Dear Cabinet Secretary,

The Chemicals (Health and Safety) and Genetically Modified Organisms (Amendment of Retained EU Law) (EU Exit) Regulations 2018

Thank you for your letter, dated 7 December 2018, seeking the Committee’s consent for the proposal for the UK Government to make provision via the above SI.

The Committee intends to consider the consent notification at its meeting on 15 January 2019 and it would be helpful if you could provide some further information to inform our discussion. The information sought is set out in the annexe to this letter. **In order to be included in the papers, it would be helpful if this information could be provided by close of play on Tuesday 8 January.**

Yours sincerely,

Gillian Martin MSP
Convener
Environment, Climate Change and Land Reform Committee
Section One
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.

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

Section Two

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”.

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

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”.

- Could the committee see a copy of this agreement?

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”.

- 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?
- 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?
- 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 notification states that “references to the UK using ECHA IT systems are amended with a provision to follow a UK system.”
• 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 notification states “reference to using EU Scientific Committees and advisory bodies are deleted”.

• How will the expertise on such committees and advisory bodies be adequately replaced, and who will pay for this?
• What formal opportunities and mechanisms will there be for stakeholder engagement in HSE decisions, which are currently provided through ECHA Committees and other practices?

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”.

• What is meant by the HSE ‘must have regard to’ opinions published by the ECHA on or after exit day?
• Why is there no similar provision for HSE to ‘have regard to’ opinions of the ECHA in the REACH Regulation?
• Is there an agreement in place for this to take place, otherwise why would it be necessary after exit day?

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”.

• What will delivery of these functions cost, and who will pay for them?
• Will businesses now be required to adhere to, and pay to access, a UK system as well as an EU system?

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”.

• 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”?
• 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.
• Does the Scottish Government anticipate that SEPA’s functions will increase or change under this requirement?
**The PIC regulation**

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

- **What reservation is the PIC Regulation subject to?**
- **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?**
- **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?**
- **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 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?**
- **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?**

**GMO CU Regulations**

The notification states:

“In addition, regulation 3(2)(a)(iii) of the 2014 Regulations, which disapplies 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:**
  - **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,**
Annexe

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?

- 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?

Section Four

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

Section Five

- 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?

- 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?

Section Six

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

- Which “stakeholders “has the Scottish Government been in “regular contact” with about the matters in this notification?
- Of those who attended the HSE event in August 2018, which were from Scotland?

Section Nine

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.

- 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?

- 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?

Section Ten

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

Section Fourteen

- 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?

Section Fifteen

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