ENVIRONMENT, CLIMATE CHANGE AND LAND REFORM COMMITTEE

AGENDA

38th Meeting, 2018 (Session 5)

Tuesday 18 December 2018

The Committee will meet at 9.00 am in the Robert Burns Room (CR1).

1. **European Union (Withdrawal) Act 2018**: The Committee will take evidence on the REACH (Amendment) (EU Exit) Regulations 2019 from—

   Mairi Gougeon, Minister for Rural Affairs and the Natural Environment;

   Don McGillivray, Deputy Director, Environmental Quality and Circular Economy, and Lorraine Walkinshaw, Solicitor, Scottish Government.

2. **European Union (Withdrawal) Act 2018**: The Committee will consider proposals by the Scottish Government to consent to the UK Government legislating using the powers under the Act in relation to the following UK statutory instrument proposals—

   The Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018; and
   The Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018.

3. **European Union (Withdrawal) Act 2018 (in private)**: The Committee will review the evidence heard earlier in the meeting. The Committee will then consider a proposal from the Scottish Government to consent to the UK Government legislating using the powers under the Act in relation to the following UK statutory instrument proposal—

   The REACH (Amendment) (EU Exit) Regulations 2019.


5. **Climate Change (Emissions Reduction Targets) (Scotland) Bill (in private)**: The Committee will consider a draft Stage 1 report.
The papers for this meeting are as follows—

**Agenda item 1 and 3**

REACH (Amendment) (EU Exit) Regulations 2019 cover paper  
ECCLR/S5/18/38/1

PRIVATE PAPER  
ECCLR/S5/18/38/2 (P)

**Agenda item 2**

European Union (Withdrawal) Act 2018 briefing paper  
ECCLR/S5/18/38/3

**Agenda item 4**

PRIVATE PAPER  
ECCLR/S5/18/38/4 (P)

**Agenda item 5**

PRIVATE PAPER  
ECCLR/S5/18/38/5 (P)
Introduction

1. This paper details a consent notification sent by the Scottish Government and related correspondence on the REACH (Amendment) (EU Exit) Regulations 2019.

2. The Committee agreed to take evidence on the consent notification before considering the Scottish Government’s request to consent to the UK Government laying the proposed SI. Accordingly, the Committee took evidence from a panel of stakeholders at its meeting on 11 December and will take evidence from the Minister for Rural Affairs and the Natural Environment and Scottish Government officials at this meeting. The Committee will then formally consider the notification.

Background

3. In anticipation of the UK leaving the EU, changes are required to devolved legislation by way of statutory instruments. Under the European Union (Withdrawal) Act 2018, and where the Scottish Government considers a UK-wide approach to the legislative changes would be appropriate (for example, to avoid duplication of effort, or where only technical or minor amendments are required), the UK Parliament can legislate on behalf of the Scottish Parliament.

4. For each UK statutory instrument which relates to a devolved matter, Scottish Ministers have undertaken to write to the Scottish Parliament setting out its proposed consent in a consent notification.

5. A protocol has been agreed which sets out the shared understanding between the Scottish Government and the Scottish Parliament on the process for obtaining the approval of the Scottish Parliament to the Scottish Ministers’ consent to the UK Parliament legislating on these devolved matters. The protocol states that the Scottish Parliament will normally have 28 days to consider a consent notification.

6. The protocol also categorises UK statutory instruments as category A (minor or technical amendments), category B (more significant policy decisions) or category C (matters which should be subject to the existing joint procedure (an SI laid in both the UK and Scottish Parliaments)).

7. Under the protocol, following its consideration of a consent notification, a committee can—

   • Write to the Scottish Government confirming its agreement with the consent notification; or

   • Report to Parliament and recommend that—

       o it is content for consent to be given for a UK SI to be made in the UK Parliament only.
It is not content with the Scottish Government granting its consent and that the proposals should be made by an SSI; or

It is not content with the Scottish Government granting its consent and that the proposals should be included as a UK SI made under the joint procedure.

8. Where a different way of dealing with EU withdrawal, or a different policy outcome, is required in Scotland, the Scottish Government will pursue Scottish statutory instruments in the Scottish Parliament.

The REACH (Amendment) (EU Exit) Regulations 2019

9. The Cabinet Secretary wrote to the Committee on 27 November 2018. The 28-day deadline is 9 January 2019. The Scottish Government has determined this is a category B notification and information about the legislative changes the SI seeks to make are set out in the consent notification. Members will note the notification states the proposed SI is “one of the most substantial pieces of legislation needed to address the consequences of EU exit”. The consent notification is attached in Annexe A for members’ information. This is subject to the affirmative procedure at Westminster.

10. The EU REACH Regulation creates a single market mechanism to promote the safe production, transport and use of chemicals to manage potential impacts on human health and the environment. The proposed SI aims to build a ‘UK REACH system’ which mirrors as closely as possible the current arrangements under EU REACH.

11. The Convener wrote to the Cabinet Secretary seeking further information on a number of points in advance of this meeting. The Cabinet Secretary’s response is attached in Annexe B.

12. Following oral evidence to the Committee on 11 December 2018, Nishma Patel, Chemicals Policy Director of the Chemicals Industries Association, submitted supplementary written evidence to the Committee. This is set out in Annexe C of this paper.

Committee consideration

Agenda item 1

13. The Committee will hear evidence the Minister for Rural Affairs and the Natural Environment and Scottish Government officials.

Agenda item 3

14. The Committee is invited to consider the consent notification and agree whether it is content for the Scottish Government to give its consent for UK Ministers to lay the REACH (Amendment) (EU Exit) Regulations 2019 in the UK Parliament.

Clerks

Environment, Climate Change and Land Reform Committee
NOTIFICATION TO THE SCOTTISH PARLIAMENT

The REACH (Amendment) (EU Exit) Regulations 2019

1. Name of instrument and summary of proposal:

The REACH (Amendment) (EU Exit) Regulations 2019 will amend existing EU and domestic legislation enabling the UK to continue to regulate substances placed on the market above 1 tonne per annum. The purpose of this regime is to provide a high level of protection for human health and the environment, to facilitate the greatest possible information sharing at all levels within the supply chain and to reduce animal testing. REACH stands for the Registration Evaluation Authorisation and restriction of Chemicals. This instrument aims to build a ‘UK REACH system’ which mirrors as closely as possible the current arrangements under EU REACH.

2. Explanation of law that the proposals amend and summary of the proposals

Controls on the use of chemicals are set out in Council Regulation (EC) 1907/2006, which provides for the registration, evaluation, authorisation and restriction of chemicals (the EU REACH Regulation). The EU REACH Regulation was introduced in 2007 and at the time was described as the most complex piece of legislation in the EU’s history. This regulation established the European Chemicals Agency (ECHA) which occupies a central role in the regulation of chemicals across all 28 Member States.

The EU REACH Regulation creates a single market mechanism to promote the safe production, transport and use of chemicals to manage potential impacts on human health and the environment. There is a “no data, no market” rule, with industry responsible for providing the ECHA with data relating to the chemicals they use. Industry is also responsible for managing the risks from their use of chemicals. Decisions made under the EU REACH Regulation include the authorisation of chemicals for particular purposes and limiting or banning the placing on the market or use of specific substances. The REACH (Amendment) (EU Exit) Regulations 2019 are necessary to ensure the UK has an effective system of chemicals regulation after leaving the EU.

Under the new UK REACH regime, the functions of ECHA will be carried out by the Health and Safety Executive (HSE) (which already exercises some functions under the EU REACH Regulation), making use of their existing capacity and experience of carrying out this technical work. The HSE must take advice from the Environment Agency, who in turn must collaborate with and pass on any advice received from the Scottish Environment Protection Agency, when exercising functions involving the consideration of environmental issues. The HSE are also under an obligation to take into account relevant scientific knowledge and advice when forming opinions and recommendations. The devolved administrations may initiate the preparation of a dossier by the HSE for the inclusion of a substance on the lists of substances subject to authorisation or restrictions.
The EU REACH Regulation established a Board of Appeal within ECHA to hear appeals against Agency decisions. The decisions, which may be subject to appeal, include specifying conditions on the manufacturer, importer or producer of a substance for the protection of workers and the environment and other issues. Since 2009, the Board of Appeal within ECHA has issued decisions in 148 appeals emanating from 28 Member States. The instrument does not continue with an appeal body within the UK Agency. Instead, it transfers the role of hearing appeals against the Agency’s decisions to the First Tier Tribunal. The Tribunal has the power to dismiss an appeal, remit the decision back to the Agency for reconsideration, or to substitute its own decision.

Decisions currently taken by the European Commission will be transferred to institutions within the UK. Ministerial powers will transfer to the UK Secretary of State, who will need the consent of the Devolved Administrations to take decisions in areas of devolved competence. These powers include decisions on the restriction of chemicals, adding substances to the authorisation list and granting authorisations, as well as the powers to amend the Annexes of REACH. Devolved Administrations will be able to take urgent provisional action in relation to a substance of concern in their own nation. The urgent action must be followed up through the REACH restriction procedure to assess whether it is appropriate to apply a UK-wide control. Such UK measures will be taken by the Secretary of State acting with the consent of the Devolved Administrations. Within the new UK regime, the Health and Safety Executive will take on a role equivalent to that currently performed by the European Chemicals Agency in the EU regime.

The instrument amends the definition of dutyholders such as manufacturers, importers and downstream users. They are now defined as being established in the United Kingdom rather than established in the Community.

The instrument provides for the automatic transfer of existing REACH registrations held by UK-based companies, including UK-based “Only Representatives”, into the REACH regime with no break in their validity. An Only Representative in the EU REACH Regulation is a natural or legal person established within the EU, who is appointed by mutual agreement with a natural legal person established outside of the EU, to fulfil obligations under EU REACH of the non-EU based entity. The effect is that UK registrants and their access to the UK market is legally secure. The automatic transfer of UK registrations is extended to any registration held by UK companies in the two years up to exit. Companies will require to submit basic data to the HSE within 60 days to support the transfer, with the full data package, appropriate to the registrant’s tonnage band, being submitted to the HSE within two years.

UK companies who sourced substances from suppliers in the rest of the EU (known as downstream users) are not under an obligation to register the substance they use under the EU REACH Regulations. However, these UK companies will become importers into the UK market after exit and will be required to register the substance(s) they import. Transitional support is available to these companies through an interim notification system instead of requiring a full registration in the first instance. The interim notification must be converted into a full registration after two years. The EU REACH regime depends on a IT system known as REACH IT. A similar UK IT system is being
built to facilitate the operation of the UK REACH regime, allowing UK companies to upload the data required of them.

The instrument also makes minor and technical changes to ensure the effective operation of the new UK REACH regime post-exit. The EU REACH Regulation cross-references to a number of other pieces of EU legislation. The instrument amends cross references, which would be deficient post exit. Amounts specified in Euros are to be converted into pound sterling and references to the single market are amended so that the legislation operates by reference to the UK.

The instrument also amends domestic legislation, which implemented the EU REACH Regulations in the UK. The REACH (Appointment of Competent Authorities) Regulations 2007, which are UK-wide regulations that appoint the Competent Authorities for the purposes of the EU REACH regulation for England, Wales and Northern Ireland. The Competent Authority for Scotland is not designated in these domestic regulations as a decision was taken to do so administratively. The proposal is to revoke The REACH (Appointment of Competent Authorities) Regulations 2007. The effect of this, together with the removal of references to the Competent Authority within the new UK REACH regime, is to remove the role of Competent Authority in UK REACH. This is being done on the basis that is not appropriate in a UK-only REACH regime. Retaining the role of the Competent Authority, would create a situation whereby the HSE is asking for advice from itself. In Scotland, the Competent Authority for devolved matters is the Scottish Ministers and the Secretary of State for the Department for the Environment Food and Rural Affairs for reserved matters. HSE are also the UK Member State Competent Authority, a role which will become defunct when the UK is no longer an EU Member State. Those functions of the Competent Authority, which continue to be relevant under new UK REACH regime, have been transferred to the HSE, in their capacity as the UK Chemicals Agency, from the Secretary of State and the Devolved Administrations. Ministers in all of the administrations have always delegated their functions as a Competent Authority to the Health and Safety Executive (HSE) by Agency Agreement. Officials in all administrations have agreed that there should be no reduction in the capability of any devolved administration to act as a result of the Competent Authority role being removed in UK REACH. The instrument provides levers by which Devolved Administrations can request and access the same information or initiate processes by HSE, as the UK Chemicals Agency, as they could use their Competent Authority title under EU REACH. These levers are likely to be supplemented by a common framework for the regulation of Chemicals and Pesticides in the UK once the UK withdraws from the EU.

The REACH Enforcement Regulations 2008 are UK-wide regulations which created a UK enforcement regime as required by Article 126 of the EU REACH regulation. These regulations set out who is responsible for enforcing EU REACH, their powers of enforcement, and a list of offences along with the penalties for non-compliance. In Scotland, enforcement duties sit with either local authorities, the Scottish Environment Protection Agency (SEPA) or the Health and Safety Executive. The existing enforcing authorities throughout the UK will continue their roles after exit. The instrument establishes new
enforcement duties with regard to the data requirements in the transitional provisions, which are enforceable by the HSE.

3. **Why are these changes necessary?**

The instruments in question are necessary to correct deficiencies arising from the UK's withdrawal from the EU and allow the continued and effective function of both domestic and retained EU law.

In the EU, the overall regulation of chemicals is provided for by a range of legislative instruments. The REACH regulation is central to the overall chemicals regulatory regime, and establishes ECHA who provide scientific and technical advice on decisions, such as whether a substance should be subject to specific control measures. It is necessary to ensure that a body is identified within the UK, equipped with the necessary resources and expertise to provide such advice when the UK is no longer an EU Member State.

The legislation is important in order to protect human health and the environment, and to facilitate trade. The majority of chemicals legislation is directly applicable EU law. The domestic legislation, which implements the EU legislation, is UK-wide. After exit the directly applicable EU chemicals regulations will become retained EU law. The current approach to the regulation of chemicals has been a consistent and coherent EU-wide approach. The Scottish Government considers there is a continuing value in maintaining a consistent and coherent approach within the UK following EU Exit. Devolution is respected in the new UK REACH regime. The devolved administrations will be able to initiate processes leading to the authorisation or restriction of chemicals under the new UK REACH regime and will be able to take urgent safeguarding measures in their own territories. The Secretary of State will only be able to exercise functions in devolved areas with the consent of the Devolved Administrations.

4. **Scottish Government categorisation of significance of proposals**

Category B. We consider that the overall intention of the approach taken by the UK Government in drafting this instrument is to replicate the existing EU regime within the UK and to avoid introducing any substantive policy changes. Instead there has been a clear and consistent desire to ensure that existing mechanisms are adapted in the simplest and most practical form in order to ensure as smooth as possible a continuation of the current chemicals regulatory regime.

Nevertheless, this is one of the most substantial pieces of legislation needed to address the consequences of EU exit.

**Impact on devolved area**

Chemicals policy engages a complex mixture of reserved and devolved competence. Environmental protection, waste management and public health are devolved while product standards, consumer protection, animal testing and health and safety at work are reserved. Reserved and devolved interests are heavily intertwined in REACH.
Taking the current EU REACH regime as a starting point, there are no significant impacts on devolved competence envisaged as a result of this instrument given its intention in maintaining current arrangements as much as possible. Scottish Ministers are likely to be given greater influence over and sight of decisions taken by HSE on a UK-wide basis.

5. Stakeholder engagement/consultation

We have written to our stakeholders setting out the general approach we are taking to correcting deficiencies in environmental legislation. However, these measures are aimed solely at translating the existing UK regime into a domestic UK context and we have not undertaken any focussed engagement on this basis.

The UK Government are of the view that as this legislation does not produce any significant practical change, formal stakeholder or public consultation is not necessary. However, they have had a consistent programme of informal consultation with stakeholders through existing fora alongside engagements stemming from the decision to exit from the EU. Part of Defra’s ‘operational readiness’ planning has been to build a UK REACH IT system to replace the current EU version used by organisations established in EU Member States, this has included demonstrations and invitations to participate in stress testing of the system as it develops.

A number of the stakeholders in this area are UK- or EU-wide, such as trade bodies, and they have been clear and consistent that they wish to see the regulatory systems of the EU-27 and the UK remain highly aligned post-Brexit.

6. Any other impact assessments

On the basis that this aims to translate existing policy into a domestic context, there is not a requirement to undertake any impact assessment.

7. Summary of reasons for Scottish Ministers proposing to consent to UK Ministers legislating

The existing provisions operate at EU level and the supporting domestic provisions were made at the UK level to reflect overlapping reserved and devolved responsibilities. In light of this, and the UK-wide nature of the proposed regime, it is most effective to make the changes to address deficiencies at UK level. Officials have worked with Defra to ensure the drafting delivers for our interests and respects devolved competence in Scotland, and so Scottish Ministers propose to agree to a UK approach for these deficiencies.

8. Have Scottish Ministers had regard to the guiding principles on animal welfare and the environment?

Yes. The guiding principles on the environment as set out in Articles 13 and 191(2) in Titles II and XX respectively of the Treaty on the Functioning of the European Union are relevant to these proposals. The existing EU REACH
regulation and the domestic legislation relating to it are already in line with these principles, and it is considered that these amendments are in adherence with these principles.

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

Later this year, Scottish Ministers will consult on the governance gaps that will be created once the UK leaves the EU, with a view to bringing proposals back to the Scottish Parliament on medium and long-term governance arrangements once the future relationship is clear.

We have been engaged in framework discussions with all the administrations of the UK and the relevant regulators specifically looking at the regulation of Chemicals and Pesticides in the UK outside of the EU and its existing regime. These framework discussions are progressing. The Scottish Government’s position is that these arrangements should be based on staying closely aligned with the EU Chemicals regulatory regime and maintaining existing standards of protection for human health and the environment.

10. Intended UK laying date

These instruments are subject to the affirmative procedure and will be laid in Westminster on 9 January. Defra have agreed that no EU Exit SIs will proceed to be made (for negative procedure SIs), or laid in draft (for affirmative SIs), until after they have been through the consent process agreed with the Scottish Parliament.

11. Does the Scottish Parliament have 28 days to scrutinise?

Yes

12. Information about any time dependency associated with the proposal?

It is essential that the Regulations are in force on the day we exit the EU in the event of a no deal scenario to ensure that legislation is operable to allow continued high levels of protection for human health and the environment, continued facilitation of trade and continued supply of chemicals between the UK and the EU.

13. Any significant financial implication?

There are no significant financial implications for the Scottish Government associated with these proposals.

While the regulations provide for the greatest possible continuity of the current regulatory landscape, the new IT UK REACH IT system has estimated building cost of £5.6 million which has been met by the UK Government, and will have ongoing running costs. There is also likely to be increased costs for stakeholders who have to re-register a substance in the UK REACH regime having already met the associated costs in EU REACH.
14. Additional Information to Note

Similar notifications have already been passed to the committee on the intention to consent to Statutory Instruments on Persistent Organic Pollutants (POPs) and Mercury with a further notification being prepared to deal with deficiencies in the Biocidal Products, Classification, Labelling & Packaging and the Prior Informed Consent regulations. All of these regulations exist as a package which form the current EU Chemicals regulatory regime.
LETTER FROM THE CABINET SECRETARY TO THE CONVENER

I am writing in response to your correspondence of 3rd December concerning the REACH (Amendment) (EU Exit) Regulations 2019. Your letter posed a number of questions on a variety of themes. In the time available I have provided high level answers for each theme and I understand that the Minister for Rural Affairs and the Natural Environment, Mairi Gurogon MSP will attend the committee on the 18th December which will allow these matters to be explored in more detail if required.

Please see below an annex which provides responses to the questions raised by the Committee.

Parliamentary procedure and reasons for not using joint procedure—

1. What parliamentary procedure will the UK SI be subject to?

2. Why did the Scottish Government rule out using the joint procedure for these Regulations given the complex nature of chemicals regulation and intertwining of reserved and devolved interests?

This instrument is subject to the affirmative procedure and the decision was taken to lay a single instrument in the Westminster parliament as this is consistent with previous practice in this area.

Common framework—

3. What stage are discussions at on the “common framework” referred to?

Discussions at official level to date have been very constructive and we plan to explore a number of areas in greater detail early in the new year when the relevant legislation has been laid. The work is focused on how the future regulation of Chemicals and Pesticides will be governed and on the practicalities of giving effect to the proposed new framework for Ministerial decision-making.

The Scottish Government hosted the latest discussion in Edinburgh on 21st November and we have agreed that these discussions should alternate around all of the nations of the UK, which reflects the view that there is a ‘marbled’ mixture of devolved and reserved competence at play in the wider Chemicals regulatory regime and no one organisation should lead or dominate these discussions or the regulatory regime.

HSE currently carry out a number of functions in the regulation of Chemicals as a result of agency agreements between them and the various administrations. We anticipate that the framework discussions will lead to updated agency agreements which allow for a greater role for all of the governments, particularly the Devolved Administrations, in the oversight of the UK’s Chemicals regulatory regime. These agency agreements are likely to supplemented by Memoranda of Understanding where Ministers agree on the overall aim and approach to Chemicals regulation.
Timing and readiness—

4. The notification states that there are three further notifications being prepared that will “exist as a package”. Will the committee be able to consider all notifications together ahead of the laying date?

The committee have already received a notification on both Persistent Organic Pollutants and Mercury, as well as this notification on REACH. There is one other SI which we intend to notify the committee of as soon as possible.

Scope of devolved competence—

5. What areas of the proposed SI does the Scottish Government consider to be within devolved competence?

6. Are the devolved competences in the area of chemicals regulation greater than, the same as, or less than the functions held by Scottish Ministers as a Competent Authority? If greater, please describe how.

There is a complex mixture of reserved and devolved competence engaged under both the existing EU REACH and the proposed UK REACH regimes which is impossible to separate without changing the structure of the regime, as the functions can be used in different contexts. The overall ambition is to protect human health and the environment, which is devolved, however the REACH model also engages regulation for the purposes of consumer protection, trading standards and health and safety at work, all of which are reserved.

The Scottish Ministers’ functions under the proposed SI are greater than those held by them as Competent Authority, and we have secured a requirement for the consent of the Scottish Ministers should there be a need for UK wide decisions which interact with devolved competence.

How will ‘consent of the Devolved Administrations’ work?—

The notification states that Ministerial powers will transfer to the UK Secretary of State, who will require the consent of the Devolved Administrations to take decisions in areas of devolved competence.

7. What decisions by the UK Secretary of State/HSE will require the consent of Scottish Ministers? For example, will these include all decisions to evaluate, authorise and restrict chemical substances.

8. Will that consent be a statutory requirement, and if not, how will the Scottish Parliament have the opportunity to scrutinise such decisions? What is the Scottish Government’s position on the role of the Scottish Parliament in decisions to authorise or restrict chemical substances under this SI?

9. Similarly, the notification states that the devolved administrations will be able to take urgent provisional action in relation to a substance of concern in their own nation. How will such decisions be effected? Will the Scottish Parliament have the opportunity to scrutinise the exercise of such powers?
10. Will the Scottish Government or SEPA be a voting member of any management or oversight board for HSE’s chemical regulation functions?

11. Will the Scottish Government or SEPA be a voting member of any technical or regulatory board for HSE’s chemical regulation functions?

The requirement for consent is written into the draft instrument. Decisions currently taken by the European Commission under EU REACH will transfer to the Secretary of State for the Department for the Environment, Food and Rural Affairs (Defra) who will require the consent of the Devolved Administrations before taking any decision which interacts with devolved competence. These include decisions on restrictions, additions to the list of substances subject to authorisation, granting of authorisations, fees structures, and other implementing measures. With the exception of decisions to grant authorisations to individual company applicants, the decisions will be given effect through Statutory Instruments. We intend to be as transparent as possible and recognise that the Scottish Government will be accountable to parliament for any decisions that it makes.

More technical decisions, such as decisions on dossier and substance evaluations, which are currently taken by the European Chemicals Agency will pass to HSE as the UK Agency. As these decisions are not currently subject to the Commission’s consent they will not be subject to consent of Ministers from any administration.

In Scotland, the Scottish Ministers may take urgent action by regulations to restrict a chemical substance using their powers under section 140 of the Environmental Protection Act 1990, as was recently done to ban microbeads in the Environmental Protection (Microbeads) (Scotland) Regulation 2018. Such regulations would be subject to the usual process of scrutiny by the Scottish Parliament.

The specific makeup of the various governance structures that will play a role in the operation of the UK REACH system is the subject of ongoing work as part of the development of a framework agreement.

Engagement—

12. Which stakeholders has Scottish Government consulted on post EU Exit proposals for the REACH regime?

13. What are the key concerns that have been raised by stakeholders?

The Scottish Government has focused its efforts on understanding and addressing the deficiencies arising from the UK’s withdrawal from the EU, which has prevented any formal stakeholder engagement.

The UK Government has undertaken informal engagement with UK-wide industry bodies as well as regulators and Non-Government Organisations. Our understanding of the key areas of concern include;
1. access to data currently held elsewhere within EU REACH and the timeframes for doing so;
2. duplication and complication for industry having to comply with both UK and EU regulatory regimes simultaneously and;
3. potential lowering of standards of environmental protection caused by falling behind EU REACH.

These are similar to the issues that the Scottish Government has identified in moving from an EU system to a separate UK system and our aim is for the new UK REACH system to mirror the EU regime as closely as possible.

**Appeals—**

14. The notification states that the SI will transfer the role of hearing appeals against HSE decisions to the First Tier Tribunal. Can the Scottish Government confirm:

(a) which Chamber of the First Tier Tribunal will hear these appeals; and

(b) whether the SI extends the jurisdiction of the First Tier Tribunal?

15. Is the Scottish Government satisfied with the proposal that the Regulations will not establish an appeal body?

Appeals against HSE decisions will be heard under the First Tier Tribunal in the General Regulatory Chamber which already has some appeal responsibilities with regard to environmental decisions.

The EU REACH regime contains a Board of Appeal within the ECHA structure. Although the Board of Appeal acts independently in practice, the aim under UK REACH is to reinforce the independence of the appeal process by use of the First Tier Tribunal.

**Regulatory autonomy and capacity of HSE and Scottish agencies—**

16. How will SEPA’s functions change as a result of this SI?

17. How will functions of local authorities change as a result of this SI?

18. Under this proposed SI, will it be possible to make different authorisation or restriction decisions in Scotland compared with other parts of the UK (other than “urgent provisional action”)?

19. Has the Scottish Government considered what additional resources may be required by bodies taking on additional duties (e.g. SEPA, local authorities)?

No practical change is anticipated to the autonomy, capacity or resource requirements of Scottish public bodies under the UK REACH regime.

The position with regards to making different restriction or authorisation decisions is as set out in the notification.
Devolved Administrations can take separate action on a provisional basis to restrict a chemical if they have justifiable grounds for believing that urgent action is essential to protect human health and the environment, this is known as safeguarding. Such action culminates in a decision to be made on whether UK wide action is required. When a decision has been made on a UK wide basis the taker of the provisional measure must revoke the measure.

Costs for affected companies—

20. What are the estimated costs to Scottish companies of complying with the additional requirements to provide data to populate a UK database?

We are not aware of UKG having made an estimate of the compliance costs for business of the separate UK regime.

Impacts on non-UK based companies—

The notification sets out the proposed process for UK based companies with existing REACH registrations transferring their registrations into a UK system.

21. What are the implications for non-UK based companies (that operate within the REACH system) that have registrations that are relevant to the UK?

22. Will non-UK based companies that currently operate within the REACH system and export chemicals into the UK be able to continue to access the UK market?

23. Is there a process to enable the transfer of existing REACH registrations held by non-UK based companies?

In the event of a no deal scenario requiring a UK REACH regime in place of the existing EU REACH, non-UK based companies wishing to comply with UK REACH will have to register their substance(s) or appoint a UK based Only Representative to fulfill their obligations and there may be a cost attached but this is not possible to estimate with any certainty at this stage. It is not possible for non-UK based companies to transfer existing EU REACH registrations to UK REACH.

Information-sharing and consumer information—

24. What will replace the EU arrangements for sharing information about the properties and safe use of chemicals with users and manufacturers in the UK?

25. What will replace RAPEX, the EU rapid alert system for dangerous non-food products?

26. Will the same information be available to Scottish consumers about chemicals in products as under the current system (including in the 2-year transitional period)?
The primary duty on economic operators to understand the hazards and risks of chemicals, and to identify, recommend and apply appropriate risk management measures will remain unchanged and unbroken at exit. The ability to meet this duty, or its enforcement, is not dependent on the submission of registration information to the UK Agency.

The duties to pass information down the supply chain will remain unchanged. The consumer right to request information about the presence of Substances of Very Concern in the products they buy will also remain unchanged from Day one.
Supplementary Evidence from Nishma Patel, Chemicals Policy Director, the Chemical Industries Association

Whilst industry recognises the need to bring REACH into UK law under a no deal Brexit and our engagement with officials have been positive over the past 18 months, we believe that UK REACH in its current form, will not only weaken our international competitiveness and stifle innovation but, more importantly, offer nothing more towards delivering a better environment for all. As a consequence we have put forward a number of suggestions to address the challenges at hand, hopefully resulting in a UK REACH system that is not only workable but provides businesses in the UK a chance of competing opposite the rest of the world.

Gaining access to information on chemicals to generate a UK REACH database

The technical notice on REACH proposes that companies will be required to re-register chemicals in the UK, with a full data package, within two years of exiting the EU. Businesses across the UK concern related to the requirement to submit ‘full data packages’ in order to manufacture and market chemicals in the UK. Issues surrounding data access are of paramount concern. Over the last decade, businesses have already submitted information jointly, with ownership of the underlying data not necessarily sitting with UK companies. This approach has helped minimise cost and, of course, avoid any unnecessary or duplicate testing. This has been no small task, with UK companies having heavily invested (£550 million) in gathering information on chemicals, assessing and sharing information and communicating safe use to our supply chains across Europe. Having to repeat that exercise will be a significant challenge involving, in many cases, complex negotiations for permission to refer to data owned by other parties. Many existing UK registration holders do not hold, nor do they have access to, the full data package as is being proposed. Instead, companies will have a ‘letter’ that allows them to refer to the underlying data and use of study summaries in submitting their registrations. Whilst companies may be able to gain permission to use these study summaries in resubmitting data under UK REACH this in itself generates a very significant cost to industry and adds nothing further towards the UK’s desired outcome for a better environment. To add to this challenge, there will of course be no obligation - and, in some cases, a commercial advantage – for EU-based companies to share data with UK firms when the UK exits the EU. This could force businesses to duplicate testing, including animal studies where data already exists or accepting incomplete datasets, severely compromising the validity of the entire data collection exercise and undermining one of the fundamental principles of REACH.

Timelines

Another key concern for industry is the proposed two year timeframe to re-negotiate access to data or potentially re-test and re-submit a registration under UK REACH. This is an extremely ambitious timeline given the significant number of registrations (over 12,000) companies would need to manage. It is critical to recognise that this will not be a simple case of transferring information from one database to another and businesses will need to review their entire registration and re-assess it for UK purposes. To put the two year proposal into
context, EU REACH required three phased, tonnage based deadlines over a period of at least 8 years to address the challenge at hand. Other global REACH regimes have also required a much longer timeframe with a much smaller portfolio of substances expected to be registered.

We also have concerns relating to the following additions in the latest UK REACH guidance

- New provision requiring a UK Only Representative to register within 180 days (6 months). Our issue here is that the timeframe to register is even shorter and comes with a fee associated. REACH allows an Only Representative to be appointed by a non-UK supplier which would alleviate the registration duties for many UK downstream chemical using companies. However the short timeframe does not make it attractive for a non-UK supplier to do so which in turn brings many new ‘chemical and chemistry using’ businesses into the scope of REACH registration duties or loss of key chemicals essential to our manufacturing industry and to consumers in the UK.

- The grandfathering 60 day information requirements go beyond ‘basic’ information and in reality businesses are being asked to submit a partial registration dossier within two months amongst all other Brexit related consequences they will be faced with under a no deal.
Environment, Climate Change and Land Reform Committee

37th Meeting, 2018 (Session 5), Tuesday, 11 December 2018

European Union (Withdrawal) Act 2018

Introduction

1. This paper details a consent notification sent by the Scottish Government and related correspondence in relation to—
   - The Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018; and
   - The Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018.

2. The Committee is invited to consider the consent notifications and agree whether it is content for the Scottish Government to give its consent for UK Ministers to lay the instruments.

Background

3. In anticipation of the UK leaving the EU, changes are required to devolved legislation by way of statutory instruments. Under the European Union (Withdrawal) Act 2018, and where the Scottish Government considers a UK-wide approach to the legislative changes would be appropriate (for example, to avoid duplication of effort, or where only technical or minor amendments are required), the UK Parliament can legislate on behalf of the Scottish Parliament.

4. For each UK statutory instrument which relates to a devolved matter, Scottish Ministers have undertaken to write to the Scottish Parliament setting out its proposed consent in a consent notification.

5. A protocol has been agreed which sets out the shared understanding between the Scottish Government and the Scottish Parliament on the process for obtaining the approval of the Scottish Parliament to the Scottish Ministers’ consent to the UK Parliament legislating on these devolved matters. The protocol states that the Scottish Parliament will normally have 28 days to consider a consent notification.

6. The protocol also categorises UK statutory instruments as category A (minor or technical amendments), category B (more significant policy decisions) or category C (matters which should be subject to the existing joint procedure (an SI laid in both the UK and Scottish Parliaments)).

7. Under the protocol, following its consideration of a consent notification, a committee can—
   - Write to the Scottish Government confirming its agreement with the consent notification; or
• Report to Parliament and recommend that—
  o it is content for consent to be given for a UK SI to be made in the
    UK Parliament only.
  o It is not content with the Scottish Government granting its consent
    and that the proposals should be made by an SSI; or
  o It is not content with the Scottish Government granting its consent
    and that the proposals should be included as a UK SI made under
    the joint procedure.

8. Where a different way of dealing with EU withdrawal, or a different policy
   outcome, is required in Scotland, the Scottish Government will pursue Scottish
   statutory instruments in the Scottish Parliament.

The Trade in Animals and Related Products (Amendment) (EU Exit)
Regulations 2018

9. The Minister for Rural Affairs and the Natural Environment wrote to the
   Committee on 22 November 2018. The 28-day deadline is 19 December 2018.
   The Scottish Government has determined this is a category A notification and
   information about the legislative changes the SI seeks to make are set out in
   the consent notification. The consent notification is attached in Annex A for
   members’ information.

10. The Convener wrote to the Minister seeking further information on a
    number of points in advance of this meeting. The Minister’s response is
    attached in Annex B.

The Import and Trade of Animals and Animal Products (Amendment etc.)
(EU Exit) Regulations 2018

11. The Minister for Rural Affairs and the Natural Environment wrote to the
    Committee on 11 December 2018. The deadline for parliamentary
    consideration is 14 January 2019. The Scottish Government has determined
    this is a category B notification and information about the legislative changes
    the SI seeks to make are set out in the consent notification. The consent
    notification is attached in Annex C for members’ information.

12. The Convener wrote to the Cabinet Secretary seeking further information
    on a number of points in advance of this meeting. The Convener asked for a
    response ahead of the meeting: this shall be circulated to members, and posted
    on the Committee’s web pages, as soon as it is received.

For Decision

13. The Committee is invited to consider the consent notification and agree
    whether it is content for the Scottish Government to give its consent for UK
    Ministers to lay following statutory instruments in the UK Parliament—
• The Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018; and

• The Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018.

Clerks
Environment, Climate Change and Land Reform Committee
Notification for the Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018

NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area

The Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018

A brief explanation of the law that the proposals amend

The Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018 ("the proposed SI") is being made using powers under the European Union (Withdrawal) Act 2018 in order to correct deficiencies in what will become retained EU law – in this case EU-derived domestic legislation - relating to trade in animals and related products.

The proposed SI will amend five GB-wide instruments and two instruments that will apply to England only (see details below). It is intended that this notification only addresses the five GB-wide instruments.

The legislation that will be amended by the proposed SI is as follows:

**Part 1 (GB-wide instruments)**

**Rabies (Importation of Dogs, Cats and Other Mammals) Order 1974**
For the purpose of preventing the introduction of rabies into Great Britain, this Order in particular controls the landing in the United Kingdom of any animal (other than man) belonging to the ten orders of mammals specified in Parts 1 and 2 of the schedule of the Order. Specified animals are prohibited from landing in Great Britain except under the authority of a licence. Exceptional circumstances may exist where animals may be allowed to land at prescribed ports and airports, however, they will have to be moved as soon as practicably possible after landing to authorised quarantine premises. The animals will then be kept for a prescribed period in quarantine. The Order also contains detailed provisions relating to the movement of animals during quarantine, the licensing of carrying agents and of quarantine premises, and the control of animals which are passing through Great Britain or which are on board a vessel in a British port.

**Artificial Insemination of Pigs (EEC) Regulations 1992**
These Regulations implement the provisions of Council Directive 90/429/EEC in relation to exports to member States and the approval of semen collection centres which engage in intra-Community trade in porcine semen.

**The Animals (Post-Import Control) Order 1995**
This Order establishes controls on certain animals after they have been imported into Great Britain by laying down requirements relating to cattle from areas not free from warble fly, pigs from areas not free from Aujeszky’s disease, cattle from Canada, cattle imported under specific Community legislation and sheep and goats from areas not free from contagious agalactia. The Order also empowers an inspector to serve a
Notification for the Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018

Notice in specified circumstances and enforcement is carried out by the relevant local authority.

The Bovine Embryo (Collection, Production and Transfer) Regulations 1995

These Regulations give effect to the provisions of Council Directive 89/556/EEC in respect to the trade in bovine embryos, the approval of collection, production and transfer teams, storage conditions for bovine embryos and also provide for domestic trade in bovine embryos.

The Non-Commercial Movement of Pet Animals Order 2011

This Order makes provision for the administration and enforcement of various EU instruments in Great Britain: Regulation (EC) No 998/2003 on the animal health requirements applicable to the non-commercial movement of pet animals; Commission Decision 2006/146/EC on certain protection measures with regard to certain fruit bats, dogs and cats coming from Malaysia (Peninsula) and Australia; Commission Decision 2007/25/EC as regards certain protection measures in relation to highly pathogenic avian influenza and movements of pet birds accompanying their owners into the Community and; Commission Delegated Regulation (EU) No 1152/2011 as regards preventive health measures for the control of Echinococcus multilocularis infection in dogs.

Overall, this Order is concerned with the preventive measures that apply to the movement of pet animals to Great Britain to protect against the risk of the introduction of rabies, Echinococcus multilocularis (tapeworm), Hendra disease, Nipah disease and highly pathogenic avian influenza. Additionally, it outlines requirements of carriers that land pet dogs, cats and ferrets in Great Britain to be approved, subject to certain exceptions, and makes provision regarding the suspension or withdrawal of carrier approvals under the enforcement section.

Part 2 (England only)

The proposed SI will also bring forward amendments to The Bovine Semen (England) Regulations 2007 and The Trade in Animals and Related Products Regulations 2011. These Regulations do not apply in Scotland and are not covered further in this notification.

Summary of the proposals and how these correct deficiencies

The amendments contained in Part 1 of the proposed SI do not change existing policy, but will be necessary in the event of a ‘no deal’ exit from the EU on 29 March 2019 to ensure the operability and continued implementation of the statutory measures detailed above.

As the UK will no longer be a Member State of the EU, the proposed SI will amend EU references. Where necessary, for example, it will replace what will become obsolete references to EC Directives with references to relevant domestic Instruments.
Notification for the Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018

An explanation of why the change is considered necessary

The changes made by this proposed SI are fairly minor and necessary to ensure that the existing GB-wide EU derived legislation continues to be operable once the UK leaves the EU.

Scottish Government categorisation of significance of proposals

Category A. The amendments which will be made by the proposed SI to the GB-wide legislation set out above do not change existing policy. The Scottish Government has worked with DEFRA on the amendments and is content that the provision to be made is necessary and appropriate to ensure that existing law continues to be operable once the UK leaves the EU. So far as the GB-wide legislation amended provides for functions to be exercisable by the Scottish Ministers, the amendments to be made by the proposed SI do not alter the position.

Impact on devolved areas

The Proposed SI will make provision in a devolved area. The relatively minor changes in the proposed SI are required to ensure the continued operability of existing measures.

Summary of stakeholder engagement/consultation

Other than engagement with Defra and other devolved administrations there has been no formal stakeholder engagement or consultation in relation to (Part 1) of the proposed SI as there will be no measureable change to policy and no operational or financial impact is anticipated.

A note of other impact assessments, (if available)

An impact assessment has not been carried out in relation to the proposed SI as its main aim is to remove what will become redundant references or provisions, add new definitions where necessary and generally ensure that existing GB legislation is operable upon EU exit.

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

The proposed SI will make amendments to existing GB-wide SIs which are minor in nature and aim to ensure the continued operability of EU derived domestic legislation. In these circumstances the Scottish Ministers consider it is appropriate that the proposed measures be brought forward by the UK Government. Where so far as the GB-wide legislation amended provides for functions to be exercisable by the Scottish Ministers, the amendments to be made by the proposed SI do not alter the position.
Notification for the Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018

Where relevant – detail how Scottish Ministers have had regard to the guiding principles on animal welfare and the environment

The proposed SI’s amendments do not change existing policy, but are necessary to ensure that existing provision, such as controls on certain imports and the non-commercial movement of pet animals, can continue to operate in the UK should we leave the EU under a ‘no deal’ scenario. The proposed SI will not make any substantive changes to the legislative provisions already in place to safeguard the welfare of animals being imported into the UK. We are content therefore that the proposed SI will not adversely impact on animal welfare (in particular that regard must be given to the welfare requirements of animals as sentient beings).

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

The proposed SI is subject to the negative procedure and will be laid for sifting at Westminster on 27 November 2018. We are working with Defra on the basis no EU Exit SIs will proceed to be made (for negative procedure SIs), or laid in draft (for affirmative SIs), until after they have been through the consent process agreed with the Scottish Parliament.

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister’s proposal to consent, why not?

The Scottish Parliament will have 28 days to scrutinise.

Information about any time dependency associated with the proposal

N/A.

Any significant financial implications?

These proposed SI is not expected to have any financial implications, including for the Scottish Government and for stakeholders in Scotland.

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

There are no anticipated broader governance issues anticipated with the proposed SI and the Scottish Government will continue its good working relationships with UK Government and the other Devolved Administrations. The proposed SI will simply make a number of technical amendments to ensure the operability of existing EU derived, GB-wide domestic legislation in the event of a ‘no deal’ UK exit from the EU on 29 March 2019.
Letter from the Minister for Rural Affairs and the Natural Environment

The Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018

For convenience, answers to the Committee’s questions are grouped in the same format as the annex to the letter of 3 December 2018.

The Statutory Instrument as Published

The Draft Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018 and associated Explanatory Memorandum were published on Tuesday 27 November.

- Are these documents in keeping with the Scottish Government’s notification?

Answer: The Committee refers to the Trade in Animals and Related Products (Amendment) (EU Exit) Regulations 2018 and associated Explanatory Memorandum published by the UK Government on Tuesday 27 November. The Committee may wish to note that the documents published were published again by the UK Government on 4 December 2018 to correct errors in the Explanatory Memorandum.

There is in place a robust mechanism of checking by officials and legal advisers designed to ensure that the documents are in keeping with the Scottish Government’s notification. As a result, we can confirm these documents are in keeping with the notification.

Grouping of Regulations – Animal Health

The Draft SI amends five GB-wide instruments and two instruments that apply to England only; the GB wide ones are:

- Rabies (Importation of Dogs, Cats and Other Mammals) Order 1974
- Artificial Insemination of Pigs (EEC) Regulations 1992
- The Animals (Post-Import Control) Order 1995
- The Bovine Embryo (Collection, Production and Transfer) Regulations 1995
- The Non-Commercial Movement of Pet Animals Order 2011

- What process was followed to decide on this grouping of instruments?

- Are there other instruments that were considered, but not included? How will other aspects of animal health be addressed?

Answer: These instruments have been grouped together for amendment in the proposed SI because they are all the GB-wide SIs relating to trade in, or import of, animals and germinal products identified as containing deficiencies requiring to be fixed under section 8 of the EU Withdrawal Act 2018. There do not appear to be any other GB-wide instruments in the subject area covered by this particular SI requiring to be fixed.
Letter from the Minister for Rural Affairs and the Natural Environment

In relation to animal health more generally, the UK Government is proposing, in exercise of powers under section 8 in particular of the EU Withdrawal Act 2018, to make a number of other SIs to correct deficiencies in what will become retained EU law in the area of animal health. Where those proposed SIs make provision on a GB or UK wide basis in areas of devolved competence they have been or will be subject to notification to the Scottish Parliament in the same way as this instrument.

Consultation

The five SIs described in the notification are underpinned by offence provisions.

- Why was no stakeholder engagement or consultation undertaken other than engagement with DEFRA and other devolved administrations?

- Are affected individuals, businesses or enforcing authorities receiving fair notice of the changes?

Answer: No consultation was undertaken because there was no change made to the offences and there was no impact on business resulting solely from the deficiency amendments in the proposed SI. Although exiting the EU without a deal would have an impact on business, that impact will not result from anything being done by the proposed SI. It is clearly important to consult stakeholders as the nature of the UK’s exit from the EU unfolds, and it becomes clearer what measures may need to be put in place to facilitate trade and to maintain animal health.

In relation to fair notice of change, as these deficiency amendments in the proposed SI are maintaining current arrangements as far as possible in order to ensure a smooth transition following an exit from the EU with no deal, only stakeholders such as pet owners who may wish to take pets to Europe, their veterinary practitioners and those importing animals and related products have been targeted in the UK Government’s communication campaigns. The UK Government has used the publication of its 80 or so technical notices between September and November to explain to affected persons what they can expect in the event of a no deal exit.

Part 2 Amendment of secondary legislation that applies in Great Britain

This section seeks further explanation of how the proposals will correct deficiencies, and why the change is considered necessary. The Notification states: As the UK will no longer be a Member State [...] the proposed SI will amend EU references. Where necessary, for example, it will replace what will become obsolete references to EC Directives with references to relevant domestic instruments."

- In what way does the Draft SI replace EU references? Why are these considered to be appropriate?

Answer: References to the EU are replaced as appropriate depending on the requirements of individual legislative instruments. For example, in amending the Rabies (Importation of Dogs, Cats and Other Mammals) Order 1974 (“the 1974
Letter from the Minister for Rural Affairs and the Natural Environment

Order”), the proposed SI will change a reference to animals brought into Great Britain “from another member State” so that this reads instead “from a member State”, as appropriate to reflect the fact that following EU Exit the UK will no longer be an EU member State.

Another example is that amendments to the 1974 Order also include amendments to article 4 of the same substituting references to Directive 92/65/EEC (which as a Directive will not form part of retained EU law following EU Exit) with a reference to the relevant domestic implementing legislation on trade in animals and related products (“TARP”) as an appropriate alternative (namely the Trade in Animals and Related Products Regulations 2011 (for England), the Trade in Animals and Related Products (Wales) Regulations 2011 and the Trade in Animals and Related Products (Scotland) Regulations 2012).

- If the “relevant domestic instruments” are UK SIs in some cases and SSIs in others, could there be policy divergence between Scotland/devolved provisions, and the rest of GB/reserved provisions?

**Answer:** For all existing GB-wide SIs amended in Part 2 of this SI the benefit of the current approach is that the amendments will be the same across GB, and we understand that similar changes will be made to the equivalent Statutory Rules in Northern Ireland.

To date, the various TARP Regulations made for England, Wales and Scotland are broadly similar, having all been made to give effect to underlying EU rules. We do not envisage that position changing in so far as amendments are to be made to the TARP Regulations to correct deficiencies. The TARP Regulations for England are to be amended by Part 3 of the proposed SI and the consensus is that the approach taken in the proposed SI to amendment of the TARP Regulations for England will be very similar to the approach to be taken when correcting deficiencies in Scotland (on which see further below) and the other devolved administrations which have almost ‘mirror’ wording in their own TARP instruments. In those circumstances it is considered that although policy divergence is possible, in practice the potential for such divergence is small.

The Notification states that the:

[…] main aim is to remove what will become redundant references or provisions, add new definitions where necessary and generally ensure that existing GB legislation is operable upon EU exit.

- What new definitions are proposed; is it limited to e.g. changing references to “Member States” to “the United Kingdom”.

**Answer:** As mentioned above, the changes proposed are those relevant to the legislation in question. In addition to amending redundant EU references, examples of new definitions being added can be found in the amendments made by the proposed SI to the Bovine Embryo (Collection, Production and Transfer) Regulations.
**Letter from the Minister for Rural Affairs and the Natural Environment**

1995 (see regulation 5(2) of the proposed SI, which substitutes the definition “intra-Area trade” means trade between the United Kingdom and another state of the European Economic Area' with the definition “national trade” means trade within Great Britain;’) and the Non-commercial Movement of Pet Animals Order 2011 (see regulation 6(4)(b) of the proposed SI, which makes various changes to definitions of a ‘carrier’).

**Part 3 Amendment of secondary legislation that applies in England**

Part 3 of the instrument covers two instruments that apply only to England. There are Scottish devolved equivalents. Of these, the Trade in Animals and Related Products (Scotland) Regulations 2012 (“TARP”) is a key domestic piece of legislation on trade in live animals and genetic material. The amendments to the Rabies (Importation of Dogs, Cats and Other Mammals) Order 1974 that are included in this notification refer to TARP. The notification does not indicate that TARP is to be amended.

This proposed SI amends the Rabies (Importation of Dogs, Cats and Other Mammals) Order 1974 (SI 1974/2211). The draft SI cross-referes to the Trade in Animals and Related Products (Scotland) Regulations 2012 (SSI 2012/177). This SI amends the equivalent English legislation.

- Are there proposals to amend SSI 2012/177, in tandem with these amendments to the 1974 Rabies Order?

Part 3 also relates to the Bovine Semen (England) Regulations 2007.

- Do the Bovine Semen (Scotland) Regulations 2007 carry out the same functions as the English Regulations? What will be done with them?

**Answer:** In relation to Scottish legislation, in exercise of the powers available to the Scottish Ministers in the European Union Withdrawal Act 2018 to fix deficiencies in retained EU law, the Scottish Government anticipates bringing forward an SSI to make amendments to various provision in existing SSIs in the area of animal health to prepare for a no deal exit from the EU on 29 March 2019. It is anticipated that SSI will include amendments to the Bovine Semen (Scotland) Regulations 2007 and the Trade in Animals and Related Products (Scotland) Regulations 2012, both of which cover more or less the same ground as the equivalent legislation in England (ie the Bovine Semen (England) Regulations 2007 and the Trade in Animals and Animal Products Regulations 2011) amended in Part 3 of the proposed SI.
Notification for the Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018

NOTIFICATION TO THE SCOTTISH PARLIAMENT

Name of the SI(s) (if known) or a title describing the policy area

The Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018.

A brief explanation of the law that the proposals amend

The Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018 ("the proposed SI") is being made using powers under the European Union (Withdrawal) Act 2018 in order to correct deficiencies in what will become retained EU law relating to trade in animals and animal products and the non-commercial movement of pet animals.

The EU legislation that will be amended by the proposed SI is extensive and is therefore set out in the Annex.

The proposed SI also amends the Trade in Animals and Related Products Regulations 2011 (for England) and the Trade in Animals and Related Products Regulations (Northern Ireland) 2011. The amendments to those Regulations are not referred to further in this notification.

Summary of the proposals and how these correct deficiencies

The legislative amendments contained in the proposed SI do not change existing policy, but will be necessary in the event of a ‘no deal’ exit from the EU on 29 March 2019 to ensure the operability of existing provision on trade in animals and animal related products.

The legislation amended currently contains various EU references, terminology and definitions that will not be appropriate once the UK is no longer an EU Member State. The proposed SI will address deficiencies in retained EU law by making appropriate deletions and/or amendments. The proposed SI will also make provision for both legislative and administrative functions to be exercised by the “appropriate authority” which, in relation to Scotland, is the Scottish Ministers or the Secretary of State with the consent of the Scottish Ministers (with similar provisions for the other devolved administrations). The amendments that will be brought forward by the proposed SI include:

• References to “Community legislation” amended to alternatives as appropriate (e.g. “EU derived domestic legislation”).
• References to “member State” amended to “the appropriate authority”.
• New definition of “third country” added to make clear that it means any country other than an EU member State or the UK, including the Channel Islands and the Isle of Man.
Notification for the Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018

- References to various certificates referenced in existing EU legislation are, where appropriate, substituted for “relevant certificates as published by the appropriate authority”.
- Reference to “Community reference laboratory” is amended to “national reference laboratory”.
- References to the “TRACES” system (the EU’s Trade Control and Expert System, tool for all sanitary requirements on intra-EU trade and importation of animals, semen and embryo, food, feed and plants) replaced where appropriate with references to “the United Kingdom’s system for import control notifications” (this is the UK’s replacement system for TRACES currently under development by the Animal & Plant Health Agency).
- Making provision for the legislative functions currently exercisable at an EU level to be exercised domestically by the “appropriate authority” (in relation for example to movement of pet animals, where the appropriate authority will have power by regulations to make provision in relation, for example, to species specific requirements for marking or describing pet animals and species specific preventive health measures for diseases or infections.

An explanation of why the change is considered necessary

The changes made by this proposed SI, whilst numerous, are fairly minor and technical in nature and are necessary to ensure that what will become retained EU law continues to be operable should the UK leave the EU under a no deal scenario. It is also hoped that maintaining in the UK a system based on EU-wide rules will help to facilitate and maintain trade between the UK and the EU.

Scottish Government categorisation of significance of proposals

Category B. The legislative amendments which will be made by the proposed SI do not change existing policy. The proposed SI does however transfer a number of administrative and legislative functions currently falling to the Commission to the Scottish Ministers. The Scottish Government has worked with DEFRA on the amendments and is content that the provision to be made is necessary and appropriate to ensure that what will become retained EU law continues to be operable once the UK leaves the EU.

Impact on devolved areas

The proposed SI will make provision in a devolved area. The legislative amendments in the proposed SI are technical in nature, do not include policy changes and are required to ensure the continued operability of existing measures. It will not have a significant impact on devolved areas of competence. It is intended that the proposed changes will respect and protect the Scottish Ministers’ powers under the devolution settlement. In particular, the proposed SI will also make provision for administrative and legislative functions in the legislation being amended to be exercised by the “appropriate authority”: in relation to Scotland, by the Scottish Ministers or the
Notification for the Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018

Secretary of State with the consent of the Scottish Ministers (with similar provisions for the other devolved administrations).

An example of provision made for legislative functions to be exercised by the appropriate authority is in relation to movement of pet animals, where the appropriate authority will have power by regulations to make provision in relation, for example, to species specific requirements for marking or describing pet animals and species specific preventive health measures for diseases or infections (being legislative functions previously exercisable at an EU level).

Summary of stakeholder engagement/consultation

We are in regular contact and communication with Defra and other devolved administrations. There has been no formal stakeholder engagement or consultation in relation to the proposed SI as it is envisaged that there will be no measurable change to policy and no operational or financial impact is anticipated.

A note of other impact assessments, (if available)

An impact assessment has not been carried out in relation to the proposed SI as its main aim is to remove or substitute what will become redundant references or provisions, add new definitions where necessary and generally ensure that what will become retained EU law is operable upon EU exit under a no deal scenario.

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

The Scottish Ministers believe that the changes in the proposed SI are necessary to secure continuation of an effective regime for trade in animals and animal related products and the non-commercial movement of pet animals. This will help to provide continuity of business in these areas on EU exit. The proposed SI will make amendments to existing EU legislation which are minor and technical in nature and aim to ensure the continued operability of what will become retained EU law. Where the proposed SI will make provision for exercise of administrative and legislative functions in the legislation being amended provision is made for those functions to be exercised by the “appropriate authority”: in relation to Scotland, by the Scottish Ministers or the Secretary of State with the consent of the Scottish Ministers (with similar provisions for the other devolved administrations). In these circumstances the Scottish Ministers consider it is appropriate that the proposed SI be brought forward by the UK Government. This is particularly the case in circumstances where the proposed SI will protect Scottish Ministers’ interests under the devolution settlement as outlined above.
ECCLR/S5/18/38/3
Annexe C

Notification for the Import and Trade of Animals and Animal Products (Amendment etc.) (EU Exit) Regulations 2018

Where relevant – detail how Scottish Ministers have had regard to the guiding principles on animal welfare and the environment

The proposed SI’s amendments do not change existing policy, but are necessary to ensure that existing controls on imports of live animals, products of animal origin, germplasm (semen, ova and embryos) and the non-commercial movement of pet animals can continue to operate in the UK should we leave the EU under a ‘no deal’ scenario. The EU instruments amended have been made with the guiding principles on animal welfare and the environment in mind. We are content therefore that the proposed SI will not adversely impact on animal welfare (in particular that regard must be given to the welfare requirements of animals as sentient beings).

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

The proposed SI is subject to the affirmative procedure and will be laid at Westminster on 14 January 2019. We are working with Defra on the basis no EU Exit SIs will proceed to be made (for negative procedure SIs), or laid in draft (for affirmative SIs), until after they have been through the consent process agreed with the Scottish Parliament.

If the Scottish Parliament does not have 28 days to scrutinise Scottish Minister’s proposal to consent, why not?

On this occasion the Scottish Parliament does not have the full 28 days to consider this proposal to consent. The Scottish Parliament is respectfully asked to consider and respond to this notification by no later than 14 January 2019. The reason for this is a recent decision within Defra to include in the proposed Instrument provision in relation to exercise of legislative functions as outlined above and which was out with our control. Accordingly, the proposed SI is now subject to affirmative procedure in the Westminster Parliament which has impacted on the timetable for its delivery and consequently the time that can be given to considering the proposal to consent.

Information about any time dependency associated with the proposal

N/A.

Any significant financial implications?

The proposed SI is not expected to have any financial implications, including for the Scottish Government and for stakeholders in Scotland.

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

There are no anticipated broader governance issues anticipated with the proposed SI and the Scottish Government will continue its good working relationships with UK Government and the other Devolved Administrations. The proposed SI will simply
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make a number of necessary amendments to ensure the operability of what will become retained EU law in the event of a ‘no deal’ UK exit from the EU on 29 March 2019.

ANNEX
Legislation amended by The Import of Animals and Animal Products (Amendments) (United Kingdom) (EU Exit) Regulations 2018

1. Commission Decision 93/52/EC recording the compliance by certain Member States or regions with the requirements relating to brucellosis (B. melitensis) and according them the status of a Member State or region officially free of the disease

2. Commission Decision 93/352 laying down derogations from the conditions of approval for border inspection posts located in ports where fish is landed


4. Commission Decision 94/360/EC on the reduced frequency of physical checks of consignments of certain products to be implemented from third countries

5. Commission Decision 1995/410/EC laying down the rules for the microbiological testing by sampling in the establishment of origin of poultry for slaughter intended for Finland and Sweden

6. Commission Decision 1997/152/EC concerning the information to be entered in the computerized file of consignments of animals or animal products from third countries which are re-dispatched


9. Commission Decision 2000/572/EC laying down the animal and public health and veterinary certification conditions for imports of meat preparations into the Community from third countries

10. Commission Decision 2001/812/EC laying down the requirements for the approval of border inspection posts responsible for veterinary checks on products introduced into the Community from third countries
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11. Commission Decision 2003/459/EC on certain protection measures with regard to monkey pox virus

12. Commission Decision 2003/467/EC establishing the official tuberculosis, brucellosis, and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds

13. Commission Decision 2003/779/EC laying down animal health requirements and the veterinary certification for the import of animal casings from third countries


15. Commission Regulation (EC) No 282/2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community


17. Commission Regulation No (EC) 2005/1739/EC laying down animal health requirements for the movement of circus animals between Member States

18. Commission Decision 2006/146/EC on certain protection measures with regard to certain fruit bats, dogs and cats coming from Malaysia (Peninsula) and Australia

19. Commission Decision 2006/168/EC establishing the animal health and veterinary certification requirements for imports into the Community of bovine embryos


21. Commission Decision 2007/25/EC as regards certain protection measures in relation to highly pathogenic avian influenza and movements of pet birds accompanying their owners into the Community

22. Commission Decision 2007/240/EC laying down new veterinary certificates for importing live animals, semen, embryos, ova and products of animal origin into the Community

23. Commission Decision 2007/275/EC concerning lists of animals and products to be subject to controls at border inspection posts

24. Commission Decision 2007/777/EC laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries
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25. Commission Decision 2008/185/EC on additional guarantees in intra-Community trade of pigs relating to Aujeszky’s disease and criteria to provide information on this disease

26. Commission Decision 2008/636/EC establishing the list of third countries from which Member States authorise imports of ova and embryos of the porcine species

27. Commission Regulation (EC) No 798/2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements

28. Commission Regulation (EC) No 119/2009 laying down a list of third countries or parts thereof, for imports into, or transit through the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements


31. Commission Decision 2009/821/EC drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces

32. Commission Regulation (EU) No 206/2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements

33. Commission Decision 2010/470/EC laying down model health certificates for trade within the Union in semen, ova and embryos of animals of the equine, ovine and caprine species and in ova and embryos of animals of the porcine species

34. Commission Decision 2010/472/EC on imports of semen, ova and embryos of animals of the ovine and caprine species


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38. Commission Implementing Decision 2011/630/EU on imports into the Union of semen of domestic animals of the bovine species

39. Commission Regulation (EU) No 28/2012 laying down requirements for the certification for imports into and transit through the Union of certain composite products

40. Commission Implementing Decision 2012/137/EU on imports into the Union of semen of domestic animals of the porcine species

41. Commission Implementing Decision 2013/139/EU laying down animal health conditions for imports of certain birds into the Union and the quarantine conditions thereof

42. Commission Implementing Decision 2013/503/EU recognising parts of the Union as free from varroosis in bees and establishing additional guarantees required in intra-Union trade and imports for the protection of their varroosis-free status

43. Commission Implementing Decision 2013/519 concerning the list of territories or third countries from which dogs, cats and ferrets are authorised to be imported in accordance with Directive 92/65/EEC


46. Commission Implementing Regulation EU 743/2013 introducing protective measures on imports of bivalve molluscs from Turkey intended for human consumption

47. Commission Implementing Decision 2013/764/EU concerning animal health control measures relating to classical swine fever in certain Member States

48. Commission Implementing Regulation (EU) No 636/2014 on a model certificate for the trade of unskinned large wild game
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49. Commission Decision 2015/1901/EU laying down certification rules and a model health certificate for importation into the Union of consignments of live animals and of animal products from New Zealand

50. Commission Implementing Decision (EU) 2018/320 on certain animal health protection measures for intra-Union trade in salamanders and the introduction into the Union of such animals in relation to the fungus Batrachochytrium salamandrivorans

51. Commission Implementing Regulation (EU) 2018/659 on the conditions for the entry into the Union of live equidae and of their semen, ova and embryos


53. Commission Implementing Regulation (EU) 2018/878 of 18 June 2018 adopting the list of Member States, or parts of the territory of Member States, that comply with the rules for categorisation laid down in Article 2(2) and (3) of Delegated Regulation (EU) 2018/772 concerning the application of preventive health measures for the control of Echinococcus multilocularis infection in dogs.