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P27. SUPPLY OF BIOCIDAL ACTIVE SUBSTANCES, DATA PROTECTION, LETTERS OF ACCESS AND ARTICLE 95 OF BPR

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Dow Microbial Control is a leading global provider of advanced sustainable microbial control technologies. In the European Union, the Biocidal Products Directive (BPD) established in 1998 a new legislative frame work regulating the placing on the market of biocidal products in the European Union (EU). The BPD introduced in particular the obligation for biocidal products to be authorized before they can be placed on the market and the need for Biocidal active substances to be approved. The BPD also initiated a review program for the so-called existing active substances which were already on the market in May 2000. This program was intended to last until 2010 but has been prolonged until 2024. On 1st of September 2013, the Biocidal Products Regulation (BPR) replaced the BPD. It reinforced the BPD provisions and introduced a number of new requirements like the exclusion and substitution hazard-based criteria, which will directly impact the evaluation and approval of existing active substances. The BPR also introduced the requirement for all suppliers of biocidal active substances on the EU market to submit a complete dossier and be listed on a positive list (the Article 95 list of approved suppliers). On the data submitted, the BPR clarified the data protection rules and set up a mandatory data sharing system. After 15 years of implementation, because of the high cost of compliance and complexity, the BPD and the BPR had a tremendous impact on the European biocides industry. This includes a decrease in the number of active substances available on the market, which so far has not been compensated by the introduction of new active substances, as innovation remains a challenge in the current regulatory framework.

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