THE UK RELEASES FURTHER TECHNICAL NOTICES OUTLINING SEPARATE REGULATORY REGIMES

Date: 17 October 2018

UK Antitrust, Competition and Trade Regulation Alert

Further to our previous Brexit alert regarding a UK-REACH regime (found here), on 12 October 2018 the UK Government released a number of other notices that outline further UK regulatory regimes on classification, labelling and packaging of chemicals ("CLP"), the export and import of hazardous chemicals, pesticides, biocides and the export of GM food and animal feed products.

THE NEW UK-CLP REGIME

It has been confirmed that a new UK-CLP regime will adopt the UN Globally Harmonised System ("GHS") for the classification and labelling of chemicals, in the same way as the EU regime currently adopts the GHS (the technical notice can be found here).

While little detail is provided on the practical considerations for participants in the new regime, it is made clear that the majority of obligations on UK manufacturers, importers and downstream users under the existing EU regime will be transposed and will continue to apply. This includes labelling requirements which will remain in place, including the exemptions where applicable. The following changes, however, are outlined in the notice:

- Companies based in the UK importing chemicals from the EU (or the third party countries for that matter) will be considered importers of chemicals and mixtures under the UK-CLP regime. Any obligations and duties in relation to the export of chemicals and mixtures from the UK into the EU will rest solely on the EU-based company importing the chemical;
- The UK equivalent of the EU-CLP competent authority (ECHA) will be the Health and Safety Executive ("HSE"), to whom companies will need to submit notifications of the classification of chemicals they trade. Any notifications will be submitted using newly developed, UK-specific IT tools onto a UK national notification database; and
- The HSE will be responsible for putting in place new arrangements for mandatory classifications and labelling going forward. This means the UK's future decisions regarding chemical hazard classification may diverge from decisions made by the EU.

The technical notice does not make mention of any transitional arrangements.

THE EXPORT AND IMPORT OF HAZARDOUS CHEMICALS

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The technical notice addressing the export and import of hazardous chemicals (found here) envisages that the UK will establish an independent, standalone regime. As with the envisaged UK-CLP, most of the current EU obligations in relation to the export and import of hazardous chemicals will be transposed into the new UK regime to meet the UK's international obligations under the Rotterdam Convention. UK exporters will continue to be required to notify exports of listed chemicals with the HSE.

However, as with the above there are a number of changes, including:

- The export of hazardous chemicals from the UK into any country, including EU Member States, will be required to comply with the new UK regime. This means that companies that trade hazardous chemicals from the UK into the EU would, post-Brexit, need to start notifying the HSE of those exports;
- UK export notifications for 2019 that are made before 29 March 2019 would continue to be recognised, with no requirement to re-submit the notification for that year since the designated national authority of the UK is already the HSE under the current EU system. Where the first export of the hazardous chemical for 2019 falls after 29 March, the exporter will be required to notify the HSE using the new UK regime;
- UK companies exporting hazardous chemicals from the UK into the EU will no longer have access to the EU IT tools used for notifications. Instead, companies will be required to notify the HSE under a new UK system, planned to be in place before 29 March 2019. When notifying under the new UK system, companies will need to provide details on the quantities of the hazardous chemicals exported to or imported from all countries, including those based in the EU; and
- Separately, where consent from an importing country has been provided by another EU Member State which was previously relied on by UK exporters, those UK exporters may need to seek their own explicit consent to export hazardous chemicals to that country following Brexit.

REGULATING BIOCIDES AND PESTICIDES

Under another technical notice (found here), plans for a new UK regime for regulating pesticides are set out, which also envisage transposing most, if not all, of the obligations under the current EU regime, with minimal change to technical requirements. As such, there is no immediate action required in respect of existing EU active substance approvals ("Approvals"), pesticide authorisations and maximum residue levels set ("MRL"), which will remain valid in the UK after 29 March 2019. This approach is broadly mirrored by the technical notice on biocides published on 12 October 2018 (found here).

For pesticides, following Brexit, new applications for Approvals, pesticide authorisations and MRLs will need to be submitted separately under both the EU and UK regimes. The process for submitting applications under the EU regime will, in substance, be retained as part of the new UK regime, other than in circumstances where such processes would not make sense in a UK-only context. Elements of the EU application process that will be retained under the UK regime include the procedure for (i) considering specific technical issues, (ii) public consultation, (iii) consultation with independent specialists where appropriate, and (iv) final decision making. Applications under the new UK regime will continue to be made to the HSE.

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To ensure continuity for the industry, a transition period is planned, which will include:

- An extension of three years for Approvals which are due to expire in the three years after Brexit, while a UK renewal arrangement is established;
- Applications being considered under the EU regime on 29 March 2019 will be progressed to completion under the new UK regime;
- Given the UK will become a third country, there will no longer be mutual recognition between UK and EU countries of Approvals, pesticide authorisations and MRLs. To reduce the impact this will have on industry, it is intended that parallel trade permits in force at the point of Brexit would remain valid for a transitional period of two years after 29 March 2019, or the expiry date (whichever is sooner). When the trade permit expires, companies will need to obtain authorisations in the UK; and
- Seeds which have been treated with pesticides that have been authorised for use in other EU countries will be able to be used in the UK market for 3 years following Brexit.

For biocides, new applications for Approvals and biocidal product authorisations will similarly need to be submitted separately under both the EU and UK regimes. Authorisation holders will need to be established in both the EU and UK under these regimes respectively.

Some elements of ECHA's functions will be retained by the HSE, including the procedure for (i) co-ordinating the UK-specific active substance evaluation process and (ii) undertaking technical equivalence assessments. The HSE will introduce its own processes for receiving and processing applications and data relating to those applications. Further changes include:

- There will no longer be mutual recognition between UK and EU countries of Approvals. Applications being processed by another EU country on Brexit will need to be re-submitted to the UK for national authorisation. Applications being processed by the HSE on 29 March 2019 will continue to be processed by the HSE to completion under the new UK regime where possible. However, re-submission of the information to the HSE may be required where supporting information is needed; and
- The EU list of approved active substance suppliers (Article 95 list) will be transposed into a new UK list. In order to remain on the list, companies will need to submit the same supporting information to the HSE as was submitted to ECHA. The technical notice does not clarify the time limit for companies to do this, but envisages that a grace period will be provided.

EXPORTING GM FOOD AND ANIMAL FEED PRODUCTS IF THERE'S NO BREXIT DEAL

Finally, the UK Government has stated that businesses importing GM food and animal feed products into the UK from the EU or vice-versa, who wish to continue to do so, will need to be established or have a representative in the EEA (notice here).

UK businesses holding EU authorisations for GM food or feed products will need to designate a representative established in the EU or EEA, such as a branch, subsidiary or sister entity, in order to continue holding the authorisation. UK based entities acting in the role of a representative for establishments in non-EU countries will

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no longer be able to fulfil this function following Brexit. These representatives will need to inform the non-EU based entities for which they hold authorisations that they must appoint a new representative based in the EU or EEA if they are to continue exporting feed products into the EU.

UK businesses that have applied for EU authorisation of GM food or feed products and whose application is still being processed at the time of Brexit will need to designate a representative established within an EU or EEA country to continue the application. Separately, UK businesses in the process of changing holder-specific authorisations for GM food or feed products need to approach the European Commission immediately. Such changes require amendments to EU legislation, which will need to be in place by 29 March 2019.

HOW K&L GATES CAN HELP

As the 29 March 2019 deadline approaches, a hard Brexit and the new UK regulatory regimes outlined above become more likely. As such, affected companies should be making preparations on how they will comply with two separate regulatory regimes so as to minimise costs, losses or disruption to business. Steps businesses can take include ensuring that they have an EU base which they can operate out of post-Brexit, obtaining insurance, inserting appropriate protections into contracts with those with whom they trade and conducting advocacy with the EU Parliament, Council and / or the relevant UK authorities in relation to specific regulatory regimes. K&L Gates has experienced teams of lawyers in offices in London, Brussels and across the EU and is well placed to assist you with any of these steps.

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