BRILL | NIJHOFF

EUROPEAN JOURNAL OF HEALTH LAW (2026) 1–23

European Journal of Health Law

brill.com/ejhl

Understanding European Union Substances of Human Origin Case Law through Defragmentation and Fragmentation

Aurélie Mahalatchimy | ORCID: 0000-0002-4365-2143
Faculty of Law, Aix-Marseille University, 5 Avenue Robert Schuman, 13628 Aix-en-Provence, France
aurelie.mahalatchimy@univ-amu.fr

Marie Glinel | ORCID: 0009-0000-7902-1581
Department of Public Law, Université Lumière Lyon 2, 4bis Rue de l'Université, 69007 Lyon, France
marie.glinel@gmail.com

Tamara K Hervey | ORCID: 0000-0002-8310-9022
The City Law School, University of London, Sebastian Street, London EC1V 0HB, UK
Corresponding author, e-mail: tamara.hervey@citystgeorges.ac.uk

Received 24 July 2025 | Accepted 24 March 2026 | Published online 5 May 2026

Abstract

Regulation of Substances of Human Origin (SoHO) is an important topic of Union health law both in the context of research and in the context of healthcare services and treatment of patients. When we observe Union SoHO law, we do not only observe a linear movement towards greater harmonisation and less differentiation between national laws. At the same time as the 'expected' harmonisation processes of an inexorable process of greater Union law coverage of a field, and less space for national difference, we also observe counter-processes in the opposite direction. Focusing on the role of the Court of Justice of the Union to understand the dynamics of Union regulation of the sector through the analysis of 19 SoHO cases, this article proposes two new legal analytical concepts to explain these processes: 'defragmentation' and 'fragmentation'

Published with license by Koninklijke Brill BV | DOI:10.1163/15718093-BJA10166
 | ISSN: 0929-0273 (print) 1571-8093 (online)

which provide an explanatory model as a tool of legal science to use to promote greater understanding of Union law.

Keywords

case law – Court of Justice of the European Union (cjeu) – defragmentation – European Union law – explanatory model – fragmentation – harmonisation – Substances of Human Origin (SoHO)

1 Introduction

Regulating substances of human origin (SoHO)[1] is an important topic of Union health law, touching upon fundamental matters of human dignity, as well as on the opportunities that arise from sharing such SoHO across the wider Union space, both in the context of research and in the context of healthcare services and treatment of patients.

Despite the acknowledged relevance to the internal market, Union SoHO legislation is often based on Article 168(4) TFEU, which gives the Union competence to adopt minimum harmonisation measures setting high quality and safety standards for SoHO. An example includes the new Regulation (EU) 2024/1938 on standards of quality and safety for SoHO intended for human application[2] (the SoHO Regulation) adopted on 13 June 2024, coming fully into effect in August 2027.[3] The rationales for Union SoHO legislation include

1 In this article, we use 'SoHO' to mean all substances of human origin. This definition includes, but goes further than, the SoHO covered by Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC [2024] OJ L1938 ('the SoHO Regulation').

2 *Supra* note 1.

3 In addition to the SoHO Regulation, *supra* note 1, the legislation covered in this article is Directive 2002/98/EC of the European Parliament and of the Council setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [2003] OJ L33/30 ('Blood Directive'); Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L102/48; Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding,

the need to protect patients; donors of SoHO, such as blood, gametes, organs, human breast milk and intestinal microbiota; and children born from donated eggs, sperm or embryos, in the light of technological developments; and that the benefits of the single market should be capitalised upon, including by supporting the European biomedicine industry.

Given the variety of rationale(s) for Union regulation, as well as the significance for patients, healthcare providers, researchers, suppliers and other stakeholders in the biomedical sector, it is important to understand the dynamics of Union law in the sector. Others have discussed the legislative landscape (and will no doubt discuss the new landscape after 2027):[4] this article focuses on the role of the Court of Justice of the Union (CJEU) in that regard.

---

processing, preservation, storage and distribution of human tissues and cells [2006] OJ L294/32; Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells, OJ L38/40; Commission Directive 2012/39/EU amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells [2006] OJ L 327/24 ('Tissues and Cells Directives'); Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions [1998] OJ L213/13 ('Patentability Directive'); Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [2001] OJ L311/67 ('Medicines Directive').

4 *See, for example*, A.-M. Farrell, 'Governing the Body: Examining EU Regulatory Developments in Relation to Substances of Human Origin', *Journal of Social Welfare and Family Law* 27 (2005) 427–437, doi: 10.1093/medlaw/fwl001; F. Sauer, F. Delaney and E. Fernandez-Zincke, 'The regulation of blood and tissues in the European Union', *Pharmaceuticals Policy and Law* 6(1) (2005) 47–58, doi:10.3233/PPL-2005-00088; A.-M. Farrell, 'Is the Gift Still Good? Examining the Politics and Regulation of Blood Safety in the European Union', *Medical Law Review* 14(2) (2006) 155–179; M Favale and A Plomer, 'Fundamental Disjunctions in the EU Legal Order on Human Tissue, Cells & Advanced Regenerative Therapies', *Maastricht Journal of European and Comparative Law* 16(1) (2009) 89–111, doi: 10.1177/1023263X0901600105; A. Mahalatchimy, P. Lau, P. Li and M. Flear, 'Framing and legitimating EU legal regulation of human gene-editing technologies: key facets and functions of an imaginary', *Journal of Law and the Biosciences* 8(2) (2021) lsaa080, doi: 10.1093/jlb/lsaa080; J.J. Elias, N. Lacetera, M. Macis, A. Ockenfels and A.E. Roth, 'Quality and safety for substances of human origins: scientific evidence and the new EU regulations', *BMJ Global Health* 9 (2024) e015122, doi: 10.1136/bmjgh-2024-015122; E. Brookes, *European Union Health Policy* (Manchester: Manchester University Press, 2025) pp. 62–85, doi: 10.7765/9781526135377.00007; J. Rodriguez, M. Cordaillat-Simmons, B. Pot and C. Druart, 'The regulatory framework for microbiome-based therapies: insights into European regulatory developments', *npj Biofilms Microbiomes* 11 (2025) 53–65, doi: 10.1038/s41522-025-00683-0; M. Dukovic, 'New organs on command: The regulatory prospects of 3D bioprinting technology in the European Union', *Law, Technology and Humans* 7(1) (2025) 84–95, doi: 10.3316/informit.T202505220000530101964351 7.

Existing understandings of the dynamics of Union (health) law draw on the concept of harmonisation.[5] Harmonisation is primarily associated with the process of creating the Union's single market,[6] but applies also in other areas of Union competence, especially where — as is the case with its public health competence — that competence overlaps and interlinks with the Union's internal market competence.[7] To simplify,[8] harmonisation is typically understood as 'maximal' or 'minimum'. Maximal harmonisation (unusual in areas of shared competence such as public health or internal market) is where Union legislation 'occupies the field', leaving no scope for national difference. Minimum harmonisation (the most commonly occurring approach) is where Union legislation sets a 'floor' of standards, and Member States enjoy discretion to impose 'higher' standards on their domestic producers, but must recognise lower standards applicable in other Member States, unless an 'objective public interest' justifies a different approach.[9] Within this logic, the roles of the CJEU are understood to be to limit national discretion, for example by adopting a strong proportionality test; and to expand the scope of application

5 *See, for example*, E. Brosset, *Manuel de droit de l'Union européenne de la santé* (Brussels: Bruylant, 2024); N. De Grove-Valdeyron, *Droit européen de la santé* (Paris: LGDJ, 2013); T.K. Hervey and J. McHale, *European Union Health Law* (Cambridge: Cambridge University Press, 2015).

6 L. Azoulai, 'The Complex Weave of Harmonization', in: D. Chalmers and A. Arnull (eds), *The Oxford Handbook of European Union Law* (Oxford: Oxford University Press, 2015) pp. 589–611; I. Maletić, *The Law and Policy of Harmonisation in Europe's Internal Market* (Cheltenham: Edward Elgar, 2013); I. Maletić, 'Theory and Practice of Harmonisation in the European Internal Market', in: M. Andenas and C. Andersen (eds), *Theory and Practice of Harmonisation* (Cheltenham: Edward Elgar, 2012) chapter 17.

7 *See, for example*, E. Derclay and G. Stupfler, *EU Copyright Law Harmonisation* (Oxford: Hart, 2025); B. Vanheusend, T. Iliopoulos and A. Vanhellmont, *Harmonisation in EU environmental and energy law* (Cambridge: Intersentia, 2022); E. Ghio, *Redefining Harmonisation: Lessons from EU Insolvency Law* (Cheltenham: Edward Elgar, 2022); J.M. Almudí Cid, J. Ferreras Gutiérrez and P. Hernández González-Barreda, *Combating Tax Avoidance in the EU: Harmonization and Cooperation in Direct Taxation* (Amsterdam: Kluwer, 2019).

8 *See further, for example*, J. Snell, 'The Internal Market and Philosophies of Market Integration', in: C. Barnard and S. Peers (eds), *EU Law* (Oxford: Oxford University Press, 2026) pp. 310–338; P. Craig and G. de Burca, *EU Law* (Oxford: Oxford University Press, 2024); C. Barnard, *The Substantive Law of the EU* (Oxford: Oxford University Press, 2025); R. Schütze, *European Union Law* (Cambridge: Cambridge University Press, 2025); M. Costa and S. Peers, *Steiner & Woods EU Law* (Oxford: Oxford University Press, 2023).

9 M. Dougan, 'Minimal Harmonization and the Internal Market', *Common Market Law Review* 37 (2000) 853–885; M. Klamert, 'What we talk about when we talk about harmonisation' *Cambridge Yearbook of European Legal Studies* 17 (2015) 360–379; S. Weatherill, 'Maximum versus Minimum Harmonization', in: N. Shuibne and L. Gormley (eds), *From Single Market to Economic Union* (Oxford: Oxford University Press, 2012) pp. 175–200.

of Union (harmonised) law, through its 'teleological' interpretative approach. The Union legislature is understood to draw on the CJEU's work, consolidating its case law in legislative settlements, presented to governments of Member States as *fait accompli*. Union SoHO legislation thus further reduces differences between Member States' legal systems.

But when we observe Union SoHO law, we do not only observe such a linear movement towards greater harmonisation and less differentiation between national laws. At the same time as the 'expected' harmonisation processes of an inexorable process of greater Union law coverage of a field, and less space for national difference, we also observe counter-processes in the opposite direction. To help us explain these processes, we propose two new legal analytical concepts: 'defragmentation' and 'fragmentation'.

Defragmentation includes — but goes further than — the existing well-understood concept of harmonisation, in the sense of creating binding uniform rules that apply in all Union Member States, displacing the previously applicable fragmented national rules ('normative defragmentation'). For example, the nature of Union law means that domestic differences, irrespective of their source, cannot remove an obligation of compliance with a Union Regulation or Directive. A Union Member State may not — as they might in ordinary international law such as the law of the Council of Europe — rely upon domestic ethical standards within a 'margin of appreciation'. Acceptable ethical standards are instead determined at Union level. But defragmentation goes further, and also describes processes by which the substantive or material scope of Union law, as interpreted by the CJEU, has the effect of reducing or removing national discretion ('material defragmentation'). For example, as we will show, Union case law creates and determines the scope of a new independent concept of Union law, such as 'human embryo', despite no legislative attempt to do so. Or, as discussed below, Union case law interprets collecting umbilical cord blood as within the concept of 'hospital or medical care', for the purposes of Union tax law.[10] Such Union concepts displace national interpretations within the scope of application of relevant Union law, and thus contribute to Union SoHO law.

Fragmentation involves the opposite processes. 'Normative fragmentation' could involve the *de facto* replacement of binding norms by non-binding guidance, for example, because of the need to update technical detail more regularly than the Union legislature can achieve.[11] The CJEU practices normative

10 *See infra*, discussion at notes 85–88.

11 An example, not in the context of SoHO law, was the replacement of aspects of hard Union border law with soft law during the COVID-19 pandemic, see T. Hervey and

fragmentation when it interprets a concept of Union law differently in one context from another, for example by using a different definition of 'blood' in the context of Union blood safety law from that used in Union taxation law. But fragmentation also relies on processes which acknowledge the existence of a margin of appreciation for Member States regarding the material scope of Union law as interpreted by the CJEU ('material fragmentation'). For example, as noted below, the reasoning of the CJEU has permitted national flexibility to some extent regarding the exemption from VAT for private stem cell banks.

2 Context: SoHO Litigation To Date

Although in general much Union health law is CJEU-developed,[12] SoHO is a field where Union legislation has dominated. Only 19 CJEU decisions relate to SoHO: one application for judicial review of a Union act,[13] six Commission allegations of non-compliance with Union law,[14] and 12 preliminary references from national courts.[15]

M. Michalak, 'European Union Border Law during the COVID-19 Pandemic', *Common Market Law Review* 62 (2025) 747–796.

12 Hervey and McHale, *supra* note 5, p. 55.

13 C-377/98 *Kingdom of the Netherlands v. European Parliament and Council of the European Union* [2001] ECLI:EU:C:2001:523.

14 Article 258 TFEU. C-456/03 *Commission of the European Communities v. Italian Republic* [2005] ECLI:EU:C:2005:388; C-7/09 *Commission of the European Communities v. Kingdom of Belgium* [2009] ECLI:EU:C:2009:704; C-9/09 *Commission of the European Communities v. Kingdom of Belgium* [2009] ECLI:EU:C:2009:571; C-13/09 *Commission of the European Communities v. Italian Republic* [2009] ECLI:EU:C:2009:734; C-29/14 *European Commission v. Republic of Poland* [2015] ECLI:EU:C:2015:379; C-481/18 *European Commission v. Italian Republic* [2019] ECLI:EU:C:2019:636.

15 C-45/83 *Ludwig-Maximilians-Universität München v. Hauptzollamt München-West* [1984] ECLI:EU:C:1984:31; C-262/08 *CopyGene A/S v. Skatteministeriet* [2010] ECLI:EU:C:2010:328; C-86/09 *Future Health Technologies Limited v. The Commissioners for Her Majesty's Revenue and Customs* [2010] ECLI:EU:C:2010:334; C-237/09 *Belgian State v. Nathalie De Fruytier* [2010] ECLI:EU:C:2010:316; C-421/09 *Humanplasma GmbH v. Republik Österreich* [2010] ECLI:EU:C:2010:760; C-34/10 *Oliver Brüstle v. Greenpeace eV.* [2011] ECLI:EU:C:2011:669; C-364/13 *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks* [2014] ECLI:EU:C:2014:2451; C-512/12 *Octapharma France SAS v Agence nationale de sécurité du médicament et des produits de santé* (*ANSM*) *and Ministère des Affaires sociales et de la Santé* [2014] ECLI:EU:C:2014:149; C-528/13 *Geoffrey Léger v. Ministre des Affaires sociales, de la Santé et des Droits des femmes and Etablissement français du sang* [2015] ECLI:EU:C:2015:288; C-412/15 *TMD Gesellschaft für transfusionsmedizinische Dienste mbH v. Finanzamt Kassel II — Hofgeismar* [2016] ECLI:EU:C:2016:738; C-296/15 *Medisanus d.o.o. v. Splošna Bolnišnica Murska Sobota* [2017] ECLI:EU:C:2017:431;

Four of these cases concern the history of SoHO patentability. The Union's first legislation on SoHO was the Patentability Directive[16] which obliges Member States to 'protect biotechnological inventions under national patent law'.[17] The legislation was controversial, so its legal basis,[18] and the interpretation of key terms within it, particularly the concept of 'human embryo',[19] were tested before the CJEU. According to data available on Eur-lex, ten Member States did not implement the Directive by the June 2000 deadline.[20] Five years after the deadline for implementation, the CJEU found that Italy had still not complied with the implementation obligation.[21]

Five cases concern the framing, safety and quality of SoHO.[22] These are all brought under the CJEU's jurisdiction to hear claims of non-compliance. They illustrate the difficulties some Member States faced with compliance with Union obligations, particularly those imposed by the Union's first Tissues and Cells Directives.[23]

A further five cases concern tax exemptions and economic incentives. They concern the tax classification of: bottles made specifically for research into tissues;[24] medical care services, in the context of collection and storage of umbilical cord blood for possible future medical treatment,[25] and of plasma supply;[26] and supplies of human organs, blood and milk.[27]

Six of the relevant CJEU cases specifically concern blood: its designation as a non-commodity and the significance of its donation.[28]

C-96/20, *Ordine Nazionale dei Biologi and Others v. Presidenza del Consiglio dei Ministri* [2021] ECLI:EU:C:2021:191.

16 Directive 98/44, *supra* note 3.

17 Directive 98/44, *supra* note 3, Article 1.

18 C-377/98 *Kingdom of the Netherlands v. European Parliament and Council*, *supra* note 12.

19 C-34/10 *Oliver Brüstle,* and C-364/13 *International Stem Cell Corporation, supra* note 14.

20 See national implementing measures available at https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:31998L0044.

21 C-456/03 *Commission of the European Communities v. Italian Republic*, *supra* note 14.

22 See cases cited *supra* note 14.

23 Directive 2004/23/EC; Commission Directive 2006/86/EC; Commission Directive 2006/17/EC; Commission Directive 2012/39/EU all *supra* note 3.

24 C-45/83 *Ludwig-Maximilians-Universität München*, *supra* note 15.

25 C-262/08 *CopyGene*, C-86/09 *Future Health Technologies*, *supra* note 15.

26 C-412/15 *TMD Gesellschaft für transfusionsmedizinische Dienste*, *supra* note 15.

27 C-237/09 *Belgian State v. Nathalie De Fruytier*, *supra* note 15.

28 C-421/09 *Humanplasma*; C-512/12 *Octapharma*; C-412/15 *TMD Gesellschaft für transfusionsmedizinische Dienste*; C-C296/15 *Medisanus*; C-528/13 *Geoffrey Léger*; C-96/20 *Ordine Nazionale dei Biologi*, *supra* note 15.

3 Normative Defragmentation

We can understand the dynamics of the CJEU's SoHO case law on compliance with implementation obligations through normative defragmentation — the concept closest to harmonisation in our proposed new analytical frame. Five aspects of the CJEU's reasoning drive Europeanisation of SoHO law through the removal of national discretion and the enforcement of common European SoHO norms.

First, the CJEU assesses timely compliance with implementation obligations in Union secondary law. The CJEU held that both Belgium[29] and Italy[30] failed to comply on time with their obligations under the Tissues and Cells Directives. Such an assessment is a strict and formalist obligation 'determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion'.[31] The political or legal realities, including 'changes made subsequently', 'cannot be taken into account by the Court'.[32]

Second, compliance with implementation obligations also includes an implementation 'with unquestionable binding force, and with the specificity, precision and clarity necessary to satisfy the requirements of legal certainty'.[33] Poland has failed to comply with its obligations under three of the Tissues and Cells Directives notably because 'guidelines' or 'recommendations' as implementing measures 'do not [...] have the unquestionable binding force required'.[34]

---

29 C-9/09, *Commission of the European Communities v. Kingdom of Belgium, supra* note 14 concerning Directive 2004/23/EC; C-7/09, *Commission of the European Communities v. Kingdom of Belgium, supra* note 14 concerning Directive 2006/86/EC.

30 C-13/09, *Commission of the European Communities v. Italian Republic, supra* note 14 concerning Directive 2006/86/EC; C-481/18, *European Commission v. Italian Republic, supra* note 14 concerning Directive 2012/39/EU.

31 C-481/18 *European Commission v. Italian Republic, supra* note 14, para. 10; and in accordance with settled case law beyond SoHO, such as Case C-384/99 *Commission of the European Communities v. Kingdom of Belgium* [2000] ECLI:EU:C:2000:660, para. 16.

32 See in particular beyond SoHO, C-23/05, *Commission of the European Communities v. Grand Duchy of Luxemburg* [2005] ECLI:EU:C:2005:660, para. 9, and C-574/08 *Commission of the European Communities v. Kingdom of Belgium* [2009] ECLI:EU:C:2009:484, para. 9.

33 C-29/14, *European Commission v. Republic of Poland* [2015] ECLI:EU:C:2015:379, para. 37; and in accordance with settled case law, such as C-81/07, *Commission of the European Communities v. Hellenic Republic* [2008] EU:C:2008:172, para. 19.

34 C-29/14 *European Commission v. Republic of Poland, supra* note 14, para. 46, concerning Directives 2004/23/EC, 2006/17/EC, and 2006/86/EC.

Third, the CJEU has held that national circumstances, whether linked to domestic difficulties or national ethical positions, are not an acceptable reason for non-compliance with implementation obligations. Indeed, in general, 'a Member State may not seek to rely on provisions, practices or circumstances in its internal legal order in order to justify failure to comply with the obligations and time-limits laid down in a directive'.[35] This principle applies equally in the context of SoHO legislation, even though it is an ethically and politically challenging regulatory domain. In two of the three relevant procedures, Italy accepted this aspect of Union law and did not contest the reality of the failure of implementation.[36] The CJEU held that Italy's difficulties — due to an internal parliamentary procedure[37] or the ban on heterologous medically assisted reproduction at this time[38] — which caused the delay of transposition of the relevant Directives, were not acceptable reasons for non-compliance. Similarly, Poland's exclusion of 'reproductive cells and foetal and embryonic tissue' from the binding national transposition acts was a failure to meet its obligation to fully transpose the Tissues and Cells Directives.[39]

Fourth, compliance with implementation obligations also involves an obligation to provide information to the Commission regarding implementation measures. The latter is 'a formal obligation' from which Member States are not

35 C-13/09 (Case available in French only) *Commission of the European Communities v. Italian Republic, supra* note 14, para. 10, and C-481/18 (only in French and Italian) *European Commission v. Italian Republic, supra* note 14, para. 11; and in accordance with case law beyond SoHO, such as C-114/02 *Commission v. France* [2003] ECR I-3783, para. 11.

36 Italy did contest the allegation of failure in C-456/03 *Commission of the European Communities v. Italian Republic*, *supra* note 14.

37 C-13/09 *Commission of the European Communities v. Italian Republic, supra* note 14, para. 8.

38 C-481/18 *European Commission v. Italian Republic, supra* note 14, para. 9. It can be highlighted that the Italian Constitutional Court decided this ban was unconstitutional by judgment no. 162 of June 10, 2014.

39 C-29/14 *European Commission v. Republic of Poland, supra* note 14, paras 45–47. It can be highlighted that these sensitive tissues and cells were covered by guidelines or recommendations only, and without the unquestionable binding force required, as mentioned earlier. Moreover, para. 47 provides: 'In the light of the specific scope of the obligations imposed by the directives at issue and the objective of protecting public health which they pursue, the transposition of those directives by a multitude of acts combined with the exclusion of certain types of tissues and cells from the scope of the principal transposing act, even though those tissues and cells are covered by those directives, fails to satisfy the requirements of specificity, precision and clarity resulting from the case-law referred to in para. 37 of the present judgment. In those circumstances, the individuals concerned by the unified framework provided for by the directives at issue are not in a position, on the basis of those acts alone, to know the full extent of their rights and obligations with the legal certainty required by the Court's case-law.'

absolved even if a directive's provision allows them 'to secure the substantive transposition of the Directive by means of their domestic legal rules [already] in force'.[40] The CJEU has linked this informational obligation to the general 'duty of sincere cooperation',[41] and it has highlighted that

> the information concerning the transposition of a directive which the Member States are obliged to provide to the Commission must be clear and precise, and it must unequivocally indicate the legislative, regulatory and administrative measures by which the Member State considers that it has fulfilled the various obligations imposed on it by the directive.[42]

Finally, as a classical Union law phenomenon flowing from the inherent function of the CJEU to move the Union in the direction of further European integration, normative defragmentation explains one further aspect of the CJEU's approach. Although in principle when the CJEU exercises its jurisdiction under the preliminary reference procedure,[43] it merely interprets Union law, and leaves its application to the referring national court, in practice the CJEU's reasoning often leaves little space for national courts.[44] And, even though national courts practically enjoy a *de facto* gatekeeping power for the reach of Union law, in that if they do not comply with the CJEU's reasoning but only its interpretative result they will still be in compliance with Union obligations, by and large they are remarkably deferential to the reasoning in the CJEU's preliminary references rulings.[45] The adoption by national courts

40 C-456/03 *Commission of the European Communities v. Italian Republic*, *supra* note 14, para. 30.

41 C-29/14 *European Commission v. Republic of Poland*, *supra* note 14, para. 32 referring to C-151/12 *European Commission v. Kingdom of Spain* [2013] ECLI:EU:C:2013:690, para. 49.

42 C-29/14 *European Commission v. Republic of Poland supra* note 14, para. 33 referring to C-456/03 *Commission of the European Communities v. Italian Republic*, *supra* note 14, paras 26–27.

43 Article 267 TFEU.

44 *See* the discussion in P. Craig and G. de Búrca, *EU Law* (Oxford University Press, 2024) pp. 540–542, and the examples therein; T. Tridimas, 'Constitutional Review of Member State Action: The Virtues and Vices of an Incomplete Jurisdiction, *International Journal of Constitutional Law* 9 (2011) 737–756.

45 *See*, on the preliminary reference procedure, for example, *C. Donnelly* 'Preliminary Rulings and EU Legal Integration: Evolution and Continuity', in: P. Craig and G. de Búrca (eds), *The Evolution of EU Law* (Oxford: Oxford University Press, 2021) pp. 228–274; T. Tridimas, 'Knocking on Heaven's Door: Fragmentation, Efficiency and Defiance in the Preliminary Reference Procedure', *Common Market Law Review* 40(1) (2003) 9–50; A.-M. Slaughter, A. Stone-Sweet and J. Weiler (eds), *The European Court and National Courts: Doctrine & Jurisprudence* (London: Bloomsbury, 1998).

of the reasoning of the CJEU extends the reach of Union (health) law into national orders.[46]

We can understand Union SoHO case law through this aspect of normative defragmentation. The CJEU, in its reasoning and independently of the results of its decisions, sets out point by point the aspects to be ascertained by a referring court. For instance, the referring court may have to verify one or several of the following: whether a national measure is a stricter protective measure further guaranteeing an objective of general interest; whether it is compatible with Union law; whether it is appropriate to achieve the targeted objective; and whether it is proportionate (meaning not exceeding what is appropriate and necessary) to attain the objectives legitimately pursued.[47] This type of reasoning exceeds the literal interpretation of the CJEU's jurisdiction under Article 267 TFEU, making it what has been termed a 'citizens' infringement procedure'.[48] The ability of citizens to deploy the preliminary reference procedure *de facto* to challenge national rules and the deference of national courts to the implied obligation to follow the CJEU's reasoning leads to increasingly uniform national rules across the Union.

4 Normative Fragmentation

But Union law is also sometimes characterised by normative fragmentation. The most noticeable situation is where a regulation is replaced by a directive, or a binding norm by a non-binding one. This direction of travel characterised the move from the 'old style' harmonisation to the 'new approach' to

46 Hervey and McHale, *supra* note 5, p. 56.

47 These steps appear in several EU SoHO cases. See for instance, C-96/20 *Ordine Nazionale dei Biologi, supra* note 15, paras 34–38.

48 *See* P. Pescatore, '*Van Gend en Loos*, 3 February 1963 – A View from Within', in: M. Poiares Maduro and L. Azoulai (eds.), *The Past and Future of EU Law: The Classics of EU Law Revisited on the 50th Anniversary of the Rome Treaty* (Oxford: Hart Publishing, 2010) 7; *see also* B. de Witte, 'The Impact of *Van Gend En Loos* on Judicial Protection at European and National Level: Three Types of Preliminary Questions', in: A. Tizzano and S. Prechal (eds.), *50th Anniversary of the Judgment in Van Gend en Loos, 1963–2013* (Luxemburg: Office des Publications de l'Union Européenne, 2013) 93; V. Passalacqua and F. Costamagna, 'The law and facts of the preliminary reference procedure: a critical assessment of the EU Court of Justice's source of knowledge', *European Law Open* 2(2) (2023) 322–344, doi:10.1017/elo.2023.26; but see J. Zglinski, *Europe's Passive Virtues: Deference to National Authorities in EU Free Movement Law* (Oxford: Oxford University Press, 2020).

harmonisation in EU legislation.[49] However, SoHO legislation was not covered in this evolution, and, in fact, the SoHO legislation does not include this type of normative fragmentation. Indeed, SoHO legislation has moved in the other direction: Directives on Tissues and Cells[50] and Blood[51] have been replaced by the SoHO Regulation.[52]

However, the concept of normative fragmentation makes sense of an important feature of the CJEU SoHO cases. Despite litigation concerning the same legal concepts, the CJEU does not 'read across' definitions from other legislation, but maintains distinct interpretations of the same concept depending on the context in which the litigation has arisen. When interpreting the word 'blood' in the Value Added Tax (VAT) Directives and their exemptions,[53] the CJEU does not rely on the definition of 'blood' as provided in the Blood Directive 2002/98,[54] but rather relies on the 'usual meaning' of this word,[55] as well as on the context of its use and the objective of the text interpreted in matters of VAT.[56] We can find a similar attitude with human organs and samples.[57] Although the CJEU refers to article 21 of the Oviedo Convention[58]

49 See notably, J. Pelkmans, 'The new approach to technical harmonisation and standardisation', *Journal of Common Market Studies* 25 (1987) 249–269; Craig and De Burca, *supra* note 44, pp. 620–627.

50 Directive 2004/23/EC, *supra* note 3.

51 Directive 2002/98/EC, *supra* note 3.

52 Regulation (EU) 2024/1938, *supra* note 1.

53 The Sixth Council Directive 77/388/EEC of 17 May 1977 on the harmonisation of the laws of the Member States relating to turnover taxes – Common system of value added tax: uniform basis of assessment [1977] OJ L145/1, and Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax [2006] OJ L347/1.

54 '"Blood" shall mean whole blood collected from a donor and processed either for transfusion or for further manufacturing.' Article 3a Directive 2002/98/EC, *supra* note 3.

55 'As regards its usual meaning, it must be pointed out that the concept of "human blood" refers to an element of the human body consisting of several, non-autonomous, complementary components, whose synergistic action allows for the irrigation of all organs and tissues.' C-412/15 *TMD Gesellschaft für transfusionsmedizinische Dienste, supra* note 15 para. 27.

56 'The meaning and scope of that concept must be determined by considering its usual meaning in everyday language, while also taking into account the context in which it occurs and the purposes of the rules of which it is part (*see*, to that effect, C-592/11, *Ketelä* [2012] ECLI:EU:C:2012:673, para. 51 and the case-law cited)', C-412/15 *TMD Gesellschaft für transfusionsmedizinische Dienste*, *supra* note 15 para. 26.

57 C-237/09 *Belgian State v. Nathalie De Fruytier*, *supra* note 15.

58 Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April 1997.

on the prohibition of financial gain regarding the human body and its parts,[59] the CJEU considers that this 'cannot be regarded as wholly depriving […] [the provision on exemptions in the VAT] Directive of its effectiveness' because the Convention has neither been signed by the Union nor been ratified by the majority of its Member States.[60] Rather than adopting a consistent interpretation of core concepts ('blood'; 'the human body and its parts'), the CJEU maintains an impermeable boundary between VAT law applied to SoHO and quality and safety of SoHO. The Union legal order is thus fragmented in that different interpretations of the same normative concept apply in different contexts.

5 Material Defragmentation

The dynamics of Union SoHO law may also be understood through what we term 'material defragmentation': the process by which national discretion is reduced or removed by CJEU interpretation of the substantive or material scope of Union law. Five different strategies of the CJEU support such material defragmentation.

The oldest argument for material defragmentation put forward by the CJEU is the rejection of linguistic specificities as a basis for differing interpretations or applications of Union SoHO law. In *Ludwig-Maximilians-Universitat*,[61] the

59 The Court's reference to the Oviedo Convention that is taken 'into account as appropriate' by the Tissues and Cells Directive in accordance with its recital (22) although the VAT directive only is questioned in the judgment, is in itself noticeable in comparison with the full omission of the Blood Directive in C-412/15 *TMD Gesellschaft für transfusionsmedizinische Dienste*, *supra* note 15.

60 'In that regard, even though it is clear from the order for reference that in Belgium human organs and samples cannot be traded, and even though Article 21 of the Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine, concluded at Oviedo on 4 April 1997, provides, under the heading "Prohibition of financial gain", that the human body and its parts are not, as such, to give rise to financial gain, those factors in themselves cannot be regarded as wholly depriving Article 13(A)(1)(d) of the Sixth Directive of its effectiveness. That convention, open for signature in particular by the member States of the Council of Europe, on the one hand, and by the European Union, on the other hand, under Article 33(1) of the convention, has not been signed by the European Union. Moreover, of the Member States, only a small majority of them have actually ratified the convention.' C-237/09 *Belgian State v. Nathalie De Fruytier*, *supra* note 15, para. 27.

61 C-45/83 *Ludwig-Maximilians-Universität München*, *supra* note 15, para. 267.

German version of Regulation 1798/75[62] adds the term 'ustensils' to 'scientific instruments' and 'apparatus' found in comparison with other languages versions. The CJEU stated that 'that [single language addition] cannot confer upon that linguistic version a wider meaning that that implied by the other versions which do not contain that word'.[63] Since that ruling, the CJEU has been consistent in decisions on linguistic divergences, not only in EU SoHO cases.[64] In *Léger*, concerning the requirements of blood donation,[65] the CJEU acknowledged a divergence between the various versions of the relevant legislative text, Directive 2004/33.[66] The French version provides for the same level of risk while other language versions distinguished the levels of risk according to the type of temporary or permanent deferral from blood donation. Relying on its settled case-law highlighting that 'the provision in question must be interpreted by reference to the purpose and general scheme of the rules of which it forms part',[67] the CJEU assessed these linguistic divergences on the grounds of the general structure of the Directive in question, within which it observes a distinction of intensity between permanent and temporary deferral 'for which, logically, the applicable criteria must be different'.[68] The CJEU's case law on linguistic divergences has become more precise, directing the interpretation to the general scheme of the rules of the text, which is an orientation conducive to significant material defragmentation. In the context of a field of law like SoHO, where technical concepts are at play, this is an important vector of European integration.

Second, we can understand as material defragmentation instances where the CJEU creates new or relies on existing independent concepts of Union law, going beyond the letter of the text to provide for a common Union law interpretation. Among the Union SoHO cases, the first area where independent concepts are almost systematically recognised and mobilised is VAT, where

62 Regulation (EEC) 1798/75 of the Council of 10 July 1975 on the importation free of Common Customs Tariff duties of educational, scientific and cultural materials [1975] OJ L184/1.

63 C-45/83 *Ludwig-Maximilians-Universität München*, *supra* note 15.

64 C-372/88, *Milk Marketing Board of England and Wales v. Cricket St. Thomas Estate* [1990] ECLI:EU:C:1990:140, paras 18-19; C-558/11, *SIA Kurcums Metal v. Valsts ieņēmumu dienests* [2012] ECLI:EU:C:2012:721, para. 48; C-307/13, *Lars Ivansson and Others* [2014] ECLI:EU:C:2014:2058, para. 40.

65 C-528/13 *Geoffrey Léger, supra* note 15.

66 Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components [2004] OJ L91/25.

67 C-528/13 *Geoffrey Léger*, *supra* note, 15 para. 35.

68 C-528/13 *Geoffrey Léger*, *supra* note, 15 para. 36.

according to its settled case law,[69] the CJEU has recalled that 'VAT exemptions' constitute 'independent concepts of European Union law whose purpose is to avoid divergences in the application of the VAT system from one Member State to another'.[70] Thus, 'the terms of a provision [...] which does not contain any express reference to the law of the Member States for the purpose of determining its meaning and scope must normally be given an independent and uniform interpretation throughout the Union'.[71] The second area where the recognition of independent concepts of Union law pervades is the patentability of inventions based on human embryonic stem cells. In *Brüstle*[72] and *International Stem Cell Corporation*,[73] the CJEU states that the 'human embryo' is an independent concept of Union law and defines it in order to clarify the extent of the exclusion of patentability of the 'uses of human embryos for industrial or commercial purposes'.[74] The Union level definition of the 'human embryo' is a powerful means of limiting the margin of appreciation of the Member States[75] despite the recognition that 'the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems'.[76]

Third, and relatedly, material defragmentation occurs where the CJEU clarifies the *use* of a concept of Union law, whether more general or more specific. In 2005, the CJEU considered that 'a state of uncertainty remains as to whether it is possible to obtain protection for biotechnological inventions under Italian patent law',[77] although Italy had argued that the term 'industrial invention'

69 The link between the existence of independent concepts and the avoidance of divergences is a classic position of the CJEU in matters of VAT which can be traced back at least to 1989 (C-348/87, *Stichting Uitvoering Financiële Acties v. Staatssecretaris van Financiën* [1989] ECLI:EU:C:1989:246, para. 11).

70 C-237/09 *Belgian State v. Nathalie De Fruytier*, *supra* note 15, para. 21; C-262/08 *CopyGene*, *supra* note 15 para. 24; C-86/09 *Future Health Technologies*, *supra* note 15,, para. 28; C-412/15 *TMD Gesellschaft für transfusionsmedizinische Dienste*, *supra* note 15 para. 24.

71 C-237/09 *Belgian State v. Nathalie De Fruytier*, *supra* note 15 para. 21.

72 C-34/10 *Oliver Brüstle*, *supra* note 15.

73 C-364/13 *International Stem Cell Corporation*, *supra* note 15.

74 Directive 98/44, *supra* note 3, Article 6.2c.

75 It should be underlined that a reversal occurred from the *Brüstle* case of 2011 insofar as the Court significantly restricted the scope of the concept of human embryo, through the new criterion of 'the inherent capacity of developing into a human being' (para. 28) on the basis of the 'current scientific knowledge' (para. 33) in *International Stem Cell Corporation* case of 2014. C-364/13 *International Stem Cell Corporation*, *supra* note 12.

76 C-34/10 *Oliver Brüstle*, *supra* note 15, para. 30.

77 C-456/03 *Commission of the European Communities v. Italian Republic*, *supra* note 14 para. 73.

was 'broad enough to include biological material'.[78] The CJEU held that the Patentability Directive imposes on Member States an obligation 'to provide that their national law does not preclude the patentability of elements isolated from the human body [...]'.[79] The requirement that national law 'does not preclude' the patentability of elements isolated from the human body constitutes a material defragmentation: the CJEU ensures that the scope of the Patentability Directive[80] remains broad enough to cover 'biological material'. The power of the legal concept of 'biological material' should be underlined here. It relies on its centripetal force, which encompasses and transcends the boundaries between human and non-human and between natural and artificial, and indeed avoids the need to define these in Union law. Thus, the CJEU has reinforced the material defragmentation that had begun with the Patentability Directive.[81]

In a different vein, the Court has used the broad Union 'principle of fiscal neutrality'[82] to protect the intended effects of the more specific independent concepts of Union law of VAT exemptions as above mentioned. The latter must be strictly interpreted, and among the SoHO cases, the CJEU has clarified the following terms: 'duly recognised establishment',[83] 'supply',[84] 'hospital and medical care and closely related activities',[85] and 'provision of medical care'[86]. For example, regarding granting the status of 'duly recognised establishment', i.e. VAT exemption, to a private stem cell bank, which receives no public aid, and whose services include the collection, transport, analysis and storage of umbilical cord blood, the CJEU has considered 'it is for the competent authorities to observe the limits of the discretion conferred upon them by the latter

78 *Ibid.*, para. 55.
79 *Ibid.*, para. 70.
80 Directive 98/44/EC, *supra* note 3.
81 *Ibid.*
82 This principle is to be considered from the consumer's point of view: 'the principle of fiscal neutrality must be interpreted as meaning that a difference in treatment for the purposes of VAT of two supplies of services which are identical or similar from the point of view of the consumer and meet the same needs of the consumer is sufficient to establish an infringement of that principle. Such an infringement thus does not require in addition that the actual existence of competition between the services in question or distortion of competition because of such difference in treatment be established.' Joined cases C-259/10 and C-260/10 *Commissioners for Her Majesty's Revenue and Customs v. The Rank Group plc.* [2011] ECLI:EU:C:2011:719, para. 36.
83 C-262/08 *CopyGene*, *supra* note 15.
84 C-237/09 *Belgian State v. Nathalie De Fruytier*, *supra* note 15.
85 C-86/09 *Future Health Technologies*, *supra* note 15.
86 *Ibid.*

provision in applying the principles of European Union law, in particular the principle of equal treatment which, in the field of VAT, takes the form of the principle of fiscal neutrality'.[87] In that context, it has guided the national court as follows:

> To that end, it would be appropriate to take into consideration, for example, established administrative practice and other practices adopted as regards the status of paramedical establishments and exemptions from VAT in sectors comparable to that in question in the main proceedings.[88]

This example, which we understand here as material defragmentation, also echoes the normative defragmentation inherent in the CJEU's approach to the preliminary reference procedure, discussed above.

Fourth, and this time related to normative *fragmentation*, we can understand instances of the CJEU's refusal to permit fragmentation as material defragmentation. In *Nathalie De Fruytier*, the CJEU asserts that the Oviedo Convention's 'Prohibition of financial gain' — establishing that 'the human body and its parts are not, as such, to give rise to financial gain'[89] — is not sufficient to allow different interpretations or applications of the VAT Directive (material fragmentation) in different Member States.[90] The double negative here means material defragmentation through the refusal to permit fragmentation in the context of the VAT Directives.

Finally, when we focus on the *result* of the judgment and not on the reasoning, material defragmentation occurs where the practical effect of a CJEU judgment is no flexibility for national courts when interpreting or applying Union law. The CJEU has established that materials playing 'a purely passive role in the research process',[91] or that the plasma 'intended to be used, not for direct therapeutic purposes, but exclusively for the manufacture of medicinal products'[92] are not exempted from VAT duties. The CJEU has also acknowledged the *possibility* for national differences, but its final decision does not permit them. In the action for annulment brought by the Netherlands against the Patentability Directive, the CJEU specifies that Article 6 of the Directive 'allows

87 C-262/08 *CopyGene*, *supra* note 15 para. 64 referring to C-45/01 *Christoph-Dornier-Stiftung für Klinische Psychologie v. Finanzamt Gießen* [2003] ECLI:EU:C:2003:595, and C-106/05 *L.u.P. GmbH v. Finanzamt Bochum-Mitte* [2006] ECLI:EU:C:2006:380.

88 C-262/08 *CopyGene*, *supra* note 15, para. 79.

89 Oviedo Convention, *supra* note 58, Article 21.

90 C-237/09 *Belgian State v. Nathalie De Fruytier*, *supra* note 15, para. 27.

91 C-45/83 *Ludwig-Maximilians-Universität München*, *supra* note 15, para. 11.

92 C-412/15 *TMD Gesellschaft für transfusionsmedizinische Dienste*, *supra* note 15, para. 40.

the administrative authorities and courts of the Member States a wide scope for manoeuvre in applying' the exclusion from patentability 'of inventions whose commercial exploitation would be contrary to *ordre public* or morality'.[93] But, if this scope for manoeuvre does exist, it is 'not discretionary, since the Directive limits the concepts in question, both by stating that commercial exploitation is not to be deemed to be contrary to *ordre public* or morality merely because it is prohibited by law or regulation, and by giving four examples of processes or uses which are not patentable'.[94] The Netherlands was unsuccessful in its challenge. Finally, in both *Humanplasma*[95] and *Medisanus*,[96] the CJEU followed its classical reasoning on the free movement of goods and potentially lawful exceptions. But, as outlined above, the CJEU removed discretion from national courts by specifying all steps, and deeming the final one, the proportionality test, not met.[97]

6 Material fragmentation

Finally, we can make sense of instances where, in contrast to material defragmentation where the result of the CJEU's judgment does not allow national differences, the *reasoning* of the CJEU may acknowledge the possibility for national discretion. In some instances, this extends also to the result. Indeed, in several EU SoHO cases, the CJEU has permitted to some extent national flexibility in the implementation of Union law. But mostly this possibility — although we understand it as fragmentation — has been limited or very limited.

In *Octopharma*, the CJEU first used, in its reasoning, a material fragmentation flowing from the existence of two different Directives with distinct legal bases.[98] The CJEU held that the maintenance or introduction of stricter national rules was only possible for the collection and control of the 'plasma

93 C-377/98 *Kingdom of the Netherlands v. European Parliament and Council*, *supra* note 14, para. 37.

94 *Ibid*., para. 39.

95 C-421/09 *Humanplasma*, *supra* note 15.

96 C-296/15 *Medisanus*, *supra* note 15.

97 C-421/09 *Humanplasma*, *supra* note 1,5 para. 45, and C-296/15 *Medisanus*, *supra* note 15, para. 98.

98 The legal basis of the Medicines Directive is the internal market (Article 114 TFEU) while it is public health for the Blood Directive (Article 168 TFEU).

SD'[99] at issue (matters within the scope of the Blood Directive)[100], and not for its processing, storage, or distribution (matters within the scope of the Medicines Directive).[101] We can also understand the result as a material fragmentation, given that it was a matter for the referring national court to determine if the 'plasma SD' met the conditions to be classified as a medicinal product.[102] Nevertheless, given the broad definition of medicinal products in Union law,[103] it would have been almost impossible for the referring national court to decide that 'plasma SD' was not a medicine. The French National Court thus subsequently ruled that plasma SD must be classified as a medicinal product.[104] The CJEU has confirmed the possibility for a Member State to maintain or introduce stricter national provisions for the collection and control (only) of plasma SD.[105]

In *Léger* case,[106] there is also very little discretion at the national level. On the basis of the margin of discretion granted to the Member States in the application of the provision at issue,[107] the CJEU held that it is for the referring court to ascertain whether, in the light of current medical, scientific and epidemiological knowledge, the data supplied by the French Institute for Public Health Surveillance were reliable and still relevant.[108] It is also for the referring court to determine whether the limitation at issue respects the principle of proportionality, as long as the CJEU has already established that the limitation is provided by law,[109] respects the essential contents of the principle of

99 '[P]lasma prepared by means of an industrial process such as, inter alia, fresh frozen plasma, leucocyte-reduced, virus-inactivated by solvent-detergent', C-512/12 *Octapharma*, *supra* note 15, para. 2.

100 Directive 2002/98/EC, *supra* note 3.

101 Directive 2001/83/EC, *supra* note 3; C-512/12 *Octapharma*, *supra* note 15, para. 43.

102 C-512/12 *Octapharma*, *supra* note 15, para. 39.

103 *See* A. Mahalatchimy and T. Hervey, 'Medicines', in: S. Garben and L. Gormley (eds), *Oxford Encyclopaedia of EU Law* (Oxford: Oxford University Press, 2025), available at https://opil.ouplaw.com/display/10.1093/law-oeeul/law-oeeul-e231?rskey=Tj51nj&result=3&prd=OEEUL.

104 Conseil d'Etat, 23 July 2014, ECLI:FR:CESSR:2014:349717.20140723.

105 C-512/12 *Octapharma*, *supra* note 15, para. 46.

106 C-528/13 *Geoffrey Léger*, *supra* note 15.

107 'The expression "persons whose sexual behaviour puts them at risk" of acquiring infectious diseases used in point 2.1 of Annex III to Directive 2004/33 does not precisely determine the persons or categories of persons concerned by that deferral, which leaves a margin of discretion to the Member States in the application of that provision'. C-528/13 *Geoffrey Léger*, *supra* note 15, para. 39.

108 C-528/13 *Geoffrey Léger*, *supra* note 15, paras 42–44.

109 C-528/13 *Geoffrey Léger*, supra note 15, para. 53.

non-discrimination,[110] and meets the objective of general interest of ensuring a high level of human health protection recognised by Union law.[111] The CJEU even guides the referring court in its determination of the proportionality principle, holding that

> if effective techniques for detecting severe diseases that can be transmitted by blood or, in the absence of such techniques, less onerous methods than the permanent deferral of blood donation for the entire group of men who have had sexual relations with other men ensure a high level of health protection to recipients, such a permanent contraindication would not respect the principle of proportionality.[112]

National discretion for the referring court exists in principle but is also quite limited in *Future Health Technologies* because the possibility to exempt analysis of umbilical cord blood from VAT is limited to the fact that 'such analysis were actually intended to enable a medical diagnosis to be made, which it is for the referring court, if need be, to determine'.[113]

Somewhat more national discretion is given in *Ludwig-Maximilians-Universität*, as the CJEU's interpretation of the VAT exemption provision neither 'preclude[s] the national authorities from deciding that' a private stem cell bank cannot be considered as an 'other duly recognised establishment[s] of a similar nature' to 'hospitals [and] centres for medical care or diagnosis', nor 'requir[es], as such, the competent authorities to refuse to treat a private stem cell bank' as such an establishment for the purposes of the VAT exemption.[114] However, such national discretion is tempered by the requirement of compliance with the Union principle of fiscal neutrality as mentioned above.

The greater extent given to national flexibility — understood as material fragmentation — is found in the qualifications of persons responsible for a blood establishment at issue in *Ordine Nazionale dei Biologi*.[115] The CJEU's convoluted reasoning here begins from the flexibility recognised to the Member States in a negative sentence of primary law expressly reproduced in secondary

110 C-528/13 *Geoffrey Léger*, *supra* note 15, para. 54.
111 C-528/13 *Geoffrey Léger*, *supra* note 15, para. 57.
112 C-528/13 *Geoffrey Léger*, *supra* note 15, para. 68.
113 C-86/09 *Future Health Technologies*, *supra* note 15, para. 47.
114 C-262/08 *CopyGene*, *supra* note 15, para. 81.
115 C-96/20 *Ordine Nazionale dei Biologi*, *supra* note 15.

law.[116] Apart from ruling that the provision at issue is a stricter protective measure,[117] in this instance, the CJEU defers to the national court all the steps of its reasoning: whether the measure at issue is meeting the objective of ensuring a high level of protection of human health,[118] whether it is 'an inappropriate measure' to achieve this objective (although in this instance, it seems the CJEU thinks not),[119] and whether 'blood establishments constitute, in Italy, services forming part of the national health system' in accordance with Article 168(7) TFEU (although it seems the CJEU thinks they are).[120] The CJEU even adds an

116 'Article 168(4)(a) TFEU provides that the Member States cannot be prevented from maintaining or introducing more stringent protective measures, since that provision is expressly reproduced in Article 4(2) of Directive 2002/98', C-96/20 *Ordine Nazionale dei Biologi*, *supra* note 15, para. 22.

117 'In the present case, the question arises as to whether the national provision at issue in the main proceedings, in so far as it allows only graduates in medicine and in surgery to be appointed to the position of responsible person of a blood establishment, may be considered a "more stringent protective measure", within the meaning of the first subparagraph of Article 4(2) of Directive 2002/98, as compared with that laid down in Article 9(2) of that directive. *That question must be answered in the affirmative.*' C-96/20 *Ordine Nazionale dei Biologi*, *supra* note 15, paras 23–24 (emphasis added).

118 'However, according to the Italian Government and *subject to verification by the referring court*, the fact remains that the objective pursued by the national provision at issue in the main proceedings, relating to the fact that qualification as a doctor is likely to further enable the responsible person to perform his or her duties fully and effectively so far as concerns all the activities of blood establishments, including those of a purely medical nature, is consistent with the objective of Directive 2002/98 which consists, in accordance with Article 1 thereof, in setting quality and safety standards for human blood and blood components in order to ensure a high level of protection of human health and the national provision at issue in the main proceedings is thus likely, as a stricter protective measure, to further guarantee that that objective is actually met'. C-96/20 *Ordine Nazionale dei Biologi*, *supra* note 15, para. 34 (emphasis added).

119 'In the light of the documents provided to the Court and *subject to verification by the referring court*, it *does not appear*, having regard also to the discretion granted to the Member States, referred to in the preceding paragraph, that the national provision at issue in the main proceedings may be considered an inappropriate measure to achieve the objective of enhanced protection of the protection of human health which it pursues in the field of quality and safety standards for human blood and blood components.' C-96/20 *Ordine Nazionale dei Biologi*, *supra* note 15, para. 37 (emphasis added).

120 'Moreover, the compatibility of the national provision at issue in the main proceedings with EU law *seems to be supported by the fact*, noted by the Italian Government and *which is also for the referring court to ascertain*, that blood establishments constitute, in Italy, services forming part of the national health system, from which it follows that that provision falls under the responsibilities incumbent on the Member States pursuant to Article 168(7) TFEU so far as concerns the definition of their health policy and the organisation and provision of health services and medical care, which include the management

additional aspect to be defined by the host Member State in its national legislation: 'the field of activities covered by the profession of biologist'.[121]

Finally, we can understand as material fragmentation instances where the CJEU distinguishes national law concepts from Union law concepts. The CJEU has thus clarified which items,[122] activities closely related to hospital or medical care,[123] and intended use of plasma[124] fall or do not fall within the Union VAT exemptions.

7 Conclusions

It is crucial for lawyers, policy-makers, healthcare professionals/providers and patients to understand the dynamics of Union SoHO law. The new Union legislation is the latest stage in an unfolding process driven by interactions between institutions at Union and national levels, including courts. We have shown that the concept of European integration based on the idea of harmonisation is limited in providing an explanatory account of the dynamics of Union SoHO law, especially when focusing on the role of the CJEU. The granular investigation of the reasoning and result of the CJEU's case law in the 19 cases that embody Union SoHO case law at present, offered in our analysis in this article,

---

of such services and the allocation of the resources assigned to them.' C-96/20 *Ordine Nazionale dei Biologi*, *supra* note 15, para. 38 (emphasis added).

121 'It is *for the national legislation of the host Member State to define* the field of activities covered by the profession of biologist and it is only if, under that legislation, an activity is regarded by that Member State as falling within that field that the requirement of mutual recognition means that migrant biologists must also be able to pursue that activity'. C-96/20 *Ordine Nazionale dei Biologi*, *supra* note 15, para. 44 (emphasis added).

122 '[I]tems which , by virtue of their particular technical structure and functioning , themselves serve directly as a means of scientific research' are exempted from customs duties, while 'an item which is used not as a means but only as an object of scientific research cannot be described as a scientific instrument or apparatus ; indeed , where research is carried out not by means of that item but on it , the item plays only a purely passive role in the research process' is not exempted. C-45/83 *Ludwig-Maximilians-Universität München*, *supra* note 15, paras 10–11.

123 'Services which are logically part of the provision of hospital and medical-care services, and which constitute an indispensable stage in the process of the supply of those services to achieve their therapeutic objectives' are covered by the exemption, while activities that 'are merely potentially related' to 'the medical care provided in a hospital environment' which 'has not been performed, commenced or yet envisaged' are not. C-262/08 *CopyGene*, *supra* note 15, paras 40 and 52.

124 Plasma intended for direct healthcare or therapeutic use is covered by the VAT exemption, while the plasma used 'solely for pharmaceutical purposes' is not. C-412/15 TMD *Gesellschaft für transfusionsmedizinische Dienste*, *supra* note 15, paras 33–38.

shows that the idea that the Union and its courts move SoHO law inexorably and unidirectionally towards greater Europeanisation is much too simplistic.

Therefore, we offer a novel model, based on the concepts of normative and material defragmentation and fragmentation. We have shown that the CJEU's case law not only moves Union SoHO law in the direction of greater standardisation at Union level (normative and material defragmentation), but also that the case law at times and in some instances allows for greater and sometimes lesser, but still available, national flexibility (normative and material fragmentation). We have outlined the principal mechanisms and methods through which the CJEU reaches these positions, situating our analysis in a deep and careful reading of the case law. The CJEU uses a range of approaches from more to less recognition of, and legal space for, national preferences, which we see on a continuum. Where the CJEU offers more national discretion, this is more readily recognised as fragmentation; the converse is true for defragmentation. In the middle of the continuum, it is more difficult to see how our model offers a clear explanatory frame, but it is inherent in the nature of models that they help to make sense of the world, in all its complexities, by simplifying to some extent that which is not simple.

Rather than an inexorable flow to greater Union-level standardisation, our analysis reveals an ebb and flow over time of both defragmentation and fragmentation. These concepts go beyond 'harmonisation' (a legal tool for creating Union law), to provide an explanatory model as a tool of legal science to use to promote greater understanding of Union law, not only in the context of SoHO law.

Funding

This work has been supported by the French National Agency for Research (ANR) ANR-funded I-BioLex project (ANR-20-CE26-0007-01).