determined by the legislative programme of the UK Government. The notification was submitted before the Committee took evidence from Ministers on REACH.