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Guidance document¹

The relationship between Directive 2001/95/EC and the Mutual Recognition Regulation

1. INTRODUCTION

This document seeks to provide ‘user-friendly’ guidance on issues regarding Regulation (EC) No 764/2008² (the ‘Mutual Recognition Regulation’ or ‘the Regulation’) and in particular the relationship between the Regulation and Directive 2001/95/EC³ (the ‘GPSD’ or ‘the Directive’) on general product safety. It will be updated to reflect experience and information from the Member States, authorities and businesses.

2. THE REGULATORY FRAMEWORK APPLICABLE TO PRODUCTS PLACED ON THE EU MARKET

Directive 2001/95/EC aims to ensure that products placed on the market are safe.

Article 2 states that ‘for the purposes of this Directive ‘products’ shall mean any product — including in the context of providing a service — *which is intended for consumers* or likely, under reasonable conditions, *to be used by consumers* even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned’ [italics added].

The GPSD therefore applies to consumer products, viz. those which are subject to EU harmonising legislation (where that legislation contains no specific provisions with the same objective as in the GPSD) and those which are not ‘harmonised’.

Under the Directive, all consumer products should be safe. To this end, the GPSD lays down obligations for producers, distributors and the Member States.

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² Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, OJ L 218, 13.8.2008, p. 21.

³ Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, p. 4–17.

3. THE MUTUAL RECOGNITION REGULATION (EC) 764/2008

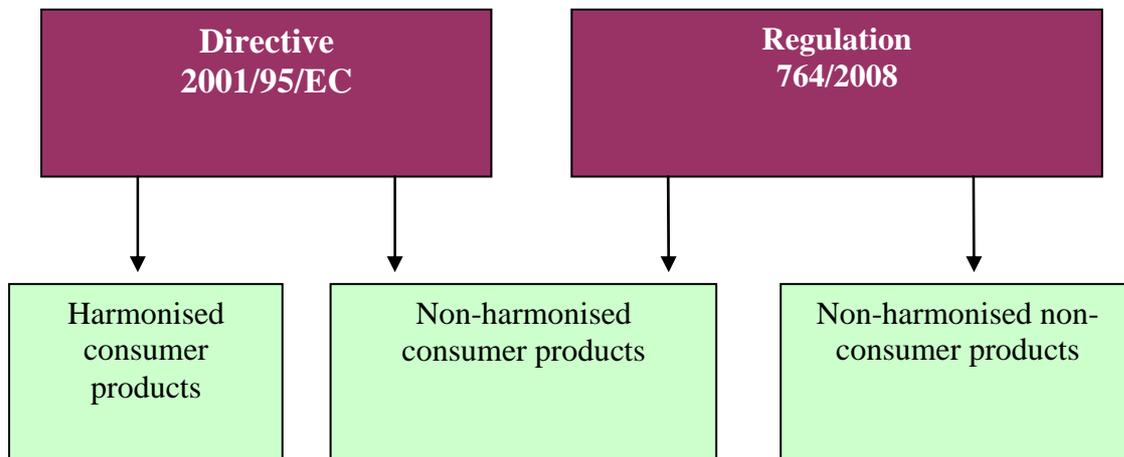
The Regulation operates in the non-harmonised area, covering in particular products for which there is no harmonisation of laws at EU level, or aspects of a product falling outside the scope of EU harmonisation measures.

The main aim of the Regulation is to make the mutual recognition principle fully operational. Article 2 says that it should apply to administrative decisions whether taken or intended which have the effect of impeding access to the national market of a product lawfully marketed in another Member State, and which are addressed to economic operators on the basis of a technical rule.

Under the Regulation, a technical rule is any provision of a law, regulation or other administrative provision of a Member State:

- (1) which is not the subject of harmonisation at EU level, and
- (2) which prohibits the marketing of products from another Member State in the territory of the Member State where the administrative decision is or will be taken, or compliance with which is compulsory for marketing that product in the Member State, and
- (3) which lays down the characteristics required of that (type of) product, such as levels of quality, performance or safety, or dimensions, including requirements as regards the name under which it is sold, terminology, symbols, testing and test methods, packaging, marking or labelling.

The Mutual Recognition Regulation should apply to any non-harmonised product: non-consumer and consumer.



4. THE APPLICATION OF THE MUTUAL RECOGNITION REGULATION TO PRODUCTS PLACED ON THE EU MARKET

4.1. Consumer products

4.1.1. Measures concerning products posing a risk to the health and safety of consumers

Under Article 3(2)(a), the Regulation does not apply to measures taken by the authorities of the Member States under Article 8(1)(d), 8(1)(e), 8(1)(f) and 8(3) of the GPSD to prevent or restrict the marketing or use of a consumer product by reason of the risk it poses to the health and safety of consumers.

It follows that the following measures taken by national authorities on the basis of national laws adopted to give effect to Articles 8(1)(d) to (f) and Article 8(3) of the GPSD are excluded from the scope of the Mutual Recognition Regulation:

- for any product that could be dangerous: temporary ban on its supply, the offer to supply it or its display for however long is needed for the various safety evaluations, checks and controls (Article 8(1)(d) of the GPSD);
- for any dangerous product: ban on its marketing and introduction of the accompanying measures required to ensure the ban is complied with (Article 8(1)(e) of the GPSD);
- for any dangerous product already on the market: (i) order for or organisation of its actual and immediate withdrawal, and alert to consumers of the risks it presents; (ii) order for or coordination – or, if appropriate, organisation together with producers and distributors – of its recall from consumers and its destruction (Article 8(1)(f) of the GPSD);
- for products posing a serious risk: any of the measures mentioned above as well as (i) the requirement that it be marked with clearly worded and easily comprehensible warnings on the risks it may present in the official languages of the Member State in which the product is marketed, (ii) making its marketing subject to prior conditions to make the product safe; (iii) order that persons to whom the product could pose risks are given warning in good time and in an appropriate form, including the publication of special warnings (Article 8(3) of the GPSD).

4.2. Measures concerning products posing other risks

The Mutual Recognition Regulation should apply where the competent authorities of a Member State intend to prohibit the marketing or use of a non-harmonised consumer product, lawfully marketed in another Member State, on the basis of a technical rule and for reasons other than a risk to the health and safety of consumers. This is the case, for example, when a product is not allowed to be marketed for reasons based on the denomination, size, composition or packaging, or for environmental reasons.

5. NON-CONSUMER PRODUCTS

The Mutual Recognition Regulation applies to non-harmonised non-consumer products.

Article 7 says that, when a non-consumer product poses a serious risk to the safety and health of users, Member States can temporarily suspend the marketing of that product. Any Member State applying a temporary suspension must inform the economic operator concerned and the European Commission, giving due technical or scientific justification.