

Exiting the European Union – Chemicals

Notification to the Scottish Parliament

6 December 2018

1. Name of instrument and summary of proposal:

The Chemicals (Health and Safety) and Genetically Modified Organisms (Amendment of Retained EU Law) (EU Exit) Regulations 2018 (The CGMO Regulations) will amend existing EU and UK domestic legislation relating to chemicals, pesticides and genetically modified organisms (GMO) ensuring that the UK has an operable regulatory regime in place upon withdrawal from the European Union.

The CGMO Regulations do not make any policy changes and are limited to ensuring continued operability of the relevant legislation. However, 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.

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

The Biocidal Products Regulation (Regulation (EU) No 528/2012) (“the BPR”) concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, such as pests or bacteria, by the action of the active substance contained in the biocidal product. The BPR establishes an EU list of active substances which may be used in biocidal products and simplifies the approval and authorisation of active substances contained in the biocidal products across the EU.

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. There is a simplified authorisation procedure for biocidal products considered to be less harmful for human and animal health and the environment. By way of derogation from the usual procedures for approval, a competent authority may for a limited period permit the marketing available on the market or use of a biocidal product, which does not fulfil the conditions for authorisation, if such a measure is necessary because of a danger to public or animal health or the environment. The Commission may take a decision to extend such a measure for a further limited period. Furthermore, the Commission may allow a Member State to authorise a biocidal product containing a non-approved active substance if its use is essential for the protection of cultural heritage. The BPR also introduces timelines for Member State evaluations, opinion-forming and decision-making and promotes the reduction of animal testing by mandatory data sharing obligations and encouraging alternative testing methods.

The CGMO Regulations amend the BPR to fix inoperabilities which will arise from EU exit. Where ECHA previously undertook functions acting as the ‘Agency’, these functions are transferred to the competent authority. The competent authorities for the

BPR are the Secretary of State in relation to England, the Scottish Ministers in relation to Scotland, and the Welsh Ministers in relation to Wales. Where a matter is outside the competence of the Scottish Ministers or the Welsh Ministers, the competent authority is the Secretary of State. In practice, Ministers in all of the administrations have delegated their functions as a competent authority to the HSE by Agency Agreement. The intention is that, through updated agency agreements, the HSE will continue to undertake the functions of the competent authority throughout the UK.

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. The decisions to update the Simplified Active Substance List to include, restrict or remove a substance, to approve an active substance for inclusion on the UK List and the conditions of its approval, and to renew the approval of an active substance or amend the conditions specified for its approval will be made by the Secretary of State with the consent of the Devolved Administrations.

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

The CGMO Regulations also make minor and technical changes to ensure the effective operation of BPR post exit. References to the UK using ECHA IT systems are amended with a provision to follow a UK system. Reference to using EU Scientific Committees and advisory bodies are deleted. The appeal provisions are amended to allow appeals to be determined in accordance with the provisions specified within the BPC Regulations. Amendments are also made to a number of Commission Implementing Regulations, which relate to the BPR, to ensure that they operate in line with the amended BPR regulations upon withdrawal.

The Classification, Labelling and Packaging of substances and mixtures (Regulation (EC) No 1272/2008) (“the CLP Regulation”) adopts the UN Globally Harmonised System of the classification and labelling of chemicals throughout the EU. The CLP Regulation requires manufacturers, importers, distributors, and downstream users to classify (identify intrinsic hazards – e.g. carcinogenic, toxic for reproduction, mutagenic etc.), label (communicate those hazards) and safely package the chemicals they place on the market. Manufacturers and importers are also required to notify the details of the hazard classifications of those chemicals to ECHA for inclusion in the Classification and Labelling Inventory.

The purpose of the CLP Regulation is to ensure a high level of human health and the environment, which are devolved matters. This protection is achieved through establishing criteria for the classification of chemicals and rules on their labelling and packing. The CLP Regulation seeks to ensure consistent requirements on the labelling of chemicals and safety data sheets. Product standards, safety and liability - including product labelling - are subject to a specific reservation. Reserved and devolved interests are therefore heavily intertwined within the CLP Regulations.

The CGMO Regulations establish a UK mandatory classification and labelling list (the UK mandatory CLP list), which is the list of mandatory classification and labelling requirements of substances and groups of substances, which will replace the EU list of harmonised classification. Harmonised classification is only applicable from one nation to another so this is no longer appropriate post exit. All the existing harmonised classification and labelling already agreed by the EU and listed in Part 3 of Annex VI of the CLP Regulation will be included in the UK Mandatory CLP List.

Under the new regime, manufacturers and importers will continue to comply with the duty to notify details of the self-classifications for the substances they place on the market. The HSE will undertake the role of the Agency and carry out the relevant Agency functions for the whole of the UK. The HSE must have regard to opinions published by ECHA on or after exit day for all substances subject to harmonised classification and labelling requirements under the CLP regulation. 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.

The tasks and functions presently carried out by the EU will be carried out in the UK by the Secretary of State with the consent of the Devolved Administrations, in line with their devolved competence. Such functions include the decision to accept a recommendation from HSE on the mandatory classification and labelling of a substance, including those based on an opinion of ECHA, and the power to make regulations to adapt specific article and the Annexes of the CLP Regulations. The Devolved Administrations or the Secretary of State may request that HSE prepare and submit draft exemptions from labelling and packaging requirements.

Functions that currently sit at Member State level are conferred on the Secretary of State and the Devolved Administrations, in line with their devolved competence. 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. The Devolved Administrations may take appropriate provisional measures, within their devolved competence, if they have justifiable grounds for believing that a substance or mixture constitutes a serious risk to human health or the environment due to reasons of classification, labelling or packaging. Within a specified time, the taker of the measure must revoke the measure or begin the process to make the measure permanent UK-wide measure. The decision of whether to make the measure

permanent will be made by the Secretary of State, subject to the consent of the Devolved Administrations.

The CGMO Regulations also make minor amendment to other regulations, which refer to the CLP Regulations. References in pesticides regulations are amended so that they refer to the UK mandatory CLP list.

The Export and Import of Hazardous Chemicals Regulation (Regulation (EU) No 649/2012) (“the PIC Regulation”) implements in the EU the international *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (the Convention). It goes further than the Convention in applying the provisions to chemicals considered to be banned or severely restricted in the EU under other chemicals law. The PIC Regulation requires exports of listed chemicals to be notified to the importing country and, for some chemicals, the consent of the importing country must be sought before export can proceed.

The PIC Regulation concerns import and export control, which is subject to a specific reservation. However, the definition of chemicals, to which the PIC Regulation relates, includes pesticides. The movement into and out of Scotland of pesticides is an exception to this reservation. Therefore, the Scottish Government’s interests in relation to the PIC Regulation relate to matters concerning pesticides.

The CGMO Regulations 2018 amend the PIC Regulation, making those changes necessary to ensure the continued operation in the UK of the export notification and explicit and prior informed consent requirements within the scope of the PIC Regulation post exit and that these arrangements fully implement the requirements of the Rotterdam Convention, to which the UK is a Party. The new UK PIC regime will apply to the export of chemicals from the UK and the import of chemicals to the UK. The functions currently performed by ECHA under the EU PIC Regulation will be conferred upon the UK PIC Designated National Authorities, being the Health and Safety Executive and the Health and Safety Executive for Northern Ireland.

The CGMO Regulations provide for a UK PIC list, which will list entries (for individual chemicals or groups of chemicals) to which the PIC Regulation applies. The Secretary of State shall be responsible for participation in the Convention and communication with the Secretariat of the Convention. The Secretary of State must review the list of chemicals in the UK PIC list, at least every year, on the basis of developments in retained EU law and under the Convention. Chemicals considered to be banned or severely restricted in retained EU law, shall be included in the UK PIC list. 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 based on guidance documents received from the Secretariat or information regarding chemicals notified as banned or severely restricted by other Parties. 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 the Scottish Ministers, to the extent that it is within their devolved competence.

The UK PIC Designated National Authorities will also be responsible, for some of the Commission's current functions, upon EU exit. This includes an obligation to publish information received from the Secretariat regarding chemicals subject to the PIC procedure and the decisions of importing Parties regarding import conditions applicable to those chemicals on their websites, and to advise and assist importing Parties upon request. The CGMO Regulations make other minor and technical amendments to the PIC Regulation, such as replacing references to ECHA's ePIC IT system with references to replacement UK procedures.

The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 ("the BPC Regulations") are UK-wide regulations which appoint the competent authorities for Great Britain in respect of the BPR and the CLP Regulation and the designated national authorities for the PIC Regulation. The competent authorities designated for the purposes of the CLP Regulation are the same as those designated for the BPR. Ministers have also delegated their functions as a competent authority, for the purposes of the CLP Regulation, to the HSE by Agency Agreement.

The BPC Regulations allow for enforcement, including penalties for infringement for the BPR and the CLP Regulation in respect of Great Britain and for the PIC Regulation in respect of the United Kingdom. The BPC Regulations also provide that a person may not place on the market a biocidal product containing an essential use derogation, as granted by the European Commission, without authorisation of the competent authority.

The proposed amendments to the BPC Regulations are largely technical in nature. References to the BPR and the PIC Regulation are being altered or omitted to reflect proposed amendments to the retained version of the EU regulations to which they relate and to ensure their continued operability upon withdrawal. The provisions that refer to the essential use derogation have been amended to allow for the amendment which, upon withdrawal, enables the Secretary of State or the Devolved Administration, in line with their devolved competence, to make and extend an essential use derogation.

The Plant Protection Products (Fees and Charges) Regulations 2011 set fees and charges to recover the government's costs of implementing Regulation 1107/2009 and aspects of Directive 2009/128/EC, establishing a framework for Community action to achieve the sustainable use of pesticides, and Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin.

A set of three statutory UK-wide instruments will make corrections to the EU plant protection product (PPPs) regulatory regime becoming retained EU law so that it can continue to operate effectively in the UK following a 'no deal' UK exit from the EU on 29 March 2019. These instruments were notified to the Scottish Parliament's Rural Economy and Connectivity Committee on 1 November and the Committee have given consent in each case.

The PPP Fees and Charges Regulations need to be amended to reflect those changes to the regulatory regime for PPPs that are necessary to ensure an operable national system.

Most of the fees and charges regime will remain unchanged as a result of exit, including the fee structure and the annual charge. Changes will provide for the introduction of a small number of administrative fees to cover additional coordination and assessment work and to recover the costs of work which was previously carried out by EU institutions, but which will be repatriated to the UK after exit.

The Genetically Modified Organisms (Contained Use) Regulations 2014 (“GMO (CU)”) are GB regulations that implement Directive 2009/41/EC. The regulations lay down containment measures for the contained use (i.e. in research laboratories/institutes) of GMOs with a view to protecting human health and the environment. They cover both reserved (health and safety) and devolved (environment) responsibilities.

The Genetically Modified Organisms (Contained Use) Regulations 2014 (“the 2014 Regulations”) are amended to remove references to EU Directives and Regulations, that will become inappropriate or redundant on EU exit, and replace them with references, where appropriate, to equivalent UK regulations.

In particular, in regulation 3(2)(b)(i) of the 2014 Regulations, a reference to Regulation (EC) No 726/2004 relating to GMOs in veterinary medicines will be replaced by a reference to the domestic Veterinary Medicines Regulations 2013. Along with this change, new transitional provisions will ensure that such medicinal products, marketed in accordance with Regulation (EC) No 726/2004 pre-exit, remain exempt from the scope of The Genetically Modified Organisms (Contained Use) Regulations 2014.

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.

3. Why are these changes necessary?

These changes are necessary to allow the continuation of the effective functioning of both domestic and retained EU law. In the EU, the overall regulation of chemicals is provided for by a range of legislative instruments, including but not limited to regulations on BPR, CLP, PIC and PPPs which are covered here. The legislation is important in order to protect human health and the environment, and to facilitate trade.

4. Scottish Government categorisation of significance of proposals

The amendments on GMO(CU) and PPP Fees and Charges have been assessed as Category A. In relation to PPP (Fees and Charges) the changes made to fees do not include material increases.

The remaining elements are assessed as Category B, and can be seen as sitting alongside other chemicals notifications, most significantly the one relating to REACH.

The instrument is drafted on the basis of 'no-deal' between the UK and EU at the point of which UK leaves the EU and no future relationship with ECHA.

The political declaration [published by the UK Government on the 22nd November](#) states that the UK and the EU will also explore the possibility of cooperation of United Kingdom authorities with Union agencies including the European Chemicals Agency (ECHA) but this would not apply in a no deal context.

5. Impact on Devolved Areas

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.

Chemicals policy engages a complex mixture of reserved and devolved competence. Reserved and devolved interests are heavily intertwined in the BPR and CLP Regulation. Environmental protection, waste management and public health are devolved while product standards including product labelling, consumer protection and Health and Safety at Work are reserved.

The PIC Regulation concerns import and export control, which is subject to a specific reservation, an exception to which is the movement into and out of Scotland of pesticides. The Scottish Government's interests in relation to the PIC Regulation relate to matters concerning pesticides.

6. Stakeholder engagement/consultation

We are in regular contact with all our stakeholders regarding the move towards leaving the EU. However, these measures are aimed solely at preserving the functioning of the regulations as they are at present and we have not undertaken any focussed engagement or consultation on this basis.

HSE have been in regular contact with stakeholders, including hosting a specific EU Exit event in August 2018 which was generally well received and included over 120 attendees. Feedback from the event has been reflected in the drafting of this instrument. The UK Government have also published technical notices in relation to BPR, CLP and PIC.

Industry stakeholders are primarily UK- or EU- wide 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.

7. Any other impact assessments

On the basis that this does not result in any policy changes, an impact assessment has not been prepared.

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

The provisions were made at the UK level to reflect overlapping reserved and devolved responsibilities, and it is most effective to make the changes to address deficiencies at the same level. Officials have worked with Defra and HSE 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.

9. 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 domestic and EU legislation is already in line with these principles and as no substantive policy changes are being introduced, it is considered that these amendments are in adherence with these principles.

10. 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. This will include proposals for future monitoring and enforcement.

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. As part of these discussions, officials expect there will be updated Agency Agreements between the Scottish Ministers and the Health and Safety Executive which will continue the existing arrangements but recognise their operation in a non-EU Member State context.

Regarding reporting requirements for the Genetically Modified Organisms (Contained Use) Regulations 2014, the UK and the EU, as a whole, are signatories to the Cartagena Protocol on Biosafety. We will therefore continue to have international obligations to notify, and be notified by, other States in the event of any accidental

release of GMOs as applicable. Application procedures for GMO contained use in England, Scotland and Wales are set out in an Agency Agreement and a Memorandum of Understanding which work well and are regularly reviewed.

11. Intended UK laying date

Our latest understanding is that this instrument is to be laid in the week commencing 14th January 2019.

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

Depending on the exact laying date decided by the UK Government, there may be slightly less than the usual 28 day period for Parliament consider this notification. This is as a result of the time it has taken to finalise and agree the content of what is a complex SI with several components. We are in touch with UK Government to establish whether there is any further flexibility in the laying date.

13. 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.

14. Any significant financial implication?

Many of the amendments are minor and technical and will have no financial implications. However, it is reasonable to expect some financial implications for industry in transitioning to a new UK Chemicals regulatory regime, coupled with existing commitments to the EU regime where operators choose to pursue this.

15. Additional Information to Note

BPR, CLP and PIC are specific EU regulations, which are implemented by the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013. The Scottish Parliament has already been notified of a similar intention to consent to UK wide legislation on both Persistent Organic Pollutants and Mercury, and the EU Regulation on the Registration Evaluation Authorisation and Restriction of Chemicals (REACH).

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