Annex B to Explanatory Memorandums

Plant Protection Products (PPPs): Stand-alone UK national regulatory regime on leaving the EU

This document considers the collective impact of the set of three Statutory Instruments which have been prepared as part of contingency planning to ensure we are able to put in place an operable national plant protection product regulatory regime from March 2019 should it be required at that point. Separate Explanatory Memorandums have been prepared for each of the Statutory Instruments, these being:

- The Plant Protection Products (Miscellaneous Amendments) (EU Exit) Regulations 2019
- The Pesticides (Maximum Residue Levels) (Amendment etc.) (EU Exit) Regulations 2019
- The Pesticides and Fertilisers (Miscellaneous Amendments) (EU Exit) Regulations 2019

Rationale for intervention

Plant protection products (PPPs) can have the potential to have negative impacts on human health primarily to those who apply them, but there could also be a risk to those who consume treated produce, in a world with no regulation. They also have the potential to have negative impacts on the environment, putting at risk key ecosystem services. These externalities provide a strong rationale for intervention to ensure that the risks to those who use the product are fully understood, and where necessary human health and the environment are protected from toxic substances. This is currently done at an EU level through a risk assessment process which determines whether an active substance is safe to use.

Likewise, without any intervention, consumers cannot assess the level of pesticides on food stuffs and cannot assess any negative impact on their health. Through regulation, currently in the form of restrictions on maximum residue levels, consumers can buy in confidence. This regulation also enables trade between countries as importers (both in the UK and abroad) can buy foodstuffs with confidence, and without additional testing.

A key part of the process by which PPPs are approved/authorised is an assessment of risks to consumers, and there are robust controls which govern the level of residues permitted in food. These maximum residue levels facilitate trade in treated produce by providing assurance that PPPs have been used appropriately. Annual control and monitoring programmes also provide additional reassurance to consumers who can buy foodstuffs with confidence.

In the context of these SIs, the specific rationale for intervention is to ensure there is an operable pesticides regime in any UK only context. The terms of the European Union (Withdrawal) Act 2018 alone are not sufficient to adapt the EU regime to make it work in a national context. It is necessary to use the SI-making powers contained in the Act, for example to provide for continued effective regulation of PPPs by correcting those elements of the regime which rely on EU mechanisms and institutions so as to work in a national context.

Policy Objective

The policy objective is to ensure that effective arrangements to regulate PPPs in the UK remain in place after the UK leaves the European Union, specifically to:

- Ensure a domestic regulatory PPP regime can operate sensibly following the UK's withdrawal from the EU. This supports the Government's intention to provide continuity and stability for businesses at the point of exit.
- Use Statutory Instruments to fix areas of regulation that become inoperable outside of the EU context. This entails making corrections to the existing EU PPP regulatory regime as it is converted into national law through the powers of the EU (Withdrawal) Act, creating a UK stand-alone PPP regulatory regime with no substantive policy change and minimal modifications from the current EU regime.

This national regulatory regime will support the government's objectives for PPPs policy by enabling us to continue to:

- Manage environmental and human health risks arising from PPPs, providing a high degree of protection based on evidence;
- Recognise the importance of PPPs to farming and food production, transport infrastructure protection, maintaining public spaces and controlling invasive species;
- Minimise burdens to businesses.

This arrangement involves a stand-alone UK regime for PPP regulation. This new regime will enable the UK, after exit from the EU, to be able to take decisions on approval and renewal of active substances, authorisation of PPPs and to set MRLs that it considers are justified on the basis of scientific assessment and evidence using the same criteria that is currently applied.

Description of options considered

Option 0: Baseline

The baseline against which impacts are assessed is the 'status quo' baseline, i.e. the UK statute book before the point of EU exit in March 2019.

In addition, this section outlines what would happen in a 'do nothing' scenario whereby no additional legislation covering PPPs is introduced beyond the EU (Withdrawal) Act.

Status Quo

For the 'status quo' baseline the current body of European law is taken to be static at the point of departure.

PPPs are currently regulated through three main pieces of EU legislation as detailed in the Explanatory Memorandums, and work is shared across all 28 Member States. The regulations require input from the European Food Safety Authority (EFSA) - and numerous decisions under the regulations are taken at EU level (for example, approval of active substances and setting of Maximum Residue Levels (MRLs)). Pesticide products are authorised for use at Member State level.

Do nothing

To 'do nothing' would see the EU regulatory regime for PPPs retained in UK law as it stands by the EU (Withdrawal) Act 2018, but large parts of it would be completely inoperable. This would not provide a functioning regulatory regime.

On day one of leaving the EU, the UK would have the same list of active substances and MRLs as the EU. These lists, however, will soon become out of date unless the UK has a working mechanism to update and approve MRLs and active substances. The ability to remove products from the lists if new data indicated an unacceptable risk would also become an issue.

The inability for the UK to actively update the lists could pose the following risks:

- Currently approved active substances could not be renewed when their approval expired;
- New active substances would not be able to be approved and used in the UK;
- Current MRLs would become out of date;
- New MRLs could not be set.

The above would result in the reduction of the number of PPPs available for the UK market unnecessarily as current approvals expire and also because any new, more efficient (and possibly more environmentally friendly) PPPs would not be available to UK farmers. This could make UK farmers less efficient and mean that they have a competitive disadvantage compared to EU farmers. Similarly, the inability to update, set or amend MRLs would interfere with our ability to ensure these are at appropriate levels or, for example, to respond to requests for important tolerances, potentially creating unnecessary barriers to trade and again risks putting the UK at a competitive disadvantage.

Therefore the various risks around doing nothing are:

- The UK would be unable to take action to address environmental or human health impacts on the basis of new evidence.
- There is a risk of economic impacts on the domestic market with UK farmers being put at a competitive disadvantage as they lose access to existing PPPs and are unable to access new PPPs entering the market.
- International trade would be impacted. The inability to update MRLs would restrict the UK's ability to import food from other countries where this required a new MRL or import tolerance to be set. Further, the inability to amend MRLs or active substance approvals could impact on our ability to export to the EU as EU MRLs will continue to evolve. UK produce could be seen as higher risk and hence become subject to greater enforcement and compliance measures.
- The UK would be unable to ensure that MRLs remain appropriate and would be unable to address any concerns which might arise about existing levels on the basis of new evidence.
- Enforcement within the UK would be undermined as some offences within the EU Regulations rely on the definition of Member States.

For the above reasons the government wants to legislate to avoid these risks and impacts and to ensure that the PPP regime remains operable under any scenario following the UK's exit from the EU.

Option 1: Creating a UK stand-alone PPP regulatory regime (Preferred Option)

This option entails converting the EU legislation into national law, creating a UK stand-alone national PPP regulatory regime but with minimal modifications from the EU regime to ensure that, if required, it is practically workable on a national level.

This involves:

- A new regulatory UK PPP regime being put in place, converting the current EU regime into national law.
- Building additional operational capacity to be able to deliver the regime at national level.
- Some minimal modifications to the EU regime to ensure that the new regime is practically workable. The most significant of these are:

    A) Repatriation of decision-making functions and powers under the EU regime (including for active substances and MRLs) from EU to national level.

    B) Establish a new national mechanism to give effect to national decisions in an efficient and timely way by means the listing of approved active substances and MRLs on a statutory register.

    C) Repatriate other EU tertiary legislative powers to national level to convert them in to a power to make regulations by Statutory Instrument, therefore keeping them on a statutory footing, with minor exceptions.

    D) Replace the EU components of the decision-making processes which remain relevant in a national context with new national processes.

    E) Replace the requirements to report information to the Commission for analysis and development of an EU report on pesticide residues with a requirement to publish that information at national level.

    F) Replace the EU regime's existing power to establish a rolling EU active substance renewals programme (which is done through EU tertiary legislation) with a national power to establish a national renewals programme. Convert the provisions for the 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.

G) Extend the deadline for MRL reviews following active substance approval to 36 months in order to make the overall timeline for this work more realistic, proportionate and feasible for the UK operating alone.

H) Replace the power to establish a residue monitoring programme at EU level with national arrangements (whilst retaining the existing requirements placed upon the UK for upcoming three year period at the point of exit from the EU).

I) Replace the arrangements for EU shared decision-making and mutual recognition provisions with provision for UK competent authorities to be able to recognise decisions made in other parts of the UK and to take account of relevant assessments by other regulators in their national assessments.

J) Remove provision for parallel trade permits as they will be inoperable in a national context after exit from the EU and so are not proposed to be retained in the national regime. Parallel trade permits in force at the point of exit would remain valid. In future UK authorisations for the PPP will be required.

K) Minor corrections will be made to the text to address any references which assume EU membership and remove any elements which are reliant on EU membership.

L) Put in place any transitional measures needed to ensure that the changeover from the EU regime to the national regime is smooth, maintaining the current approvals, authorisations and requirements (including for treated seeds) over the period spanning the UK's exit from the EU.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

Status Quo

Benefits
The current set of pesticides regulations enable farmers and others to safely use plant protection products on crops. By following the regulations the health risks of applying pesticides and eating produce where pesticides have been used to support production are reduced to an acceptable level. The regulation in place also protects the environment.

Costs
Under the current arrangements there are significant costs to both business and government. Pesticide producers apply for active substances and their related MRLs to be approved by the EU (initially through an evaluation by a Member State competent authority like the HSE). They then need to apply for the specific plant protection product to be authorised in each Member State. Later companies need to apply for the renewal of the active substance's approval – the timescale on which a renewal must be sought varies depending on the substance.

Although fees are set to cover costs, Government funding does cover other elements of HSE's work on pesticides. In particular there is some funding for policy development and liaison with the Commission and EFSA. The UK Government also indirectly funds EFSA through its contribution to the EU.

Option 1
This option is compared against the 'status quo' baseline as described in the options section. There would be large benefits associated with introducing the legislation compared to the 'do nothing' option, as the legislation will offset the costs associated with 'do nothing' as outlined in the options section.

Benefits to businesses, government and society

Bringing the EU legislation into UK law will provide a functioning regulatory regime and enable the UK to make its own decisions on PPP regulation. The new system will provide the same level of health and environmental protection as the current system.

Additionally the new arrangements may help businesses through one competent authority assessing all three decisions (on the active substance, MRL and the final product) simultaneously. This may mean that products are able to be brought to market more rapidly than is currently the case.

Direct impacts to business

A new UK PPP Regulatory regime

Currently decisions on the introduction or renewal of active substances are made by the EU, whilst the UK competent authority makes decisions on products (which can only include the already approved active substances). The EU also makes decisions on MRLs, again using competent authorities to carry out the underpinning evaluation. Applicants pay fees in most cases to cover the cost of evaluations.

For businesses seeking approval or renewal of approval of an active substance, the principal difference in the new regime will be the requirement to apply to a designated UK national competent authority to seek approval or renewal of approval of an active substance in the UK. (They will also need to continue to seek approvals and renewals of approvals in other markets including the EU as now)[1]. The information required will be the same and the documentation will be in the same format as the status quo, so there will be no additional burden to businesses from these aspects.

With respect to MRLs, again the same documentation as currently required in the EU would have to be produced and submitted to a UK competent authority. (Again applications will continue to be necessary for other markets including the EU).

Cost to Government

Additional costs will be incurred by Government. This includes building national capacity to run decision making bodies, review legislation, guidance and process around the approvals of active substances and their maximum residue limits. There is also some minor work to update IT systems. To do this, the government will require extra staff to manage these processes as well as funding for additional expert advice and research.

The UK will become solely responsible for substantive regulatory functions which are currently carried out at EU level or shared with other EU Member States. For example, the UK will become responsible for a whole range of regulatory functions which are currently dealt with at EU level, including as the ultimate decision maker on active substances, maximum residue levels, import tolerances. It will also take on responsibility for the development and management of substance/MRL/product review programmes, interrelationship with other regimes, and reporting to WTO on technical restrictions. It is expected that there will be considerable scrutiny and increased frequency of legal challenge. We will also need to manage boundaries with the EU and other international regimes in a way that has not previously been necessary, for example tracking implications of changes in the EU regime for UK trade. There will be additional work managing stakeholders and communicating with the general public. A significant proportion of this work will fall to Defra.

HSE play a central role in pesticide regulation and a critical role in developing the national regime also their own operational processes, systems and capacity to deliver it after Exit Day. In particular they will be faced with completing substance reviews and product renewals. There will be interactions with international bodies to ensure that the UK's view is heard. Specifically JMPR2 and CODEX[3] as the UK can't rely on EU to ensure wider international compliance and overseeing WTO rules and appeals. Like Defra, HSE will seek to ensure the public and industry are well informed, so anticipate increased number of enquiries to handle as well as publishing reports and summaries of UK decisions.

Additional posts will also be required for the Environment Agency to link effectively with EA's wider responsibilities for environmental advice and monitoring so that this is fed back to inform PPP decision making and future policy changes. Natural England will also require additional staff to provide additional scientific and other input to policy development and monitoring design.

[1] Analysis by HSE shows that for new active substances and renewals, where admissibility, evaluation and peer reviews are required UK fees are below the mean, and in line with the median of £150,000 and £120,000 respectively.
[2] Joint FAO/WHO Meeting on Pesticide Residues
[3] Codex alimentarius commission (CAC), http://www.fao.org/fao-who-codexalimentarius/en/

These additional costs need to be weighed against any savings from no longer being part of the EU.

Summary Table

Table 1 below provides a summary of the costs and benefits of the intervention against both the do nothing and the status quo to illustrate the differences of using different baselines in this assessment.

	Option 1 relative to status quo baseline	Option 1 relative to 'do nothing' baseline
Benefits to Government and society (*Section F*)	**No change** – Introducing legislation would maintain the drivers of human health and environmental benefits of the current arrangements	**Large benefits** – Introducing legislation would enable a functioning pesticides regime to deliver the government's objectives for pesticides policy. This avoids the significant risks to human health and the environment without it.
Costs to Government	**Increased cost** for building UK regulatory capability, including for a potential increase in the number of applications.	**Increased cost** for building UK regulatory capability.
Benefits to business	**No change** – Introducing legislation would maintain legal certainty for businesses	**Large benefits** – Introducing legislation would: (i) Provide continuity, stability and legal certainty for businesses (ii) Avoid industry facing greater risks to human health and the environment and increased costs e.g. from legal liability. (iii) with respect to agricultural produce consumers can have confidence in UK produced food.
Costs to business[4]	No change for fees through this legislation, but those seeking approval for the UK market must apply through the UK competent authority, HSE, rather than choosing from any member states' competent authority or relying on arrangements which require sharing of information between member states. The documentation required will be the same.	**Large benefit –** Introducing legislation would ensure that (i) we could continue to authorise new products and renew current ones which meet the necessary requirements, therefore enabling businesses to continue to operate in the normal way rather than being unable to bring new products to the UK, and (ii) enabling the farming sector to continue to benefit from new and current products, rather than lose them whenever current approvals expire.

RATIONALE AND EVIDENCE THAT JUSTIFY THE LEVEL OF ANALYSIS

These SIs are primarily to transfer control to the government and its regulatory authorities the power to establish a PPP regulatory framework to make regulatory decisions. For this reason, this assessment of impacts is high level and cannot cover potential benefits and costs that may arise from future regulation decisions on specific substances.

[4] Costs considered here are only costs to businesses' UK operations

Risks and assumptions

The underlying assumption in this assessment of impacts is that we will make essentially the same decisions on active substances and plant protection products as the EU. This assumption may hold true as the same underpinning rules and guidance will be used to assess whether the substance meets the criteria. Having said that, it is possible that UK and EU decision-makers, when presented with the same evidence and criteria as another group make marginally different judgements, in which case we could have some occasional differences in the substances allowed in the UK compared to the EU.