Cambridge Yearbook of European Legal Studies, 17 (2015), pp. 360–379
doi:10.1017/cel.2015.12

What We Talk About When We Talk About Harmonisation

Marcus KLAMERT*
Constitutional Service, Federal Chancellery of Austria
Vienna University of Business and Economics, Institute for European and International Law

Abstract
When we talk about harmonisation, we may mean quite different things. There is a close, yet often unclear, relationship between minimum harmonisation and mutual recognition on the one hand, and between full harmonisation and the country of origin principle on the other hand. This paper will discuss harmonisation in relation to these other regulatory models with, among others, the Tobacco Products and Services Directives as illustrations. Moreover, many years after *Tobbaco Advertising I* and *II* it remains entirely unclear how minimum harmonisation instruments must be designed in order to be lawful. This paper proposes a consistent reading of the case law on what is called legislative minimum harmonisation based on Article 114 TFEU. It is also shown that the Court of Justice of the European Union applies a lenient standard to more stringent national measures under what is called constitutional minimum harmonisation based on competences for social policy and the environment.

Keywords: Consumer Rights Directive, country of origin principle, ERTA, minimum harmonisation, Services Directive, tobacco, mutual recognition

I. INTRODUCTION

When we talk about harmonisation in the context of the World Trade Organisation (WTO) law, it is quite clear what we mean: firstly, harmonisation in the WTO is above all de-regulation. Article 2(6) of the Technical Barriers to Trade (TBT)-Agreement, which mentions harmonisation, provides what a European Union (EU) lawyer would call a general prohibition or restriction.[1] Secondly, where harmonisation in the WTO

* This article expresses the personal opinion of the author, who is grateful for comments by the reviewers of this journal to an earlier draft of this article. A much shorter version of some parts of this piece has appeared under the title 'Altes und Neues zur Harmonisierung im Binnenmarkt' in the *European Journal of Business Law* (EuZW) 2015, 265.

[1] Article 2(6) TBT Agreement states: 'Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, *inter alia* national security requirements; the prevention of deceptive

comes close to what we understand by this term in the EU – such as in Article 3 of the Application of Sanitary and Phytosanitary Measures (SPS) Agreement on international standards, guidelines and recommendations – standards are not imposed upon WTO members as they are by directives and regulations in the EU. Instead, these international standards serve as a 'shield' for national measures against challenges under the SPS Agreement or the General Agreement on Tariffs and Trade (GATT).[2] Instead of conferring legislative powers upon the WTO, Article 3(2) SPS Agreement applies a presumption of legality for sanitary or phytosanitary measures of WTO Members. Higher national standards, ie stricter national measures than those based on these standards must be scientifically justified, recalling Article 114(5) TFEU discussed below. Hence, harmonisation has a specific yet quite distinct meaning and function in WTO law.[3]

In contrast, when we talk about harmonisation in the context of EU law, it is sometimes not entirely clear what precisely is meant. This is because a variety of terms are used for apparently very similar if not analogous concepts. In addition, the EU makes use of an increasing number of concepts and regulatory models besides, and within, harmonisation, and their relationship with each other often is vague. Finally, many years after some landmark judgments in this field, it still remains unclear what latitude the EU legislator has in drafting a new harmonisation measure. Different from the rules and principles that govern the scope of application of Article 114 of the Treaty on the Functioning of the European Union (TFEU) providing the competence to regulate the internal market, case law on harmonisation until now has been far from providing a drafting guide for the legislature.[4]

(F'note continued)

practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, *inter alia:* available scientific and technical information, related processing technology or intended end-uses of products.' The general prohibition in EU law can also be seen as either prescribing a presumption of legality of national law, or, to the contrary, as presuming national (trade-related) measures being *a priori* unlawful and in need of justification. For this discussion, see M Klamert, 'Of Empty Glasses and Double Burdens: Approaches to Regulating the Services Market à propos the Implementation of the Services Directive' (2010) 37 (2) *Legal Issues of Economic Integration* 111.

[2] Such national measures shall 'be deemed to be necessary to protect human, animal or plant life or health' both under the SPS Agreement and under the GATT. See Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, adopted 13 February 1998, para 177.

[3] In the context of the WTO, harmonisation has been defined 'as the process of making different regulations, principles, domestic laws and government policies substantially or effectively the same or similar'. See G Mayeda, 'Developing Disharmony? The SPS and TBT Agreements and the Impact of Harmonization on Developing Countries' (2004) 7 (4) *Journal of International Economic Law* 737, p 740; H Zúñiga Schroder, *Harmonization, Equivalence and Mutual Recognition of Standards in WTO Law* (Kluwer Law International, 2011), p 22.

[4] Compare S Weatherill, 'The Limits of Legislative Harmonization Ten Years after Tobacco Advertising: How the Court's Case Law has become a "Drafting Guide"' (2011) 12 *German Law Journal* 827.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

The centre for harmonisation in EU law is Article 114 TFEU. If it is used for full harmonisation, it is unique in providing both substantial and procedural rules for Member States wishing to maintain or enact measures that are not genuine implementing acts. In this case, any deviation from the prescriptions of the harmonising act is exclusively governed by the 'derogations' in Article 114(4) and (5) TFEU. Article 114(5) TFEU not only limits the public reasons available to Member States, but in addition requires the existence of a specific problem for a Member State; a condition that has been notoriously difficult to satisfy.[5]

If, in contrast, Article 114 TFEU is invoked as the basis for secondary law allowing for more stringent measures by Member States, different rules apply to national 'reinforcements', and questions of legality arise. This will be referred to as 'legislative minimum harmonisation', and will be distinguished from 'constitutional minimum harmonisation', where the Treaty allows Member States to pass more stringent measures in the areas of social policy, consumer policy, environmental policy and – since the Treaty of Lisbon – in the field of health policy. With these provisions, the right to national reinforcements is already built into primary law, prohibiting full harmonisation while offering no direction on the rules applying to (stricter) measures adopted by the Member States.

In this article it will be argued that minimum harmonisation under Article 114 TFEU differs from minimum harmonisation under legal bases such as Article 193 TFEU. Article 114(4) and (5) TFEU will only be considered as way of comparison, especially when discussing the increasing number of 'tools' the Union legislature uses in order to ensure compliance with its harmonisation instruments in a final part of this article. The main part of this article will discuss the different forms of harmonisation and their relation to other regulatory models, starting with full harmonisation.

II. FULL HARMONISATION

A. *Introduction*

I would suggest that it is useful to distinguish the scope of harmonisation measures from their intensity, bearing in mind that this article focuses on the intensity of harmonisation rather than its scope.[6] Harmonisation is 'full' in scope when there is comprehensive or exhaustive legislative harmonisation in a specific area; harmonisation will otherwise be said to be 'partial' in scope. But, distinct from the scope of harmonisation, the standard(s) set by European legislation may also vary in their intensity. They may provide for 'full (or 'maximum', or 'total')' harmonisation, in the sense of setting standards which Member States cannot derogate from, or they may provide for 'minimum' harmonisation only, leaving some discretion to Member States in, for example, setting a higher standard than the minimum standard(s) adopted under European law.

[5] *Land Oberösterreich v Commission*, C-439/05 P and C-454/05 P, ECLI:EU:C:2007:510.

[6] See M Wagner, *Das Konzept der Mindestharmonisierung* (Duncker and Humlot, 2001), p 42.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

Some other distinctions must be mentioned. Vertical harmonisation and horizontal harmonisation are two concepts related to partial harmonisation (in scope), the former referring to harmonising rules for specific products or services and the latter referring to a legal act covering all or several different products and services. It has been argued that harmonisation is necessarily partial harmonisation and that it would be misleading to speak of full harmonisation in respect of a certain field.[7] It is however possible to regulate a precisely defined area exhaustively. Take the Tobacco Products Directive 2014/40/EU, which claims to regulate tobacco products and related products.[8] Take the Services Directive 2006/123/EC, where however there is a gap between assertion (at least in its title) of regulating 'services' and the reality of a rather curtailed scope of application.[9]

In addition, the notion of targeted harmonisation refers to measures that provide only very selectively for harmonised rules. A case in point is the Consumer Credit Directive 2011/83/EU, which states in its Recital 9 that where it does not provide for harmonised rules, Member States are free to act, and clearly states which national rules this could concern.[10] The mentioned Tobacco Products Directive 2014/40/EU is another recent example for targeted full harmonisation, regulating tobacco products and nicotine containing products and explaining in Recital 55 that Member States 'should remain free to maintain or introduce national laws applying to all products placed on its national market for aspects not regulated by this Directive, provided they are compatible with the TFEU and do not jeopardise the full application of this Directive'.[11] Also Chapter V on the quality of services in the Services Directive 2006/123/EC could be seen as a case of targeted harmonisation.

There are also, it is proffered, different 'shades' of the completeness of harmonisation. Whether a measure provides for minimum or full harmonisation can sometimes be unclear. In the *Gallaher* case, the Court found that text warnings on 6% of the surface of the cigarette pack did not breach the first Tobacco Products Directive, which allowed for warnings on 'at least' 4% of the surface.[12] In contrast, some directives such as the E-Money-Directive 2009/110/EC explicitly prohibit national measures other than implementing measures.[13] The most absolute form of full harmonisation occurs in blacklists such as Annex I of the Unfair Commercial

[7] C Tietje in E Grabitz et al (eds), *Das Recht der Europäischen Union: EUV/AEUV*, 56th ed (Beck, 2015), art 114, para 36.

[8] Directive 2014/40/EU [2014] OJ L127/1.

[9] Directive 2006/123/EC [2006] OJ L376/36.

[10] Rec 9 Directive 2011/83/EU [2011] OJ L304/64.

[11] This is stated to concern, *inter alia*, paraphernalia used for tobacco products (including waterpipes) and for herbal products for smoking, and products resembling in appearance a type of tobacco or related product.

[12] *Gallaher*, C-11/92, ECLI:EU:C:1993:262; *Ratti*, C-148/78, ECLI:EU:C:1979:110; *Cindu Chemicals*, C-281/03 & C-282/03, ECLI:EU:C:2005:549.

[13] See Art 16 Directive 2009/110/EC [2009] OJ L267/7; Rec 1 Directive 97/27/EC [1997] OJ L233/1; Rec 9 Directive 2008/48/EC [2008] OJ L133/66.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

Practices Directive 2005/29/EC, laying out business practices that must be banned by Member States without allowing recourse to justification.[14]

B. A preference for minimum harmonisation?

In the field of consumer protection, 'full' legislative harmonisation has eclipsed 'minimum' legislative harmonisation as the 'instrument of choice' favoured especially by the European Commission. The Consumer Rights Directive 2011/83/EU has replaced a number of minimum harmonisation instruments such as the Doorstep Selling Directive 85/577/EEC – which had championed the right of Member States to foresee stricter measures in the interest of consumer protection – and is now clearly cast as a measure of 'full' harmonisation.[15] Earlier drafts had still argued for keeping the traditional 'minimum' approach while adding 'full' harmonisation only in a narrow technical area.[16]

It is plain that national preferences and sensitivities are better served by 'minimum' harmonisation leaving Member States free to engage in 'gold-plating', in the sense of adding requirements that are not strictly necessary under the European harmonising instrument. However, it makes a difference whether 'minimum' harmonisation is applied to products or to selling arrangements, which are the subject of harmonisation of EU consumer law. Arguably, minimum harmonisation for products in general is considerably more disruptive to the functioning of the internal market than minimum harmonisation for directives on matters such as doorstep-selling. With product harmonisation, it would appear that the interest in preserving preferences of the Member States cannot outweigh the interest in furthering the internal market. These considerations will also play a role regarding the legality of minimum harmonisation (see Section III.B below). Thus, there doesn't seem to be a case for generally preferring minimum harmonisation over full harmonisation. Yet it is true that the price of full harmonisation might be unclear language, because resistance to the loss of the right to determine one's regulatory standards often translates into ambigious drafting.[17]

If it is argued that full harmonisation would be radically less cooperative and thus more hierarchical than minimum harmonisation,[18] this can only be a difference of sorts. Intuitively, it seems ludicrous qualifying any form of harmonisation as a cooperative regulatory model. What could possibly be cooperative about an approach that prescribes uniform or at least approximated standards for all Member States? Yet if harmonisation is done by directives, then there is a cooperative element

[14] See Annex I Directive 2005/29/EC [2005] OJ L149/22. See *Galatea*, C-261/07 and C-299/07, ECLI:EU:C:2009:244, paras 51–53. See also Art 14 Services Directive 2006/123/EG.

[15] See Art 4 Directive 2011/83/EU [2011] OJ L304/64.

[16] See G Howells and N Reich, 'The current limits of European harmonisation in consumer contract law' (2011) 12 *ERA Forum* 39, p 40.

[17] S Weatherill, 'Maximum or Minimum Harmonisation – What Kind of "Europe" Do We Want?' in C Boele-Woelki and W Grosheide (eds), *The Future of European Contract Law, Liber Amicorum E.H. Hondius* (Kluwer Law International, 2007), pp 140–141.

[18] Ibid, p 145.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

already built into the legal instrument used. Directives – at least as they were meant to be, and perhaps not as they are sometimes crafted in technical areas such as the energy market[19] – are supposed to co-opt the Member States for the achievement of a certain objective. It is telling of the cooperative nature of directives how (literally) outgoing the European Commission has been in assisting the Member States on site fitting the – complex and fully harmonising – Patients' Rights Directive 2011/24/EU on cross-border health-care into their national legal regimes.[20]

C. *Standard of review for reinforcements*

It is plain that if matters are not covered by the scope of a directive or regulation, such as in the case of partial or targeted harmonisation, the fundamental freedoms continue to apply to national measures.[21] Conversely, this means that when a regulation or a directive governs a certain matter conclusively, divergent national measures cannot be justified under Article 36 TFEU. In *Hedley Lomas*, English authorities refused to grant the export of animal live-stock to Spain, arguing that while Spain had implemented Directive 74/577/EEC on the proper treatment of animals before slaughter, there would not be adequate controls and sanctions in case of infringements in Spain.[22] The Court held that Article 36 TFEU was not applicable, since the aim of protecting the health of animals in the context of slaughter was taken care of in the Directive. The lack of rules on enforcement and sanctions was held to be immaterial and the UK was referred to the principle of loyalty, requiring it to trust the Spanish authorities on controls.[23] This has been framed in the following words by the Court:[24]

> Article 36 of the Treaty allows the maintenance of restrictions on the free movement of goods, justified on grounds of the protection of the health and life of animals, which constitutes a fundamental requirement recognized by Community law. However, recourse to Article 36 is no longer possible where Community directives provide for harmonization of the measures necessary to achieve the specific objective which would be furthered by reliance upon this provision.

Recourse to 'national' interests of protection is thus no longer permissible when a directive harmonises those measures which are required for the attainment of the specific objective that would otherwise be protected by Article 36 TFEU. Protection is then afforded by the Union and there is no 'mandate' for the Member States, the public interest in need of protection having been 'unionised' or 'harmonised'.

---

[19] See, for instance, the Renewable Energy Directive 2009/28/EC [2009] OJ L140/16.

[20] Directive 2011/24/EU [2011] OJ L88/45. See also the voluminous *Handbook on Implementation of the Service Directive* (2007) issued by the European Commission.

[21] *Denkavit*, 251/78, ECLI:EU:C:1979:252.

[22] *Hedley Lomas*, C-5/94, ECLI:EU:C:1996:205. Directive 74/577/EEC [1974] OJ L316/10.

[23] *Hedley Lomas*, ECLI:EU:C:1996:205, p 19.

[24] Ibid, p 18. See also *Monsees*, C-350/97, ECLI:EU:C:1999:242, p 24.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

D. Mixing the models: the Services Directive

In the process leading to the Services Directive 2006/123/EC, several regulatory approaches were discussed, from the country of origin principle to mutual recognition and various forms of harmonisation.[25]

Article 16 of the Commission proposal – the famous Bolkenstein/'Frankenstein' draft – provided for the country of origin principle.[26] This can be seen as a full harmonisation approach, if one considers that it leaves the host state with no right of reinforcement, since it has to apply the law of the Member State of origin to the service provider operating on its territory.[27] Full harmonisation and the country of origin principle as proposed by the European Commission may therefore be 'close relatives' as it has been put by Stephen Weatherill, but placing them under the same conceptual umbrella might be somewhat confusing. The country of origin principle as proposed did not provide for active, positive approximation of laws, but instead for a form of *renvoi* of law where the law of the home state of the service provider would be applied by the courts of the host state in case of a dispute. Thus, regulatory differences would not be affected as a matter of principle.

Moreover, even if we were to ignore this (highly practical) difference between full harmonisation and the country of origin principle as had been proposed by the Commission, we might just as well understand the latter as an option in the configuration of minimum harmonisation by considering the following: The proposal for the Services Directive – and this also counts for the adopted version – does have parts that harmonise national laws, such as on the quality of services requiring providers to furnish certain information to the recipient in Chapter V.[28] If national law were more stringent then these standards, these national standards would only apply to domestic service providers, while providers from other Member States would obtain market access by complying with the legal requirements in their home Member State. Since the home state would also have to implement the harmonised parts of the Directive, the outcome would not be any different from minimum harmonisation with market access for the foreign provider, discussed below.

The adopted version of the Services Directive, in place of this country of origin principle, provides a variation of the general prohibition of restrictions for services in its Article 16. While it is not based on Article 114 TFEU, Article 16 of the Services Directive curtails the 'mandatory requirements' Member States may invoke to justify national restrictions following the *Cassis de Dijon* case law[29] over the full range of the parts of the directive pertaining to non-established service providers. However, on a substantive level, the Services Directive does not itself satisfy any of these

[25] Directive 2006/123/EC [2006] OJ L376/36.

[26] COM/2006 226 final.

[27] See S Weatherill, note 17 above, p 142.

[28] See note 26 above.

[29] *Rewe-Zentral AG*, 120/78, ECLI:EU:C:1979:42.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

public interests, except in the above mentioned Chapter on the quality of services. It does therefore, it is submitted, not follow the logic of *Hedley Lomas*.[30] This contributes to make the Services Directive a hotchpotch of regulatory models. It kept elements typical of full harmonisation from the proposal, such as the safety clause in Article 18, which allows taking protective measures against providers that are considered unreliable. Recital 7 of the Directive speaks of targeted harmonisation, but also of the freedom to provide services, and of coordination, and there are elements of mutual recognition.[31] The only qualification that can probably be excluded is that of minimum harmonisation, since neither Article 16 nor any other provision of the Services Directive provides a floor or a ceiling for standards on the provision of services.

III. LEGISLATIVE MINIMUM HARMONISATION

A. Introduction

I have suggested in Section II.A above, that the intensity of the harmonisation helps to distinguish between full (or maximum) harmonisation and minimum harmonisation. However, whether Member States have an absolute right to pass more stringent measures vis-à-vis other EU Member States or whether they must accept the harmonised standard for imports, adds the issue of market access to the equation. Market access clauses are something like 'harm reduction' from the perspective of the internal market, as they sustain regulatory differences but neutralise their practical consequences for market participants.

In that context, some authors have distinguished between 'total' and 'optional' harmonisation.[32] 'Total' harmonisation would oblige Member States to permit goods complying with a directive to be freely imported and marketed (under a free movement clause), but would prohibit the sale of goods not complying with a directive (under an exclusivity clause). By contrast, 'optional' harmonisation would require only the former with Member States being free to allow the sale of goods not meeting the standards laid down in the directive. By contrast, some others have defined 'optional' harmonisation as a model that leaves the producer the choice whether to comply with the national or with the harmonised rules.[33] The definition of 'optional' harmonisation becomes even more blurred when considering that others have introduced the notion of alternative/facultative harmonisation which would give Member States several options on how to reach a directive's objective,[34] or would give producers the option to either follow the national or the harmonised rules.[35] That this may be confusing also becomes

[30] See M Klamert, see note 1 above, pp 126–129.

[31] Art 10(3) Directive 2006/123/EC [2006] OJ L 376/36.

[32] S Weatherill, 'Union Legislation Relating to the Free Movement of Goods' in PJ Oliver (ed), *Oliver on Free Movement of Goods in the European Union*, 5th ed (Hart Publishing, 2010), para 13.91.

[33] PJ Slot, 'Harmonisation' (1996) 21 *European Law Review* 378, p 378; M Wagner, see note 6 above, p 54.

[34] PJ Slot, ibid, p 386.

[35] M Wagner, see note 6 above, p 51.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

clear when we consider that in German literature 'optional' harmonisation has also been referred to as 'minimum' harmonisation without a market access clause, meaning that Member States could provide for stricter measures and also require imports to conform to these stricter standards.[36]

It is suggested that, instead of using ambiguous terms such as 'optional', 'facultative' or 'alternative' harmonisation, focus should be put on the way 'minimum' harmonisation is drafted in a European legislative act. Arguably the most straight-forward manner is to stipulate that Member States are allowed to pass stricter measures than provided by the respective directive.[37] This may then be combined with a market access/free movement clause, which can bar Member States from denying the placing on the market of products in compliance with the directive.[38] To the same effect, such a clause can prohibit the Member States from restricting the application of the freedoms for products falling under the directive. Thus, Member States could pass stricter measures than foreseen under the directive, but these measures would need to comply with the fundamental freedoms and might eventually be set aside if in breach of the fundamental freedoms. A more indirect approach would have a clause inserted in the European legislative act, stating that Member States must take all necessary measures to ensure that only compliant products may be placed on the market.[39] This, it is submitted, can only mean that products that do not conform to the (environmental, safety, etc) standards set by the directive are not allowed on the market. It thus states the obvious for a binding legal act such as a directive, and if such a clause is missing, it doesn't follow that either stricter standards are permitted or that Member States can allow products that do not conform to a directive's rules. Equally, the mere inclusion of a clause providing for the free movement of goods complying with a directive cannot be taken to imply that Member States may pass more stringent measures.[40]

The new Tobacco Products Directive 2014/40/EU, being the successor to the legal acts enticing some of the leading cases in this field (see Section III.B below), now provides for full harmonisation in its Article 24(1):

> Member States may not, for considerations relating to aspects regulated by this Directive, and subject to paragraphs 2 and 3 of this Article, prohibit or restrict the placing on the market of tobacco or related products which comply with this Directive.

This is qualified by paragraph 2 reserving Member States the right 'to maintain or introduce further requirements, applicable to all products placed on its market, in relation to the standardisation of the packaging of tobacco products ...', and by

---

[36] C Tietje, see note 7 above, art 114 para 41; similarly, S Leible and M Schröder in R Streinz (ed), *EUV/AEUV*, 2nd ed (Beck, 2012), art 114 para 34.

[37] See eg Art 1(3) Directive 2010/31/EU [2010] OJ L153/13; Art 1(2) Council Directive 2007/43/EC [2007] OJ L182/19.

[38] See the example given by S Weatherill in note 32 above.

[39] This has been termed exclusivity clause. See note 31 above.

[40] See Art 12 Toys Directive 2009/48/EC [2009] OJ L170/1: 'Members States shall not impede the making available on the market in their territory of toys which comply with this Directive.'

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

paragraph 3 allowing them to prohibit a certain category of tobacco or related products, as already mentioned above. Article 24(1) thus prohibits national measures diverging from the Directive unless they are allowed under paragraphs 2 and 3. For products falling under these paragraphs, there is no market access and Member States with reinforcements may prohibit the placing on the market of products (from other Member States) that 'merely' comply with the Directive but not with these stricter measures.[41]

B. Legality

Whereas the legality of 'minimum' harmonisation in general is not disputed, it has been unclear whether its legality is subject to the existence of a market access clause.

In *Tobacco Advertising I,* regarding the legality of Directive 98/43/EC, the Court criticised the absence of a free movement or market access clause in that Directive.[42] When it upheld the validity of the subsequently amended Directive, it pointed to the existence of such a provision.[43] It is more likely however, that in both cases the scope of the measures concerned was key to the Court's judgments.[44] Also in the *BAT* case on the legality of the 'old' Tobacco Products Directive 2001/37/EC, the Court referred to the existence of a free movement clause only as a final argument and to confirm that 'the Directive is fully effective in terms of its pursued aim of improving conditions for the functioning of the internal market'.[45] With its validity pending before the European Court of Justice, Directive 2014/40/EU is likely to prolong the tradition of tobacco regulation being a testing ground for the boundaries of harmonisation.[46]

In a series of judgments on directives preceding the abovementioned Consumer Rights Directive 2011/83/EU, which were all based on Article 114 TFEU, the Court did not discuss the lack of a market access clause. These judgments are seen to confirm that at least under Article 114 TFEU the existence of such a clause is not crucial.[47] Then, however, the judgement in *Laval* again caused some uncertainty.[48] The minimum harmonisation clause in Article 3(7) of Directive 96/71/EC was interpreted by the Court so that for certain matters, Member States may not exceed

[41] See Rec 53: 'Tobacco and related products which comply with this Directive should benefit from the free movement of goods. However, in light of the different degrees of harmonisation achieved by this Directive, the Member States should, under certain conditions, retain the power to impose further requirements in certain respects in order to protect public health.'

[42] *Tobacco Advertising I*, C-376/98, ECLI:EU:C:2000:544.

[43] *Tobacco Advertising II*, C-380/03, ECLI:EU:C:2006:772.

[44] See S Weatherill, note 17 above, p 137.

[45] *Ex parte BAT*, C-491/01, ECLI:EU:C:2002:741, para 74.

[46] Directive 2014/40/EU [2014] OJ L127/1. See the pending preliminary reference proceeding concerning the validity of parts of Directive 2014/40/EU, *Philip Morris*, C-547/14. See also the pending action for annulment of parts of Directive 2014/40/EU, *Poland* v *European Parliament and Council*, C-358/14.

[47] *Quelle*, C-404/06, ECLI:EU:C:2008:231, para 36; *Ausbanc*, C-484/08, ECLI:EU:C:2010:309; *Gysbrechts*, C-205/07, ECLI:EU:C:2008:730; *DocMorris*, C-322/01, ECLI:EU:C:2003:664.

[48] *Laval*, C-341/05, ECLI:EU:C:2007:809.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

the standards set in Article 3(1) of the Directive. Article 3(7) was thus made redundant by a judicial fiat. It is however suggested that *Laval* is a special case since the Directive primarily determined which national law should be applicable to posted workers.[49]

Two different views can be taken on the legality of minimum harmonisation: on the one hand, full harmonisation, one could argue, is the rule provided in the Treaty for the core of the internal market. The Treaty does not allow for the 'gold plating' that is the hallmark of minimum harmonisation. Quite clearly, allowing Member States to provide for stricter measures means perpetuating regulatory divergences in the internal market and, thus, runs counter to the Treaty objectives. On the other hand, one could point to Article 114(4) and (5) TFEU explicitly allowing such divergences, albeit under strict scrutiny. One could also point to Article 114(3) TFEU demanding a high level of protection for proposals on this basis concerning health, safety, environmental protection and consumer protection.

However, it is submitted that a more nuanced argument can be made beyond those two views if we draw analogies with the Court of Justice's case law on national restrictions to the fundamental freedoms.[50] It is suggested that the more intrusive a European Union measure is for the functioning of the internal market, the more a European legislation is liable to affect market access, the harder it will be to justify permitting national stricter measures without allowing products from other Member States on the market.[51] Thus, we might argue that market access would have to play a role if the regulation of rules on the sale of products is highly disruptive to trade in the Union, as is the case with full bans of certain forms of advertising as was the case in *Tobacco Advertising I and II*. In such case, the above-mentioned cases on consumer law would only prove that the minimum harmonisation of (sales-related) rules must not go hand in hand with the granting of market access, unless it is potentially disruptive to intra-Community trade. In contrast, market access would generally have a greater role to play in genuine product regulation, such as on the regulation of ingredients or packaging of tobacco products, as in the *BAT* case.

Moreover, one might wonder whether social policy, environment and consumer policy stand apart, because they are shared competences. Also, the protection and improvement of human health mentioned in Article 6 TFEU is a mere supporting competence. It is possible to argue that if harmonisation based on Article 114 TFEU involves objectives of public health (provided that the conditions for invoking Article 114 TFEU are satisfied), then harmonisation must be more considerate of national souvereignty, as it would have to be in areas of shared competence.

---

[49] See M Dougan, 'Minimum Harmonization after *Tabacco Advertising* and *Laval Un Partneri*' in M. Bulterman et al (eds), *Views of European Law from the Mountain: Liber Amicorum Piet Jan Slot* (Kluwer Law Publishing, 2009), p 13.

[50] Which is notoriously difficult in view of the more recent case law on restrictions of use. See, among others, E Spaventa, 'Leaving Keck behind? The Free Movement of Goods After the Rulings in Commission v Italy and Mickelsson and Roos' (2009) 35 *European Law Review* 914.

[51] See *Gourmet International Products*, C-405/98, ECLI:EU:C:2001:135.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

This argument however goes against the existence of market access clauses[52] with market/health-measures and would thus not support a consistent reading of the case law on tobacco regulation, which has made a point of the existence of such clauses in that field. Minimum harmonisation coupled with market access, after all, means 'more harmonisation' rather than less, as explained above.

C. *Mutual recognition versus (minimum) harmonisation*

Mutual recognition is a regulatory technique that is also a darling of European studies.[53] As catchy as it is as a concept, its contours are blurred in European Union law.[54] In positive terms, the 'flexibility' introduced under mutual recognition has been considered to be one of the principle's main virtues.[55] But it is so flexible that there are several ways to understand its relation with harmonisation in general, and with minimum harmonisation specifically.

First, minimum harmonisation can be seen as a form of mutual recognition if minimum harmonisation is combined with a market access clause. In this case, the standard harmonised by EU law must be recognised by the Member State that is imposing stricter measures – albeit lawfully because this is allowed by the EU directive. Second, a more general way of framing the relation between harmonisation and mutual recognition is that, in order to be acceptable/legitimate, the latter requires some degree of harmonisation of standards.[56] If standards between Member States are comparable/equivalent, conversely, this then cannot be ignored when considering what legitimate regulatory controls may be applied in the host state.[57]

It is plain that both harmonisation and mutual recognition entail a loss of regulatory autonomy for Member States.[58] With harmonisation, standards are imposed that are created by a norm-setting authority outside the Member State. With mutual recognition, standards set and administered by another Member State must be recognised by the Host Member State (provided they are substantially equivalent). Mostly, however, mutual recognition is seen as somewhat 'inferior' to harmonisation. Thus, it has been argued that mutual recognition is chosen when

[52] See Section III above: market access clauses sustain regulatory differences but neutralise their practical consequences for market participants.

[53] See, among many others, SK Schmidt (ed), *Mutual Recognition as a New Mode of Governance* (Routledge, 2007).

[54] V Hatzopoulos, 'Forms of mutual recognition', in I Lianos and O Odudu (eds), *Regulating Trade in Services: Trust, Distrust and Economic Integration* (Cambridge University Press, 2012), pp 70–72. For a comparision with WTO law, see M Klamert, *Services Liberalization in the EU and WTO – Concepts, Standards and Regulatory Approaches* (Cambridge University Press, 2014), pp 258–263.

[55] V Hatzopoulos, see note 54 above, p 98.

[56] M Möstl, 'Preconditions and Limits of Mutual Recognition' (2010) 47 (2) *Common Market Law Review* 405, p 415.

[57] See K Armstrong, 'Mutual Recognition', in C Barnard and J Scott (eds), *The Law of the Single European Market: Unpacking the Premises* (Hart Publishing, 2002), p 230.

[58] M Möstl, see note 56 above, p 407.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

substantive harmonisation is not available.[59] Conversely but in the same vein, mutual recognition has been seen as an instrument of last resort when harmonisation has failed.[60] The underlying concern here seems to be the perceived limitations of mutual recognition and the assumption that the development of the internal market ultimately requires the intervention of the European legislator.[61] A slightly different way to come to the same conclusion is to argue that mutual recognition enables trade and, by doing so, creates a situation in which harmonisation is 'politically necessary and possible', whereby successful mutual recognition gradually leads to harmonisation.[62] I have argued elsewhere that this may be true for the goods market (even though the evidence seems patchy), but that it is not a convincing story for services, where harmonisation often is not politically viable.[63]

European secondary law however also shows that mutual recognition and harmonisation can work hand in hand without any antagonistic element. Article 126 of the Medicinal Products Directive 2001/83/EC fully harmonises the reasons for refusing the marketing of pharmaceuticals:[64]

> An authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive. No decision concerning suspension of manufacture or of importation of medicinal products coming from third countries, prohibition of supply or withdrawal from the market of a medicinal product may be taken except on the grounds set out in Articles 117 and 118.

This full harmonisation approach is coupled with Chapter 4 of the Directive titled 'Mutual recognition procedure and decentralised procedure'. Pursuant to Article 28 of the Directive, in order to gain a marketing authorisation for a medicinal product in more than one Member State, an applicant must submit an application based on an identical dossier in his/her chosen Member States, including a list of Member States concerned with the application. One Member State then acts as a 'reference Member State'. Alternatively, where the medicinal product has already received a marketing authorisation at the time of application, the concerned Member States must recognise the marketing authorisation granted by the reference Member State.[65] The quintessentially centralised regulatory model of harmonisation on standards is thus combined with a decentralised approach of mutual recognition on procedures.

---

[59] Ibid, p 406.

[60] See V Hatzopoulos, *Regulating Services in the European Union* (Oxford University Press, 2012), p 269.

[61] JHH Weiler, 'Epilogue: Towards a Common Law of International Trade', in JHH Weiler (ed), *The EU, the WTO, and the NAFTA* (Oxford University Press, 2001), pp 223–225.

[62] G Davies, 'Is Mutual Recognition an Alternative to Harmonization? Lessons on Trade and Tolerance of Diversity from the EU', in L Bartels and F Ortino (eds), *Regional Trade Agreements and the WTO Legal System* (Oxford University Press, 2006), p 271.

[63] See M Klamert, note 54 above, pp 263–264.

[64] Directive 2001/83/EC [2001] OJ L311/67.

[65] If this does not happen, then the Commission decides centrally. Compare with Art 34 Directive 2001/83/EC [2001] OJ L311/67.

IV. CONSTITUTIONAL MINIMUM HARMONISATION

A. *Introduction*

In the areas of health, environment and consumer protection, the Treaty prohibits full harmonisation, which also cannot be achieved by resorting to Article 114 TFEU. While the Treaty prescribes a high standard of protection, it therefore does not require EU law to set the highest possible standard of protection – hence the reference to 'constitutional' (ie Treaty-based) minimum harmonisation.[66] Article 153(4) TFEU on social policy states that it 'shall not prevent any Member State from maintaining or introducing more stringent protective measures compatible with the Treaties'. Article 169(4) TFEU on consumer policy and Article 193 TFEU on environmental policy 'shall not prevent any Member State from maintaining or introducing more stringent protective measures. Such measures must be compatible with the Treaties. The Commission shall be notified of them.' Regarding health policy, there is no general requirement of minimum harmonisation. However, Article 168(4)(a) TFEU on measures setting high standards of quality and safety of organs and substances of human origin provides that 'these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures'. The Blood Directive 2002/98/EC, one of the legal acts applying this legal basis, repeats this limitation.[67]

Hence, full harmonisation is constitutionally ruled out for measures passed under those legal bases. Could a market access clause apply to a European measure in those areas? In the Blood Directive 2002/98/EC, for example, a market access clause would mean that stricter national standards would not apply to blood imported from other Member States. It arguably is doubtful whether that would be compatible with the telos of Article 168 TFEU.

Another question in this context is whether constitutional minimum harmonisation could somehow 'trump' legislative full harmonisation. This was argued by France in defence of its national monopoly for the marketing of plasma in *Octapharma*.[68] Plasma fell under both the Blood Directive 2002/98/EC – adopted on the basis of Article 168(4)(a) TFEU, thereby requiring minimum harmonisation only – and under the Medicinal Products Directive 2001/83/EC, which anticipates full harmonisation as discussed above (Section III.C). France argued that constitutional minimum harmonisation represented by the Blood Directive 2002/98/EC should take priority over the European legislator's decision to require full harmonisation in the area of medicinal products. The Court in *Octapharma* however did not have to decide this issue, as both Directives quite clearly regulate their relationship to each other regarding the relevant plasma. In the *Octapharma* case, the plasma was held to fall under the Blood Directive 'solely with respect to its collection and testing'.[69]

---

[66] See M Dougan, 'Minimum Harmonization and the Internal Market' (2000) 37 *Common Market Law Review* 853, p 864.

[67] Art 4(2) Directive 2002/98/EC [2003] OJ L33/30.

[68] *Octapharma*, C-512/12, ECLI:EU:C:2014:149.

[69] Ibid, para 46.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

B. Standard of review for reinforcements

Member States can have the right to take more stringent measures either on the basis of Treaty provisions (constitutional minimum harmonisation) or by European legislative choice (minimum harmonisation). One may think that the standard of scrutiny of those more stringent measures would be the same in either situation: Member States must provide a valid reason or justification for their restriction(s) to the fundamental freedoms, and they must comply with the principle of proportionality. However, the current case law suggests otherwise.

The *Borsana* case dealt with Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work, based on (now) Article 153 TFEU for social policy (formerly Article 118a EEC).[70] In line with (now) Article 153 TFEU, the Directive allowed for more stringent measures to be taken by Member States.[71] An Italian law obliged employers to reduce workers' exposure to carcinogens irrespective of the assessment of risk and thus constituted a more stringent measure for the protection of working conditions. The Court held that the Italian legislation was confined to reinforcing the obligation of protection laid down in Article 5 of Directive 90/394 and that it therefore would not 'undermine the coherence of Community action in the area of workers' health and safety'.[72] Moreover, it would apply in a non-discriminatory manner and would not hinder the exercise of the fundamental freedoms guaranteed by the Treaty. The Court concluded its examination as follows:[73]

> Since the legislation at issue is a more stringent measure for the protection of working conditions compatible with the Treaty and results from the exercise by a Member State of the powers it has retained pursuant to Article 118a(3) of the Treaty, it is not for the Court to rule on whether such legislation and the penalties imposed therein are compatible with the principle of proportionality.

This deference to the national legislator is put in even clearer terms in the case *Deponiezweckverband*.[74] It concerned the Waste Directive 1999/31/EC based on (now) Article 193 TFEU (formerly Article 176 EC).[75] Under Article 5(1) of the Directive, Member States were to set up national strategies in order to reduce the amount of biodegradable waste going to landfills by certain percentages before certain fixed dates. This was a case where the minimum harmonising nature of the measure was found by interpretation. The Court held that the 'wording and broad logic of those [Directive] provisions make it clearly apparent that they set a minimum reduction to be achieved by the Member States and they do not preclude

---

[70] *Borsana*, C-2/97, ECLI:EU:C:1998:613. See also M Bleckmann, *Nationale Grundrechte im Anwendungsbereich des Rechts der Europäischen Union* (Mohr Siebeck, 2011), pp 44–45.

[71] *Borsana*, ECLI:EU:C:1998:613.

[72] Ibid, para 38.

[73] Ibid, para 40.

[74] *Deponiezweckverband Eiterköpfe*, C-6/03, ECLI:EU:C:2005:222.

[75] Directive 1999/31/EC [1999] OJ L182/1.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

the adopting by the latter of more stringent measures'.[76] While these stricter measures would have to be compatible with the Treaty, it would fall to the Member States to define the extent of the reduction of biodegradable waste going to landfills. The Court in two sentences only then excludes the application of the proportionality principle:[77]

> In that context, in so far as it is a matter of ensuring that the minimum requirements laid down by the Directive are enforced, the Community principle of proportionality demands that measures of domestic law should be appropriate and necessary in relation to the objectives pursued.
>
> In contrast, and inasmuch as other provisions of the Treaty are not involved, that principle is no longer applicable so far as concerns more stringent protective measures of domestic law adopted by virtue of Article 176 EC and going beyond the minimum requirements laid down by the Directive.

It is not that proportionality would otherwise play a prominent role in policing the exercise of Union competence by the EU legislator.[78] This statement, curt as it is, is nonetheless striking. As is visible from the quote above, the Court does not explain why proportionality is not relevant in the scrutiny of national measures taken on the basis of constitutional minimum harmonisation, when proportionality applies in the scrutiny of national measures adopted under legislative minimum harmonisation.[79] This would suggest that legislative minimum harmonisation and constitutional minimum harmonisation are two different animals, with the former conferring less legitimacy to the national legislator when it passes stricter measures than those required under EU law. That the proportionality principle did not apply in *Deponiezweckverband* is also striking because the Court is less benevolent towards the Member States regarding 'sovereignty clauses' in other areas such as in Articles 166 and 167 TFEU on national education systems. Those Articles would seem much better suited to show deference to the national legislator, but so far have not served that pupose at all.[80]

C. (Minimum) harmonisation and pre-emption

If a directive provides for full harmonisation, Member States are fully pre-empted from passing (conflicting) laws and regulations, whereas there is no such pre-emption with either partial or minimum harmonisation.[81] It has been argued that,

---

[76] *Deponiezweckverband Eiterköpfe*, ECLI:EU:C:2005:222, para 32.

[77] Ibid, paras 62–63.

[78] See S Weatherill, note 4 above, p 827.

[79] See N Boeger, 'Minimum Harmonisation, Free Movement and Proportionality' in P Syrpis (ed), *The Judiciary, the Legislature and the EU Internal Market* (Cambridge University Press, 2012), pp 73–88, for evidence from case law for legislative minimum harmonisation.

[80] See D Damjanovic, '"Reserved areas" of the Member States and the ECJ: The Case of Higher Education', in B DeWitte and H Micklitz (eds), *The European Court of Justice and the Autonomy of the Member States* (Intersentia, 2012), p 149.

[81] I have argued elsewhere that there is no convincing reason to conceive of pre-emption as a distinct legal principle in Union law, but that this should not discourage the use of the term in the context of the various duties of abstentions in EU law and especially with those that are unrelated to both supremacy

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

in the case of full harmonisation, pre-emption would already have been triggered by the Commission proposal for a legislative act.[82] It has also been submitted that the prohibition of frustration pursuant to the *Inter-Environnement Wallonie* case law should generally set in with the entry into force of a directive because there would be no situations imaginable where national measures after that point would not jeopardise the attainment of the directive's objective.[83] Both positions seem too far-reaching. The Commission proposal would have a pre-emption effect only under very narrow circumstances, and the Court has carefully subjected the prohibition of frustration to precise conditions in *Inter-Environnement Wallonie* and *Adenlener*.[84]

The implications of the passing of a directive on the rights of Member States to enter into international agreements with third states, in contrast, are a somewhat different matter. While the *ERTA* doctrine is based on the correspondence between the scope of the 'common rule' and the envisaged international agreement, there is no such strict correlation between the scope of a directive and the extent to which Member States are pre-empted in the external sphere under other grounds for establishing external competences.[85] This is because the Court has ruled that Member States are also prohibited from acting when Union exclusive competence is necessary to exercise its internal competence, or when the EU has largely (but not exhaustively) regulated an area.[86]

What happens if we add minimum harmonisation to this equation? In Opinion 2/91, the Court had to decide whether the Union had exclusive competence to conclude Convention No 170 of the International Labour Organization (ILO) concerning safety in the use of chemicals at work.[87] Community competence in general terms was conferred in (now) Article 153 TFEU (formerly Article 118a EEC), which provides for constitutional minimum harmonisation. However the ILO Convention equally allowed its Members to adopt more stringent measures.[88] The Court held that the provisions of Convention No 170 could not affect rules adopted under (formerly) Article 118a EEC (now Article 153 TFEU).[89] Notably, this statement is not yet about *ERTA*; the *ERTA* principle concerns an international agreement to be concluded on

(F'note continued)
and exclusivity. See M Klamert, *The Principle of Loyalty in EU Law* (Oxford University Press, 2014), pp 115–121.

[82] Opinion of Advocate General Poiares Maduro in *Commission v Austria* and *Commission v Sweden*, C-205/06 and C-249/06, ECLI:EU:C:2008:391, paras 33–38.

[83] Tietje, see note 7 above, art 114 para 67.

[84] *Inter-Environnement Wallonie*, C-129/96, ECLI:EU:C:1997:628; *Adeneler*, C-212/04, ECLI:EU:C:2006:443.

[85] M Klamert, see note 81 above, pp 150–157.

[86] See, among others, *Opinion 1/76 (European laying-up fund for inland waterway vessels)*, ECLI:EU:C:1977:63; and *Lesoochranárske*, C-240/09, ECLI:EU:C:2011:125.

[87] *Opinion 2/91 (ILO Convention No 170)*, ECLI:EU:C:1993:106.

[88] A more recent example is Art 7(3) of the Protocol to the 1979 Convention on Long Range Transboundary Air Pollution on Persistent Organic Pollutants [2004] OJ L81/37.

[89] *Opinion 2/91 (ILO Convention No 170)*, ECLI:EU:C:1993:106, para 18.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

the one hand and Union measures on the other hand. Put shortly, if the former might affect the latter, Union competence is exclusive.

In Opinion 2/91, the Court goes on to distinguish between two situations.[90] Firstly, when the Union adopts less stringent rules than those in a convention, then Member States can adopt more stringent measures then those provided in EU secondary law, by applying the (stricter measures of) the international agreement. Secondly, if the Union passes more stringent measures than those of the (minimum standard setting) international agreement, that agreement does not prevent the full application of the more stringent Union measures by the Member States. It could be added that in the second case, neither the agreement nor the Union measures would bar Member States to regulate even stricter measures than foreseen by both acts. Thus, the *ERTA* pre-emption principle does not apply if both the international agreement and the provisions of Union law provide minimum standards.[91] Opinion 2/91 however still concluded by acknowledging the exclusive competence of the EU on the basis that a number of directives in that field were fully harmonising and, while not correlating entirely with the scope of the Convention, covered the area to a large extent.[92]

V. PROCEDURAL VARIANTS

A wide range of instruments are available to the European legislature for exercising control over Member States within the scope of directives.

Article 114 TFEU is not only unique in substantive terms as discussed above; it is also exceptional in the force of its procedural prescriptions. In a measure providing for full harmonisation, the validity of national derogations is subject to the notification duties in Article 114(4) and (5) TFEU.[93] This stands in conspicuous contrast to the notification obligations provided in the Treaty rules providing constitutional minimum harmonisation, such as in the area of consumer policy or environmental policy. In those areas, the failure to notify the Commission of stricter measures does not have any explicit implications for the Member State concerned.

There is however a middle ground between the maximum approach to policing Member States in Article 114 TFEU and the minimum approach chosen, eg in Article 153 TFEU. The best known example is the Technical Standards and Regulations Directive 98/34/EC based on Article 114 TFEU.[94] Its Article 9(3) requires Member States to postpone the adoption of a draft technical regulation for 12 months from the date of receipt by the Commission of the notification, if either the Commission announces its intention to propose or adopt a measure, or announces its finding that the draft technical regulation concerns a matter which is already covered by secondary law. The Commission must make this declaration within three months of the notification. Paragraph 5 explicity calls this a 'standstill period' and extends it

[90] Ibid.

[91] See also PJ Slot, note 33 above, p 386.

[92] See note 89 above, paras 22–25.

[93] *Kortas*, C-512/12, ECLI:EU:C:1999:272.

[94] Directive 98/34/EC [1998] OJ L204/37.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

to 18 months if the Council adopts a common position during that time. This strict regime has been given even more bite by the Court, which gave direct effect to that standstill obligation.[95]

One step down the ladder, the Services Directive 2006/123/EC provides a duty of notification for what it calls requirements under the principle of freedom of establishment as well as a right of examination for the Commission, without however any standstill obligation. Thus, Article 15(7) of the Services Directive provides that Member States shall notify the Commission of any new laws, regulations or administrative provisions falling under a list of supect requirements together with the reasons for those requirements. The Commission shall then communicate the provisions concerned to the other Member States. Such notification shall however not prevent Member States from adopting the provisions in question. Within a period of three months from the date of receipt of the notification, the Commission shall examine the compatibility of any new requirements with Union law and, where appropriate, shall adopt a decision requesting the Member State in question to refrain from adopting them or to abolish them.

The latest addition to the arsensal of control instruments provided in secondary law is a tacit approval regime in Article 24(3) of Tobacco Products Directive 2014/40/EU. According to this, a Member State may prohibit a certain category of tobacco or related products. Such prohibition must be notified to the Commission together with the grounds for introducing them. The Commission then must, within six months of the date of receiving the notification, approve or reject the national provisions. In the absence of a Commission decision within this period, the 'national provisions shall be deemed to be approved'.[96] Thus, in contrast to the above-mentioned legal acts, the new Tobacco Products Directive establishes a quite distinct supervision mechanism paired with a minimum harmonisation approach.

VI. FINAL REMARKS

In this piece I have aimed to show that when we talk about harmonisation, we may mean quite different things. This is true for the use of the concept within the EU and the WTO, but also for the variety of terms available within the EU law discourse. This article has argued for a distinction between full and partial harmonisation in scope, and between full and minimum harmonisation in standards reflecting the necessary distinction between the scope and the intensity of harmonisation. I have also argued that there is a close yet often unclear relation between minimum harmonisation and mutual recognition on the one hand, and between full harmonisation and the country of origin principle on the other hand. As a result, classifying legal acts by reference to a particular approach to harmonisation becomes increasingly difficult. Thus, the Services Directive could be described as an instrument of targeted full harmonisation coupled with a general prohibition of restrictions

[95] *CIA Security*, C-194/94, ECLI:EU:C:1996:172.

[96] Art 24(3) Directive 2014/40/EU [2014] OJ L127/1.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press

and mutual recognition. The new Tobacco Products Directive, in contrast, could be seen as combining targeted minimum harmonisation with full harmonisation.

Fundamentally, there is always the search for a balance between market integration and respect for the Member States' preferences. If minimum harmonisation is the safety valve for the regulatory autonomy of Member States, then as a counterbalance market access clauses in European legislation provide some harm reduction from the perspective of the functioning of the internal market. I have also suggested that the legal necessity of a market access clause is determined by the potential effect of the harmonised rules on intra-Community trade, which tends to be less with sales-related rules. While this cannot be deduced from case law with certainty, it would at least give a generally opaque case law a semblance of inner logic. There is less logic, in contrast, in the nearly complete deference to the national legislator when constitutional minimum harmonisation applies.

It is striking that what is the butter and bread of market integration in the EU continues to be shrouded in ambiguity in so many different ways. It is less surprising that tobacco regulation may again be the testing ground for further elucidation of these matters.

https://doi.org/10.1017/cel.2015.12 Published online by Cambridge University Press