

4.1.2 Understanding the requirements of rules and regulations

Practical guidance – cross domain

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Guidance on product safety and product liability legislation

European product safety

The product safety and liability regime may be applicable to robots because they can generally be classified as products [1]. The Product Safety Directive was passed in 2001 [2]. Its goal is ‘to ensure that products placed on the market are safe’ [3]. As such, it plays a preventative role [4]. In general, a product is considered to be safe if it ‘does not present any risk or only the minimum risks compatible with the product’s use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons’ [5].

This means that products that are not manufactured in the EU but are meant to be used by those in the EU would also have to abide by the Directive. The manufacturers of the robots, or others in the supply chain, must ensure that any products they make available to consumers must be safe by conforming to national laws of the Member State where the product is marketed, so long as those laws are ‘in conformity with the Treaty ... and [lay] down the health and safety requirements which the product must satisfy in order to be marketed’ [6]. If the technical safety standards promulgated by the industry and standardisation organisations, and subsequently published in the Official Journal of the European Communities, are met by the product, it is presumed to be in conformity [7]. These published standards giving rise to the presumption of conformity are called harmonised standards [8]. Although the standards are voluntary, the European Commission is dedicated to facilitating the process because ‘standards can influence most areas of public concern such as the competitiveness of industry, the functioning of the Single Market, the protection of the environment and of human health, [and] the enhancement of innovation’ [9].

In the alternative, if no published standards exist, the product must conform to safety requirements that consider the following:

- a) voluntary national standards transposing relevant European standards other than those referred to in paragraph 2;
- b) the standards drawn up in the Member State in which the product is marketed;
- c) Commission recommendations setting guidelines on product safety assessment;
- d) product safety codes of good practice in force in the sector concerned;
- e) the state of the art and technology;
- f) reasonable consumer expectations concerning safety [10].

A major caveat that must be noted is that this Directive applies to products for consumers. Although it does not define 'consumer', it is clear under EU law that only natural persons can be considered consumers and those who act for business or professional purposes are not consumers [11]. As a result, businesses that use robots for infrastructure purposes would not be considered consumers and would consequently not fall within the ambit of this Directive.

Nonetheless, the safety measures offered by the Directive can serve as guidance for best practices and for legal reform in the future to extend the regime to the commercial setting. Furthermore, some Member States may extend consumer protection to legal persons or some enterprises, so it would be important to be aware of the national laws of the Member State in which one is considering to conduct business, as robot manufacturers and distributors may still have to abide by the safety standards [12]. Similar to other products, robots would not have to be risk free; they just need to meet the standards [13].

This Directive is not applicable to pharmaceuticals or medical devices [14]. In the realm of robotics, this may mean that those used for healthcare may not fall under the jurisdiction of this Directive, but for robots in infrastructure inspection and maintenance, this is unlikely to be a concern.

European product liability

The Product Liability Directive 85/374/EEC came into effect in 1985 [15]. It has largely harmonised the central tenets of product liability laws in EU Member States since its introduction, though there are still diverging interpretations on the margins [16]. The Directive specifies that producers, which include manufacturers and suppliers, are 'liable for damage caused by a defect in [their] product' [17]. Similar to the Product Safety Directive, the protection covers consumers, which again raises the same set of issues discussed previously, though the product liability regime could serve as useful guidance. While the Product Safety Directive is preventative in nature, the Product Liability Directive seeks to create certainty on how to allocate liability when products do cause personal injuries, death, or property damage.

The burden of proof is on the injured party to show that there is damage, a defect in the product, and that the defect caused the damage [18]. The damage could include bodily injuries, death, or damage to property [19]. The Directive states that '[a] product is defective when it does not provide the safety which a person is entitled to expect', a standard that should consider the following:

- a) the presentation of the product;
- b) the use to which it could reasonably be expected that the product would be put;
- c) the time when the product was put into circulation [20].

These relevant factors show that 'the assessment of the defective character of a product is entirely focused on the consumer' and not the manufacturer or supplier [21]. Nonetheless, this is an objective standard [22]. With new technologies that have autonomous and machine learning capabilities, 'the question of whether unpredictable deviations in the decision-making path can be treated as defects' is one that will have to be answered [23]. Although EU product liability is a strict liability regime, the foreseeability of damage is still relevant and may be used as a defence if an external cause can be shown by the defendant

[24]. It has been noted that placing the burden of proof on the consumer is particularly burdensome due to the possible complexity of the matter where the manufacturer would have superior knowledge, though discussions of amending the provision has not resulted in any changes [25].

Besides showing there was no damage, defect, or causation, there are six defences to liability that the producer and supplier may present. The three that are most notable are that 'he did not put the product into circulation' [26], 'the defect is due to compliance of the product with mandatory regulations issued by the public authorities' [27] and 'the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered' [28]. The last defence, known as the state-of-the-art defence or the development risk defence, is one Member States could have chosen not to implement in their national laws per the Directive [29]. Finland and Luxembourg have chosen to derogate from the Directive and not apply this state-of-the-art defence, while France, Hungary, and Spain exclude the defence for certain products [30].

The 'interdependency between the different components and layers' of new technologies and the increasing autonomy of artificial intelligence and robots that are able to interpret their environment may cast doubt on the present product liability regime [31]. Concepts such as product, producer, and damages may have to be rethought [32]. In addition, questions like 'whether concepts like the liability of a guardian or similar concepts are appropriate to technologies like AI' and 'whether and to what extent it matters for determining liability whether the damage could have been avoided or not' would need to be tackled [33].

The European Commission set up an Expert Group [34]. The formation of this Expert Group shows that the EU is serious about ensuring that the liability regime will be adequate to address the allocation of responsibility of robotics technology should accidents occur. For now, enterprises manufacturing or using robots must understand and follow the product safety and liability frameworks. However, the rapid development in the legal realm to keep pace with technological advances must be monitored by enterprises to ensure that they make business decisions that would ensure high safety standards possible and minimise risks of liability.

Summary of applicable guidance

- The Product Safety Directive and the Product Liability Directive are generally applicable to robots, as they can be considered as products.
- The Product Safety Directive and the Product Liability Directive are only applicable to robots where they are for consumers, and not for businesses.
- While the Product Safety Directive is preventative in nature, the Product Liability Directive seeks to create certainty on how to allocate liability when products do cause personal injuries, death, or property damage.

References

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[3] European Parliament and Council Directive 2001/95/EC of 3 December 2001 on general product safety [2001] OJ L11/4, art 1(1).

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[18] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L210/29, art 4.

[19] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L210/29, art 9.

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[22] Lucas Bergkamp and Rod Hunter, 'Product Liability Litigation in the US and Europe: Diverging Procedure and Damage Awards' (1996) 3 Maastricht Journal of European & Comparative Law 399

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