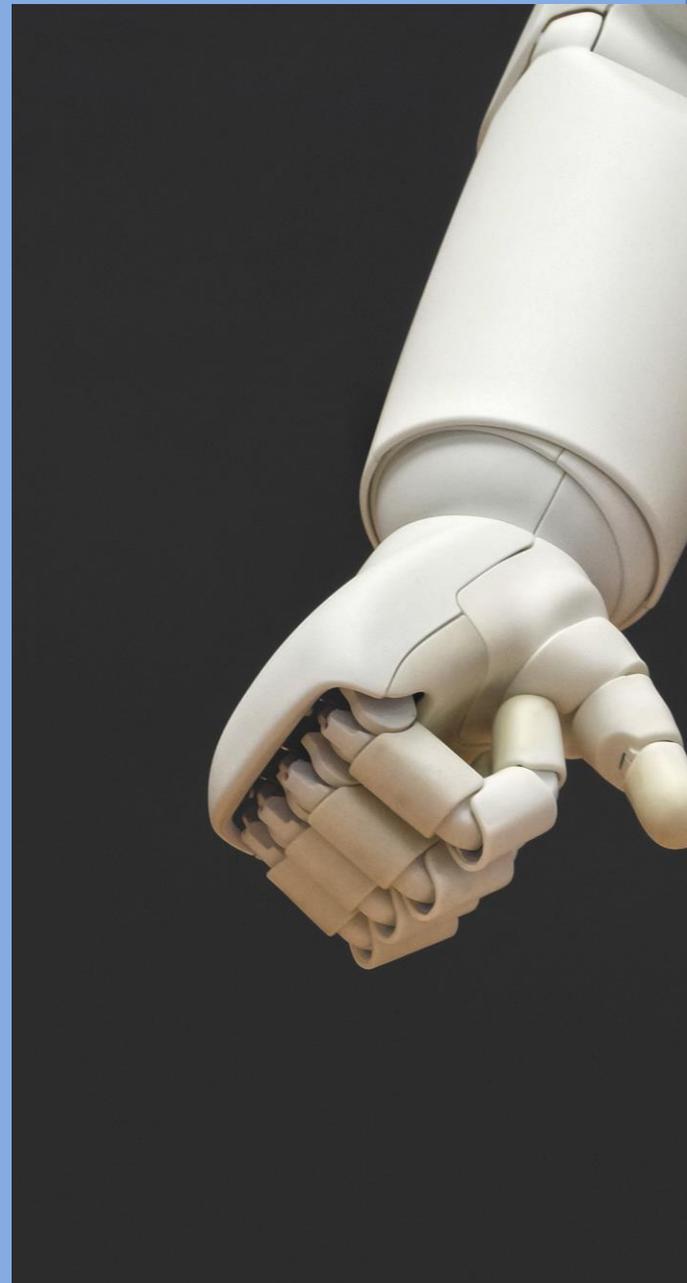


Bird & Bird

# Product Compliance & Liability

2023



# Contents

Why product compliance matters to your business

Where can we help?

Product disputes

Where we add value

4

5

7

8

Bird & Bird LLP's product compliance and liability group offers a cradle to grave service for clients, providing commercial and regulatory advice on design, testing, labelling, and safety for clients in the UK and EU.

*Legal 500 UK 2023*

# Why product compliance matters to your business

Any business which manufactures, imports or distributes products in any territory around the world needs to understand the regulatory landscape which exists for that type of product.

The regulatory landscape can encompass a range of frameworks relating to product safety, environmental protection, packaging, waste and recycling. Understanding these frameworks, the requirements for the products and the obligations placed on those in the supply chain is of fundamental importance.

Our job is to help manufacturers, importers, and distributors understand and comply with the often varied and complex regulatory requirements which apply to their business and their products throughout the product lifecycle.

We have advised clients from a vast array of different industries, including life sciences & medical devices, aerospace & defence, consumer electronics, homeware & furniture, machinery, toys and packaging. To allow us to do this, we have first-class sector-specific experts to ensure that clients are advised and supported by teams

with specific knowledge of the intricacies of the technology and market in those sectors.

Whilst robust compliance is always the goal, we are also here to support clients if an issue arises. The consequences of non-compliance can be severe, including investigations & enforcement action by regulators, product recalls, corporate criminal sanctions, as well of course as product safety and contractual claims, together with the associated reputational damage. Swift responsive action is almost always essential in such circumstances, and our team of experts (including litigators and reputational management specialists) are there to help guide clients through the steps that need to be taken.

Our Product Compliance & Liability practice complements Bird & Bird's sector focused approach and specialist expertise. We support manufacturers, importers, distributors and customers not only in ensuring their own compliance with regulatory requirements but also fully realising the market advantage that stems from compliance.

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# Where can we help?

## *Identifying the relevant regulations which apply to your business*

Most products will fall within the scope of a number of different regulations and need to comply with each of them. Some of these regulations will apply only to a specific type of product, others will apply to all products with a specific characteristic, whereas others will apply more generally.

Examples of key EU and UK regulatory frameworks include:

- General product safety regulations provided under the EU General Product Safety Directive 2001 (GPSD) and the UK equivalent regulations, as well as the EU Market Surveillance Regulation 2019 (MSR)
- Product-specific regulations relating to:
  - Machinery
  - Radio equipment (RE)
  - Low voltage electrical equipment (LVD)
  - Electromagnetic compatibility (EMC)
  - Medical devices
  - Toys
  - Pressure equipment
  - Personal protective equipment (PPE)
- Chemicals, including the EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**) and the Great Britain equivalent regulations
- Environmental regulations, including
  - Restriction of Hazardous Substances in Electrical and Electronic Equipment regulations (**RoHS**)
  - Waste Electrical and Electronic Equipment regulations (WEEE)
  - Packaging regulations
  - Battery regulations
  - Ecodesign regulations
  - Energy labelling regulations
- Chemicals regulations, including the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**)

In some cases, it will be straightforward to assess which set of regulations will apply to a given product. In other cases, particularly in relation to borderline products, such an assessment becomes more complex (e.g. smart watches which potentially have the functionality as medical devices).

## *Practical guidance on applying the design, testing, documentation, labelling and marking requirements*

The regulations which apply to a given product will typically set out a range of requirements relating to:

- The design of the product and mandatory safety features;
- Conformance assessment procedures;
- Labelling & marking (CE marking, UKCA marking, Wheelie Bin marking, etc);
- User information/manuals, warnings and language requirements;
- Documentation requirements (e.g. declarations of conformity and technical files);
- Market surveillance and reporting; and
- Obligations imposed on the manufacturer, importer and distributor.

Given that the applicable regulations are frequently lengthy and complex, we assist clients by providing clear and practical guidance as to

what is required and how this can be implemented.

## *Dealing with product compliance obligations in supply chain contracts*

Product safety and environmental regulations typically impose a range of obligations on the various parties in the supply chain: the manufacturer, the importer and distributor, including (where applicable) authorised representatives

We advise clients on ensuring those obligations are properly understood and, where relevant, are addressed in the contractual arrangements as between the parties in the supply chain.

## *Representation before regulatory authorities*

Given that the applicable product compliance legislation can often be ambiguous, voluminous and/or complex, it is not uncommon for a disagreement or query to arise with a regulator in relation to a product. We assist in advising clients on the best way to address these issues with the regulator and formally represent them as needed.

# Product disputes

*When a defective or unsafe product has been placed on the market, specific legal challenges and risks arise for businesses and economic operators involved in the supply chain.*

First, manufacturers, distributors, importers and suppliers of products need to ensure that obligations and responsibilities imposed under product safety legislation and regulations are fully satisfied. Otherwise, there is a risk that criminal sanctions or other enforcement actions could be imposed. Product recalls across industry sectors are generally on the rise, with market regulators having increased scrutiny on the management of supply chains and their participants in view of new or emerging regulations on customer safety, product labelling, packaging disposal and sustainability.

Secondly, business-critical disputes often arise between members of the supply chain and with customers (whether business customers or individual consumers). Such product liability claims can be technically and legally complex, especially where the defective products in question have been supplied across different jurisdictions or where their production involved the input of multiple entities.

Our product liability team supports designers, manufacturers, distributors, importers and suppliers in a wide range of sectors on these issues, using their first-hand industry experience and know-how. As we adopt an integrated approach with our non-contentious colleagues, we can become involved in product liability issues from a very early stage, which enables us to provide clients with prompt advice so that risks and challenges can be mitigated and managed effectively. In recent years, our experience in this area has particularly been driven by: (a) our clients' need to understand the product liability risks inherent in emerging or disruptive technologies (for example, self-driving and autonomous vehicles in the automotive sector and AI software systems); and (b) the rapid growth in the delivery of products through new business and distribution models such as online marketplaces.

We have experience and expertise in advising clients on the following issues, especially within the technology & communications, IT, electronics, food and drink, automotive, energy & utilities, construction, medical devices and retail &

consumer sectors, and very often with a cross-border element:

- Advising on product safety obligations when a safety hazard arises in the market, including on how to conduct safety risk assessments and testing and, in turn, what corrective action should be taken.
- Advising on product recalls and market surveillance actions, including: (i) the preparation, coordination and submission of product safety notifications to authorities and regulators; (ii) dealing with market surveillance/product safety authorities and regulators; and (iii) advising on an effective communication and media programme (including towards affected customers and consumers).
- Acting in domestic and international product liability claims relating to the supply of defective consumer or commercial products, whether in contract, tort or under a strict liability regime. Such claims often involve working with technical experts, in-house engineers and insurers. We aim to help resolve such disputes in the most commercial and cost-effective way.
- Further, our international network of first-class litigators enables us to handle cross-border or multi-jurisdictional class actions in a seamless and fully co-ordinated manner. We advise consumer-facing organisations on strategy to deal with threatened group litigation resulting from defective products.
- Crisis and reputational management.
- Advising on the management and mitigation of product liability risks, especially for new and anticipated products – including with respect to contractual and governance measures that can be adopted.

Advising on product liability insurance coverage issues.

# Where we add value

*We offer more than just standard legal advice.*

Of course, we provide clients with first-class regulatory advice and also help to negotiate commercial contracts, properly allocating compliance obligations. We also support clients through managing the consequences of non-compliance. We use sector-specific experts to advise on the complexities of legislation affecting particular industries and sectors, and also a wider team to cover areas such as reputation management, intellectual property, advertising and franchising issues.

But the services of our Product Compliance & Liability team are wider than that. We can, for instance, also provide:

- 1 Regular industry-specific legislation updates (for example, through legislative or risk registers), focusing on your particular products in relevant jurisdictions, making sure you are kept up to date with developments;
- 2 Tailored training sessions, targeting the issues and obligations that your business actually faces;
- 3 A compliance audit of your product portfolio, including application of legislation, red flags and recommended solutions;
- 4 An audit of your supply chain contracts to ensure appropriate that all regulatory obligations are covered and appropriately allocated; and
- 5 Engagement with relevant trade associations and industry groups, ensuring that your interests are represented at the forefront of legislative and policy development.

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