in focus

The biocides sector post Brexit: What firms should expect when the transition period ends

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With the end of the Brexit transition period in sight, biocide manufacturers will be among the many businesses wondering what comes next. While the future is still uncertain, details of some of the changes to regulatory processes are now becoming clearer. This paper addresses some of the concerns United Kingdom (UK) and European Union (EU) businesses are likely to have as they prepare for the changes that lie ahead. In it, TSG's regulatory experts cover amendments to Article 95, how active substance and biocidal product authorisation applications will be handled, what data sharing will look like, what's next for Northern Ireland (NI), and where all of this leaves biocide firms trading in the UK.

What biocide companies should expect when the transition period ends

What changes are we already seeing?

The transition period governing the UK's exit from the European Union (EU) is set to end on 31 December 2020. Yet industry is already beginning to feel the immediate impacts when it comes to biocidal products previously governed by Regulation (EU) No 528/2012, better known as the Biocidal Products Regulation (BPR).

The Withdrawal Agreement, which provides the legislative basis for this transition period, states that the UK cannot act as the lead in any EU level business such as risk assessments, examinations or authorisations, from the point at which it entered into force on 31 January 2020. That includes ongoing active substance approval processes within the review programme, which have been redistributed to EU Member States (MSs) (Commission Delegated Regulation (EU) 2019/227). It also includes cases where the UK is acting as the reference Member State (rMS) for biocidal product national authorisations with mutual recognitions, in parallel or in sequence, or cases where the UK is acting as the evaluating Competent Authority (eCA), for Union authorisations concerning biocidal products.

The UK can still accept mutual recognition applications from EU MSs during the transition period, however. The European Chemicals Agency (ECHA) will no longer act as the 'Agency' on behalf of the UK and this would transfer to the Health and Safety Executive (HSE), who will continue to be the UK's competent authority. Functions such as technical equivalence assessments will therefore be handled by the HSE. HSE will no longer have access to ECHA's databases after the end of the transition period. HSE will not charge for any resubmission of information previously submitted to ECHA or other competent authorities. Evaluation fees can still be expected, however.

Where the UK has been acting as the rMS/eCA for product authorisation – in applications that are currently ongoing, or where changes are required to existing authorisations – the applicant has been required to pursue the transfer of responsibility from the UK to an EU Member State. This transfer of rMS/eCA does not happen automatically and, in practise, this has proven an almost impossible task, with Member States balancing workload and resources and, therefore, not finding themselves with the capacity to take on these cases.

This shared responsibility has left the industry in an uncertain situation and puts pressure on the European Commission (EC) and the European Chemicals Agency (ECHA) to prioritise discussions, to find a way forward. Existing non-UK biocidal product authorisation 'assets' and Article 95 listings, held by UK legal entities, will also need to be transferred by the end of 2020 to an EU legal entity.

Brexit is a fast moving topic. All information stated in this paper is correct at time of printing and subject to change without notice.

What does the future hold for the UK?

The UK EU (Withdrawal) Act 2018, as amended, made it clear that the UK will establish a standalone biocidal products regulation. This will mean continued levels of protection for human health and the environment and provide some certainty to UK businesses placing biocidal products on the UK market.

As a result, the UK has enacted legislation covering BPR but also the Classification, Labelling and Packaging Regulation (CLP) and the Export and Import of Hazardous Chemicals (Prior Informed Consent (PIC) Regulation, under Statutory Instrument 2019 No. 720 The Chemicals (Health and Safety), as well as the Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019. It also implements the Government's commitment for Northern Ireland-based businesses to have 'Unfettered Access' to Great Britain (GB) for these regimes.

Note: There has been a change in the terms used by HSE, from UK to Great Britain (GB) to accommodate the Northern Ireland Protocol (see page 7).

The Statutory Instrument should be regarded as a modification into the UK of the BPR, with amendments and supplements only, rather than a complete copy of the BPR (although it is still applicable in the UK). We therefore look forward to a UK consolidated version, to avoid the need to refer to the two documents in parallel for UK compliance.

What key changes can we expect?

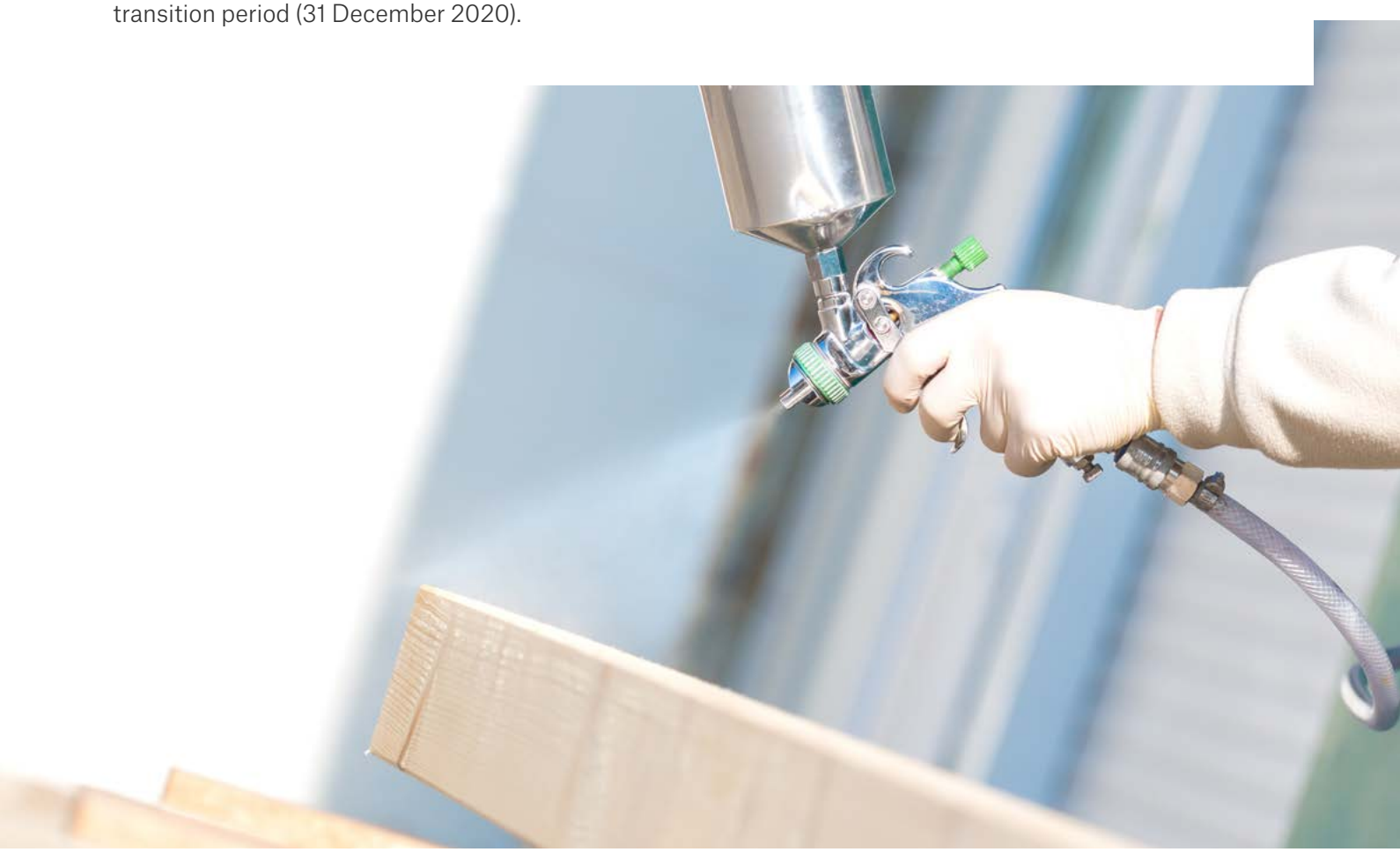
The key date of 31 December 2020 triggers the need for applicants to take additional action in ensuring market access continues within the EU and the UK, depending on the applicant's specific circumstances.

Article 95

Great Britain will have its own separate Article 95 list, covering UK legal entities; for access to the (GB) market, companies must be on this list. Article 95 listings will be grandfathered into the GB list for two years, after which data will need to be resubmitted to remain on the UK Article 95 list. If data submission is supplied via a Letter of Access (LoA), it must be to a complete substance dossier and is dependent on the data owner having submitted the data to the HSE. The UK may grant a grace period for biocidal products if the contained active substance GB Article 95 listing is not in place, for up to 180 days, but this should be treated with caution. Regarding BPR, GB companies can be represented on the EU Article 95 list by an EU representative, and this needs to be in place before the end of the transition period (31 December 2020).

Active substances

Existing active substance approvals will be grandfathered into UK law with the same renewal date, i.e. they will remain valid until the existing expiry date. Pending active substance applications in the review programme, including renewals, will be maintained in the UK regime and redistributed to a new eCA. There is then the requirement for resubmission to the UK within 90 days (if UK was the eCA) or within 180 days (if UK was not the eCA) after the end of the transition period on 31 December 2020. Data access can be via a LoA (and the data owner resubmits the data to the UK) or direct data submission. New applications and renewals will need to be made to the EU and the UK to have access to both markets.

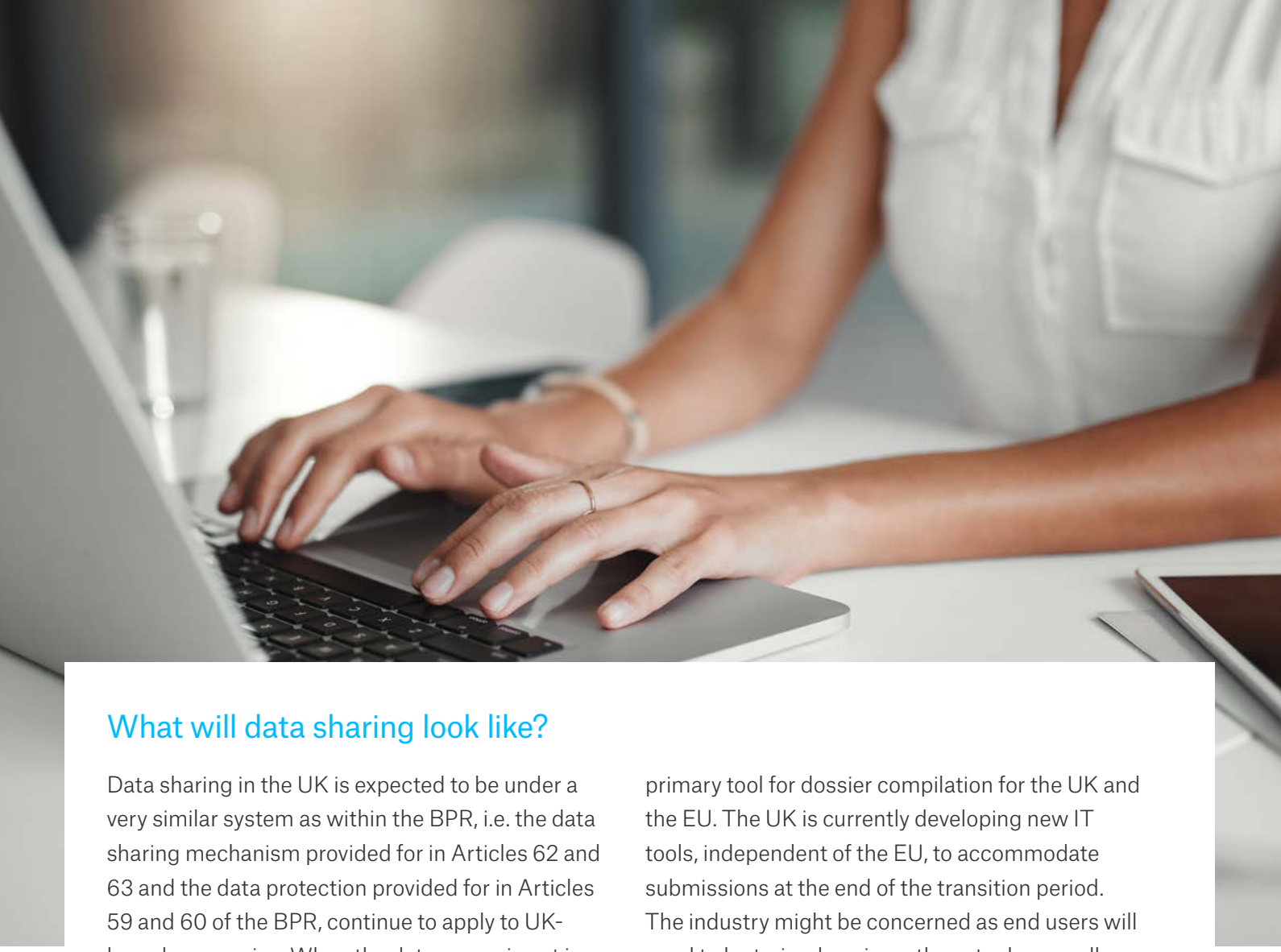


Biocidal products

Products already authorised under BPR will be 'lifted and shifted' from EU BPR to UK BPR. Thus, product authorisations valid in the EU before the transition end date will remain valid in the UK. However, a company will need to be established in the UK within 365 days. HSE might also request additional data such as scientific and authorisation data which will need to be provided within 60 days of the request being made. Existing non-UK biocidal product authorisation 'assets' held by UK legal entities will also need to be transferred by the end of 2020 to an EU legal entity.

Ongoing applications for national authorisation, mutual recognition, Union authorisation, renewals and simplified authorisation, including changes to these, will be maintained in the UK if they are resubmitted to the UK, within 90 (where UK active) or 180 days (where UK passive), after the end of the transition period on 31 December 2020, depending on the situation. Companies will also need to be established in the UK within 365 days. Any related EU BPR authorisations will also need to find a new EU rMS/eCA by the end of the transition period, and be held by an EU legal entity, if this was previously the UK.

The active substance supplier for a product authorisation might also need to submit supporting data to HSE if the active approval was carried across at the end of the transition period. New applications and renewals will need to be made to the EU and the UK to have access to both markets. Note that low-risk biocidal products authorised via the simplified authorisation procedure in the UK and notified to EU MSs in accordance with Article 27(1) of the BPR can no longer be placed on the EU market after the end of the transition period. Regarding treated articles, it remains the responsibility of the person placing a treated article on the market to ensure compliance with Articles 58 and 94 of the BPR and within the UK.



What will data sharing look like?

Data sharing in the UK is expected to be under a very similar system as within the BPR, i.e. the data sharing mechanism provided for in Articles 62 and 63 and the data protection provided for in Articles 59 and 60 of the BPR, continue to apply to UK-based companies. When the data owner is not in the UK market, a way forward will need to be established, specific to a company's access needs. Data sharing does not need to be across EU and UK, a company can negotiate rights specifically as needed. It is important to check existing agreements to see if 'outside of the EU' is already covered or not. Be aware there may be short timelines for submission of data and proof of access rights.

Since March 2020, the UK CA no longer has access to ECHA IT tools which are pivotal for BPR submissions. This includes but is not limited to R4BP and the SPC editor. It is expected that (ECHA-OECD) IUCLID files will remain the primary tool for dossier compilation for the UK and the EU. The UK is currently developing new IT tools, independent of the EU, to accommodate submissions at the end of the transition period. The industry might be concerned as end users will need to be trained again on these tools, as well as EU tools if they wish to market biocides throughout the UK and the EU. As with any new IT tool, there is potential for disruptions due to bugs and errors in the software.

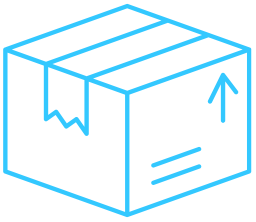
It is important to remember that for biocidal products, most are placed on the market as mixtures of co-formulants; therefore the impacts of Brexit upon the REACH Regulation (EC) 1907/2006 and CLP (Regulation (EC) No 1272/2008) apply here.

Where does this leave Northern Ireland?

NI remains an interesting and complicated regulatory challenge, as EU law will still apply in NI. As part of the Withdrawal Agreement between the UK and the EU, the Northern Ireland Protocol (applicable from 1 January 2021) was designed to avoid a hard border on the island of Ireland. NI will still have access to the EU market after the transition period. Companies established in NI can hold EU BPR biocidal product authorisations and be listed on EU BPR Article 95. Similarly, a biocidal product produced in NI and shipped to the EU will not be classified as an 'imported product'. However, products shipped from GB to NI will have to follow the respected import laws.

It is important to note that the UK will still not be able to participate in the decision-making process on behalf of NI. However, NI could potentially become a regulatory backdoor for shipping biocides between the EU and UK. In cases where EU 'establishment' requirements for biocidal product authorisations are satisfied by a NI legal entity, and where the NI-based business holds an EU BPR biocidal product authorisation or other permit, HSE will treat the product as authorised in the whole of the UK should the company wish to market the same product in Great Britain. The contained active substance must be on the GB Article 95 list, the NI-based business must notify the HSE with submission of the original information and provided the HSE has no objections, the biocidal product can be marketed after 90 days.

EU law will still apply between NI and the UK; and NI will still have access to the EU market after the transition period.



Industry questions answered

What is the issue for products already on the UK market (under BPR and biocide transitional rules)?

The primary issue for products already on the UK market (under BPR and biocide transitional rules) will be to pay great attention to the supply chains to ensure and maintain compliance not only under UK BPR, but also UK REACH as the co-formulants will also need to comply.

What about products placed on the EU market with a UK based authorisation holder?

All BPR product authorisations must be held by an EU legal entity. Therefore, all products on the EU market with a UK-based authorisation holder will need to transfer their authorisation BEFORE the end of the transition period to an EU legal entity.

What is the primary issue for products still under evaluation (that will not be finished before the end of the Brexit transition period) with a MR in UK?

Ongoing applications will be maintained in the UK if they are resubmitted to the UK, within 90 (where UK active) or 180 days (where UK passive) after the end of the transition period on 31 December 2020, depending on the situation. Companies will also need to be established in the UK within 365 days. Any related EU BPR authorisations will also need to find a new EU rMS/eCA by the end of the transition period, and be held by an EU legal entity, if this was previously the UK; this is currently an issue as it is not automatic!

How can I prepare for the transition period deadline, 31 December 2020?

There are three main actions companies should take in preparation for 31 December 2020:

- Review entire supply chain (ensure products will be UK REACH and UK BPR compliant)
- Begin data sharing discussions with all concerned parties
- Prepare for dual applications in EU and UK

Where does this leave firms trading in the UK?

We are still left in a situation where we do not know for certain if it will be a hard Brexit, with no 'deal' in place, or if there will be a new agreement available. This is something to keep monitoring and understand the implications for the UK and EU relationship with regards to biocides. What we are essentially left with is duplication in regulatory process and fees, unfortunately without scientific advancement.

HSE is expected to issue updated guidance on 1 December 2020. The UK regulator aims to ensure regulatory continuity and minimal disruption with regards to biocides in the UK, displaying an ever-pragmatic approach. Nevertheless, Brexit isn't going anywhere and the knock-on effect will continue to evolve. It is therefore more important than ever to ensure you are ready to take the necessary action as the deadline of the end of the year approaches.

How can TSG Consulting help?

TSG is committed to helping clients achieve the best possible outcome for their business. We have been actively assessing the impact that the differing Brexit scenarios will have on biocides regulations following the UK's decision to leave the EU. We are in a strong position to advise clients on the actions they may need to take in order to secure and maintain product authorisations and manage the impact on active substance evaluations, approvals and approved suppliers.

Interested in learning more?
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This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance. TSG Consulting has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

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