Submission from ClientEarth and response from Defra

Draft Pesticides (Amendment) (EU Exit) Regulations 2020

Q1: Regulation 2(2) provides that the requirements to submit supplementary dossiers for the renewal procedure of an active substance no later than 30 months before the expiry of the approval only applies to substances approved for use where the approval expires on or after 12 May 2026. It is not clear why this change has been made.

A1: This measure is to provide a smooth transition between EU and retained law. It has the effect that the relevant requirements which apply to active substances under retained law will be the same as for those same substances when they are considered under the EU regime, given that in retained law active substance approvals which expire in the first three years after the end of the Transition Period will be extended to allow the necessary time for evaluation.

Commission Implementing Regulation 2020/103 makes a number of amendments to one of the supporting PPP EU Regulations i.e. Regulation (EU) No 844/2012. Implementing Regulation 2020/103 came into force during Feb 2020 which requires amendments to be made to the retained law. Article 1(1) of 2020/103 amends Article 6 of Regulation (EU) No 844/2012 by replacing paragraph 3 with "The supplementary dossiers shall be submitted no later than 33 months before the expiry of the approval".

We have added the sentence "The requirement applies to substances approved for use within Great Britain where that approval expires on or after 13 May 2026". Although this means that the requirement for alignment of CLP dossiers (under Regulation (EU) No 844/2012) with active substance renewal dossiers (under Regulation (EU) No 1107/2009) will apply in GB at a later date, the requirement will apply to the same substances in GB at the same point in the process as it applies in the EU renewals process. The date at which the requirement will apply will be 3 years later in GB than in EU in line with the extension of approvals. Notifiers will be treated equitably in both the GB and EU programmes. The extension also allows some time for the new GB CLP processes to 'bed in'.

Implementing Regulation 2020/103 applies to those substances with approvals expiring on or after 13 May 2023, and Regulation (EU) No 844/2012 requires applications for renewal to be made 3 years before the expiry of the approval. This means that CLP dossiers must be submitted with EU active substances applications which were due for submission from May this year. Because of the extension of approvals achieved by the Schedule 1 para 2(4) amendment (of 2019 No. 556 The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019), the new expiry date for those active will be May 2026 in GB, and applications for renewal of those active substances will not be due in GB until May 2023. We have therefore applied this new requirement to the same substances under the GB regime at the same point in the procedure as it applies to in the EU regime.

Q2: Regulation 2(3)(a)(i)(bb) supplements a reference to the "European Chemicals Agency" with simply the "Agency". It is not clear which body is being referred to here.

A2: This change is made so that the legislation links correctly to the retained CLP Regulation. As above, this amendment also refers to changes made by Implementing Regulation 2020/103 to Regulation (EU) No 844/2012. Article 1(3)(e) of 2020/103 adds a new paragraph 9 to Article 11 which includes references to the European Chemicals Agency ('the Agency') and the Committee for Risk Assessment of the Agency. This

new paragraph needs to be amended in various places to ensure that it works in national law. Given that ECHA Committee for Risk Assessment is defined in the retained PPPR legislation, it is necessary to define 'the Agency' in line with the retained CLP Regulation (Article 2(23)) i.e. 'the Agency' means "the Health and Safety Executive".

Q3: Regulation 3(8) sets out requirements for monitoring and controls of compliance with Regulation 1107/2009 on placing of plant protection products on the market. However, this regulation removes wording which would permit the appropriate authority to make regulations in respect of the official controls to be carried out, in particular concerning (a) the production, packaging, labelling, storage, transport, marketing, formulation, parallel trade and use of plant protection products and (b) the collection of information and reporting on suspected poisonings." It is unclear why this change has been made.

A3: This change brings retained law into line with changes which have already been made elsewhere. The new Official Control Regulations (OCRs - Regulation (EU) No 625/2017) came into force on 14 December 2019 (N.B. this was implemented by The Official Controls (Plant Protection Products) Regulations 2020 (SI No 2020/552) to enable the UK to strengthen and develop the efficiency and effectiveness of its control system). Article 161 of the OCRs makes various amendments to Regulation (EC) No 1107/2009; Article 161(1)(b) deletes the second and third paragraphs of Article 68 of Regulation (EC) 1107/2009. Therefore, we need to remove the specified wording from retained EU law.

Q4: Regulation 6(7) makes amendments to Commission Implementing Regulation (EU) 2019/533. In particular, at (7)(c) it omits requirements for Isoprothiolane and Pymetrozine to not be analysed in or on any product in 2021 and 2022. It is unclear why this change has been made.

A4: These provisions remove redundant references only and do not omit any active provisions. The monitoring requirements placed on the UK by Regulation (EU) No 2019/533 until 2022 will be retained law. On the specific questions raised:

- For Isoprothiolane: Annex 1, Part C of Regulation (EU) No 2019/533 (the 'Remarks' column) states that *"The substance is not to be analysed in or on any product in 2021 and 2022"*. Therefore we have removed this sentence from GB retained law as it will no longer be a future requirement.
- For Pymetrozine: We have not omitted the requirement to analyse this during 2021 and 2022. We have simply tidied up the comments within the 'Remarks' column to omit the reference *"The substance is not to be analysed in or on any product in 2020"*, because it is superfluous.

19 October 2020