EurO$_3$zon UK Ltd: Keeping ozone legally on the market after the Brexit

Dr. Jaak Ryckeboer and Dr. Bart Kerré (EurO$_3$zon ivzw*); Dr. Jörg Mielcke (Xylem Services GmbH, WEDECO); Dr. Matthias Rothe (ProMinent GmbH); Dr. Matthias Hoffmann (BWT Wassertechnik GmbH); Mr. Bernhard Paolini (SUEZ Ozonia), Chairman of EurO$_3$zon ivzw.

*Address: EurO$_3$zon ivzw, Eilandstraat 4, 1981 Hofstade, Belgium; e-mail: info@euro3zon.org

Abstract

The United Kingdom (UK) has left the European Union (EU) and on 31 December 2020 the so-called transition period took an end, requiring companies that operate in the UK market to comply with the new local requirements set by the UK authorities. However, Northern Ireland (NI) continues following the European (chemicals) legislations, such as the EU Biocidal Products Regulation (BPR) and EU REACH. On November 30, 2020, EurO$_3$zon UK Ltd (United Kingdom) has been established by the founding members of EurO$_3$zon ivzw (Belgium) in order to have a UK foothold allowing to be fully prepared and to avoid any risk of market disruption for ozone.

EurO$_3$zon UK Ltd

During the last months of 2020 it became gradually clear that the Brexit transition period was expected to end definitively by 31 December 2020. Therefore, on November 30, 2020, EurO$_3$zon UK Ltd (United Kingdom) has been established by the founding members of EurO$_3$zon ivzw (Belgium) in order to have a UK foothold allowing to be prepared and to avoid any risk of market disruption for 'Ozone generated from oxygen' (further called 'ozone') as biocide as well as REACH substance.

Indeed on 31 December 2020, the so-called transition period (TP) took an end, requiring companies that operate in the UK market to comply with the new local requirements set by the UK authorities.

So EurO$_3$zon UK Ltd has been established with, among others, the objectives to advise its Members about initiatives to be taken to ensure compliance with relevant legislation in the UK and to assist with authorisations to be obtained on behalf of its Members, which may benefit other companies.

However, as Northern Ireland (NI) continues following European (chemicals) legislations, such as BPR and REACH, the focus of EurO$_3$zon UK Ltd is on Great Britain (GB), covering England, Scotland and Wales.

'Ozone' under GB BPR

Under the GB Review Regulation, EurO$_3$zon UK Ltd will take the role of participant for supporting the active substance (AS) 'ozone' having the right to refer to the full AS dossier submitted or referred to by the existing participant EurO$_3$zon ivzw (BE).

Although the EU approval process of the active substance (AS) 'ozone' is making good progress, the AS 'ozone' is not approved in the EU yet (more details on this progress can be read in the previous issue of Ozone News). Consequently, the biocidal product (BP) 'ozone' can't be authorised yet in the EU either. Therefore, no approval or authorisation for 'ozone' can be transferred to the UK. In order to keep 'ozone' (generating devices) legally on the market in the UK, this requires in turn that the AS 'ozone' needs to be approved and subsequently the BP 'ozone' needs to be authorised specifically in the UK, in fact in Great Britain (GB) as Northern Ireland (NI) continues to follow the EU BPR.

The contents and data of EurO$_3$zon's EU BPR dossiers will of course be re-used for those purposes, but as a Europe-based entity EurO$_3$zon ivzw (Belgium) cannot apply for these dossiers. If EurO$_3$zon's founding members would not have organised these dossiers under the umbrella of EurO$_3$zon UK Ltd., this would have to be done by all UK subsidiaries of each individual member. This would be a complex process, which would have been less time and cost effective.

Applications for biocidal AS approval and biocidal product authorisation in Great Britain (GB) have to be made to the UK Health and Safety Executive (HSE). HSE charges fees for processing and evaluating applications for biocidal AS approval and product authorisation under the GB Biocidal Products Regulation (GB BPR).

Where there is no GB-specific guidance, HSE will use relevant technical guidance for the EU Biocidal Products Regulation (EU BPR), as the two sets of legislation are very similar.

More information and updates can be found on:
https://www.hse.gov.uk/biocides/index.htm

'Ozone' under the GB Review Programme

'Ozone' is falling under the Great Britain (GB) Review Programme, more specific, under the GB system of evaluating existing biocidal AS. Similar to the EU BPR the AS 'ozone' is

also supported under the transitional measures of Article 93 of GB BPR.

Similar to the EU List of AS also a GB List of AS was released, which provides details of biocidal AS in Great Britain (GB), the list includes 'ozone' ('ozone generated from oxygen') and can be found here: https://www.hse.gov.uk/biocides/uk-list-of-active-substances.xlsx

EurO$_3$zon UK Ltd is planning to submit a full application to HSE including the 'ozone' AS dossier by the end of TP (31 December 2020) plus 180 days as another Member State was evaluating the original 'ozone' AS dossier.

The UK (GB) competent authority HSE has developed its own (IT) systems for receiving and processing applications, and of course, due to the short notice, further developments of the systems can be expected, too.

GB Article 95 list

The AS 'ozone' of EurO$_3$zon ivzw has now also a GB Article 95 entry for the 4 product types (including PT02 - Disinfectants and algaecides not intended for direct application to humans or animals, PT04 - Food and feed area, PT05 - Drinking water, and PT11 - Preservatives for liquid-cooling and processing systems) in place before the end of TP, which needs to be transferred to the GB Article 95 list, the list can be found here: https://www.hse.gov.uk/biocides/uk-article-95-list.xlsx

'Ozone' generation devices under Great Britain BPR

In situ generation of 'ozone' using a device is under GB BPR typically defined as type 2 use. For type 2 use, as in situ generation devices do not meet the definition of a biocidal product, the 'ozone' device can be kept in operation in GB regardless of the status of the AS under GB BPR.

Equal to EU BPR once the AS 'ozone' that is generated by the device is approved, use of the BP 'ozone' generated by the device must be authorised under GB BPR if users of the device want to continue in situ generating and using of the BP 'ozone'.

In line with EU BPR EurO$_3$zon UK Ltd is also planning to support 'ozone' during the BP authorisation stage under GB BPR. So, once the AS 'ozone' will be approved under GB BPR for the relevant product types, EurO$_3$zon UK ltd is planning to ensure all relevant uses being part of a valid product authorisation ensuring to continue generating and using the in situ BP in Great Britain.

'Ozone' is falling under the so-called Type 2 generation

EurO$_3$zon UK Ltd is planning to support 'ozone' falling under the so-called Type 2 generation. Type 2 generation means that only general commodities/chemicals (e.g. LOX) or unmarketable precursors (e.g. air or water) are used to generate 'ozone', i.e. which are not being supplied as a biocidal product.

In situ generated 'ozone' can be used as BP in Great Britain if:

- the AS is a 'review programme AS' and is still 'under review' as an in situ generated AS from the relevant precursor(s)
- only general chemicals (not supplied for biocidal purposes) or unmarketable precursors are used and the AS is still 'under assessment' as an 'Article 93 AS'
- Once 'ozone' is 'approved' as AS under GB BPR for the relevant product type, EurO$_3$zon UK Ltd is planning to ensure product authorisation covering all relevant uses and allowing to continue generating and using the in situ generated BP 'ozone' in Great Britain.

What should end users of "ozone" in situ generation equipment do once the active substance (AS) is "approved"?

Similar to the EU BPR users of general chemicals and non-marketable precursors and where a device is being used (Type 2 generation), EurO$_3$zon UK Ltd is planning to take all necessary steps to complete the product authorisation on behalf of all their members (manufacturers of the 'ozone' devices), in turn covering all relevant uses of their customers (the end-users). In other words, end-users of 'ozone' in situ generation devices that purchased from a EurO$_3$zon UK Ltd BP dossier participant will not have to take care of this, once the AS is 'approved'.

More explanation concerning "In situ generation: Active substances vs biocidal products" can be found on: https://www.hse.gov.uk/biocides/eu-bpr/in-situ-generation.htm

'Ozone' under GB REACH

The EU REACH regulation was brought into UK law on 1 January 2021, known as UK REACH.

In order to help minimising the impacts of introducing UK REACH and providing continuity for businesses, the UK Government has implemented transitional provisions for GB-based EU REACH registration holders. It is not possible for EU-based legal entities to have their EU registrations recognised under UK REACH. As UK REACH only applies in the UK, legal entities based in the EU and EEA do not have obligations under this regime.

EurO$_3$zon UK Ltd is planning to take all necessary actions needed in order to fulfil now also the requirements under UK

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REACH, similar to the role EurO$_3$zon ivzw (Belgium) took under EU REACH, on behalf of Lead Registrant (LR) Xylem.

Relevant EU REACH registrations can be recognised under UK REACH, a process which is known as 'grandfathering'.

Grandfathering allows having continued access to the GB market. However, there are steps EurO$_3$zon UK Ltd is planning to take in order to comply with UK REACH.

Depending on the tonnage band (and hazard profile if relevant) of the substance within 2, 4 or 6 years plus 300 days of the end of the Transition Period compliance with the full information requirements for the concerned tonnage band under UK REACH is needed.

More explanation concerning "UK Registration, Evaluation, Authorisation & restriction of Chemicals (REACH)" can be found on: https://www.hse.gov.uk/reach/index.htm

The GB CLP Regulation

The EU CLP Regulation (Regulation (EC) No 1272/2008) adopts the United Nations' Globally Harmonized System of the classification and labelling of chemicals (GHS) across all EU countries, including the UK, when the UK was an EU Member State.

In order for GB CLP to operate fully and effectively in GB, the EU CLP Regulation has been amended. This means there are changes to the requirements or allowances in existing processes and procedures.

Where necessary EurO$_3$zon UK Ltd is planning to take also all necessary actions to keep 'ozone' legally on the market related to GB CLP.

More explanation concerning "The GB CLP Regulation" can be found on:https://www.hse.gov.uk/chemical-classification/legal/clp-regulation.htm

Disclaimer

This paper is not intended to be used as a substitute for any UK or GB legal or regulatory advice, nor should you consider it as such. You should not act (or refrain from acting) based upon information in this paper without consulting the UK Health and Safety Executive (HSE) regarding your particular facts and circumstances.