Case studies

on mutual recognition principle

in the field of goods

1. Do the goods fall in the non-harmonised area?

A. Company X sells its goods in Member State A. Subsequently, it started selling its goods in Member State B. However, a competent authority from Member State B intends to issue a decision that the goods cannot be sold in Member State B because they do not meet the criteria envisaged in a national technical rule. The national technical rule is implementing EU legislation.

Answers:

- If the national technical rule is only implementing EU legislation, then the mutual recognition principle and Regulation (EU) 2019/515 do not apply.
- If the national technical rule is not only implementing EU legislation but contains further rules, then the mutual recognition principle and Regulation 2019/515 apply to the aspects of the goods that are not covered by the EU harmonisation legislation but covered by the further national technical rules.

B. Company X sells its goods in Member State A. Subsequently, it started selling its goods in Member State B. A competent authority from Member State B is assessing the goods and intends to issue a decision that the goods cannot be sold in Member State B because they do not meet the criteria envisaged in a national technical rule. The national technical rule was not notified under Directive (EU) 2015/1535[1] ('Single Market Transparency Directive').

Answer: If the national technical rule was not notified under Directive (EU) 2015/1535, it is unenforceable against individuals. See Judgment of 30 April 1996, *CIA Security v Signalson,* C-194/94, EU:C:1996:172. See also Judgment of 26 September 2000, *Unilever,* C-443/98, EU:C:2000:496, and Judgment of 19 December 2019, *Criminal proceedings against X*, C-390/18, EU:C:2019:1112.

C. Company X sells a protein supplement in Member States A, B and C. Upon market surveillance in Member State D, company X is requested to withdraw its goods because the packaging includes a photo of lemon while the goods do not contain natural but artificial lemon flavouring. The competent authority assessed the goods in relation to the

[1] Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services, OJ L 241, 17.9.2015, p. 1–15

compatibility of its labelling with EU legislation on flavourings and certain food ingredients with flavouring properties for use in and on foods.

Answer: The relevant technical rules stem from EU legislation. Therefore, it concerns the harmonised area and the mutual recognition principle and Regulation (EU) 2019/515 do not apply. This issue is covered by Regulation (EU) 1169/2011 on the provision of food information to consumers. The Court of Justice held in its judgment *Teekanne*[2] C-195/14, that Directive 2000/13/EC (repealed by Regulation (EU) 1160/2011) requires that the consumer has correct, neutral and objective information that does not mislead him and that the labelling of food cannot mislead. While the consumer is assumed to read the list of ingredients before purchasing a product, the Court does not exclude the possibility that the labelling of the product may be such as to mislead the purchaser, when some of the items on the labelling are misleading, erroneous, ambiguous, contradictory or incomprehensible.

The fact that the same goods in a same packaging have been sold in other Member States where the authorities did not question the labelling does not mean that this issue should be solved based on the principle of mutual recognition. This is a question to be assessed under the EU harmonisation legislation, more precisely Directive 2000/13/EC.

D. Company X sells its goods as food supplements in Member States A, B C and D. However, a competent authority informed company X that in Member State D the goods fall under the category of medicinal products and will be assessed under the respective rules for medicinal products.

Answer: The CJEU held in its judgment *Orthica*[3] that a product which constitutes a medicinal product within the meaning of Directive 2001/83 relating to medicinal products for human use[4] may be imported into another Member State only upon acquisition of a marketing authorisation issued in accordance with the provisions of that Directive, even where it is lawfully marketed as a foodstuff in another Member State.

Consequently, if the goods fulfil the criteria set out in EU harmonisation legislation to be categorized as medicinal products, they should be treated as such, independently of whether they have been otherwise

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[2] *Bundesverband der Verbraucherzentralen und Verbraucherverbände - Verbraucherzentrale Bundesverband e.V. v Teekanne GmbH & Co. KG. Request for a preliminary ruling from the Bundesgerichtshof,* C- 195/14.

[3] *HLH Warenvertriebs GmbH and Orthica BV* (C-299/03 and C-316/03 to C-318/03) v Bundesrepublik Deutschland.

[4] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; OJ L 311, 28.11.2001, p. 67–128, Current consolidated version: 26/07/2019

categorised (e.g. as food supplements or foodstuff) in another Member States. This is not a question of mutual recognition.

2. Are the goods lawfully marketed in the Member State of origin

A. Company X is selling its goods on the market of Member States A and B. The competent authority of Member State B is assessing the goods and intends to take a decision that company X did not prove that the goods are lawfully marketed in Member State A. It considers that company X did not supply the necessary documents to demonstrate that the goods were sold in Member State A. Company X submitted a MR declaration that contains all the information specified in Part I and Part II of the declaration, as set out in Annex of Regulation (EU) 2019/515, and the supporting evidence. The competent authority requests a written proof from an independent authority that the goods are lawfully marketed in Member State A.

Answer: If an economic operator has submitted a mutual recognition declaration that contains all the necessary information, together with the supporting documents for the information declared in it, the competent authority should not request any further information (including such a proof that the goods are lawfully marketed in another Member State).

3. Assessment of the national technical rule and the characteristics of the goods

A. Company X sells its goods in Member State A. There is no EU harmonisation legislation and Member State A has national technical rule for these goods. Company X enters the market of Member State B. Member State B also has national technical rules for these goods. The rules in Member State B are stricter than those in Member State A. When the competent authority that is assessing the goods establishes this, it intends to deny market access because the rules with which the goods comply in Member State A are not as strict as the rules in Member State B.

Answer: The competent authority in Member State B should not compare the national technical rules. It should assess the characteristics of the goods against its national technical rules.

B. Company X sells its goods in Member State A. There is no EU harmonisation legislation and Member State A has national technical rule for these goods. Company X enters the market of Member State B. Member State B also has national technical rules for these goods. The rules in Member State B are stricter than those in Member State A. The competent authority decides that, having regard to the characteristics of the goods, the legitimate public interest in the national technical rule in the Member State of destination is not adequately protected because:

a) There is no certificate or test report for one or some of the characteristics of the goods.

b) Company X provides certificate that was **issued by a conformity assessment body** of Member State A **accredited** for the appropriate field of conformity assessment activity in accordance with Regulation (EC) No 765/2008 to demonstrate that the goods are compliant with the national technical rules. However, the authority does not take into account test or certificate by accredited body because it doubts its competence.

c) Company X provides certificate that was **issued by a non-accredited conformity assessment body** of Member State A. The authority does not take into account the certificate because it was issued by a non-accredited body.

Answers:

a) If the missing information would question the attainment of the public interest objective pursued with the national technical rule, the authority should first consider less restrictive measures than denying market access. For example, before denying market access to the goods because important information for the assessment of the goods is missing, the authority could require additional information or testing for the relevant characteristic(s) of the goods, taking due account whether this is proportionate.

b) Article 5(8) of Regulation 2019/515 stipulates the obligations of competent authorities to accept test reports and certificates issued by accredited conformity assessment bodies. The authority should not refuse to accept test reports and certificates issued by an accredited conformity assessment body on grounds related to the competence of that body.

c) In order to avoid as far as possible the duplication of tests and procedures which have been already carried out in another Member State, Member States should not refuse to accept test reports and certificates issued by other conformity assessment bodies in accordance with Union law. Competent authorities should take due account of the content of the test reports or certificates submitted by any economic operator as part of the assessment (see the first sentence of Article 5(8) and Recital 30 of Regulation 2019/515).

4. Proportionality analysis

A. Company X sells its goods in Member State A. There is no EU harmonisation legislation. Member State A has national technical rules applicable to these goods. Company X enters the market of Member State B. In Member State B there are also national technical rules for these goods. The rules in Member State B are stricter than those in Member State A. The competent authority takes the view that denying market access is justified because it will ensure the public interest objective pursued with the national technical rule. The authority does not assess whether there are other appropriate and less restrictive measures that could ensure the objective.

Answer: The authority has to assess whether denying market access is the only possible way to ensure safeguarding the public interest objective(s) pursued by the national technical rule. This means that if there is a less restrictive measure that would also ensure safeguarding the public interest objective(s) pursued by the national technical rule, then the administrative decision will be disproportionate. For example, if adjusting the packaging or labelling would be sufficient for the goods to ensure safeguarding the public interest objective(s) pursued by the national technical rule, this should be requested instead of denying market access.

B. Company X sells its goods with certain type of plugs in Member State A. Company X enters the market of Member State B. In Member State B a different type of plugs is used. Company X includes adapters with every device to transform the plug for Member State B market. However, the competent authority denies market access because the goods do not have the type of plug used in Member State B.

Answer: If this practice does not prejudice the attainment of the public interest objective(s), then the authority should not deny market access. In other words, if the use of the electric device with the adapter is safe and no safety issues are raised, the access of the goods to the market should not be denied. Nonetheless, if the regular use of the adapter with that type of electric device would jeopardize public interest objectives, the authorities could deny market access to such goods.