Post-Brexit pesticides SIs

PAN UK briefing for parliamentarians and policy makers

February 2019

Overview:

The stated aim of these two Statutory Instruments is to replace all pesticide-related EU processes with national processes and build additional national capacity to operate a standalone UK regime. The two SI's are as follows:

- Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019
  ('PPP SI' - *concerns the process around authorising active substances)*
- Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019
  ('MRL SI' - *concerns the setting of levels of pesticide residue that is permitted to be detected in food)*

When discussed in the Lords (on 12th February 2019) the government chose to speak to the two SIs together and it is presumed they will repeat this approach when they are discussed in the Common's delegated Legislation Committee (DLC) on 21st February. Therefore, this briefing sets out PAN UK's key concerns regarding both SIs, from the perspective of the protections they will offer for human health and the natural environment. The following specific concerns are outlined in this document:

1. Loss of oversight, checks and balances and a significant consolidation of power
2. Weakening of requirement to obtain independent scientific advice
3. Weakening of other standards
4. Important parts of regime left unclear or detail to be filled in later through guidelines
5. Loss of capacity and lack of investment in standalone regime

Before outlining the key concerns, here are some suggested recommendations for the government:

i) Many of the substantive aspects of the new UK Regulation will be set out in future guidelines which can be issued, amended or withdrawn by the competent authority. Given that these guidelines have the potential to impact greatly on how the UK pesticide regime functions, the government should guarantee to consult stakeholders formally for the making, amending or revoking of guidance and principles related to pesticides.

ii) Given that these SIs grant the Secretary of State significant individual power in determining the future authorisation of pesticides, and in order to mitigate the high potential for corporate capture by the agrochemical industry, the government should formalise the role for independent scientific advice within the process, including upgrading the requirement to obtain advice from 'may' to 'shall'.

iii) Given the risks that these SIs pose to the UK's pesticide standards, and in particularly to the protection of human health and environment, would the government reverse its decision to cancel the previously promised public consultation on the UK's National Action Plan under the Sustainable Use Directive? This is particularly urgent in light of recent evidence that pesticides are the key factor driving to us towards the sixth mass extinction.

Key concerns:

1. Loss of oversight, checks and balances and a significant consolidation of power

- Full power to make, amend or revoke guidance, principles and regulations on the implementation processes for the UK regulations rests with the Secretary of State, the Welsh and Scottish Ministers and relevant body in Northern Ireland (referred to as 'Competent Authorities') . It is unclear what oversight, checks and balances there will be in terms of these powers, and whether there will be any requirement for consultation with interested parties. Within the current EU Regulations there are multiple bodies involved in determining guidance and regulations, with oversight by the Commission and Authority.

- EFSA (responsible for verifying residues are safe for consumers), European Commission (responsible for setting new, amending or removing MRLs after EFSA's opinion), the Standing Committee on the Food Chain and Animal Health and Member States (assisting the Commission), national authorities (responsible for authorisations defining how and when a pesticide may be used) are replaced by the 'competent authorities for the constituent territories'.

- The competent authorities will set the details and formats for evaluation, assessment and concluding procedures, they will also carry out these procedures. It appears there is no independent body or division of duties set out in the UK Regulations, whereas such tasks are carried out by different bodies (Rapporteur Members States, the Commission and the Authority) in the EU Regulations, providing a level of separation of responsibilities and independence of decision processes. There is broad discretion for the 'competent authorities' (see below use of "may", "take into account", "have regard to").

- Provisions for processes of appeal/administrative review of decisions appear to have been removed from both SIs and not replaced by reference to UK procedures.

- The EU Regulations specify that evaluation and decision making will take into consideration guidance development by the Standing Committee on the Food Chain and Animal Health. This is deleted in the UK Regulations and there does not appear to be a similar reference made to consideration of guidance by any specific food or animal health bodies within the UK Regulations.

- There is no reference to an independent body with assessment, monitoring or enforcement powers.

<u>Key critique from the Lords:</u>

- Baroness Jones: “At the moment, we have in the EU a thorough process of evaluation of products. The responsibilities for risk assessments are shared out across member states. There are clear decision-making roles for the European Food Safety Authority, the rapporteur member state, individual member states and the European Commission. All this is supported and backed up by access to the best scientific advice. While no process is perfect, there is considerable assurance that within the EU a detailed assessment of the risks has been carried out and cross-checked. These proposals are intended to replace all of this with an assessment by the Health and Safety Executive and a decision in the hands of one person, the “competent authority” as described in the text—otherwise known as the Secretary of State. Under these proposals, full power to make, amend or revoke guidance, principles and regulations for the UK rests with the Secretary of State and the devolved Ministers. There is a major loss of scrutiny, checks and balances, and audit powers.”

<u>Response from the government to the Lords:</u>

- Lord Gardiner of Kimble didn’t respond to this criticism satisfactorily. He downplayed the huge role played by EU institutions in the EU pesticide regime simply stating… “Decisions at EU level are taken on the basis of evaluations and assessments undertaken by member states, such as by our own Health and Safety Executive. In future, these evaluations will inform a national decision, rather than informing UK input into an EU decision.”

2. Weakening of requirement to obtain independent scientific advice

- There is no requirement for the “competent authority” (the body that considers and grants approvals in the respective territories of the UK) to obtain or consider independent scientific reports, although they “may” do so if they deem it appropriate (for example – “may consider” in UK Regulations vs “shall consider” in EU Regulations).

  - PPP SI - In the EU Regulation, the Commission “shall” ask the authority for an opinion or for scientific or technical assistance; whereas in the replacement UK text, “*the competent authority must have regard to* –

…….(b) where the competent authority considers it appropriate to obtain it, any independent scientific advice"

- MRL SI - 'scientific opinion of the Authority' substituted for "a competent authority may obtain independent scientific advice, where the competent authority considers it appropriate to so do".

This would mean any such checks are at the discretion of the competent authority, rather than being required by law. It is unclear in the new UK Regulations what the criteria will be for seeking such advice, how it will carried-out consistently over time and between the different constituent territories.

Key critique from the Lords:

- Baroness Jones: "We are also concerned that these two sets of regulations place no requirement for the Secretary of State to seek independent scientific advice. They enable the advice to be sought but do not make it compulsory. There is much use of the word 'may' rather than 'must' in terms of seeking advice. Again, that really is not acceptable. The SI should spell out the specific independent role that the scientists should be required to play; otherwise, there is a real danger that, when budgets are cut in the future, the lack of scientific capacity will be used to short-circuit this requirement and put even more power in the hands of the Secretary of State. This is particularly vital given that there are plans within the document to extend the times for which pesticides are authorised before they are reviewed, meaning that the scientific advice applied might not even be the most up to date available."

Response from the government to the Lords:

- Lord Gardiner of Kimble did not deal with the issue of moving from a situation in which scientific advice is required to one in which the competent authority can decide if it is necessary. He stated "I reassure noble Lords that the functions set out in the EU regime, including those of the European Food Safety Authority, remain relevant in the national context and are being repatriated to the national regime. These will be carried out mostly by the HSE, which will, for example, produce reasoned opinions on maximum residue levels and undertake public consultations on active substances, alongside the independent advice that will be provided by the ECP.
  I stress that other UK bodies with scientific expertise will also play a role in ensuring that the system is robust and sound. Input goes wider than just the HSE. For example, the Food Standards Agency will continue to take an overview of food safety that will encompass pesticides residues in food. FERA will continue to undertake the UK's comprehensive residues-testing programme on behalf of HSE, which currently monitors much more than is required by the current EU monitoring regime. In replacing the EU active substance decision-making processes with national processes, we have made it explicit that the decision-maker must take account of environmental monitoring information submitted by the Environment Agency and its devolved equivalent bodies."

3. Weakening of other standards

- States that a rolling active substance renewals programme will be established but says that 'it will need to be proportionate for one country alone to deliver' which implies a paired back process with less stringent scrutiny. Also states that 'current approvals may be extended using existing powers where necessary' but doesn't appear to limit this power. If the UK doesn't create the capacity required to run its renewals programme efficiently then this creates a loophole under which extensions on approvals could theoretically be given indefinitely.

- EU has requirements to review MRLs within 12 months of an active substance being authorised. This SI extends 12 months to 36 months. However, it doesn't list any additional measures that will be taken to ensure residue levels stay below those which pose a risk to consumers during that period. It also states that 'This may be extended further where the competent authority considers it necessary' but doesn't limit this power so

deadlines could theoretically be extended indefinitely, particularly within a system that doesn't have sufficient capacity.

- Weakening of emergency measures - the EU Regulations, specify steps to be followed in both an emergency and in cases of extreme urgency, namely that restrictions on use and/or sale of the relevant substance shall be taken immediately. However, timescales referred to in the EU Regulations are not carried forwards into the UK Regulations which could result in delays, even if an active substance is causing irreversible damage to health or environment.

- MRL SI - omits sections on infringement procedures and sanctions.

- PPP SI - the EU Regulations setting out the process for review of approval specify that "monitoring data" shall be taken into account when the Commission "reviews" the approval of an active substance. It is unclear whether such "monitoring data" is required to be reviewed by the competent authority in the UK regulations.

<u>Key critique from the Lords:</u>

- Baroness Jones: "Explanatory Memorandum states that the renewal programme will, 'need to be proportionate for one country alone to deliver'. It also says that, 'current approvals may be extended using existing powers'. This inevitably means that we will not be applying the latest scientific advice because we will be letting these products exist on the market for longer and longer periods. It also creates a loophole under which extensions on approvals could become indefinite. This is not the rigorous system we were promised in the withdrawal Bill debates."

<u>Response from the government to the Lords:</u>

- Lord Gardiner of Kimble: "We will be taking our own independent decisions under the UK-wide regime but the instruments carry across all the statutory requirements on standards of protection unchanged. All the considerable body of EU technical guidance which has been officially noted under the EU regulations, and which sets the standards to be met in informing decisions, is carried across by these instruments and will remain the basis for the national regime. These statutory instruments make technical adjustments. There will be minimal modification of the current EU regime and these represent no changes of policy; nor will they have any significant impact on businesses or the public."

4. Important parts of regime left unclear or detail to be filled in later through guidelines

- Many of the substantive aspects of the new UK Regulation will be set out in guidelines. However, it is not clear whether these will be in place on exit day from the EU, which could result in an interim period during which the regime may not operate to appropriate standards.

- PPP SI - a completely new section is added to the UK Regulations, specifying those areas where the competent authority may issue, amend or withdraw technical and other guidance documents including, but not limited to:
  (a) Format or summary or complete dossier for approval applications
  (b) Draft assessment report in response to an application
  (c) Application of Article 54 [Research and development] including on minimum data to be submitted in accordance with Article 54(2) [Dossier of data containing information on assessment of possible effects on human or animal health or the possible impact on the environment]

- It is within these guidelines that substantive changes to the EU Regulations are most likely to occur, and therefore vital that these guidelines are scrutinised in light of the EU Regulations to ensure the current rules are not weakened.

Key critiques from the Lords:

- Baroness Parminter: "The EU regime sets out decision making processes in considerable detail. The EU has done; I only wish that the British Government had done the same in setting out the proposals before us tonight. There is quite a lot to be taken on trust. They talk about setting up a statutory register, but there are no details. They talk about a process for taking independent scientific advice, but again there are no details. They talk about proposals for a renewal and that is where I get particularly worried. Paragraph 7.7(E) of the EM says: 'We will … establish the national renewals programme in a way which maintains effective protection but enables the UK to ensure it has a manageable and proportionate workload for one country alone'. That is quite open-ended and does not guarantee the protections that we have at present."

- Baroness Jones: Does he agree that there should be a requirement set out in the SI to consult stakeholders formally in the future for the making, amending or revoking of guidance and principles?

Response from the government to the Lords:

- Lord Gardiner of Kimble did not respond to this point.

5. Loss of capacity and lack of investment in standalone regime

- Lack of capacity is a huge issue facing the UK pesticide regime. At present, the authorisation of active substances is shared out among all various bodies of the EU and all 28 Member States. The UK currently does far more than its fair share, undertaking roughly 30% of the overall workload of authorising active substances. A UK standalone system needs to find the extra capacity to cover the remaining 70%. It has been estimated that approximately 60 decisions on active substances would need to be made each year under a UK standalone system.

- The SIs name a number of UK bodies as stepping in to fill the governance gap. The key roles will be played by:
  - Chemicals Regulation Division (CRD) of the Health and Safety Executive (HSE)
    The CRD already has around 150 people working on pesticides according to the government. However, the majority of these will be engaged in existing work – such as authorising pesticide products – which has always been done at the national level. In addition, it was reported in February 2019, that the HSE is under pressure to make 19% spending cuts by 2019-20 under the government's austerity plans.
  - Expert Committee on Pesticides (ECP)
    Has 16 appointed members (all with other jobs) and no research budget of its own. It is set to replace the role played by EFSA which, in 2018, had 435 staff and a budget of 80 million euros.

    The SIs also name the Environment Agency, Food Standards Agency (FSA), FERA and Defra as playing key roles.

Response from the government to the Lords:

- Lord Gardiner of Kimble: "… extra public funding will be required from government for the national legislative framework for pesticides, plus the related policy and regulatory capability to operate a UK-wide regime. While budgets for future years have not yet been finalised, this will vary depending on the exit scenario. However, additional costs will be broadly in the order of £5 million per year, with slightly more in the set-up phase over the first couple of years. The costs relate primarily to additional staff in Defra and the HSE to manage the additional responsibilities that will fall at national level but also to a lesser extent the Environment Agency."

  £5 million sounds like an underestimation of the costs required for the UK standalone regime to function in order to replicate the standards of protection the UK has enjoyed as an EU Member State.