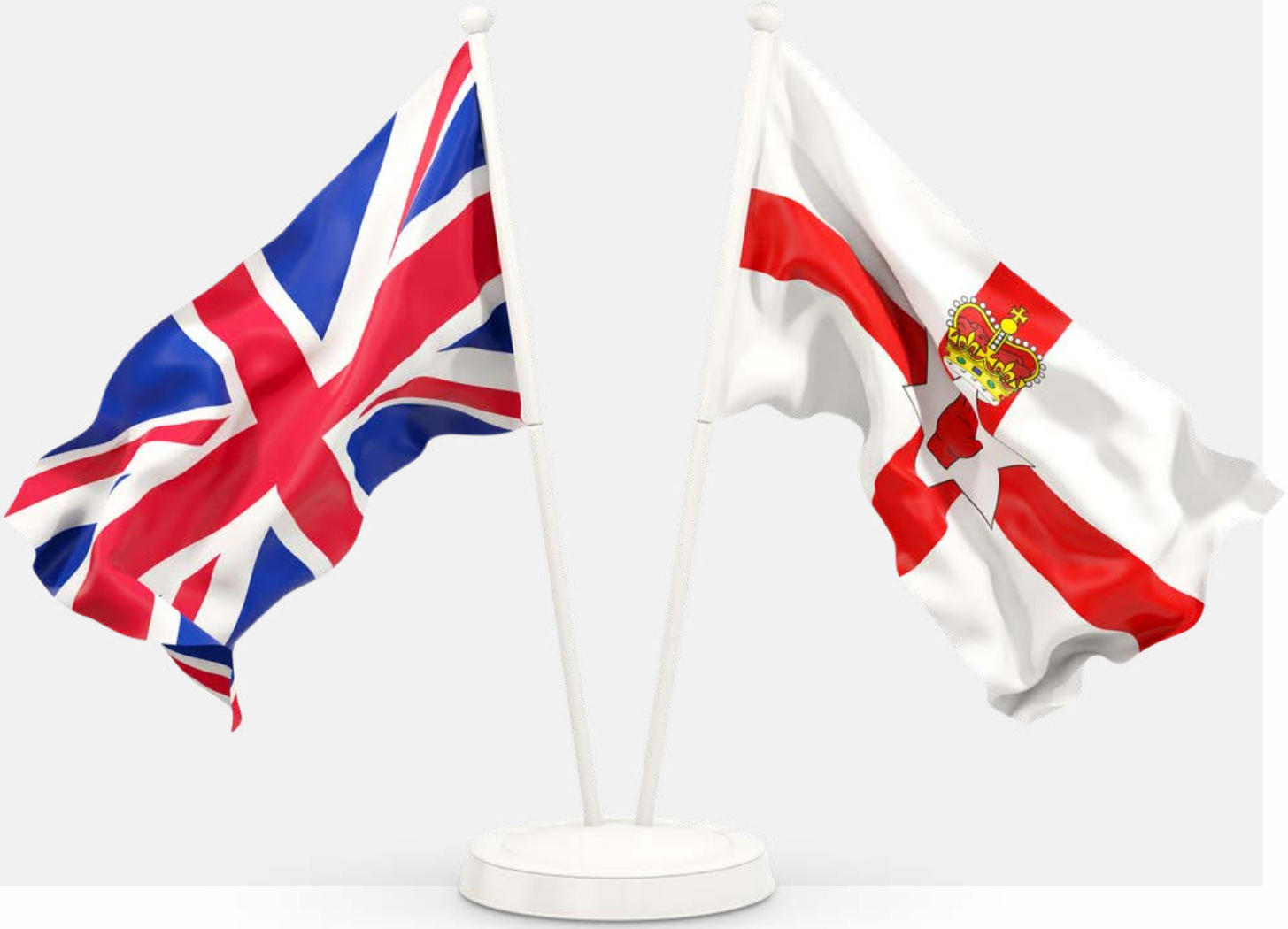
in focus

One Brexit, two systems:
Trading in uncertain times for Plant Protection Products



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The end of the Brexit Transition Period is in sight, yet many questions remain unanswered and a no-deal scenario is back on the table. Whatever the outcome of the future relationship negotiations, there are complexities and changes ahead for the Plant Protection Products (PPP) sector. Amidst the uncertainty, indications of future regulatory processes are starting to come to light. This paper addresses specific concerns of PPP manufacturers as they get ready for the new Great Britain Regime and the implementation of the Northern Ireland Protocol.

Shedding light on key concerns of PPP manufacturers as the Brexit Transition Period nears closure

For the UK's Plant Protection Products industry, the end of the Transition Period marks the next step into a new chapter where evaluation of active substances and products will be handled nationally. However, there is no guarantee that the switch from the EU regime will be seamless. In fact, as the end of the year approaches there is still a high level of ambiguity over key matters.

One thing is certain: the industry needs to orient itself to new circumstances and changeable requirements. This is going to require additional investment of time and effort over a sustained period.

Earlier this year, TSG co-hosted a webinar with the UK government's Chemicals Regulation Division (CRD) looking at the impact of Brexit on the UK's PPP regime. More recently, we ran a session on the same topic at Chemical Industry Regulations Digital Week. Questions posed by delegates at these online events indicate that the PPP industry is beset with uncertainty. Yet clearly business must continue. It's no good simply waiting until 1 January 2021 to 'see what happens'. The situation will continue to evolve beyond this date.

Most of the immediate concerns voiced by industry players relate to four key areas:

- Product mutual recognition to/from UK
- Active substance evaluation
- Product reauthorisation
- Maximum Residue Levels and technical equivalence

In this paper, we explore some of the key issues at stake. We can't take the uncertainty away, but we outline TSG's perspective on how things stand at present. Our aim is to help you make more informed decisions about the best way forward, depending on your individual circumstances.

PPP and the Northern Ireland Protocol

The Northern Ireland Protocol (NIP), which seeks to ensure the NI/Irish border can remain open following the Transition Period, brings additional complexity for PPP manufacturers. From 1 January 2021, UK regulation will consist of two separate regimes for Great Britain (GB) and Northern Ireland (NI).

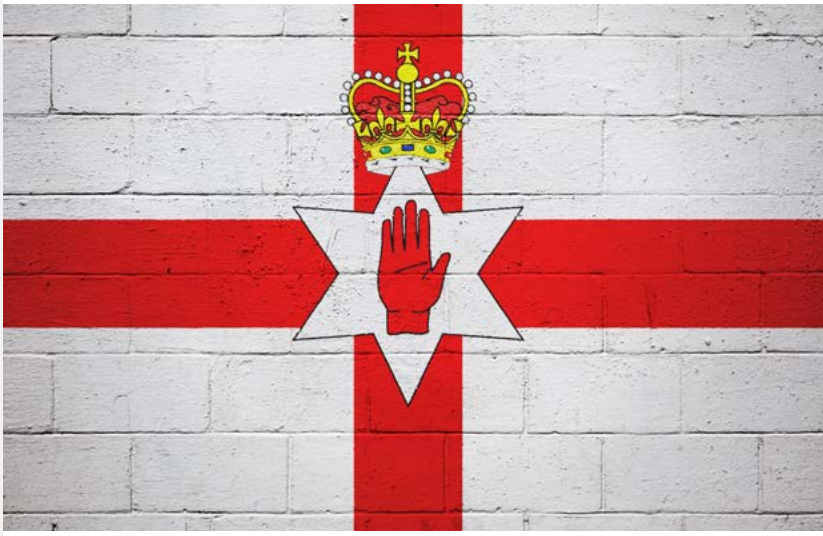
For the foreseeable future, NI will remain within the jurisdiction of EU PPP and MRL regulations 1107/2009 and 396/2005. It will however not have a role in EU decision making and it will not be able to act as a lead evaluator. Nevertheless, Mutual Recognition into NI will still be able to continue.

The CRD has been asked to operate NI's PPP regime under similar arrangements to those established for the UK as a whole during the Transition Period. In January 2025, the Northern Ireland Assembly will vote on the potential continuation of the NIP. If the vote is in favour of replacing it, there will be a two year transition.

This situation puts new constraints on PPP manufacturers. There are fears that the relatively small size of the NI market could deter them from seeking or maintaining authorisations. The UK Government has indicated that it is aware of the adverse impact this could have on growers and industry, and steps are being taken to mitigate risks by streamlining the way legal requirements will be implemented. For instance, the reciprocal arrangement already in place for IRE and GB labelling could provide a model for future developments relating to NI.

On 1 January 2021, there will be a 'lift and shift' of current EU regulation into the GB regime. In the early stages, the underlying rules will be the same (subject to necessary operational amends). Over time, as new rules and decisions are passed in the EU and GB, there will be increasing divergence between the respective regulatory requirements for PPP registrants.

While regulatory changes will be gradual, there will be an immediate impact on 'business as usual' for core PPP processes. In the following sections we look at four key concerns that are occupying the industry at present. Due to the NIP, they relate only to the GB PPP regime. The NI market will continue to operate under EU rules, although the CRD has stated that it will maximise harmony between NI and GB wherever possible.



Mutual recognition

The EU's Mutual Recognition principle, where a product that is sold lawfully in one member state can seek to be sold in another, no longer applies to GB. And GB no longer has access to the EU's CIRCABC system which holds details of historic and ongoing evaluations.

Once the Transition Period ends, all GB applications for product evaluation will be subject to the regulations and timescales set out in GB legislation. Mutual recognitions and parallel import trade permits into GB will not be possible under the new GB regime. Nevertheless, there is an expectation that the CRD will be able to draw on publicly available assessments conducted by EU regulators where this is relevant to GB decisions on products.

Active substance renewal

Until the end of 2020, the UK is bound by any EU decisions related to active substances. So, when the Transition Period closes, current EU active substance regulation will be mirrored by the GB regime. From this point, GB is not required to follow new EU decisions. However, the CRD has indicated that it will continue to monitor progress surrounding active substances in the EU and beyond. It will consider the relevance of any decisions and potentially apply them to the GB regime.

Going forward, the CRD will launch its own renewal process for active substance approvals. However, this will take time to develop and implement, so steps have been taken in the meantime to minimise inconvenience and disruption for the PPP industry. For instance, where the expiry date of approval for an active substance is three years or less from the end of the Transition Period, the approval will be extended for three years from the existing expiry date.

The CRD cannot make decisions surrounding new active substances (or maximum residue levels (MRLs) or technical equivalence) until the end of the Transition Period. However, it can begin the evaluation process. Any EU decisions taken before the end of the year will apply to the new GB regime, and the CRD will continue using EU judgements to inform its own decisions beyond this point. Where decisions are considered novel or contentious, the CRD will seek relevant independent scientific advice, most likely from the Expert Committee on Pesticides (ECP).

In addition, the CRD is putting measures in place to ease the transition to the GB regime and streamline the wider PPP approval process. For the short term, the regulatory body has committed to publishing a GB statutory register of approved active substances on its website. In the longer term, there are plans to create a more streamlined approval process where new active substances, MRLs and first products are all considered in parallel. The intention is that this will be faster and more efficient than the more linear, sequential system currently adopted by the EU.

Product reauthorisation

The CRD will develop a standalone product reauthorisation programme for GB. The aim is to accelerate the process without compromising its integrity, for the benefit of manufacturers, growers and consumers alike.

While the end of the Transition Period is now in sight, Article 43 product renewals still need to be applied for. EU deadlines set during the Transition Perion will continue to apply under the GB regime.

For product reauthorisations that are underway at the end of the year, the CRD will complete the process and make decisions related to sale and use of the product in GB.

In our webinar with CRD, many delegate questions centred on the issue of product reauthorisation. A core piece of feedback from the CRD was that:

> "For any GB decisions on active substance renewals taken after the Transition Period, the product renewal applications would be required three months after the GB approval decision. It is likely, at least in short-term, a GB decision will be soon after the EU approval/ renewal date."

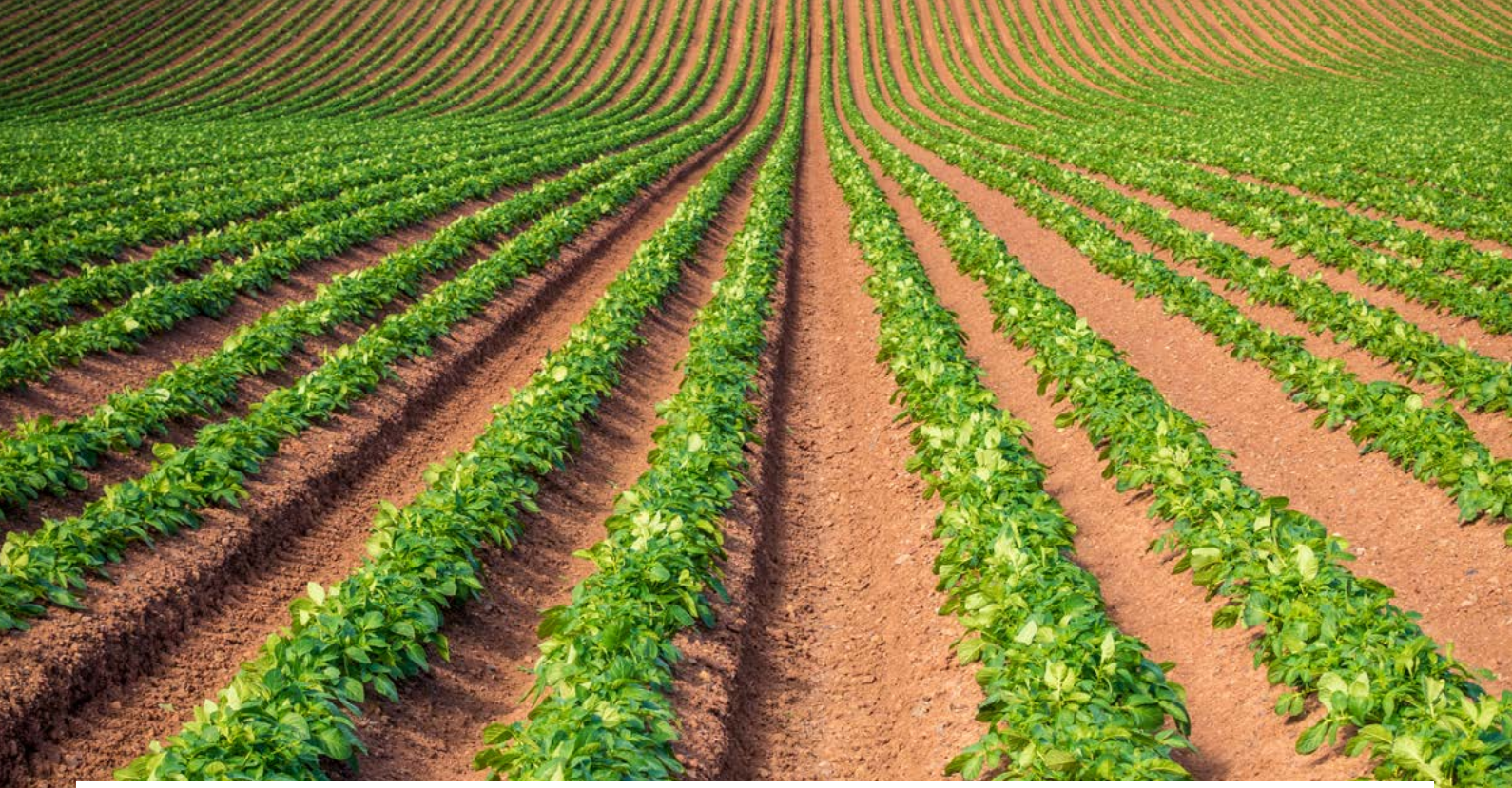
However, bear in mind that where active substances' approvals expire within three years of the end of the Transition Period, they are granted a three year extension. So, the subsequent reauthorisation requirement for products containing those active substances will be delayed.

Maximum Residue Levels (MRL) and technical equivalence

As with the evaluation and approval of active substances and products, MRL and technical equivalence requirements for the GB regime will initially match those of the EU. The current legal default will be retained, with the operability amendments that were developed in 2019.

The CRD has indicated that the GB regime will include setting MRLs as defined under Article 10, including those pending from the Transition Period and before. In the initial stages, the GB regime will review the EU pipeline of MRL decisions and take action as required (including making data call-ins). Codex MRLs will also be assessed and implemented.

In the future, a standalone review programme for MRLs will be developed. For technical equivalence, the CRD will finalise any applications started during the Transition Period and take GB decisions from 1 January 2021.



Six critical factors

Much still depends on the negotiations that must conclude before the end of the Transition Period. Depending on the direction and outcome of these, it is likely that further operability amendments or transitionary measures will be introduced.

In light of this ongoing uncertainty and the possibility of a 'no deal' outcome to negotiations, TSG believes the PPP industry needs to keep six critical factors front of mind:

1. It is likely that considerable duplication of effort will be required as company regulatory teams accommodate the now different requirements for NI and GB vs EU.
2. GB / NI differences will present challenges for NI growers and registrants for the foreseeable future.
3. It appears that extra effort will be required for pending active substances, dossier updates and further submission into CRD.
4. Transitional measures will ensure that where an existing active substance's approval expiry is three years or less from the end of the Transition Period, GB approval will be extended by three years.
5. Article 43 product reauthorisation submission deadlines set during the Transition Period will still need to be applied in GB as well as NI, as in the EU, after 1 January 2021.
6. For the duration of the NIP (and beyond) EU Article 43 product reauthorisation submission deadlines will be applicable in NI.

PPP manufacturers need to find ways to adjust and adapt to the additional requirements and a certain amount of ongoing instability. Those that can continue driving progress in these challenging times may have an opportunity to make significant market gains.

How TSG can help

If you lack the capacity for the additional regulatory requirements, we can handle core technical and administrative aspects of this. Our team is highly experienced in the preparation and submission of dossiers as well as the generation and interpretation of supporting data. With specialist regulatory expertise, insights and a close working relationship with the CRD, we can help you achieve the best possible outcome for your business.

Interested in learning more?
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We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry.

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TSG Consulting has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

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