REVIEW OF EUROPEAN ADMINISTRATIVE LAW; VOL. 13, NR. 3, 7-35, PARIS LEGAL PUBLISHERS © 2020

One and Triune – Mutual Recognition and the Circulation of Goods in the EU

Luca De Lucia*

Full professor of Italian and European Administrative Law, University of Salerno

Abstract

This article deals with mutual recognition in relation to the free movement of goods and aims to demonstrate that, as a result of harmonisation policies, this principle is not unitary in its design. Focusing in particular on the role of national authorities (or that of other bodies that carry out this same function), it examines three models through which mutual recognition operates. These models are: a) mutual recognition under the Treaty (the European legislator has laid down three different regulations over the years to facilitate the functioning of this mechanism); b) transnational administrative authorisations; c) conformity assessments and certifications of conformity issued by notified bodies. This article first highlights how these models protect the free circulation of goods to varying extents and how they are aimed at coordinating different forms of pluralism: regulatory, administrative and that of the market. Two legislative developments regarding this subject are then briefly discussed. Finally, after having mentioned some consequences of the harmonisation legislation on the principle of mutual recognition, some observations are made about possible research developments in this matter.

1. Introduction

The concept of mutual recognition (MR) in EU law refers to many different situations.[1] It is applied both to the free movement of goods, services, persons and capital, and to the 'area of freedom, security and justice'. While in the first case the principle essentially supports the fundamental freedoms, on the other hand, in the context of the (former) 'Third Pillar', it

* DOI 10.7590/187479820X16007576818771 1874-7981 2020 Review of European Administrative Law
The author would like to thank the editors of this special issue for their helpful comments on an earlier draft.

1 For the concept of mutual recognition in international public law, see eg K Nicolaidis and G Shaffer, 'Transnational Mutual Recognition Regimes: Governance without Global Government' [2005/3] 68 Law Cont. Probl. 263-318; M Ruffert, 'Recognition of Foreign Legislative and Administrative Acts' [2011] MPEPIL. With regards to mutual recognition within the World Trade Organization: see eg JHH Weiler, 'Mutual Recognition, Functional Equivalence and Harmonization in the Evolution of the European Common Market and the WTO' in F Kostoris Padoa Schioppa (ed), *The Principle of Mutual Recognition in the European Integration Process* (New York 2005), 25ff; A Correia de Brito, C Kauffmann & J Pelkmans 'The contribution of mutual recognition to international regulatory co-operation' OECD Regulatory Policy Working Papers, No 2/2016.

potentially threatens the freedom of people.[2] To add to its complexity, at times MR is based directly on the Treaty, whereas in some cases it is regulated by secondary law. For some scholars, MR should even be interpreted as an ethical principle – as an acknowledgement of others, their identities and dignity – which should shape the relationship between the peoples of the European Union.[3]

Such a wide concept[4] can clearly be analysed in many different ways.[5] Often, for example, it is studied from a unitary standpoint, alongside the four fundamental freedoms and the 'area of freedom, security and justice', focusing on the role of Member States as a whole. In other cases, it has been examined from the point of view of conflicts between the laws of different Member States, i.e. from the viewpoint of regulatory pluralism.[6] While these different approaches have made a major contribution to the research on this subject, they do not always allow for the necessary distinctions to be made or for all the aspects of this topic to be captured.

This article deals with MR in relation to the free movement of goods, analysing in particular the role of national authorities (or those bodies deemed equivalent). It aims to demonstrate that, as a result of harmonisation policies, the principle is not unitary in its design, since it operates through different legal instruments. In particular, after mentioning the case law of the Court of Justice on this matter and identifying the two principal components of MR (Section 2), the three models that operationalise MR are briefly described (Sections 3-5). The point of view adopted here allows for an understanding of how these models of MR protect the free circulation of goods to varying extents and how they are aimed at coordinating different forms of pluralism: regulatory, administrative and that of the market (Section 6). Two recent legislative developments regarding MR are then briefly analysed (Section 7). Finally, after briefly highlighting some consequences of the harmonisation legislation on the principle of mutual recognition, some observations are made about possible research developments in this area (Section 8).

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2 See eg M Möstl, 'Preconditions and Limits of Mutual Recognition?' [2010/2] Comm. Mkt. L. Rev. 405–436; C Janssens, *The Principle of Mutual Recognition in EU Law* (Oxford 2013). Also, K Lenaerts, 'The principle of mutual recognition in the area of freedom, security and justice' [2015/3] Il Diritto dell'Unione Europea 525-552.

3 See eg C Sternberg, K Gartzou-Katsouyanni & K Nicolaidis, *The Greco-German Affair in the Euro Crisis. Mutual Recognition Lost?* (London 2018) 121ff.

4 Given how wide this concept is, it has even been defined as 'verwirrend' (or, 'bewildering') by M Ruffert, 'Der transnationale Verwaltungsakt' [2001/4] Die Verwaltung 453, 458.

5 See eg SK Schmidt, 'Mutual recognition as a new mode of governance' [2007/5] Journal of European Public Policy, 667-681.

6 See eg K Nicolaidis, 'Mutual Recognition of Regulatory Regimes: Some Lessons and Prospects' (1997) Jean Monnet Working Papers, n 7/97. Also, G Rossollillo, *Mutuo riconoscimento e tecniche conflittuali* (Padua 2002), 227ff and the references made therein; J Agudo, 'Mutual Recognition, Transnational Legal Relationships and Regulatory Models' (2020) 13 REALaw 17-40.

2. Three models of mutual recognition

The obvious starting point for analysing mutual recognition applied to the free movement of goods is that of the well-known *Cassis de Dijon* judgment of 1979 that interpreted Article 30 of the EEC Treaty.[7] The principle identified by the Court of Justice (ECJ) was summarised as follows by the EU Commission: 'any product lawfully produced and marketed in one Member State must, in principle, be admitted to the market of any other Member State. Technical and commercial rules, even those equally applicable to national and imported products, may create barriers to trade only where those rules are necessary to satisfy mandatory requirements and to serve a purpose which is in the general interest and for which they are an essential guarantee. This purpose must be such as to take precedence over the requirements of the free movement of goods, which constitutes one of the fundamental rules of the Community'.[8]

On the one hand, this judgment essentially recognised that under the Treaties the movement of certain goods has a transnational nature,[9] potentially transcending national borders. The presupposition behind this is the equivalence of individual Member State provisions that guarantee certain overriding public interests. On the other hand, Member States, in order to satisfy mandatory requirements (public health, protection of consumers or the environment, the fairness of commercial transactions, etc.), may proportionately restrict the cross-border movement of these goods.

The ECJ subsequently defined the scope of MR, establishing that – where substantially equivalent national regulations exist – EU States cannot duplicate controls 'which have already been carried out in the context of other procedures' in another Member State.[10] In this way the principle limits the application of certain provisions contained in the legislation of the destination State. Nevertheless, the Court mitigated this statement, ruling that goods that have already been authorised in another EU legal system can be subjected to further controls in order to protect important public interests – essentially, those now listed in Article 36 of the Treaty on the Functioning of the European Union[11] or one of

7 Case C-120/78, *Rewe v Bundesmonopolverwaltung für Branntwein* [1979] EU:C:1979:42.

8 Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in Case 120/78 ('Cassis de Dijon') [1980] OJ C256/2.

9 In general, on the concept of transnationality, eg P Jessup, *Transnational Law* (New Haven 1956) 1 f.

10 Case C-432/03 *Commission v Portugal* [2005] EU:C:2005:669, para 45. Also, Case C-390/99 *Canal Satélite DigitalSL* [2002] EU:C:2002:34, para 36; Joined Cases C-388/00 and C-429/00 *Radiosistemi* [2002] EU:C:2002:390, para 40-42. In general, G Sydow, *Verwaltungskooperation in der Europäischen Union* (Tübingen 2004) 25ff.

11 *Consolidated Version of the Treaty on European Union* (TFEU) [2008] OJ C115/13, art 36.

the overriding requirements recognised by the case law of the Court –[12] 'where a subsequent control is to be regarded as being too late to be genuinely effective and to enable it to achieve the aim pursued'.[13] According to case law, however, this regime is compatible with the Treaty on condition 'that technical or chemical analyses or laboratory tests are not unnecessarily required when the same analyses and tests have already been carried out in that other Member State and their results are available to the competent authorities of the importing Member State or can, at their request, be made available to them'.[14] In these cases then, 'the authorities of the Member States are ... required to assist in bringing about a relaxation of the controls existing in intra-Community trade and to take account of technical or chemical analyses or laboratory tests which have already been carried out in another Member State'.[15]

Ultimately, the Court of Justice has placed both substantial limits (i.e. the prohibition of repeating the checks made by the authority in the country of origin) and procedural limits (i.e. the obligation to take into consideration the results of the checks already carried out in other EU countries) on the control activities undertaken by the State of destination. Although to varying extents, these two limits are found in all forms of MR.[16]

As can be understood from these brief observations, MR solely based on the case law of the Court of Justice is not always automatically applicable,[17] as in many cases it allows individual Member States to balance two values, such as free movement of goods and protection of public interests, on a case-by-case basis. This has obviously led to considerable difficulties in the practical application of this principle.[18] As a result, there has been intensive EU 'positive legislation' aimed at facilitating the implementation of mutual recognition (and thus the movement of goods). Without retracing the stages of the complex evolution of the single market of goods in detail,[19] it can be said that nowadays MR basic-

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12 See eg Case C-14/02 *ATRAL SA* [2003] EU:C:2003:265, para 42; Case C-354/14 *SC Capoda Import-Export SRL* [2015] EU:C:2015:658, para 40. Eg Court of Justice, judgment of 8 May 2003, C-14/02, *ATRAL SA*, EU:C:2003:265, para 42; Case C-354/14, *SC Capoda Import-Export SRL*, EU:C:2015:658, para 40.

13 C-390/99, *Canal Satélite Digital SL* (n10), para 39 and previously Case C-272/80, *Biologische Producten* [1981] EU:C:1981:312, paras 14-15.

14 Case C-400/96, *Harpegnies* [1998] ECR I-05121, para 36.

15 Case C-25/88, *Wurmser and Others* [1989] EU:C:1989:187; Case C-293/94, *Jacqueline Brandsma* [1996] EU:C:1996:254, para 12.

16 In general, KA Armstrong, 'Mutual Recognition' in C Barnard & J Scott (eds), *The Law of the Single European Market* (Oxford 2002) 235-238.

17 However, Möstl (n2) 410ff.

18 JHH Weiler, 'The Constitution of the Common Market Place: Text and Context in the Evolution of the Free Movement of Goods' in P Craig & G De Burca (eds), *The Evolution of EU Law* (Oxford 1999) 349ff, 368.

19 See eg ibid; P Craig, 'The Evolution of the Single Market' in C Barnard & J Scott (eds), *The Law of the Single European Market* (Oxford 2002), 9-40. More generally S Weatherill, *The Internal Market as a Legal Concept* (Oxford 2017).

ally takes on three different forms that will be analysed in the following sections.[20]

a. In some cases, in the absence of EU harmonisation legislation, MR applies directly under the Treaty, as interpreted by the Court of Justice. However, in an attempt to simplify its implementation, the EU legislator has laid down rules governing the assessment of goods lawfully circulating in another Member State. In view of the failures of previous regulations, a new regulation was enacted in this area in 2019.[21]

b. In other cases, EU law has established harmonised legal frameworks alongside prior authorisation procedures at national level. These national measures, in turn, are subject to recognition – through administrative procedures of varying levels of complexity – by other national authorities. These are national administrative acts with transnational effects.

c. In a number of areas, the EU legislator has introduced harmonised standards, such as technical specifications with which individual goods must comply in order to circulate within the territory of the Union. In certain cases, the conformity of the products with technical specifications must be assessed by private bodies with specialist expertise.

To complete the picture, it should also be recalled here that at times the authorisation power for the marketing of certain goods is entrusted to the Commission or other EU bodies. These regulations do not amount to a variation of the MR principle but are rather forms of harmonisation accompanied by administrative centralisation.[22]

3. The Mutual Recognition Procedure

In the absence of harmonisation legislation, the principle of mutual recognition applies directly under the Treaty as interpreted by the Court of Justice. In these cases, the host administration can carry out a twofold assessment: a) whether a good or goods of a given type are lawfully marketed in another Member State; and b) if so, whether certain legitimate public interests (essentially, those listed in Article 36 TFEU)[23] are adequately protected, in view of the characteristics of the goods in question. Over the years, the EU legislator

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20 On the administrative governance of the common market, see in general Sydow (n10), part II; F Velasco Caballero & F Pastor Merchante (eds) *The Public Administration of the Internal Market* (Groningen 2015). For a different model, see Agudo (n6).

21 Regulation (EU) No 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 [2019] OJ L 91/1.

22 See eg Sydow (n10) 25ff. See also Section 7 below.

23 TFEU (n11) art 36.

has adopted three different regulations aimed at directing the activities of the host State administrations.

The first regulation in this area was enacted under Decision No 3052/1995[24] which stated that: 'Where a Member State takes steps to prevent the free movement or placing on the market of a particular model or type of product lawfully produced or marketed in another Member State, it shall notify the Commission accordingly' of which measures had been taken.[25] The main purpose of this procedure was to enhance knowledge concerning the implementation of the free movement of goods in non-harmonized sectors, in order to identify the problems encountered and find appropriate solutions to them.[26] Moreover, this system aimed to give both the Member States and the Commission the opportunity to react to any illegitimate measures derogating from the principle of the free movement of goods – for example by initiating an infringement procedure.[27]

However, this regulation proved largely unsuccessful, since its implementation failed to provide the Commission with sufficient information to identify sectors where harmonisation might have been appropriate, nor did it bring about a rapid resolution of certain problems regarding free movement.[28]

The 1995 Decision was thus replaced by Regulation No 764/2008,[29] which established an administrative procedure for MR and the direct involvement of economic operators in the assessment of products. More specifically, this Regulation applied to all administrative (rather than judicial) decisions taken on the basis of a technical rule – i.e. any provision of a law, regulation or other administrative provision that aims to protect the overriding requirements – where the direct or indirect effect of the decision was to limit the marketing of certain products lawfully sold in another Member State.[30]

Where a national authority submitted a product to an evaluation in order to determine whether or not to adopt such a decision, it: a) could request information from the economic operator concerned on the characteristics of the product

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24 Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community [1995] OJ L 321/1.

25 ibid, art 1.

26 ibid, Recital 5.

27 ibid, Recital 9; see eg Case C-358/00, *Commission v Kingdom of Spain* [2003] EU:C:2003:599; Case C-423/03, *Commission v Portugal* [2005] EU:C:2005:669; Case C-88/07, *Commission v Kingdom of Spain* [2009] EU:C:2009:123.

28 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 [2008] OJ L 218/21, Recital 36.

29 On this Regulation, S Weatherill, 'The principle of mutual recognition: it doesn't work because it doesn't exist' [2018/2] Eur. Law Rev. 224-233.

30 Regulation No 764/2008 (n28), art 2.

in question and on its lawful marketing in another Member State;[31] b) had then to communicate its intention to the economic operator, demonstrating that the intended decision was justified on the grounds of public interest, as set out in the Treaty, or by reference to other overriding reasons of public interest, and was appropriate for the purpose of achieving the objective pursued;[32] c) also had to specify the time limit within which comments could be submitted by the party concerned.[33] The competent authority was required to adopt a decision within a period of 20 working days from the expiry of the time limit for receiving comments from the interested party. The decision had to take these comments into consideration and adequately state the grounds on which it was based.[34] However, if the authority failed to notify the economic operator of a decision within this time limit, the product was deemed to be lawfully marketed in that Member State, to the extent to which the public interests involved in the assessment were concerned.[35]

However, according to scholars, Regulation No 764/2008 was widely ignored.[36] Moreover, an analysis carried out between 2014 and 2016 in fact showed that it had had limited effect in facilitating the application of the principle and that the requirement to notify administrative decisions restricting or denying market access was rarely complied with.[37] A new Regulation on mutual recognition was thus enacted – Regulation No 2019/515 – which entered into force in April 2020.

Regulation No 2019/515 applies to the same administrative decisions as those covered by the previous Regulation. There are, however, a number of differences in its provisions. The producer (or their authorised representative) of goods, or of goods of a given type, 'that are being made or are to be made available on the market in the Member State of destination may draw up a voluntary declaration of lawful marketing of goods for the purposes of mutual recognition ("mutual recognition declaration") in order to demonstrate to the competent authorities of the Member State of destination that the goods, or the goods of that type, are lawfully marketed in another Member State'.[38] To this end, the 'mutual recognition declaration' must provide the competent authorities

31 ibid, art 4.
32 ibid, art 6(1).
33 ibid, art 6(2)
34 ibid.
35 ibid, art 6(4).
36 S Weatherill (n29) 229.
37 Regulation No 2019/515 (n21), Recital 7. See also, Commission, 'Evaluation of the Application of the mutual recognition principle in the field of goods' [2015] ENTR/172/PP/2012/FC – Lot 4.
38 Regulation No 2019/515 (n21), art 4.

with all necessary information on the goods, their characteristics and their compliance with the rules applicable in the Member State of origin.[39]

Where the self-declaration is supplied to the national competent authority (NCA) of the destination state, this, together with supporting evidence provided in response to a request from this authority, has to be accepted as sufficient to demonstrate that the goods are lawfully marketed in another Member State. No further information or documentation can be requested to this end.[40] On the contrary, if no self-declaration is supplied, the NCA may request the economic operators concerned to provide all the documentation and information necessary for the assessment concerning the characteristics of the goods in question and the lawful marketing of these goods in another Member State.[41] During the evaluation procedure, the destination NCA may contact that of the country of origin in order to verify the information provided by the economic operator,[42] but must take into due account the content of test reports or certificates issued by a conformity assessment body and accept reports or certificates issued by a conformity assessment body accredited in accordance with Regulation No 765/2008.[43]

If the assessment is negative, the NCA must issue a decision that is sufficiently detailed and reasoned regarding the national technical rule and the legitimate public interest grounds on which the decision is based, the technical/scientific evidence that has been taken into consideration, etc.[44] The decision has to be promptly notified to the operator concerned, as well as to the Commission and the other Member States. In addition to challenging the unfavourable decision in court, the private party concerned can, in turn, submit the administrative verdict to SOLVIT.[45] Subsequently, the Home Centre of SOLVIT can request the Commission to give an opinion in order to assist in solving the case

39 ibid, Recital 17 and Annex.
40 ibid, art 5(4).
41 ibid, art 5(5).
42 ibid, art 5(7).
43 ibid, art 5(8).
44 ibid, art 5(10-11).
45 The SOLVIT (Effective Problem Solving in the Internal Market) Network 'has been set up to help citizens and businesses when they run into a problem resulting from possible misapplication of Internal Market rules by public administrations in another Member State. It builds on an existing network of Co-ordination Centres, one for each Member State, which have been established in 1997 to deal with such problem cases.': Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, 'Effective Problem Solving in the Internal Market ("SOLVIT")', COM(2001) 702 final. See also, Commission Recommendation of 17 September 2013 on the principles governing SOLVIT [2013] OJ L 249/10. On this issue, see eg E Kokolia, 'Strengthening the Single Market through informal dispute-resolution mechanisms in the EU: The case of SOLVIT' (2018) 25(1) Maastricht Journal of European and Comparative Law 108-117.

and to assess whether the national decision is compatible with the principle of mutual recognition.

Finally, Regulation No 2019/515 provides for forms of cooperation between the various NCAs[46] and for the possibility for the State of destination, under specific conditions, to suspend the marketing of the goods under evaluation.[47]

Despite notable differences, both the Regulations of 2008 and that of 2019 have the same aim: to govern the MR procedure in order for the administration of destination to take into due consideration the 'regulatory history of a product'.[48] In particular, the two Regulations attempt to limit the amount of information and documentation that the host authority can request from the operators concerned and clearly place the burden of proof regarding the need to protect the essential requirements (and thus to limit the marketing of the goods) on the destination NCAs.[49] Furthermore, although neither establishes a prior authorisation system, they require that the technical rules (and thus the restriction of free movement) be applied only by means of an express administrative decision.[50] This solution should, on the one hand, avert the risk that the marketing of the goods in the host State gives rise to criminal proceedings;[51] on the other hand, it should enable the private party to challenge the unfavourable decision in the national courts (with the possible involvement of the Court of Justice regarding the compatibility of the national rule with the Treaty).

4. Transnational authorisations

In accordance with a number of pieces of EU harmonisation legislation, the marketing of certain goods is subject to a prior national authorisation, which must be recognised by the other Member States. In such cases the national authorisation has transnational effects. Since the subject has already been studied in detail,[52] a few brief references will suffice here. Although there

46 Regulation No 2019/515 (n21), arts 9-11.

47 ibid, art 6.

48 In general, KA Armstrong (n16) 231.

49 On this issue, see eg C-14/02, *ATRAL* (n12), paras 67-68.

50 See, however, the Opinion of Advocate General Bobek in Case C-672/15, *Noria* [2016] EU:C:2016:961, paras 62ff.

51 See eg Case C-672/15, *Noria* [2016] EU:C:2017:310, para 22. See also, Weatherill (n29) 224ff.

52 See eg E Schmidt-Aßmann, 'Deutsches und Europäisches Verwaltungsrecht' [1993/12] Deutsches Verwaltungsblatt, 924 f and 936 f; S Galera Rodrigo, *La aplicación administrativa del derecho comunitario* (Madrid 1998) 108ff; J Becker, 'Der transnationale Verwaltungsakt' [2001/11] Deutsches Verwaltungsblatt 855-866; M Ruffert, 'Der transnationale Verwaltungsakt' (n4) 453-485; Sydow (n10) part II; L De Lucia, *Amministrazione transnazionale e ordinamento europeo* (Turin 2009); AM Keessen, *European Administrative Decisions. How the EU regulates Products on the Internal Market* (Groningen 2009); HCH Hofmann, GC Rowe & AH Türk, *Administrative Law and Policy of the European Union* (Oxford 2011) 645-648; C Ohler, 'Europäisches und nationales Verwaltungsrecht' in JP Terhechte (ed), *Verwaltungsrecht der Europäischen Union* (Baden Baden 2011) 331, 345ff; M Gautier, 'Acte administratif transnational et droit communautaire',

are various forms of administrative decisions that can be categorised as 'transnational', most of the legal provisions on this matter represent the transposition of the case law of the Court of Justice on mutual recognition, following two basic patterns.[53]

The first pattern is that of the national act with automatic transnational effects.[54] In this case, the authorisation issued by a national administration allows the beneficiary to market a good in all Member States without the host administrations having to give their own consent or being entitled to review the legality or the merits of the authorisation issued in the country of origin. These regulations incorporate the substantial limits identified by the case law of the Court of Justice regarding the duplication of administrative controls.[55]

In the second pattern, the authorisation issued in another Member State must be effectively recognised in the country of destination.[56] However, contrary to the claims of some scholars, the host administration cannot check the legality of the administrative decision issued in another EU state.[57]. It is limited to examining the results of the scientific or technical tests on which the first authorisation is based and, without repeating them, can simply determine the effects in its legal system by means of the mutual recognition act. From a structural point of view, the administration of origin thus substitutes that of the host country by carrying out the majority of checks on a given good. From a functional point of view, these regulations leave room for national diversity, as they allow the second authority to adapt the effects of the first act to the

in J-B Auby & J Dutheil de la Rochère (eds), *Traité de droit administratif européen* (2nd edn, Bruxelles 2014), 1303-1316; L De Lucia, 'From Mutual Recognition to EU Authorization: A Decline of Transnational Administrative Acts' [2016/1] IJPL 90-114; JJ Pernas García, 'The EU's Role in the Progress Towards the Recognition and Execution of Foreign Administrative Acts: The Principle of Mutual Recognition and the Transnational Nature of Certain Administrative Acts' in J Rodrigo-Arana Muñoz (ed), *Recognition of Foreign Administrative Acts*, (Cham and others 2016) 15-31; J Ortega Bernardo, 'El acto administrativo transnacional en el derecho europeo del Mercado interior' in L Arroyo Jiménez & A Nieto Martìn (eds), *El reconocimiento mutuo en el Derecho español y europeo* (Madrid 2018), 97-121.

53 On what will be said below, see De Lucia, *Amministrazione transnazionale* (n52) chap 2 & 4; L De Lucia, 'Administrative Pluralism, Horizontal Cooperation and Transnational Administrative Acts' [2012/2] REALaw, 17-45, spec. 24ff.

54 See eg Council Regulation (EC) No 116/2009 of 18 December 2008 on the export of cultural goods [2009] OJ L 39/1; Consolidated Version of Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items [2009] OJ L 134/1; Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters [2009] OJ L 164/45.

55 See the case law quoted in n10.

56 See eg Consolidated Version of 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 [2001] OJ L 311/67; Consolidated Version of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products [2012] OJ L 167/1.

57 See eg G Rossollillo (n6) chap. 4.

specificities of its country. These legal provisions transpose the case law of the Court of Justice regarding the procedural limits of the controls carried out in the destination State.[58]

As is well known, the EU legislator has provided for numerous variants on these basic patterns: for example, joint decisions[59] or authorisations in parallel.[60] Despite their many differences, all transnational authorisations have certain elements in common, which can be summarised as follows:

1. They presuppose a high level of harmonization between national legal orders. In particular, EU harmonization legislation removes the technical and legal obstacles of national origin to the circulation of goods, while at the same time establishing a single legal obstacle for the protection of certain overriding public interests.[61] Only transnational authorisations – which are often discretionary – can remove this legal obstacle;[62]
2. Since it is implementing the principle of mutual recognition, the regulation of the different types of transnational authorisation is a result of the balance between the need to protect market unity and the need to protect certain overriding national public requirements. This is matched by various forms of administrative division of labour which are made effective by a number of limits imposed on the administration of destination regarding the authorisation issued by another national authority;
3. As compensation for the reduction in the decision-making powers of the host authority, intensive forms of administrative cooperation (information, procedural and decision-making) are foreseen before and after the issuing of the transnational authorisation. In particular, specific procedures are provided for to resolve possible conflicts between administrations – this also includes safeguard measures enacted by Member States on the basis of Article 114(10) TFEU regarding goods authorised in another Member

58 See eg Case C-272/80, *Biologische Producten* (n.13), paras 14-15; C-390/99, *Canal Satélite Digital SL* (n10), para 39.

59 The joint decision is a national authorisation which is the result of a composite procedure in which all the State administrations involved (and at times also the Commission) participate with a co-decisional role: see eg Consolidated Version of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] OJ L 106/1, art 6ff.

60 In these cases, checks and controls are carried out by only one national administration and, on the basis of this, other national authorities issue individual authorisations whose legal effects are limited to their own territory: see eg Regulation No 528/2012 (n56), arts 34ff.

61 See eg P Maduro, *We the Court* (Oxford and Portland, Oregon, 1997), 110ff.

62 For example, pursuant to art 19 Directive No 2001/18 (n59), 'only if a written consent has been given for the placing on the market of a GMO as or in a product may that product be used without further notification throughout the Community'.

State.[63] This set of tools – all based on a marked procedural dialogue – also allows for mutual control between the various authorities involved, and the cooperative resolution of any problems that may occur;

4. In this legal context, the producer has specific obligations (eg the monitoring and handling of new information) to protect certain general values and is liable for any damage to third parties.[64] While this solution is consistent with the objective of liberalisation that these provisions pursue, it does not rule out that – for example where the issuance an illegal authorisation or a lack of surveillance activity causes damage to a third party – a State may incur liability for the breach of EU law,[65] or a national administration may incur civil liability on the basis of individual national laws.[66]

5. Conformity assessments

The third model of mutual recognition involves a system of so-called technical harmonisation. In this case national authorities play a different and, in some ways, more marginal role. A central position is held instead by private bodies. As the subject is highly complex, the following provides a general overview of the essential aspects of the issue.

5.1. Legal framework

The functioning of the single market requires uniform guarantees regarding the safety of products.[67]

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63 TFEU (n11), art 114(10). More details are provided in L De Lucia, 'Conflict and Cooperation within European Composite Administration (Between Philia and Eris)' [2012/1] REALaw 43-77.

64 See eg Directive No 2001/18 (n59), art 20.

65 On the condition of the liability of Member States for the breach of EU law, see eg P Craig, *EU Administrative Law* (3rd edn, Oxford 2018), 782-794. On the effectiveness of the remedy, however, see T Lock, 'Is private enforcement of EU law through State liability a myth? An assessment 20 years after Francovich' [2012/5] Common Mkt. L. Rev., 1675-1702.

66 See eg N Reich, 'Product Liability and Beyond: An Exercise in "Gap-Filling"' [2016/3&4] ERPL, 619-644.

67 On the following, see J McMillan, 'La «certification», la reconnaissance mutuelle et le marché unique' [1981/1] Revue du marché unique européen 181-122. See also, HC Röhl, *Akkreditierung und Zertifizierung im Produktsicherheitsrecht* (Heidelberg 2000); HC Röhl, 'Conformity Assessment in European Product Safety Law' in O Jansen & B Schöndorf-Haubold (eds), *The European composite administration* (Cambridge 2011) 201-227; J-P Galland, 'The difficulties of Regulating Markets and Risks in Europe through Notified Bodies' [2013/3] Eur. J. Risk Regul. 365-373; Commission Notice, 'The 'Blue Guide' on the implementation of EU products rules 2016' [2016] OJ C272/1.

To this end, in the second half of the 1980's, a 'new approach' to harmonisation was adopted.[68] Essentially, the technique of detailed harmonisation legislation of safety requirements (the so-called 'old approach') was abandoned and the EU legislator opted instead for legislative harmonisation that is limited to the essential requirements that individual products must meet in order to benefit from free movement. Under this system, the Commission can request the European Standardisation Organisations (which are private bodies) to draw up harmonised standards – i.e. the technical specifications (obviously in conformity with EU legislation) that individual goods must comply with and which, once published in the Official Journal of the EU, prevail over national specifications.[69] The application of harmonised standards is voluntary and the manufacturer can apply other technical specifications in order to meet essential requirements. [70] However, the EU legal order clearly supports harmonised standards, as products manufactured in compliance with these technical rules benefit from a presumption of conformity with the corresponding essential requirements of the applicable EU legislation[71] and can be marketed throughout the common market.[72]

The Council and the Parliament have also adopted a number of acts containing the general guidelines and detailed procedures for the assessment of product safety ('global approach') which must be transposed in the Directives regarding individual goods.[73] Under this regulatory framework, compliance with the es-

68 Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards [1985] OJ C136/1.

69 Consolidated Version Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council [2012] OJ L 316/12. On this issue, see eg M Eliantonio & M Medzmariashvili, 'Hybridity Under Scrutiny: How European Standardization Shakes the Foundations of EU Constitutional and Internal Market Law' [2017/4] Leg. Issues of Econ. Integration 323-336, as well as the other articles published in the same issue of this Journal. More generally H Schepel, *The Constitution of Private Governance* (Oxford and Portland 2005) chap 2 & 7.

70 These are eg national, European or international standards which are not harmonised (ie not published in the OJ) or the manufacturer's own specifications: Commission Notice, The 'Blue Guide' (n67) 51.

71 See eg Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys [2009] OJ L 170/1, art 13.

72 See eg ibid, art 12; Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles [2013] OJ L 127/78, art 4. On this Directive, eg Case C-220/15, *Commission v Germany* [2016] EU:C:2016:815.

73 Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC [2008] OJ L 218/82. On this Decision, see eg Commission Notice, The 'Blue Guide' (n67).

sential requirements and the harmonised standards can be demonstrated in different ways depending on the characteristics of each good. [74]For example, for products with a low risk potential, the manufacturers themselves can carry out all the required controls and checks, draw up the technical documentation and ensure the conformity of the production process.[75] For the most dangerous goods, a central role is played instead by third parties: the notified bodies.[76]

Based on the sector-specific legislation, notified bodies are called upon to assess the product design and/or the manufacturing process, as well as to issue or refuse examination certificates which attest the conformity of the product (or product type) with the safety requirements set out in the relevant legislative acts, as well as with harmonised standards, if approved. Furthermore, if during the monitoring of conformity following the issuance of an examination certificate, a notified body finds that a good is no longer in compliance, it can require the manufacturer to take appropriate corrective measures, and, where necessary, suspend or withdraw the examination certificate.[77] In addition, there are a number of information obligations towards the notifying authority (eg on the refusal, restriction, suspension or withdrawal of a certificate) and other notified bodies operating in the same sector (eg on issues relating to negative and, on request, positive conformity assessment results).[78]

Given their sensitive functions, notified bodies must obviously act in a technically qualified, impartial and independent manner, and are subject to public supervision.[79] In particular, the NCA can authorise the certification activities (the notification procedure) only if the applicant satisfies a number of conditions[80] and, also on request of the Commission, can restrict, suspend or withdraw the authorisation if the notified body no longer meets these conditions.[81] Although the notification procedure takes place at national level, it has a transnational dimension, as the notified bodies may provide their services to producers in all EU countries. This explains why other Member States and the Commission may raise objections to the notification of a body.[82]

In order to guarantee higher quality assessment activities and the effective impartiality of notified bodies, and thus to facilitate confidence building between Member States, Regulation No 765/2008 provided for a complex accreditation

74 Decision No 768/2008 (n73), annex.
75 Commission Notice, The 'Blue Guide' (n67) 66.
76 The intervention of notified bodies is also required, as a rule, for those goods that do not comply with harmonised standards: eg Directive No 2009/48 (n71), art 19(3)(b).
77 See eg Directive No 2009/48 (n71), art 35(4-5); Directive No 2013/29 (n72), art 33(5-6).
78 See eg Directive No 2009/48 (n71), art 36(2); Directive No 2013/29 (n72), art 35.
79 See eg Directive No 2009/48 (n71), art 26; Directive No 2013/29 (n72), art 25.
80 See in general F Péraldi Leneuf, 'Le cadre juridique de la notification des organismes habilités' [2002/1] Annales des Mines 63-68.
81 See eg Directive No 2009/48 (n71), arts 33-34; Directive No 2013/29 (n72), arts 31-32.
82 See eg Directive No 2009/48 (n71), art 31(4); Directive No 2013/29 (n72), art 29.

system.[83] In particular, a national accreditation body – which may be a private organisation – is designated by each Member State and is responsible for certifying that the conformity assessment bodies fulfil the criteria established by harmonised standards.[84] If an application for notification is accompanied by an accreditation certificate issued by a national accreditation body, the notification procedure is simplified.

Finally, the national administrations are entrusted with the task of carrying out market surveillance. When a surveillance authority believes that a product presents a risk to the health or safety of persons, it can subject the product to evaluation. If the results demonstrate that the product does not comply with the relevant essential safety conditions, the authority can require the economic operator concerned to take all appropriate corrective actions. In the case that no corrective measures are taken, the authority can withdraw the product from the market or limit its marketing. These national measures can be contested by another Member State or the Commission, which has to decide whether or not they are justified.[85]

5.2. Private mutual recognition

The regulatory framework briefly outlined above calls for different levels of analysis.

First, in this context, MR concerns the legal status of the goods: when products have been placed on the market of a Member State in accordance with the essential safety requirements, the other Member States can no longer restrict their circulation in their territory.[86] At most, in the presence of serious safety risks, the surveillance authority can issue a safeguard measure – which is, however, subject to 'a Union control procedure'.[87] This system thus prevents public authorities other than those entrusted with market surveillance (including the national courts) from limiting the free movement of the goods.[88] As a con-

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83 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 [2008] OJ L 218/30.

84 Note that the national accreditation bodies may be subject themselves to peer evaluation organised by the so-called European accreditation infrastructure: ibid, arts 10, 13 and 14.

85 ibid, arts 16-29; Directive No 2009/48 (n71), arts 42-3; Directive No 2013/29 (n72), arts 39-40. In general, on the scope of the Commission's decision on safeguard measures issued by Member States in these cases, see eg Case T-474/15, *Global Garden Products Italy v Commission* [2017] EU:T:2017:36, paras 39-40.

86 See eg Case C-220/15, *Commission v Germany* (n72), paras 36ff.

87 TFEU (n11), art 114(10).

88 See Case C-815/79, *Cremonini* [1980] EU:C:1980:219, which ruled out the possibility that, where there is a presumption of conformity, the judicial authority could adopt a measure restricting the free movement of goods. Also, see Case C-489/06, *Commission v Hellenic Republic* [2009] EU:C:2009:165, which ruled out the possibility that contracting authorities which have issued an invitation to tender for the supply of medical devices bearing the CE marking can reject, on the grounds of protection of public health, the tender in respect of such products directly

sequence, mutual recognition concerns both the certifications issued by the notified bodies and the declarations of the manufacturer (when admitted). Since these are the result of a fully harmonised verification procedure and produce (relative) certainty as to the safety of a certain product, they must then be accepted by all Member States. In this respect, the Court of Justice has repeatedly stated that products which have been certified as conforming with the essential requirements of the relevant Directive and 'which bear a CE marking[,] must be allowed to move freely throughout the European Union, and no Member State can impose a requirement that such a product should undergo a further conformity assessment procedure'.[89]

Second, in order to facilitate the free movement of goods, the EU legislator has set up a hybrid (or mixed) administration for large segments of the market.[90] In other words, a decentralised (i.e. transnational) governance has been progressively established, consisting of private entities (the notified bodies) which, in cooperation with the NCAs, must ensure product safety. This explains why these bodies, despite being economic operators, must respect certain principles which are typical of public administrations, such as impartiality, independence and the absence of conflicts of interest, as well as the obligation to give reasons for their decisions – i.e. the refusal or withdrawal of a certification.[91]

On this point, it is important to note that the privatisation objective has been largely achieved: the data available show that more than 2580 notifications were made in November 2017 covering 32 sectors.[92]

Third, this system gives rise to a number of problems, as it is actually based on a plurality of operators who compete on the market but who must, in any

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without following the safeguard procedure provided for in the relevant EU legislation. In particular, according to this judgment, if a contracting authority considers that the tender in respect of medical devices bearing the CE marking may compromise public health, it is required to inform the competent authority with a view to setting the safeguard procedure in motion.

89 Case C-277/17, *Servoprax* [2016] EU:C:2016:770, para 37. Also, Case C-6/05, *Medipac-Kazantzidis* [2007] EU:C:2007:337, para 42.

90 See eg Eliantonio & Medzmariashvili (n69).

91 See, in general, J Barnes, 'An Expanding Frontier of Administrative Law: The Public Life of Private Actors', [2018/3] Eur. Public Law 595-612. However, the fact that notified bodies are required to protect general interests does not necessarily mean that their activities must be governed by public law. This depends on the individual State legal systems. For example, in Italy, the Court of Cassation has ruled that the assessment of conformity of a medical device does not have a 'legal and administrative', but merely a 'technical and scientific' nature. Consequently, in the event of a dispute (the modification of a certification), jurisdiction lies with the ordinary judge and not with the administrative judge: Corte Suprema di Cassazione, Sezioni Unite Civili (Supreme Court of Cassation, United Civil Chambers), judgment of 23 April 2001, No 169. Also, Tribunale Amministrativo Regionale per il Lazio (Regional Administrative Court for Lazio), Section III, judgment of 9 March 2016, No 3455. The same has been said, for example, for the German legal system: see eg Röhl, *Akkreditierung* (n67) 94.

92 Report from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the implementation of Regulation (EC) No 765/2008, COM (2017)789 final.

case, ensure compliance with strict safety standards. In this respect, EU regulation is in some ways insufficient, as was demonstrated by the Poly Implant Prothèse ('PIP') scandal.

This notorious case concerned the marketing (and later the implantation) of industrial silicone breast implants, which clearly did not conform to quality and safety standards but which were fitted on approximately 300,000 women worldwide.[93] Given that the quality system, the design of the product and the surveillance were certified by a notified body and the manufacturer subsequently became insolvent, the question arose as to whether culpable failure by the notified body to comply with its obligations could give rise to liability on its part vis-à-vis the users. In a 2017 judgment the Court of Justice addressed this issue, stating that even though it is incumbent on the manufacturer, in the first place, to ensure that the medical device complies with the essential requirements laid down in the relevant Directive, the Directive also imposes obligations to that end on the Member States and notified bodies.[94] More specifically, the ECJ ruled that the involvement of the notified body in the procedure relating to the EC declaration of conformity is aimed at ensuring protection for the health and safety of persons.[95]

However, the Court also clarified that 'it does not necessarily follow from the fact that a directive imposes surveillance obligations on certain bodies or the fact that one of the objectives of the directive is to protect injured parties that the directive seeks to confer rights on such parties in the event that those bodies fail to fulfil their obligations, and that is the case especially if the directive does not contain any express rule granting such rights'.[96] As a consequence, 'the conditions under which culpable failure on the part of a notified body to fulfil its obligations under the procedure relating to the EC declaration of conformity ... may give rise to liability on its part vis-à-vis the end users of medical devices are governed by national law, subject to the principles of equivalence and effectiveness'.[97]

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93 On the PIP case, eg S Unger, 'Herstellerbegleitung oder Marktüberwachung? Zur Haftung "benannter Stellen" im Medizinproduktrecht' [2017/8] Europäische Zeitschrift für Wirtschaftsrecht 299-303: P Verbruggen & B van Leeuwen, 'The liability of notified bodies under the EU's new approach: The implications of the PIP breast implants case' [2018/3] Eur. Law Review 394-409; G Wagner, 'Marktaufsichtshaftung produktsicherheitsrechtlicher Zertifizierungsstellen' [2018/3] JuristenZeitung 130-140; P Rott, 'Certification of Medical Devices: from the PIP Scandal' in P Rott (ed), *Certification – Trust, Accountability, Liability* (Cham, 2019) 189ff; C Glinski & P Rott, 'Regulating Certification Bodies in the Field of Medical Devices: The PIP Breast Implants Litigation and Beyond [2019/2] ERPL 403-428.

94 Case C-219/15, *Schmitt* [2017] EU:C:2017:128, paras 49ff.

95 ibid, paras 49ff.

96 ibid, para 55, as well as Case C-222/02, *Paul and Others* [2004] EU:C:2004:606, paras 38ff.

97 C-219/15, *Schmitt* (n94) para 59. The literature on the subject is very extensive, eg Verbruggen & Van Leeuwen (n93); Rott (n93).

Ultimately, at present there is no EU law-based liability of notified bodies which, if anything, can be established through national laws in individual Member States.[98] In addition, according to a recent judgment of the Court of Justice concerning the same dispute, the civil liability insurance taken out by the manufacturer which limits its cover to damage caused in the country of production, is compatible with the Treaty.[99]

These statements are certainly problematic from several points of view. In fact, the differences between national civil liability systems result in differences not only in the possibility of protecting injured parties, but also in the quality standards that notified bodies and producers can maintain in the various countries (in view of the specific civil liability regime): the absence of third party liability is 'suitable to "relax" the supervision of manufacturers by notified bodies due to the adverse incentive of solicitation and payment by the manufacturers'.[100] This is obviously a potential distortion for the functioning of mutual recognition, since it can lead to a market fragmentation.[101]

In short, the PIP scandal brought to light a highly critical element of private MR that potentially goes beyond the medical device sector:[102] the risk of a deterioration in the protection of end consumers in the face of a high level of producer liability (with the risk of insolvency on their part) and of a low level of liability for notified bodies and national public administrations for market surveillance.[103]

6. A comparison

According to a large number of scholars, MR in EU law represents a meta-norm that regulates the horizontal openness of state systems.[104]

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98 Verbruggen & Van Leeuwen (n93) 394ff.

99 Case C-581/18, *RB TÜV Rheinland LGA Products and Allianz IARD* [2020] EU:C:2020:453.

100 Rott (n93) 203.

101 Moreover, since the Court of Justice accepted, in principle, the civil liability of notified bodies, it was assumed that the number of civil actions could even lead to the collapse of the certification system: Unger (n93) 301 f.

102 Wagner (n93) 130-140.

103 Glinski & Rott (n93) 424ff. For example, in Italy, with reference to the silicone breast implants produced by PIP, the Tribunale Amministrativo Regionale per il Lazio (Regional Administrative Court for Lazio), Section III-quarter, judgment of 12 December 2019, No 14311, excluded any liability of the Ministry of Health and of the Ministry of Economic Development for lack of market surveillance .

104 See eg C Joerges, 'Rethinking European Law's Supremacy' EUI Working Paper Law No 12(2005) and 'The idea of a three-dimensional conflicts law as constitutional form', RECON Online Working Paper No 2010/05. However, Joerges' approach is more complex, as he believes that, in the European system, conflicts of laws have three dimensions: horizontal (i.e. conflicts between provisions of different Member States), transnational (i.e. administrative cooperation for market regulation) and private transnational (i.e. standardisation processes). While this idea is highly interesting, as it gives the concept of conflicts between laws a constitutional value, there is no doubt that it refers to very different aspects of the EU legal system and in particular of EU administrative law.

More specifically, this principle consists of a set of criteria for the resolution of conflicts between national legal orders, as it identifies which laws should be applied to a specific product: those of the country of origin or those of the country of destination.[105] However, the analysis carried out here demonstrates that this conclusion is over-inclusive, since MR regarding the circulation of goods is not implemented in a unitary manner. In fact, only the first model is aimed at resolving conflicts between national laws, i.e. to govern regulatory pluralism. The remaining two patterns deal with other forms of pluralism.

In order to discuss this issue, the two basic elements of which MR is composed must be taken into account. The first element is substantial and consists of the prohibition for the destination State to repeat the checks already carried out by the State of origin. The second element is procedural and concerns instead the requirement of the destination authorities to take into consideration the results of the checks that have already been performed in another EU country.[106]

A) In the first model, notwithstanding the case law of the Court of Justice regarding MR, the substantive element is clearly weak. Given the absence of harmonization legislation, the countries of destination actually enjoy wide discretion in deciding whether, and to what extent, the circulation of a good lawfully produced and marketed in another Member State can be prevented or limited in order to protect certain public interests. Regulation No 2019/515 (like Regulation No 764/2008) attempts simply to regulate the investigation activities that the host authorities can carry out. More specifically, the goal of the regulation is to influence a procedure aimed at issuing an act with unfavourable effects for the economic operator.[107] However, the purely procedural nature of these EU provisions obviously reduces the level of protection over the circulation of goods.

Nevertheless, the hope is that through specific training programs for state officials, alongside public communication initiatives, Regulation No 2019/515 will effectively be able to direct these decisional processes of national administrations more incisively than the previous Regulations. Otherwise, the functioning of MR would ultimately continue to be reliant upon actions that the economic operators would take in national courts against decisions limiting market access.[108] However, this would actually mean the failure of MR, given that 'one

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105 See eg Rossolillo (n6) chap 4, for other references of doctrine. Also, Sydow (n10) 24-22 with broad references to German doctrine; Agudo (n6) 35-40.

106 See Section 2 above.

107 Regulation No 2019/515 (n21), art 2(b).

108 See eg Commission Staff Working Document, 'Impact assessment accompanying the document proposal for a regulation of the European Parliament and of the Council on the mutual recognition on goods lawfully marketed in another member state', SWD(2017) 471 final, 76-82. Also, in general terms, J Masing, *Die Mobilisierung des Bürgers für die Durchsetzung des Rechts: Europäische Impulse für eine Revision der Lehre vom subjektiv-öffentlichen Recht* (Berlin 1997).

cannot plan, produce and market product lines hoping that eventually a court decision will vindicate a claim of mutual recognition …'.[109]

B) As regards transnational administrative acts, it is important to touch on the distinction put forward by some international law scholars between the 'indirect' and 'direct relevance' of an act of a foreign public body (eg an administrative decision) in the legal system of destination.[110]

In the first case, the host State must take into consideration only the legal consequences that are produced by the foreign act.[111] This typically occurs with authorisations with automatic transactional effects under EU law. In this case, the authorisation granted in another Member State has, in itself, no relevance for the host legal system, but rather the legal situation which arises as an effect of this - i.e. the possibility for manufacturers to market a product. This means that MR tends here 'to operate at the level of symbolic forms …'[112], as the destination State is 'compelled merely to give practical and legal effect to a regulatory process which has already been carried out in another state'.[113] As a consequence, the authority of destination has to accept the decisions of the home State as regards the circulation of a product.[114] A central role is played here by the substantive component of mutual recognition, which ensures a high level of continuity in the exercise of the fundamental freedom involved.[115] This is possible because the authorisation with automatic transnational effects is regulated by EU harmonisation legislation. These provisions actually deal with criteria for the division of administrative work, rather than with conflict of laws issues.

On the other hand, authorisations subject to recognition are of direct relevance in the host legal order, where the competent administration has to examine the results of the investigation on which the first authorisation is based and determine its effects within the margins allowed by EU law. The procedural element is thus pivotal, as this decision-making pattern aims at 'the domestification of the foreign regulatory process through its translation into some equivalent national regulatory requirement either in whole or in part'.[116] However, as far as the circulation of goods is concerned, as a rule the destination administration cannot autonomously refuse to recognise an authorisation issued in

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109 Weiler (n18) 368.

110 On the concept of direct and indirect relevance of a foreign administrative act, see G Biscottini, *Diritto amministrativo internazionale* (Padua 1964).

111 ibid, 71. Also, R Luzzatto, *Stati stranieri e giurisdizione nazionale* (Milano 1972) 251ff and Rossolillo (n6) 236ff.

112 Armstrong (n16) 241.

113 ibid

114 P Picone, 'La teoria generale del diritto internazionale private nella legge italiana di riforma della materia' [1996/2] Rivista di diritto internazionale 289ff.

115 See eg Luzzatto (n111) 186 f.

116 Armstrong (n16) 241-42.

another Member State – for example due to a disagreement on the technical evaluations carried out by the administration of origin. In fact, in the majority of cases, refusal of recognition leads to the initiation of procedures designed to resolve the conflict which are normally decided by the Commission if no agreement is reached.[117] Also in this context, MR does not represent a mechanism to resolve the conflict between laws, but rather a set of tools for coordination and conflict resolution between national authorities.[118]

Ultimately, the regulation of transnational authorisations essentially performs the function of coordinating the different activities of national administrations – in other words to guarantee and govern administrative pluralism and to balance it with the free circulation of goods.[119] At times, however, this has led to the provision of highly complex procedural regulations (Section 7).

C) As in the case of authorisations with automatic transnational effects, the certificates of conformity of a good (guaranteed by the CE marking) limit the control powers of the destination administrations,[120] which are entrusted merely with the task of market surveillance. Although there is considerable similarity between these certificates and authorisations with automatic transnational effects, the differences between the two models should not be overlooked.

The regulation of this model does not lay down criteria for the division of administrative work or administrative coordination. Rather, it aims to guarantee the coexistence of competition on the market in terms of certifications of conformity (i.e. market pluralism) and the task of the notified bodies in guaranteeing the safety of products.[121] This has obvious consequences. The EU nature of legislation establishing the essential safety requirements, the private nature of notified bodies and the fact that they can provide their services to economic operators in all EU countries are all factors that converge towards the de-nationalisation and de-politicisation of product safety verification and control activities.[122] By limiting the role of public administrations (including through the accreditation mechanism), the risks of protectionist behaviour that could affect the functioning of mutual recognition should also be reduced.[123] On the other

117 See eg Directive 2001/83 (n56), arts 28ff; Regulation No 528/2012 (n56), arts 32ff.
118 In general, Joerges, 'The idea of a three-dimensional conflicts law' (n104) 15ff.
119 See eg E Schmidt-Aßmann, 'Verwaltungskooperation und Verwaltungskooperationsrecht in der Europäischen Gemeinschaft' [1996/3] Europarecht, 270ff.
120 See eg McMillan (n67) 206.
121 In other words, the purpose of this model is to prevent notified bodies from acting in their own interest of acquiring and maintaining business rather than in the consumers' interest in safety: Glinski & Rott (n93) 425.
122 See eg Röhl, *Conformity Assessment* (n67) 218ff and Galland (n67) 368.
123 Galland (n67), ibid.

hand, the curtailing of the functions of public authorities worsens the problem of the uncertain regime of the civil liability of the notified bodies.[124]

In any case, conformity certificates also differ from transnational authorisations in other respects. The latter remove a legal obstacle to free movement posed by EU legislation in order to protect overriding public interests and, as a rule, are discretionary in nature. On the contrary, the activity of the notified bodies consists of a technical assessment.[125] The declarations of conformity thus ensure that products meet the conditions for free movement. This is demonstrated by the fact that, at times, the manufacturers themselves can attest the conformity of a product (of low risk) with harmonised standards.[126]

Obviously, in some circumstances, the distinction between the two models can be rather subtle, especially when the transnational decision is not discretionary. For example, from a functional point of view, the authorisation for the marketing of a mineral water, just like that of certification from a notified body, essentially provides a guarantee as to the conformity (backed up by the necessary checks) of the mineral water with specific scientific standards.[127] The difference between certification and authorisation essentially consists of the public nature of the body managing the decision-making process.[128]

7. The choice of MR model: two recent legislative developments

The EU legislator has a wide margin of discretion in the choice of the most appropriate form of governance to apply to each sector.[129] As a result, they can opt either for the model of transnational authorisation or for that of certifications of conformity, just as they can place the decision-making process at EU level or, on the contrary, decide not to issue any harmonisation legislation (with the consequent application of Regulation No 2019/515).[130] Clearly, over time these decisions can be corrected or modified to ensure that the market functions as efficiently as possible.

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124 See eg Unger (n93).
125 See again Joerges, 'The idea of a three-dimensional conflicts law' (n104) 21ff.
126 See eg Directive 2009/48 (n71), art 19. Also, Case C-192/17, *Cobra* [2018] EU:C:2018:554.
127 Directive No 2009/54 (n54).
128 See also Section 7 below.
129 See eg Case C-66/04, *United Kingdom v EU Parliament and Council* [2005] EU:C:2005:743, para 45.
130 Similarly, the EU legislator can identify mixed forms of market governance: for example, a pre-marketing authorisation which must be followed by a certification of conformity.

Below two recent developments in the regulation of MR that have provided an answer to the problems that have arisen in some sectors, are briefly discussed.

The first trend is found in the model of transnational authorisations. In order to understand this point, it is important to remember that, pursuant to Article 291 TFEU, it is the job of the Member States to adopt all measures to implement legally binding Union acts (para 1).[131] Nevertheless, 'where uniform conditions for implementing legally binding Union acts are needed, those acts shall confer implementing powers on the Commission' (para 2).[132] As a consequence, when the legislator believes that the state administrations are unable to adequately apply EU law (also through transnational acts), they can confer implementing powers on the Commission (or on an EU agency).[133] This has happened following the revision of a number of sectoral regulations.

One example of this concerns the placing on the market of railway vehicles and other types of vehicles, which, until 2016, was subject to a transnational authorisation.[134] However, the difference in the modus operandi of the national authorities and the widespread difficulties in applying the harmonised norms in a uniform manner created serious barriers to free circulation.[135] As a consequence, with the 'fourth railway package' the model based on administrative pluralism was abandoned and these powers were placed with the European Railway Agency.[136] Another example can be found in the regulation for the placing on the market of novel foods. Under Regulation No 258/97, these foods had to be authorised through a joint decision.[137] Also in this case, the new regulation on this matter has handed the authorisation powers to the Commis-

131 TFEU (n11), art 291(1).

132 ibid. In general, J Bast, 'New Categories of Acts after the Lisbon Reform: Dynamics of Parliamentarization in EU Law' [2012/3] Common Mkt. L. Rev. 885, 908-914.

133 Case C-270/12, *United Kingdom v EU Parliament and Council* [2014] EU:C:2014:18, para 103ff and previously Case C-217/04, *United Kingdom v Parliament and Council* [2006] EU:C:2006:279, para 44.

134 Directive 2008/57 (EC) of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community [2008] OJ L 138/1, art 21ff.

135 Commission Staff Working Document, 'Impact assessment accompanying the documents: Proposal for a Regulation of the European parliament and of the Council on the EU Agency for railways and repealing Regulation (EC) no 881/2004. Proposal for a Directive of the European Parliament and of the Council on the interoperability of the rail system within the European Union (recast). Proposal for a Directive of the European Parliament and of the Council on railway safety (Recast)', SWD (2013) 8 final, 8, 15ff.

136 Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (recast) [2016] OJ L 138/44, art 21ff.

137 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients [1997] OJ L 43/1, art 4.

sion,[138] since the previous system proved to be overly complex and inefficient.[139] Similar developments have taken place for the authorisation of certain pesticides.[140]

Essentially, the EU legislator has shown awareness of the fact that at times forms of governance based on administrative pluralism – i.e. on transnational authorisations – can lead to a dissipation of administrative (and private) resources or to the uneven application of EU law. For this reason, the simplification (and in particular the centralisation) of administrative procedures is one of the aims of some recent pieces of EU legislation, that are moving in the direction of a reduction in the use of transnational authorisations (especially when they presuppose complex technical evaluations and their effects involve the entire EU territory).[141]

The second trend is more ambivalent and concerns the level of involvement of the national authorities in the safety assessment of those products that represent a serious and direct risk to important public interests. As confirmed by Article 6 of Decision No 768/2008, in these cases EU legislation can stipulate that the verification of conformity with the essential requirements be carried out by public authorities rather than notified bodies (i.e. economic operators acting under market conditions). This legal provision is clearly based on the presupposition that public administrations are better able to protect public interests. For example, pursuant to Regulation No 858/2018 (as well as the previous regulations), regarding vehicle surveillance, the certification activity is entrusted to national public administrations.[142] The legal dynamic here is similar to that of private certifications, despite the fact that it takes place in a public law environment. This means that, due to the sensitivity of this sector, the EU legislator has deemed a form of governance that comes close to that of the transnational authorisation more appropriate than one based on market pluralism.

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138 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 [2015] OJ 327/1, art 10ff.

139 Commission, 'Proposal for a Regulation of the European Parliament and of the Council on novel foods' COM (2013) 894 final, 6.

140 Regulation (EU) No 528/2012 (n156), art 41ff. See also, Commission, 'Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products' COM (2009)0267 final – COD 2009/0076, 6 f.

141 For further details, see De Lucia, 'From Mutual Recognition' (n52) 104ff.

142 Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC [2018] OJ L 151/1, art 3.

After the PIP scandal, the recourse to a similar solution for high-risk medical products could have been expected. However, with Regulation No 2017/745[143] the EU legislator did not abandon the model of certifications of conformity in favour of forms of transnational authorisations[144] (that can, at most, be provided for in exceptional cases).[145]

On this matter, the Commission stated that the PIP case 'has not provided any evidence that a marketing authorisation granted by a governmental authority would have prevented deliberate fraudulent practices of a manufacturer occurring once a product is approved for being placed on the market'.[146] Moreover, they maintained that 'a decentralised marketing authorisation (done by Member States) would have a significant negative impact on the internal market for medical devices. In fact, the CE marking that automatically allows devices on which it is affixed access to the whole EU market would be replaced by the application of the mutual recognition of national marketing authorisations which would not offer automatic access to the market of other Member States. Under such a regime, a Member State could refuse a device authorised by another Member States access to its market because it considers that this device does not ensure an appropriate level of protection of health and safety'.[147] To conclude: 'a change towards a marketing authorisation would also have consequences on Notified Bodies which would have to cease their activity in the field of medical devices'.[148]

Without analysing these statements in depth, it should be underlined that they are not particularly convincing, since the Commission believes that the fact that a national authority could limit the circulation of a medical device on the grounds that it 'does not ensure an appropriate level of protection of health and safety' could actually be counterproductive. Their arguments are also incomplete, as, for example, in this case, the Commission does not consider the

143 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L 117/1.

144 Moreover, the Commission has also excluded the provision of a central marketing authorisation (at EU level), as this 'would require building a new EU public body ... It would have enormous impact on the EU budget, on manufacturers in terms of costs and administrative burden and on innovation in terms of costs for regulatory compliance and time to market': Commission Staff Working Document, 'Impact assessment on the revision of the regulatory framework for medical devices accompanying the documents: Proposals for Regulations of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009' SWD(2012) 273 final, 26.

145 Regulation No 2017/745 (n143), art 59.

146 Commission Staff Working Document (n144) 26.

147 ibid.

148 ibid, 28 where it is added that 'Such a fundamental change was widely rejected during the public consultation and the subsequent dialogue with competent authorities, manufacturers and most other stakeholders ...'.

possibility of providing for a national authorisation with automatic transnational effects.

There is, however, another aspect that needs to be considered. In many national legal orders, the privatisation of the administrative functions (such as that of the certificates of conformity)[149] is admitted on condition that the full protection of fundamental rights – in particular those of third parties – is not restricted.[150] Without dwelling on the question of whether this condition for privatisation is part of the 'constitutional traditions common to the Member States', the fact remains that Regulation No 2017/745, while significantly expanding the obligations of notified bodies and outlining their tasks in much more detail, still does not expressly regulate the liability issue of these bodies.

Ultimately, the EU legislator has decided to perfect the system of certifications of conformity for high-risk medical products, without providing for the more direct involvement of public authorities in the evaluation procedure. It seems that the opportunity to devise with a more balanced and satisfying regulation in this complex and delicate sector has been missed.[151]

8. Conclusions

This brief analysis has shown that, as far as the circulation of goods is concerned, the concept of MR has changed significantly over time.

This principle was originally established by the Court of Justice. As such, MR represented a form of negative integration of the internal market, since it was aimed at 'eliminating national restraints on trade and distortions

149 See eg Unger (n93).

150 Röhl, *Akkreditierung* (n.67) 80 f. In general, see eg I Appel, 'Privatverfahren' in W Hofmann-Riem, E Schmidt-Aßmann & A Voßkuhle (eds), *Grundlagen des Verwaltungsrechts*, vol. II (2nd edn, München 2012), 851, 896ff; V Cerulli Irelli, *L'amministrazione costituzionalizzata* (Turin 2019), 119ff.

151 In this regard, it could be interesting to recall one particular situation. In the context of the current global outbreak of COVID-19, the demand for personal protective equipment (eg face masks, gloves, protective coveralls), as well as for medical devices (eg surgical masks and exploration gloves) has seen exponential growth: see Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. This has led to the circulation of false certificates accompanying imported products. To tackle this problem, the Italian government has waived EU certification legislation. In particular, it is now possible to place surgical masks on the Italian market without the EC marking, on the condition that the producers, importers and traders provide a self-declaration, together with all elements useful for the assessment of the masks, to the Istituto Superiore di Sanità (Italian National Institute of Health), which have three days to confirm that they can be placed on the market. The INAIL (National Institute for Insurance against Accidents at Work) must follow the same procedure in the evaluation of personal protective equipment: Art. 15 Law Decree 17 March 2020, n. 18.

of competition'.[152] Despite the application of the principle remaining outside political process, the decisions of the Court of Justice on this matter have, in many circumstances, had significant political impact.[153]

Subsequently, MR was included in the 'common European policies to shape the conditions under which markets operate' becoming an instrument of positive integration (Article 114 FTEU and previously Article 95 TEC).[154] Thus, the system changed from being one founded on the application of a principle – and therefore essentially on a balancing of interests carried out case by case by the ECJ – to one based on specific rules that are implemented by public administrations or equivalent bodies.[155]

This change has led to at least three consequences. First, in these areas, MR does not directly regulate the free circulation of goods; it has instead been incorporated into the wider EU harmonisation legislation and in particular in the three models of market governance analysed here. From this point of view, the principle now has a more symbolic rather than a heuristic value.[156]

Second, the regulation of MR has become the subject of the EU political process.[157] More specifically, the identification (as well as the modification) of the MR models for each sector is the fruit of the political choices of the EU legislator, that has the responsibility of balancing the different interests at stake in each case. As a result, the role of the courts (either national or European depending on the case) is now generally limited to checking whether the EU rules have been interpreted and applied correctly by administrations or by notified bodies. Above all, the EU Court of Justice now has a more defined and tendentially depoliticised role.[158]

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152 F Scharpf, 'Negative and Positive Integration in the Political Economy of Welfare States' (1995) Jean Monnet Chair Papers No 28, 1.

153 See eg R Dehousse, *The European Court of Justice. The Politics of Judicial Integration* (London 1998), ch 3.

154 Scharpf (n152) 1.

155 For an overview of the difference between legal systems based on principles and legal systems based on rules, see R Dworkin, *Taking Rights Seriously* (Harvard 1977); also G Zagrebelsky, 'Ronald Dworkin's principle based constitutionalism: An Italian point of view' [2003/1] Int. J. Const. Law 621-50.

156 This obviously does not rule out the fact that, looking at the phenomenon from a broader perspective, the principle may be highly significant.

157 Scharpf (n152) 12. Also, Maduro (n61) 110ff.

158 To understand the transformation in the role of the ECJ regarding MR, it may be helpful to look at 'the distinction between two different conceptions of the role of the judiciary in the system of government': P Cane, *Controlling Administrative Power* (Cambridge 2016) 220-231. In the first – defined as a 'co-ordinated judiciary' – courts play a creative role, adopting more 'purpose-based and less text-focused modes of interpretation' and their decisions can have significant political impact; in the second – defined instead as a 'subordinate judiciary' – their role is seen as that of 'subordinate agents of the ... legislature in relation to which their main function is to interpret and apply statute law'. It is also clear that in the case of MR, the ECJ, beyond the preliminary rulings on the validity of EU harmonisation legislation, has moved tendentially from a 'co-ordinated judiciary' to a 'subordinate judiciary'.

Third, the three models of MR are incarnated in supervisory activities carried out at national level. This means that national laws have been enriched with specific instruments aimed at facilitating the circulation of goods – eg transnational administrative acts, checks on conformity with harmonised standards, and procedures for information sharing and cooperation.[159] These are instruments that have also been used by the EU legislator for the exercise of other fundamental freedoms, as well as for the governance of different activities.[160]

This opens up many research fields. While some of these tools have been examined extensively by scholars (eg transnational acts),[161] others are still not understood in depth: for example, the protection of rights against certification denials or withdrawals by notified bodies, [162]or how exactly conformity checks really work, are subjects that have not yet been adequately studied (at least from a legal point of view).[163]

Overall, the understanding of the three models analysed here can still be defined as 'law on the books', since it is not clear how the various players (both public and private) act in practice in the context of legal frameworks aimed at guaranteeing the free circulation of goods.[164] A more accurate assessment of the functionality and the effectiveness of the regulations of the various sectors

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159 See eg in general Schmidt-Aßmann 'Verwaltungskooperation' (n119) 270-301; L De Lucia, 'Cooperazione amministrativa' in L De Lucia & B Marchetti (eds), *L'amministrazione europea e le sue regole* (Bologna 2015) chap. 7.

160 See eg Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data [2016] OJ L119/1, art 42. On this issue, see R Rodrigues, D Barnard-Wills, P De Hert & V Papakonstantinou, 'The future of privacy certification in Europe: an exploration of options under Article 42 of the GDPR' [2016/3] Int. Rev. Law Comput. Tech. 248-270.

161 See eg the authors cited in n52.

162 This matter is the subject of quite fragmented legal regulation. While art 4 of Decision No 768/08 provides that an 'appeal procedure against decisions of notified bodies shall be available' (see also eg Directive No 2013/29, art 35), sometimes the EU legislator has made different choice. For example, according to art 32 Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC [2016] OJ L81/99, 'notified bodies shall ensure that an appeal procedure against their decisions is available'. Further solutions have been adopted at national level. For example, pursuant to the decree transposing Regulation No 2016/426 in Italy, 'decisions of notified bodies relating to the certification of apparatus and accessories may be subject to the appeal procedure established by the single National Accreditation Body': Consolidated Version Decreto del Presidente della Repubblica of 15 November 1996, No 661, Regolamento per l'attuazione della direttiva 90/396/CEE concernente gli apparecchi a gas (Regulation for the implementation of Directive 90/396/EEC relating to appliances burning gaseous fuels), art 8.

163 In general, Galland (n67) 368.

164 In general, see eg P Cane & M Kritzer (eds), *The Oxford Handbook of Empirical Research* (Oxford 2010); in different terms A Voßkuhle, 'Neue Verwaltungsrechtswissenschaft' and C Möllers, 'Methoden' both in W Hoffmann-Riem, E Schmidt-Aßmann & A Voßkuhle (eds.), *Grundlagen des Verwaltungsrechts*, vol. I (2nd edn, München, 2012) 29ff and 142ff, respectively.

could perhaps be achieved through a Legal Realism-based research approach that could also provide a reference point for the choices of the European legislator.