

EU Drinking Water Directive

What are the challenges?



The EU regulatory framework on water has substantially evolved in recent years to become a central avenue for the regulation of chemicals and the management of the impact of industrial activities.

This tendency is largely visible in the 2020 [Recast Drinking Water Directive](#). Among other additions, it has introduced a **positive list of components** that can be used in the composition of materials and products in contact with drinking water.

This broadly encompassing requirement notably concerns **starting substances** (e.g. ethylene to manufacture polyethylene); **compositions** (e.g. stainless-steel compositions, based on iron with specified levels of chromium, nickel, molybdenum and other alloying elements); and **constituents** (e.g. organic substances deliberately incorporated into cement, such as water-repellent or hydrophobic agents, including silanes).

For manufacturers relying on **components that are not yet listed**, the clock is now ticking.

Strategic decisions need to be made within a **short time frame**:

- Should you notify on your own, or in cooperation with other market actors?
- What form should cooperation take?
- When should new testing be initiated? Before or after the notification?
- What are the consequences if a substance, composition or constituent is not included on the positive list?
- How can newly generated data be protected from unjust access by third parties?

While new to the DWD, such considerations **largely mirror existing situations** under the food contact and biocidal products legislation (PT 4 in particular), chemical data sharing and the wider EU water regulatory framework.

We **have significant expertise** in all of these domains, and from a commercial perspective, can assist companies from the beginning of their compliance journey with **scoping questions** (e.g. do I need to submit or am I exempted?), through to defining a **compliance strategy**, forming and managing **consortia or task forces** with other companies to **share data, costs and know-how** and towards the successful **submission of petitions** for new listings.

Our ability to work seamlessly with **scientific consultants** in dossier preparation is an added advantage in this space, as is our extensive experience of **data sharing arrangements** in the context of petitions.



What are the implications for your business?

Compliance costs

Who pays for the data? The positive list regime raises familiar issues for companies with experience of REACH and the EU Biocidal Products Regulation. Businesses are particularly conscious of the need to minimise data costs while ensuring that the burden of data generation is fairly shared amongst market actors, thereby limiting freeriding.

We advise on **consortium structures**, data sharing frameworks, cost allocation mechanisms and access rights, helping organisations manage both compliance requirements and the commercial consequences of **sharing information with competitors** and supply chain partners.

Are you funding compliance twice? Many companies affected by the positive list are already **managing data sets and registrations/authorisations** under other regulatory frameworks (chemicals, PT4 biocides, food contact materials). The challenge is often not generating new data, but understanding how existing data sets or access rights can be leveraged to support DWD compliance, noting that data access under one regime does not automatically amount to access under another regime.

We help businesses identify **overlaps between regulatory regimes**, assess where existing investments can be reused, and avoid unnecessary duplication of testing, data acquisition and compliance expenditure.

Commercial and legal implications

The hidden commercial opportunity in drinking water compliance. Regulatory approvals can influence competition just as much as product performance or pricing. Businesses that already hold relevant data, possess established portfolios or have experience navigating EU chemicals and biocides legislation, are better placed to secure and maintain market access.

We help clients evaluate how approval requirements **may affect supply chains, market entry, product portfolios** and relationships with competitors, suppliers and customers, ensuring regulatory decisions are assessed through both a compliance and commercial lens.

Our expertise

- Consortia management in the context of REACH, Plant Protection and the Biocidal Products Regulation (establishment of consortium agreements; organising consortium dataset; and day to day management).
- Extensive experience advising on data-sharing and compensation arrangements in the chemicals sector, including the negotiation and drafting of consortia and joint submission agreements, letters of access and hardcopy access to data.
- Representation of data owners in data sharing disputes before ECHA's Board of Appeal.
- Acting as the interface between scientific consultants and petitioners in requests for approval of active substances under the Biocidal Products Regulation and the EU food contact materials legislation.
- Submission of petitions to EFSA for the inclusion of substances in the positive list of substances used to manufacture plastic food contact materials.
- Ongoing support to applicants for product-type 4 (disinfection of food contact applications) and product-type 5 (drinking water disinfection) under the Biocidal Products Regulation, including input on implementing laws on the interface between food contact materials and biocides.
- Assisting companies in their compliance and testing strategies following requests for information and testing from ECHA and national competent authorities.
- Advice to companies in a wide range of sectors (including pharmaceutical and biocides) on the impacts of priority substance listing under the Water Framework Directive.

Contacts



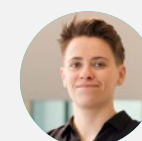
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