in focus

GB Biocidal Products Regulation

Key changes under the new stand-alone regime

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On 1 January 2021, Great Britain (GB) introduced a stand-alone regulatory regime governing the placing of biocidal products on the GB market. Such products are now regulated under: Great Britain Biocidal Products Regulation (GB BPR); Great Britain Classification, Labelling and Packaging Regulation (GB CLP); and Statutory Instrument 2019, No 720. In this paper, TSG Consulting's biocides experts summarise the key regulatory changes, with a particular focus on Northern Ireland requirements, Article 95, establishment rules, and how active substance approvals and biocidal product authorisations are handled.

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Stand-alone regime for Great Britain

Following the end of the transition period governing the UK's exit from the European Union (EU), GB enacted a new, stand-alone regulatory regime. The new regulations provide continuing levels of protection for human health and the environment as well as structural proceedings for businesses placing biocidal products on the GB market.

The primary regulation governing biocides is the Great Britain Biocidal Products Regulation (GB BPR). The pre-existing EU BPR was officially copied across to GB law and amended to work more effectively in GB.

Several other EU regulations applying to biocides were also transcribed and enacted on 1 January 2021. These are:

- The Classification, Labelling and Packaging Regulation (CLP now GB CLP)
- REACH (now UK REACH)
- The Export and Import of Hazardous Chemicals – Prior Informed Consent (PIC now GB PIC) Regulation
- Statutory Instrument 2019 No. 720 – The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019; and The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2020. This piece of legislation implements the Government's commitment for Northern Ireland-based businesses to have 'unfettered access' to GB for these regimes.

The Statutory Instrument should be regarded as a modification into GB of the EU BPR, with amendments and supplements only, rather than a complete copy of the EU BPR.

The Health and Safety Executive (HSE) continues to be the UK's competent authority for GB BPR as well as other regulations for the chemical industry.

Northern Ireland

Northern Ireland (NI) remains an interesting and complicated regulatory challenge as, under the Northern Ireland Protocol, the EU BPR still applies in NI. Thus, NI still has access to the EU market post Brexit. Companies established in NI can hold EU biocidal product authorisations and be listed on EU Article 95, which details suppliers of active substance/product-type combinations that can be used in biocidal products in Europe.

Therefore, companies wishing to make biocidal products or treated articles available on the NI market must comply with the EU BPR.

NI to GB exports

Biocidal products exported from NI to GB, where a NI based business holds a valid authorisation for the product under the EU BPR, must first notify HSE 90 days before the product is placed on the GB market. For these types of exports from NI to GB, the authorisation holder must be established in NI, the active substance must be approved under GB BPR and the active substance must be sourced from a GB Article 95 supplier.

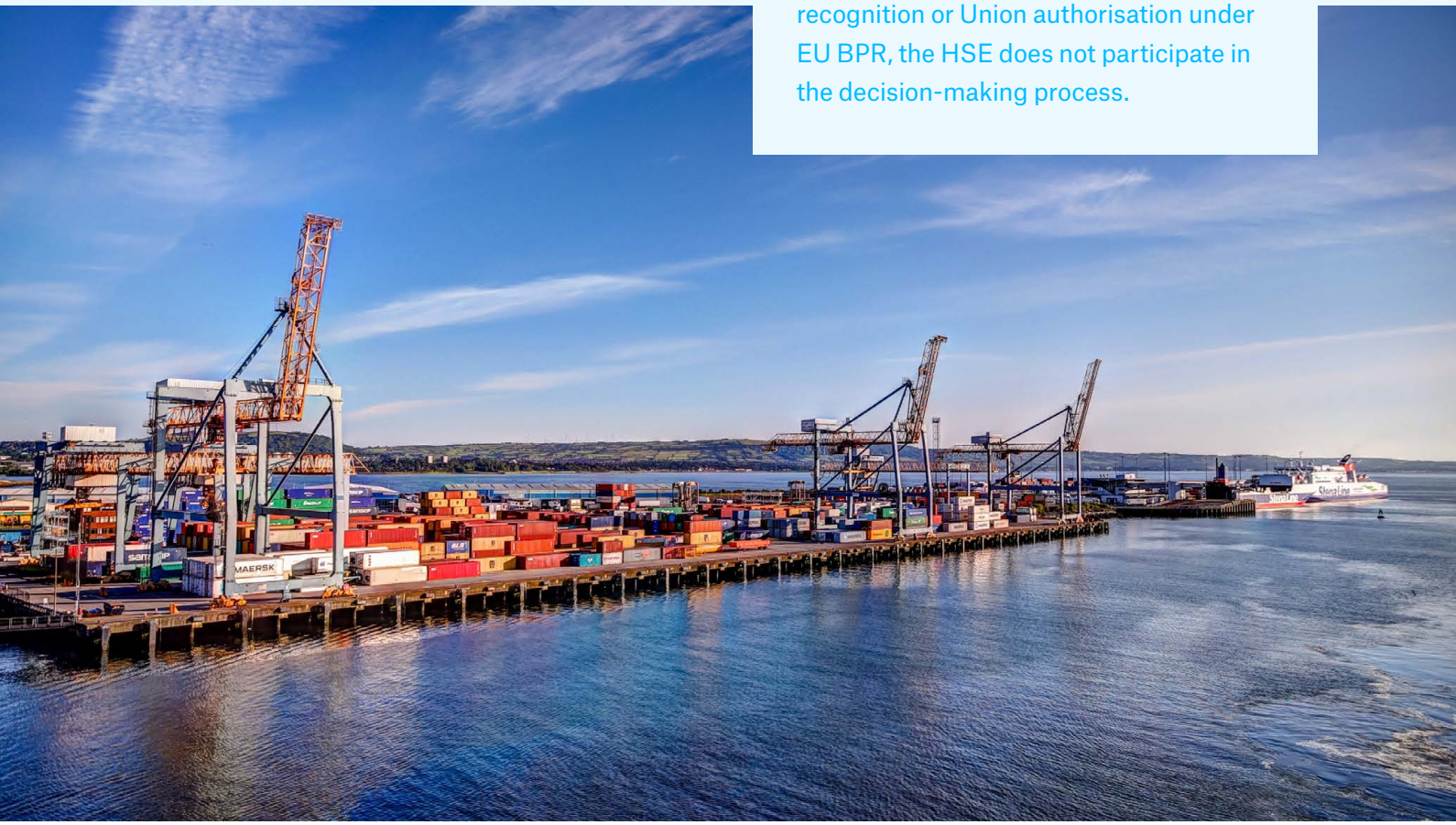
GB to NI exports

Exports from GB to NI must also comply with EU BPR. In addition, businesses may also be required to comply with other GB legislation such as GB PIC or specific customs and export rules.

NI to Europe exports

Exports from NI to Europe must follow EU BPR.

Whilst NI can be treated as a rapporteur Member State (rMS) for mutual recognition or Union authorisation under EU BPR, the HSE does not participate in the decision-making process.



Key changes

Whilst the GB regime mirrors that of the EU regulatory framework, there are some minor deviations as well as actions companies need to take in order to ensure continued market access within Great Britain.

Data requirements and process

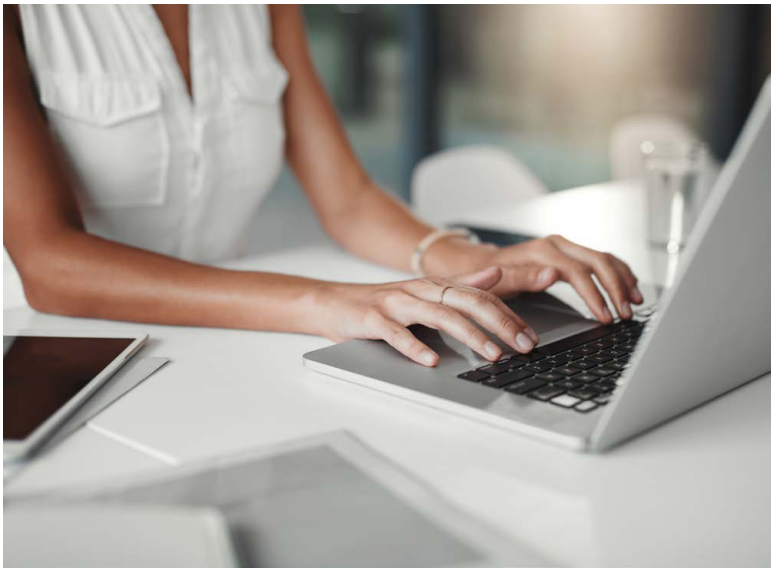
The same data requirements for EU BPR apply to GB BPR, with the addition of UK-specific national requirements. Similar formats are used for applications, however the process has changed. For example, one of the changes requires applicants to submit a separate, standalone reference list for the active substance and biocidal product, in a specific GB format.

In addition, any future decisions made by the EU, the European Economic Area (EEA) and Switzerland will no longer automatically apply in GB.

Data protection

In terms of data protection, the same data protection periods apply to data supporting active substance approvals and biocidal product authorisations granted under GB BPR, the same as those seen under EU BPR.

ECHA (European Chemicals Agency) does not get involved in data sharing disputes for GB, and further, industry has shown concern regarding the costs of obtaining a Letter of Access (LoA) to data for both the EU and GB.



Article 95

GB now has its own separate Article 95 list, covering UK legal entities. The list gives details of suppliers for active substances/product-type combinations that can be used in biocidal products in GB under the GB BPR. In order to access the GB market as an active substance supplier, companies must be on this list.

EU Article 95 listings were grandfathered into the GB Article 95 list for two years, after which data needs to be resubmitted to remain on the GB 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.

In order for companies to remain on the list, Article 95 legal entities must also be established in the UK (GB or NI) before the 31 December 2022 deadline. This may occur sooner if necessary to support other applications. The use of a UK representative is possible.

Active substances

GB now has its own review programme for existing biocidal active substances which includes active substances already in the EU Review Programme on 31 December 2020. To stay in the GB Review Programme, companies must have resubmitted information to HSE by 31 March 2021 if the UK was the evaluating Competent Authority (eCA) under EU BPR, and 29 June 2021 if the UK was not the eCA. Data access could have been via a LoA or direct data submission (with the data owner resubmitting the data to GB). The full original data package along with any later submissions were necessary and any data gap required justification. To note, submission of the application form to the HSE by email meets the deadline. If companies missed these deadlines, the result for active substances will be the publication of an open invitation allowing any business to notify an intention to take over the role of supporting the relevant active substance/product-type combination for assessment in the GB Review Programme.

Existing EU active substance approvals have been grandfathered into GB law with the same renewal date, i.e. they will remain valid until the current approval expiry date. New applications and renewals need to be made to the EU and GB to have access to both markets. The EU BPR Annex I was copied into the GB Simplified Active Substance list with 3 categories (A is equivalent to categories 1 to 5 of EU Annex I; B is equivalent to category 6; and C is equivalent to category 7).

HSE does not issue 'automatic' non-approval decisions and will work with applicants on a case-by-case basis.

Biocidal products

Biocidal products on the market under UK HSE national transitional legislation The Control of Pesticides Regulations (COPR) remain unaffected. No action is required until GB BPR product authorisation procedures are required.

Biocidal products already authorised under EU BPR were 'lifted and shifted' from EU BPR to GB BPR. Thus, product authorisations valid in the EU before the transition end date remain valid in GB with the same authorisation expiry date. However, the authorisation holder will need to be established in the UK for the GB market by 31 December 2021. 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.

Ongoing applications

Ongoing applications for national authorisation, mutual recognition, Union authorisation, renewals and simplified authorisation, including changes to these, should have been resubmitted to GB by 31 March 2021 if the UK was the lead reference Member State (rMS)/eCA and 29 June 2021 if UK was not the lead rMS/eCA. Looking forward, authorisation holders will need to be established in the UK by 31 December 2021. If companies missed these deadlines, the result for biocidal products is that any ongoing evaluations will cease, and phase-out periods will apply to existing products. HSE will work with applicants on a case-by-case basis.

Active substance suppliers

The active substance supplier for a biocidal product authorisation might also need to submit supporting data to HSE if the active substance approval was carried across at the end of the transition period. New applications for product authorisations and renewals will need to be made to the EU and GB to have access to both markets.

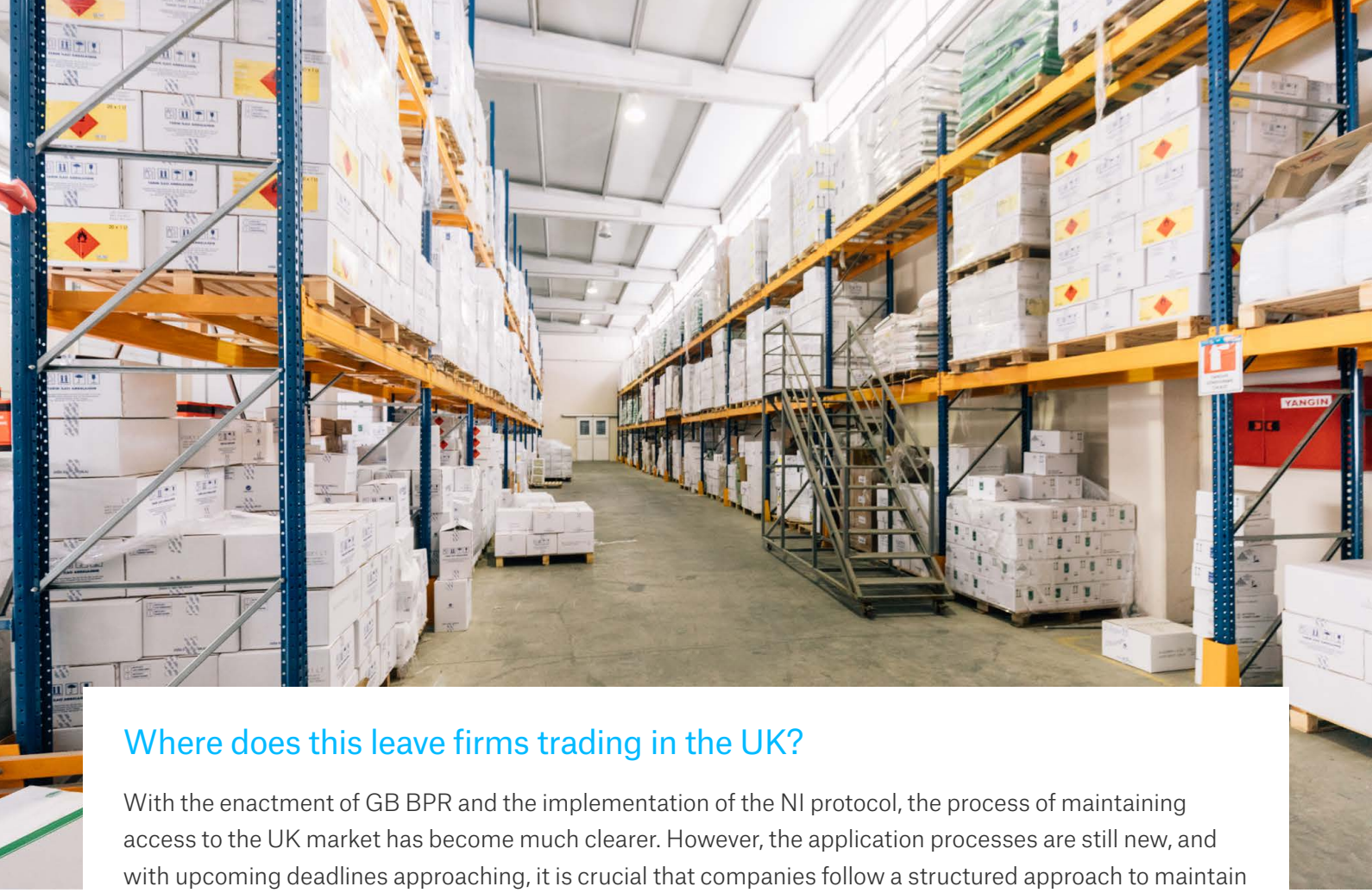
Note that low-risk biocidal products authorised via the simplified authorisation procedure with UK as eCA before Brexit and notified to EU Member States (MSs) in accordance with Article 27(1) of the BPR can no longer be placed on the EU market.

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 EU and GB BPR.

Process for resubmission and establishment

The method for submitting applications and data to HSE has changed for active substances, the GB Article 95 list and biocidal products:

- The application form for each application type is in Word document format. The appropriate form must be downloaded, completed, and emailed to HSE.
- HSE then emails back an application-specific secure link (valid for 30 working days, renewal possible) to upload the files associated with the relevant application. The applicant must submit the original dossier submitted under EU BPR such as an IUCLID 6 file, and EU draft RAR/PAR, however a separate, specific reference list in accordance with the GB template must also be submitted. This is a key requirement of the new GB BPR.
- HSE will not charge fees for resubmission, but fees are incurred for ongoing evaluations required by HSE.
- GB BPR requires authorisation holders to be established within the UK by the end of 2021 and GB Article 95 legal entities to be established within the UK (or represented by a UK established legal entity) by the end of 2022. An 'establishment form' is available to formally advise HSE.



Where does this leave firms trading in the UK?

With the enactment of GB BPR and the implementation of the NI protocol, the process of maintaining access to the UK market has become much clearer. However, the application processes are still new, and with upcoming deadlines approaching, it is crucial that companies follow a structured approach to maintain compliance as well as access to the GB market.

HSE has demonstrated a pragmatic approach to helping the biocides industry adjust to the new GB BPR and has sought to minimise disruption by continuously updating guidance and providing other helpful resources. Nonetheless, the GB BPR landscape is still complex to navigate and can be difficult to understand.

HSE has extensively updated its webpages regarding biocides in GB:
https://www.hse.gov.uk/biocides/

GB fact sheets are a useful resource as they provide step-by step guidance for specific tasks:
www.hse.gov.uk/biocides/biocides-fact-sheet.pdf

Application forms are available to make all submissions to HSE:
www.hse.gov.uk/biocides/information.htm

HSE has hosted a series of free podcasts:
https://hsepodcast.podbean.com

How can TSG Consulting help?

TSG's multidisciplinary team of scientists and registration specialists has years of proven experience helping companies secure and maintain biocidal product authorisations in the EU and, more recently, supporting applications under GB BPR.

Through our in-depth knowledge of the regulations and processes, we can advise of the actions needed to secure and/or maintain biocidal product authorisations. We can also help manage the impact on active substance evaluations, approvals and approved 'Article 95' suppliers.

TSG Consulting can act as representative of GB companies on the EU Article 95 list as well as EU companies on the GB Article 95 list.

Interested in learning more?

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We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

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.

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, GB, USA and Canada. TSG is a Science Group (London listed) company.

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