



ARTICLES

REFORM OF EPIDEMIC SURVEILLANCE EXPOSING “STANDARDISING” DECISIONS AND THEIR REPLACEMENTS BY REGULATIONS

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ABSTRACT: The reform of epidemic surveillance in the European Union as a reaction to the Covid-19 pandemic attracts attention to one sporadically discussed phenomenon. Following the usual meaning of this term in legal settings, many decisions address individual cases. Nevertheless, a new category of decisions establishing rules has emerged in the past decades, *i.e.* “standardising” (“normative”, “norm-setting”, or “general”) decisions. These decisions have addressed the cooperation between the EU and national authorities, funding programmes and assistance to foreign countries. The European Parliament and the Council approved them. Theoretical reflections on these decisions are rare, but their pitfalls are identifiable. Namely, their possible effects on individuals are limited. The definition of unaddressed decisions provided by the Lisbon Treaty did not clarify the situation. Therefore, the recent tendency to replace these decisions with regulations deserves attention.

KEYWORDS: European Union – secondary law – decision – regulation – law-making – official languages.

I. INTRODUCTION

The following *Article* extends the research on replacing directives with regulations within the framework of the EU law.¹ Several regulations also replace decisions. Unlike

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¹ F Křepelka, 'Transformations of Directives into Regulations: Towards a More Uniform Administrative Law?' (2021) EPL 781.



directives, this instrument of secondary law has received only limited attention. Reform of the epidemic surveillance in the European Union provides an incentive to examine *decisions-legislative acts* adopted by the European Parliament and the Council, or by the Council, providing for cooperation, spending programmes or other general standards.

The conceptualisation of the *Article* reflects this intent. Replacing decisions addressing cross-border threats to health with a regulation (section II) results in re-examining the existing knowledge about decisions (section III), which reveals exciting language aspects (section IV). The identified complexity of decisions (section V) deserves a comparative perspective (section VI), resulting in distinguishing decisions stipulating rules and standards from other decisions (section VII). The decisions addressing all Member States or without addressees require critical scrutiny regarding their legal effects (section VIII). Their transformations into regulations (section IX), their evaluation (section X) and the perspective and limits of this trend (section XI) resulted in considerations about the possible reform of founding treaties concerning secondary law instruments (section XII).

In this way, this *Article* contributes to *Rechtsdogmatik*, *i.e.* the doctrine of “standardising” decisions as a subtype of the third secondary law instrument. This research is becoming retrospective. The European Union increasingly resorts to regulations to address agendas previously addressed by decisions. Therefore, this *Rechtspolitik* also deserves our evaluation.

Extended citations of discussed acts emerge in footnotes. Namely, mentioning their pages in the Official Journal indicates the tendency towards increasingly detailed frameworks.

II. REFORM OF EPIDEMIC SURVEILLANCE

Regulation 2022/2371 on serious cross-border threats to health (SCBTHR)² has recently replaced the homonymous 2013 Decision (SCBTHD).³

Strengthening the Member States' cooperation regarding epidemics and other similar threats, this regulation is the keystone of the European Health Union as a long-term reaction to the Covid-19 pandemic. It is noteworthy that its components are regulations.⁴ Demands for improving cooperation and coordination among public health authorities resulting in an adequate assessment of infections was an expectable reaction to the crisis.

² Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision 1082/2013/EU. SCBTHR has applied (art. 35) since 26 December 2022.

³ Decision 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health, repealing Decision 2119/98/EC.

⁴ The already adopted Regulation 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, and Regulation of the European Parliament and of the Council of 23 November 2022 amending Regulation 851/2004 establishing a European Centre for disease prevention and control; and proposal for a Regulation COM/2022/197 final of the European Parliament and of the Council of 3 May 2022 on the European Health Data Space.

Similar views also prevailed in the World Health Organization (WHO). The Member States have begun negotiating a treaty on pandemic preparedness,⁵ intended to replace the existing International Health Regulations (IHR).⁶ Contrary to the past, the European Union participates in these negotiations.⁷

Unsurprisingly, the interest in this issue diminished with the retreat of the Covid-19 in 2022. The Russian invasion of Ukraine and skyrocketing energy prices started new crises. Despite this ensuing deprioritisation, the EU lawmakers completed the task. The momentum in the twenty-four months of deliberations on the initial proposal⁸ of this regulation was the compromise the European Parliament, the Council, and the Commission achieved in June 2022,⁹ while the final vote in the Council was quasi-unanimous.¹⁰

In the first place, SCBTHR specifies the planning of preparedness for public health,¹¹ coordinates cooperation on a global scale, specifies epidemic surveillance and establishes a warning and response system.¹² The Commission can proclaim public health emergency at the EU level,¹³ with repercussions for controlling medical stocks.

SCBTHR established a health security committee composed of national representatives and an advisory committee of distinguished experts.¹⁴ Concurrently, the Commission has institutionalised its increased political attention to the issue with the Health Emergency Preparedness and Response Authority (HERA) as a specific directorate-general.¹⁵

⁵ World Health Organization: the World Health Assembly kick-started the negotiation on an instrument on its session 29.11.-1. 12. 2021, establishing the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, for developments see dedicated web pages inb.who.int.

⁶ *Ibid.* The World Health Assembly adopted existing International Sanitary Regulations in 1951, renamed to International Health Regulations in 1969 and revised last in 2005.

⁷ Decision 2022/451 of the Council of 3 March 2022 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the IHR (2005).

⁸ Proposal for a Regulation COM(2020) 727 final of the European Parliament and the Council of 11 November 2020 on serious cross-border threats to health and repealing Decision 1082/2013/EU, for deliberations, see “Procedure” in EUR-Lex.

⁹ See Document ST 10925 2022 - Letter to the Chair of the European Parliament Committee on the Environment, Public Health and Food Safety, reflecting the compromise in COREPER achieved 29 June 2022, available at eur-lex.europa.eu.

¹⁰ Bulgaria abstained in the Council of EU 3903rd meeting on 24 October 2022. There is no information about its reasons.

¹¹ Arts 5-11 SCBTHR.

¹² Arts 13-14 SCBTHR.

¹³ Art. 23 SCBTHR.

¹⁴ Arts 4 and 24 SCBTHR.

¹⁵ Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02, C/2021/6712.

SCBTHR is twice as long as SCBTHD because its detailed provisions introduce more elaborate plans and procedures. Nevertheless, it is not a revolutionary change. Though the official correlation table exposes differences, it confirms continuity.¹⁶

The choice of instrument has become a part of the explanatory memoranda for the proposals. Regarding SCBTHR, it says: "The proposal takes the form of a new Regulation. This is considered to be the most suitable instrument as a key element of the proposal is to establish procedures and structures for cooperation on joint, EU-level work focussing on preparedness for and response to serious cross-border threats to health. The measures do not require the implementation of national measures and can be directly applicable".¹⁷

Explanatory memoranda accompanying proposals of regulations replacing directives claim that divergent transpositions by the Member States cause inefficiency and complexity. Therefore, a uniform framework should replace them.¹⁸ As far as decisions are concerned, the explanation could be better. The explanatory memorandum for SCBTHR contains no critical scrutiny of this instrument.

The explanatory memorandum for SCBTHD lacked the "choice of the instrument". The Commission added it in the accompanying "Impact Assessment", but it solely mentioned¹⁹ the then-existing instrument, the 1998 Decision.²⁰ Unfortunately, the preparatory documents accompanying the proposal of this decision are unavailable. We thus cannot learn about arguments for this instrument.

The developing competence provisions could explain the instrument change because several specify the instrument.²¹ Nevertheless, SCBTHD, adopted in 2011-2013, relied on the same competence provision 168(5) TFEU. It is not a new competence that enables this instrument. The first decision already relied on the then art. 129 TEC (renumbered art. 152

¹⁶ Annex II SCBTHR.

¹⁷ Proposal COM/2020/727 final for a Regulation of the European Parliament and of the Council of 11 November 2020 on serious cross-border threats to health and repealing Decision No 1082/2013/EU Choice of the instrument (pages not indicated).

¹⁸ F Křepelka, 'Transformations of Directives into Regulations' cit. 793.

¹⁹ See Commission Staff Working Paper SEC(2011) 1519 final, 'Impact Assessment Accompanying the Proposal: Serious Cross-Border Threats to Health' (8 December 2011) 28 (principle of proportionality and choice of instrument).

²⁰ Decision 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community.

²¹ For the discussion the role of competences and recent legislative trends in the EU, see A Engel, *The Choice of Legal Basis for Acts of the European Union* (Springer 2018), for a critical assessment of regulations instead of directives, see N Wunderlich, T Pickartz, 'Hat die Richtlinie ausgedient? Zur Wahl der Handlungsform nach Art. 296 Abs. 1(6) AEUV' (2014) *Europarecht* 659. T van den Brink, 'The Impact of EU Legislation on National Legal Systems: Towards a new Approach to EU – Member State Relations' (2017) *CYELS* 211; or F Rösch, *Zur Rechtsformenwahl des europäischen Gesetzgebers im Lichte des Verhältnismäßigkeitsgrundsatzes. Von der Richtlinie zur Verordnung. Exemplifiziert anhand des Lebensmittelrechts und des Pflanzenschutzmittelrechts* (Duncker & Humblot 2013).

by the Amsterdam Treaty) defining European Community/European Union's and Member States' roles in healthcare.²²

This 1998 Decision was the first EC/EU standard addressing the issue. Nonetheless, the Member States had already cooperated according to the then-applicable International Health / Sanitary Regulations of the World Health Organization.

Both SCBTHD and SCBTHR result from ordinary legislative procedure. The European Parliament and the Council approved the 1998 Decision already in the co-decision procedure as its predecessor.

III. LIMITED ATTENTION TO DECISIONS

SCBTHD and SCBTHR show that two secondary law instruments may establish the cooperation of the Member States on an identical agenda. Nobody questions a regulation as the recent choice of instrument. The feasibility of a decision as the previous instrument is an issue. For this purpose, we refresh our knowledge about decisions as the third secondary law instrument.

The citation of art. 288(4) TFEU defining decisions is instrumental for this task: “[a] decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them”. SCBTHD belongs to the latter definition, as EU lawmakers addressed it to the Member States. As the European Parliament and the Council adopted it in the ordinary legislative procedure, it was a “legislative act”.²³

Complex doctrines have developed to address the implementation of directives, their shortcomings, and their consideration in national law. Even German scholars writing extensive commentaries admit that *ausufernde Rechtsdogmatik*, i.e. an overcomplex doctrine, has emerged.²⁴ Regulations enjoy significantly less attention. Their direct effect on individuals makes them standard legislation.

Nonetheless, decisions as the third secondary law instrument have always been even behind regulations. Extensive commentaries on the founding treaties, such as the 2019 Oxford Commentary by Manuel Kellerbauer, Marcus Klammert and Jonathan Tomkin et

²² See the recent formulation of art. 168(5) TFEU: “[t]he European Parliament and the Council, acting in accordance with the ordinary legislative procedure [...], may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, [...], excluding any harmonisation of the laws and regulations of the Member States”.

²³ Art. 289(4) TFEU.

²⁴ See C Callies and M Ruffert (eds), *EUV AEUV mit Europäischer Grundrechtecharta. Kommentar* (C. H. Beck 2016) 2467, also the criticism I Ward, *A Critical Introduction to European Law* (Cambridge University Press 2009, 3 edn) 60.

al.²⁵ and 2016 C. H. Beck by Christian Calliess and Matthias Ruffert,²⁶ dedicate only one page to them. Considering these commentaries summarising the existing knowledge of EC/EU decisions, the following pages mention their authors: Marcus Klammert, Paul-John Loewenthal²⁷ and Matthias Ruffert. Among textbooks, that of Rudolf Streinz, having two pages in this respect,²⁸ deserves attention.

Monographs and articles addressing EU decisions as the third secondary law instrument are rare. There is no treatise in English for the international readership. Three German monographs deserve attention, the first by Andrea Bockey in 1998,²⁹ the second by Matthias Vogt in 2005,³⁰ and the third by Jürgen Bast in 2006.³¹ In addition, one should not omit the seminal article by Ulrich Stelkens in 2005.³² The interest in decisions culminated two decades ago, *i.e.* before the Lisbon Treaty.

We will resort to these authors in the following sections. Let us start by reiterating common knowledge. Unsurprisingly, the post-Lisbon texts emphasise the recognition of unaddressed decisions by the Lisbon Treaty and their differentiation from the addressed ones as the previous version expected addressed decisions.³³ Klammert and Loewenthal refer to several judgments specifying the effects of this instrument, namely, *Grad* establishing the right of individuals to invoke decisions addressed to the Member State,³⁴ *Hansa Fleisch* reiterating the prescribed deadline in this regard,³⁵ and *Albako* enabling invocation towards their private addressees, *i.e.* horizontal effect.³⁶ In addition, Ruffert outlines the discussion of German scholars about the types of decisions and the evolution of this instrument. Mentioning *Grad*, Streinz critically examines both addressed and unaddressed decisions.

²⁵ M Klammert and J Tomkin (eds), *EU Treaties and the Charter of Fundamental Rights. A Commentary* (Oxford University Press 2019).

²⁶ C Calliess and M Ruffert (eds), *EUV AEUV mit Europäischer Grundrechtecharta* cit. 2437-8.

²⁷ M Klammert, PJ Loewenthal, 'Art. 288 - Decision' in M Kellerbauer, M Klammert and J Tomkin (eds), *EU Treaties and the Charter of Fundamental Rights* cit. 1897; and M Ruffert, 'Art. 288 - Entscheidungen' in C Calliess, M Ruffert (eds), *EUV AEUV mit Europäischer Grundrechtecharta* cit. 2437.

²⁸ R Streinz, *Europarecht* (C. F. Müller 2016, 10th edn) 183-184.

²⁹ A Bockey, *Die Entscheidung der Europäischen Gemeinschaft* (Peter Lang 1998).

³⁰ M Vogt, *Die Entscheidung als Handlungsform der Europäischen Gemeinschaftsrechts* (Mohr Siebeck 2005).

³¹ J Bast, *Grundbegriffe der Handlungsformen der EU: entwickelt am Beschluss als praxisgenerierter Handlungsform des Unions- und Gemeinschaftsrechts* (Springer-Verlag 2006).

³² U Stelkens, 'Die „Europäische Entscheidung“ als Handlungsform des direkten Unionsrechtsvollzugs nach dem Vertrag über eine Verfassung für Europa' (2005) *Zeitschrift für Europarechtliche Studien* 62.

³³ Unchanged art. 249(4) TEC and art. 188(4) TE(E)C: "A decision shall be binding in its entirety upon those to whom it is addressed".

³⁴ Case C-9-70 *F Grad v Finanzamt Traunstein* ECLI:EU:C:1970:78.

³⁵ Case C-156/91 *Hansa Fleisch v Landrat des Kreises Schleswig-Flensburg* ECLI:EU:C:1992:423.

³⁶ Case C-249/85 *Albako Margarinfabrik v Bundesanstalt für landwirtschaftliche Marktordnung* ECLI:EU:C:1987:245.

IV. LINGUISTIC DIMENSION

German literature addressing EC/EU decisions indicates an interesting linguistic dimension of this instrument. With the Lisbon Treaty, its German version switched from *Entscheidung* to *Beschluss* as their equivalent. Similar changes emerged in Danish with *beslutning* to *afgørelse*, in Dutch with *beschikking* to *besluit*, and in Slovenian with *odločba* to *sklep*.

This terminological change was not a correction of an outright translation error, as several previous reforms of primary law kept using *Entscheidung*. The Lisbon Treaty changed the provision addressing decisions, introducing the distinction between unaddressed and addressed.³⁷ The four language versions changed the words in the way mentioned above.

Publishing the proposal in EUR-Lex³⁸ indicates that the EU translation service assisted in the negotiations of the Lisbon Treaty and the Treaty establishing a Constitution for Europe. However, the founding treaties are also an issue for the Member States as the “masters of treaties”. Their ministries of foreign affairs, government offices or parliaments have their own translation and interpretation services or hire them.

Such asymmetric terminological change is unusual. Generally, countries agree on international treaties in their authentic versions. One may expect the concerned state(s) to engage primarily in clarifications in their version. Checking other versions could be necessary to avoid outright discrepancies. However, questioning nuances could be sensitive.

Such changes may reflect semantic shifts, but this case is different. Matthias Ruffert considers *Beschluss* as another instrument besides *Entscheidung*. His commentary does not provide examples, referring to Jürgen Bast identifying *Beschluss* as a homegrown phenomenon.³⁹ Nonetheless, Ulrich Stelkens found no explanation and thus considered this change a mistake.⁴⁰

Yet, this terminological differentiation has emerged in the German version already before. The Maastricht Treaty labelled the instruments for cooperation in judicial and police matters as *Beschluss* and *Rahmenbeschluss*.⁴¹ The decision in the catalogue of the (then) Treaty establishing a European (Economic) Community continued to be *Entscheidung*.

This similarity in Germanic languages (English *decision* is of Latin/Romance origin) in *Beschluss*, *besluit*, *beslutning*, plus the unchanged *beslut* in Swedish, is apparent. However,

³⁷ Point 235 of the Lisbon Treaty: art. 249 shall be amended as follows: *a)* the first paragraph shall be replaced by the following: “to exercise the Unions competences, the institutions shall adopt regulations, directives, decisions, recommendations and opinions”; *b)* the fourth paragraph shall be replaced by the following: “A decision shall be binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them”.

³⁸ Treaty of Lisbon [2007].

³⁹ M Ruffert, *EUV AEUV mit Europäischer Grundrechtecharta* cit. 2467 (Rn. 335).

⁴⁰ U Stelkens, ‘Die „Europäische Entscheidung“ als Handlungsform des direkten Unionsrechtsvollzugs nach dem Vertrag über eine Verfassung für Europa’ cit. 65.

⁴¹ Art. 34 TEU; see also W Schroeder, ‘Neues vom Rahmenbeschluss – ein verbindlicher Rechtsakt der EU’ (2007) *Europarecht* 349.

there are nuances, as Denmark shows by abandoning this word. Without access to scholarly literature in these languages and consulting national legal scholars, we could only speculate whether these countries followed Germany or whether their move was independent.

Focusing on English, French, and German is understandable, as politicians, officials, diplomats, experts and scholars use them. Scholarly reflections primarily appear in these *de facto* working languages. Additionally, scholars may prefer the older versions to be the original ones from a linguistic viewpoint. Significantly, Ruffert does not mention that most language versions did not follow suit, confirming that discussing the supranational legal system by national scholars and experts in their respective languages is separate and different.⁴²

Therefore, it is advisable to emphasise the European Union's legal multilingualism. The comparison of versions is desirable for compliance with the equality of EU official languages.⁴³ In this case, however, the changes in four versions cannot outweigh the other twenty versions. Besides English, the French version has retained *décision*. Therefore, this text does not need to devise equivalents for decision-*Entscheidung* and decision-*Beschluss*.

Finding that the German (plus Austrian) negotiators, possibly joined by their Danish, Dutch, and Slovenian colleagues, embraced distinguishing the decisions with two terms, but failed to convince others, would be the proof of the desirable striving for terminological clarity. Unfortunately, Stelkens did not confirm that. While lamenting that mixing the categories of decisions establishes an unduly differentiated phenomenon, Ruffert is responsive to this differentiation at least.⁴⁴

V. DIVERSITY AND INCIDENCE OF DECISIONS

Nonetheless, rich terminology often indicates complex reality. Indeed, EU decisions are diverse. When reading textbooks⁴⁵ or asking teachers for examples, students probably learn about the Commission's decisions on competition issues⁴⁶ and the Council's decisions in the Common Foreign and Security Policy (CFSP decisions).⁴⁷ SCBTHD would not fit this picture, as it specified cooperation in epidemic surveillance with general rules.

⁴² D Thym, 'Die Einsamkeit des deutschsprachigen Europarechts' (29 May 2014) *Verfassungsblog* verfassungsblog.de.

⁴³ Art. 55 TEU and Regulation 1/58 of 6 October 1958 determining the languages to be used by the European Economic Community, 385-386.

⁴⁴ M Ruffert, *EUV AEUV mit Europäischer Grundrechtecharta* cit. 2467.

⁴⁵ Streinz, *Europarecht* cit. 182-183.

⁴⁶ As specified by arts 7-10 of Regulation 1/2003 of the Council of 16 December 2002 on the implementation of the rules on competition laid down in arts 81 and 82 of the Treaty, 1-25. The frequent mentioning of "decisions by associations of undertakings" in the regulation and in art. 101 TFEU exemplifies the polysemous nature of the term in English and other languages (see section VI).

⁴⁷ Arts 28 and 29 TEU, for an analysis including the practice, see G Wessel, 'Resisting Legal Facts: Are CFSP Norms as Soft as They Seem?' (2015) *European Foreign Affairs Review* 123.

Both Mathias Ruffert and Marcus Klammert and Paul-John Loewenthal, respectively, give no lists expanding on the two categories, as they do not mention them in their commentaries of art. 288(4) TFEU. Ulrich Stelkens addresses this diversity with a classification developed on the German legal theory.⁴⁸ Unsurprisingly, Jürgen Bast examined many aspects of various decisions in his monograph but did not focus on categorisation.⁴⁹ Matthias Vogt was the only author who emphasised that several EU decisions go beyond administrative acts, cautiously appreciating this instrument as flexible.⁵⁰

The founding fathers conceived the Lisbon Treaty as saving the substance envisaged by the Treaty establishing a Constitution for Europe. Therefore, considering the latter document may improve our understanding of the issue. Unsurprisingly, an in-depth consideration of that barely started in several months between its signing in October 2004 and the negative results of the referenda in June 2005 and their assessment as the end of this reform. The planned commentaries became irrelevant.

Despite that, the basic conclusions are possible. The Treaty establishing a Constitution for Europe envisaged *European (framework) laws* instead of regulations and directives as legislative acts. Nonetheless, we focus on decisions here: “A European decision shall be a non-legislative act, binding in its entirety. A decision which specifies those to whom it is addressed shall be binding only on them”. The distinction should have been the same, but the Treaty stated that decisions would have been non-legislative acts. Addressing cross-border health threats would thus have been a decision or a legislative act. One could expect the latter solution to be adopted when considering the related competence provision.⁵¹

Mentioning that the European decision would have been a non-legislative act hints at the most notable change by the Lisbon Treaty concerning secondary law: distinguishing legislative acts and specifying the derived ones as implementing and delegated acts.⁵²

⁴⁸ U Stelkens, ‘Die „Europäische Entscheidung“ als Handlungsform des direkten Unionsrechtsvollzugs nach dem Vertrag über eine Verfassung für Europa’ cit. 74. The author differentiated “acts of government”, decisions related to supervision of the Member States, decisions enforcing EC law adopted by national authorities, decisions by the EC authorities with effects on private entities (competition) and decisions related to EC public servants.

⁴⁹ Among others, J Bast, *Grundbegriffe der Handlungsformen der EU* cit. pays attention to definitions and procedures, concluding that TEC does not exclude other instruments (Handlungsformen) (p 43). He pays attention to multilingualism (p 110), distinguishes private and public decisions-making (110), identifies *Beschluss* as result of deliberation (p 117), considers addressees and their absence, and analyses judicial control (p 67). To sum up, his opus magnum is mainly the theory of decision-making in the EC/EU based on German legal theory than an empirical scrutiny of the existing practices. Being published in 2006, this monograph realised the failure of TECE, but could not address the Lisbon Treaty.

⁵⁰ M Vogt, *Die Entscheidung als Handlungsform der Europäischen Gemeinschaftsrechts* cit. discusses Entscheidungen as “Scheinverordnungen” (p 34), and “die Entscheidung als Mittel normativer Steuerung” (chapter 7, p. 150).

⁵¹ See art. III-278(5) TECE.

⁵² Arts 289, 290 and 291 TFEU, respectively; for an analysis, see H Hofmann, ‘Legislation, Delegation and Implementation under the Treaty of Lisbon: Typology Meets Reality’ (2009) ELJ 482-505; A Türk,

This change retained the intent of the Constitutional Treaty but did it in another context, so the result is different.

The Lisbon Treaty was no recast but a complex amendment of the existing treaties. This approach resulted in several pitfalls, which also concerned secondary law. On the one hand, removing “the Maastricht pillars” suppressed the second pillar’s common positions, actions and strategies and the third pillar’s decisions and framework decisions.⁵³ On the other hand, it cemented many combinations of secondary law instruments.⁵⁴ Unsurprisingly, there was little enthusiasm about the result.⁵⁵

Recently, the European Union has enacted regulations, directives and decisions which could be either *legislative (acts)*, adopted in ordinary legislative procedure, or *delegated* and *implementing* ones adopted by the Commission. Additionally, some acts do not fit the classification mentioned above as the Council relies on the specific provisions in TFEU and TEU. Magdaléna Svobodová proposes to label these acts *innominate*.⁵⁶

The EUR-Lex statistics were instrumental in the research. Its classification of the published acts is even more complex. Concerning decisions, it sorts out *i)* legislative acts – ordinary legislative procedure – decisions of the European Parliament and the Council, SCBTHD being among them, *ii)* other legislative acts – Council decisions, non-legislative acts: *iii)* Commission delegated decisions, *iv)* Council implementing decisions, *v)* Commission implementing decisions, other acts: *vi)* Commission decisions, and *vii)* European Central Bank decisions.

EUR-Lex distinguishes *basic, i.e. new/recast, and amending* acts in each category. The basic decisions adopted in the ordinary legislative procedure since the Lisbon Treaty or in the co-decision procedure before it (category 1) were numerous, about ten each year.⁵⁷ The decisions adopted by the Council, classified as other legislative acts – Council decisions, *i.e. the second category*, are much more frequent, with hundreds of them annually.

'Legislative, Delegated Acts, Comitology and Interinstitutional Conundrum in EU Law—Configuring EU Normative Spaces' (2020) ELJ 415.

⁵³ Art. 34 TEU, as amended by the Amsterdam Treaty. For an in-depth analysis of the framework decisions, see W Schroeder, 'Neues vom Rahmenbeschluss – ein verbindlicher Rechtsakt der EU' (2007) *Europarecht* 349. We mentioned already that differentiation in German language emerged there.

⁵⁴ Arts I-33-I-37 TCE and art. 291 TFEU, respectively.

⁵⁵ Among others, E Best, 'Legislative Procedures after Lisbon: Fewer, Simpler, Clearer?' (2008) *Maastricht Journal of European Law* 85.

⁵⁶ M Svobodová, 'On the Concept of Legislative Acts in the European Union Law' (2016) Charles University in Prague Faculty of Law Research Paper II/1.

⁵⁷ According to Eur-Lex, *Legal Acts – statistics* eur-lex.europa.eu 1994: 2, 1995: 6, 1996: 9, 1997: 5, 1998: 7, 1999: 11, 2000: 10, 2001: 7, 2002: 8, 2003: 13, 2004: 8, 2005: 1, 2006: 18, 2007: 10, 2008: 13, 2009: 7, 2010: 4, 2011: 6, 2012: 3, 2013: 9, 2014: 13, 2015: 2, 2016: 3, 2017: 5, 2018: 3, 2019: 0 (!), 2020: 8, 2021: 3, 2022: 7, 2023: 2, 2024: 1 (until 29. 2.).

VI. INSPIRATION FOR COMPARISON

The cited classifications distinguish secondary law acts according to the procedures. At the same time, the substance of the third binding instrument is diverse. Decisions address individual cases, formulate policies, and manage cooperation. We need to develop methods to understand them.

The European Union is a unique supranational structure with a specific law. Despite it, exceptionalism in EC/EU legal scholarship⁵⁸ is unfortunate. Worldwide, legal systems share commonalities. Therefore, a comparative perspective is also feasible concerning transnational laws.⁵⁹

The European Union has acquired several federal features. Comparing it with countries is thus inherent. Nonetheless, international law forms its fundamentals. Therefore, examining whether similar phenomena exist in international organisations may be helpful.

Distinguishing “normative” (“general”) and “individual” (“single case”) legal acts/instruments seems to be a paradigm in central European legal education. The “normative” acts include statutes (broadly understood), forming the primary source of national law.⁶⁰ These statutes exist in a hierarchy, sometimes visualised as a pyramid, with a constitution at its top, parliamentary statutes in the middle, and legislation of the executive branch (statutory instruments in British terminology) at the bottom. The “individual” acts are decisions and judgments of administration and courts confirming or establishing the rights and duties of identified persons or entities.

Unsurprisingly, the reality is complex. There are confusing hybrid and mixed phenomena. Statutes are general if they address any case defined by them. They retain this feature also when addressing specific and temporary phenomena, such as the Covid-19 pandemic. However, these statutes may become *de facto* individual: laws on nuclear energy if only one power plant exists. Regional and local laws are less general as the number of cases diminishes. *Allgemeinverfügung* in German administrative law⁶¹ and its emulations elsewhere form the most localised “norm”.

Parliaments deciding on issues other than laws as sources of generally applicable rules form another borderline phenomenon. Annual budgets, as plans of revenues and expenditures, often allocating money to specified institutions, exemplify that best. Other cases include spatial plans, establishing institutions, launching programmes and projects, and approving large contracts. These issues are politically significant. Constitutions or

⁵⁸ J Shaw, 'European Union Legal Studies in Crisis? Towards a New Dynamic' (1996) OJLS 231-253. The author deplors (p 235) the tendency of EU legal scholars to exclusivism by stressing EC law specifics, namely *sui generis* teleological interpretation, writing about “monster dominating its environment”. An excellent study of these specifics in interpretation and their limits in the author's native language D Sehnálek, *Specifika výkladu práva Evropské unie a jeho vnitrostátní důsledky* (C. H. Beck 2019).

⁵⁹ U Kischel, *Rechtsvergleichung* (C. H. Beck 2015) 945, 956.

⁶⁰ *Ibid.* 392.

⁶¹ Para. 35(2) *Verwaltungsverfahrensgesetz* (Bund), BGBl. I-1253, 25. May 1976.

statutes/laws confer decision-making on directly elected bodies. Activating and deactivating emergencies is another issue the directly elected bodies decide about. Parliaments approve international treaties before their ratification by presidents or monarchs. They may also stipulate policies toward other countries. Some countries consider these acts laws/statutes, while others classify them otherwise.⁶²

Laws/statutes stipulating special arrangements exist in several countries, *Specustawa* in Poland or *Einzelfallgesetz* in Germany. Unsurprisingly, such acts incite discussions as they undermine equality in general. Other countries, such as the author's Czech Republic, avoid it as frustrating the expectations towards statutes as "systemic solutions".

Law(making) in international law means primarily concluding international treaties, either bilateral or multilateral, the latter often in international organisations. Concerning substance, international treaties are diverse. The doctrine of international law distinguishes *traités-lois* and *traités-contrats*.⁶³ Lawmaking by international organisations is limited and resembles negotiations on treaties: an example is the International Health Regulations adopted by the World Health Assembly, composed of national delegates.

Some treaties and quasi-treaties may expect decisions addressing particular events or situations. The United Nations Organisation Security Council adopts *resolutions* for protecting and restoring peace and security among nations.⁶⁴ Similarly, the World Health Organisation proclaimed *public health emergency of international concern* and, finally, *a pandemic*.⁶⁵

One linguistic remark closes this cursory overview for comparison. Similarly to *decisions* in English, other languages also use their equivalents for results of consideration and deliberation. Parliaments *decide* on laws. Meanwhile, individuals also *decide* while choosing options in their lives. The term is polysemous. Taking context into account is necessary.

VII. SUBSTANTIAL CLASSIFICATION OF DECISIONS

In-depth scholarly analyses of the theory and practice concerning decisions would be helpful, as the mentioned literature is almost twenty years old. Such studies should encompass acts labelled as decisions and ascertain whether they match the cited definition. These analyses might also evaluate acts not considered decisions if there are arguments for their classifying them as such, starting with the EU courts' judgments.⁶⁶ As the implementation of EU

⁶² The German theory emphasises that the annual *Haushaltgesetz* is a statute/law in the formal sense, but not in the material one, for a textbook explanation, see, among others, M Hütwohl, *Einführung in Recht* (C. H. Beck 2020) 17-19.

⁶³ For such distinction, see, D Carreau and F Marella, *Droit international* (A. Pedone 2012, 11th edn) 149.

⁶⁴ The United Nations Charter [1945], art. 27.

⁶⁵ World Health Organization, 'Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCov)' (30 January 2020) who.int; World Health Organization, 'WHO Director-General's Opening Remarks at the Media Briefing on COVID19' (11 March 2020) who.int.

⁶⁶ It is interesting that EU legal scholars do not answer this question. Undoubtedly, it is an academic question as specific provisions define judgments, but there are arguments for both conclusions.

law by the Member States prevails, such analyses might also include decisions of national authorities implementing comprehensive EU legal frameworks.

Monographs will be needed as the primary and secondary law range is immense. Indeed, the EU law is primarily administrative law in its broad meaning. This text focuses on several decisions establishing norms for generally defined addressees, considering others only to distinguish them.

Undoubtedly, many decisions are administrative acts addressing individual cases, similar to their national counterparts. In addition to the decisions mentioned above on competition (cartels and abuse of dominant position, mergers, and state aid), other centralised agendas have emerged. As this text deals with the laws reflecting the Covid-19 pandemic, it may mention conditional and standard authorisations of the vaccines by the European Commission, which the European Medicines Agency advised.⁶⁷

It isn't easy to find parallels to *Allgemeinverfügung*, as the European Union relies on the Member States concerning implementing its laws in local settings. Perhaps, the approvals of national acts establishing protected areas⁶⁸ are its supranational version.

Comparing CFSP decisions with the Security Council resolutions is not surprising. Undoubtedly, there are significant differences, reflecting the ones between the United Nations and the European Union, the universality of the former and the regionality of the latter. However, both instruments address international relations.

Nonetheless, we put these two categories aside, focusing on the decisions the European Parliament and the Council adopted in the ordinary legislative procedure or its predecessors.

Their first group is close to the CFSP decisions, which often exist concurrently. There are decisions stipulating assistance to non-Member States.⁶⁹ Its realisation usually relies on an international treaty with the respective country, also approved by decisions.

⁶⁷ According to Regulation 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. For an analysis, see A Donati 'The Conditional Marketing Authorisation of Covid-19 Vaccines: A Critical Assessment under EU Law' (2022) *European Journal of Health Law* 33.

⁶⁸ In accordance with the Council Directive 92/43/EEC of 28 November 1992, such as Commission Implementing Decision (EU) 2020/96 of 28 November 2019 adopting the thirteenth update of the list of sites of Community importance for the Mediterranean biogeographical region (notified under document C(2019) 8583) establishing the list of protected areas in the member states in accordance with the Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora.

⁶⁹ Decision 2022/1628 of the European Parliament and of the Council of 20 September 2022 providing exceptional macro-financial assistance to Ukraine, reinforcing the common provisioning fund by guarantees by Member States and by specific provisioning for some financial liabilities related to Ukraine guaranteed under Decision 466/2014/EU.

Their second group is the programmes on spending EU money on specified purposes. These programmes apply for a specified period, so EUR-Lex does not indicate that these decisions are not valid anymore.⁷⁰

The EU annual budgets – to which these programmes relate – result from a specific procedure with necessary deadlines.⁷¹ Nonetheless, the institutions approving them are the Council and the European Parliament. Commentaries do not discuss whether budgets are decisions. One may resolve the dilemma by considering them *acts sui generis*. The accompanying measures use standard instruments. The decision adopted in a specific legislative procedure encompassing “ratifications” by national parliaments specifies the European Union’s “own” resources.⁷² At the same time, the regulation specifies managing expenditures.⁷³ Finally, the directive harmonises national criminal laws for combatting fraud of EU money.⁷⁴

The third group is decisions that deserve to be labelled the legislative ones in the plain meaning at most, as they specify cooperation between the Member States and EU institutions. SCBTHD belonged to these decisions.

As “legislative” identifies the procedure, we seek alternative adjectives. One may label these decisions “normative”⁷⁵ or “norm-setting”. These decisions are “general” as they denote generally applicable rules. After repeated reflection and consideration, this text in English labels them “standardising”. “Standard” implies both “norm” as “rule” and “generality”. Quotes alert the readers. As the phenomenon escapes attention, there is no settled terminology.

Nonetheless, one need not reject this adjective concerning the decisions in the first and second groups, as they also establish standards discussed here.

⁷⁰ Decision 574/2007/EC of the European Parliament and of the Council of 23 May 2007 establishing the External Borders Fund for the period 2007 to 2013 as part of the General programme Solidarity and Management of Migration Flows.

⁷¹ “A decision addressed to all MS will often constitute a legislative act” in M Klammert, PJ Loewenthal, ‘Art. 288’ in M Kellerbauer, M Klammert and J Tomkin (eds), *EU Treaties and the Charter of Fundamental Rights* cit. 1909.

⁷² Council Decision (EU, Euratom) 2020/2053 of 14 December 2020 on the system of the own resources of the European Union and repealing Decision 2014/335/EU, based on art. 311 TFEU. Inconsistently, the decision labels itself “legislative act”.

⁷³ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012.

⁷⁴ Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union’s financial interests by means of criminal law.

⁷⁵ Vladimír Týč uses the adjective in the Czech textbook by M Tomášek, V Týč and D Petrlík (eds), *Právo Evropské unie* (Leges 2021, 3rd edn) 106, highlighting their similarity to regulations while citing several Commission decisions.

Two of the existing decisions – legislative acts – stipulate the cooperation of national authorities in allocating wavelengths in the radio spectrum.⁷⁶ This issue is subject to international collaboration due to its cross-border nature. Similar decisions establish a multiannual programme for environmental protection encompassing comprehensive monitoring by the Commission collaborating with the Member States⁷⁷ or expect the selection of “the European capitals of culture”.⁷⁸

Among the decisions adopted by the Council, CFSP decisions (identified with this abbreviation in brackets) form their minor part.⁷⁹ Numerous decisions are appointments of persons to EU institutions.⁸⁰ EUR-Lex classification is misleading as CFSP decisions are, *per definition*, non-legislative,⁸¹ and appointments lack this feature, too.

Other Council's decisions are approvals of international treaties⁸² or mandates to their negotiation.⁸³ Following the differentiation between *traités-lois* and *traités-contrats*, one may consider those related to the former as “standardising”.

Several decisions of the Council are also “standardising” as they establish a legal framework, albeit *ad hoc*. The two 2015 decisions redistributing asylum seekers⁸⁴ to

⁷⁶ Decision 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision), and Decision 243/2012/EU of the European Parliament and of the Council of 14 March 2012 establishing a multiannual radio spectrum policy programme, together with Directive 2018/1972 of the European Parliament and of the Council of 11 December 2018 establishing the European Electronic Communications Code (Recast).

⁷⁷ Decision 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030.

⁷⁸ Decision 445/2014/EU of the European Parliament and of the Council of 16 April 2014 establishing a Union action for the European Capitals of Culture for the years 2020 to 2033 and repealing Decision 1622/2006/EC.

⁷⁹ Among the latest, Council Decision (CFSP) 2022/2245 of 14 November 2022 on an assistance measure under the European Peace Facility to support the Ukrainian Armed Forces trained by the European Union Military Assistance Mission in support of Ukraine with military equipment, and platforms, designed to deliver lethal force, or Council Decision (CFSP) 2022/1965 of 17 October 2022 in support of the United Nations Programme of Action to Prevent, Combat and Eradicate the Illicit Trade in Small Arms and Light Weapons in All Its Aspects.

⁸⁰ Among the latest, Decision 2022/2248 of 14 November 2022 appointing a member of the Court of Auditors, confirming expiration of office of Mr Šadžius (Lithuania) and appointing Ms Andrikiénė.

⁸¹ Art. 31(1) TEU, see P Eeckhout, 'The EU's Common Foreign and Security Policy after Lisbon: From Pillar Talk to Constitutionalism' in A Biondi, P Eeckhout, S Ripley (eds), *EU Law after Lisbon* (Oxford 2012).

⁸² Among the latest, Council Decision 2022/1987 of 13 October 2022 on the signing, on behalf of the Union, of the Framework Agreement on Partnership and Cooperation between the EU and its Member States, of the one part, and the Government of Malaysia, on the other part.

⁸³ Council Decision 2022/451 cit. about the EU engagement in negotiating the Pandemic Treaty.

⁸⁴ Council Decision 2015/1523 of 14 September 2015 establishing provisional measures in the area of international protection for the benefit of Italy and of Greece, and Council Decision 2015/1601 of 22 September 2015 establishing provisional measures in the area of international protection for the benefit of Italy and Greece.

mitigate the unbalance resulting from the general framework set by regulation⁸⁵ were subject to judicial disputes⁸⁶ and political upheavals. The Council initially established the Court of First Instance (the General Court) with such a decision.⁸⁷

Concerning implementing decisions adopted by the Commission, the same instrument specifies clauses for contracts on transferring personal data to third countries⁸⁸ and assessing the equivalence of personal data protection in a particular third country.⁸⁹ The former decision is general, and we may thus consider it “standardising”. The latter may result from evaluation. We can thus consider it an administrative decision. Still, its impacts on the related international trade and cooperation with a country bring them closer to the above-mentioned country-specific decisions.

VIII. OUTLINING THE DOCTRINE OF “STANDARDISING” DECISIONS

Markus Klammert and Paul-John Loewenthal label the decisions addressed to the Member States and the unaddressed ones as legislative acts.⁹⁰ It is understandable as they often establish legal standards. SCBTHD was one of them. However, using the adjective this way is unfortunate because it does not match the definition of decisions – legislative acts.⁹¹ Therefore, Matthias Ruffert labels these decisions better as former *quasi-legislative Beschlüsse*.⁹²

Nonetheless, these authors did not refine a doctrine for the decisions which this text identifies as “standardising” (“normative”, “norm-setting”, or “general”). As mentioned, Matthias Vogt has considered the normative effects of decisions at most.⁹³ Nonetheless, he wrote his monograph-dissertation years before the Lisbon Treaty. This section will

⁸⁵ Regulation 604/2013 of the European Parliament and of the Council of 26 June 2013 establishing the criteria and mechanisms for determining the Member State responsible for examining an application for international protection lodged in one of the Member States by a third-country national or a stateless person.

⁸⁶ Joined cases C-643/15 and C-647/15 *Slovakia and Hungary v Council* ECLI:EU:C:2017:631, and joined cases C-715/17, C-718/17 and C-719/17 *Commission v Poland, Hungary and the Czech Republic* ECLI:EU:C:2020:257.

⁸⁷ Council Decision 88/591/ECSC, EEC, Euratom of 24 October 1988 establishing a Court of First Instance of the European Communities.

⁸⁸ Commission Implementing Decision 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 (GDPR).

⁸⁹ Commission Implementing Decision 2022/254 of 17 December 2022 on the adequate protection of personal data by the Republic of Korea under the Personal Information Protection Act.

⁹⁰ M Klammert and PJ Loewenthal, ‘Art. 288’ in M Kellerbauer, M Klammert and J Tomkin (eds), *EU Treaties and the Charter of Fundamental Rights* cit. 1909: “A decision addressed to all MS will often constitute a legislative act”.

⁹¹ Art. 289(3) TFEU: “Legal acts adopted by legislative procedure shall constitute legislative acts”.

⁹² C Callies and M Ruffert (eds), *EUV AEUV mit Europäischer Grundrechtecharta* cit. 2467 (Rn. 85).

⁹³ M Vogt, *Die Entscheidung als Handlungsform der Europäischen Gemeinschaftsrechts* cit. distinguishes decisions coordinating the Member States (p 151) and supporting regulations (p 159) and directives (p 172) and considers delineation of regulations and decisions as limited to specified persons and locations (p 183).

thus reconsider the principal doctrinal aspects of these decisions following the differentiation introduced by it.

The decisions addressed to the Member States – SCBTHD being among them – can impose duties on them, and they do it. The question is whether one could generalise the existing case law stipulating individual rights towards these Member States. Concerning SCBTHD, the question was whether people could demand particular anti-epidemic engagements from the Member States.

Another question is whether these decisions may require harmonisation. It is easy to answer affirmatively as no provision explicitly excludes that. However, such an approach would render directives as specific instruments redundant. Therefore, we agree with Markéta Whelanová criticising⁹⁴ the decision expecting the implementation of its detailed standard concerning imported meat products⁹⁵ with national laws because directives serve this purpose.

The unaddressed decisions (*adressatenlose Beschlüsse*) are even more confusing. As the addressed decisions are binding upon specified Member States, entities or individuals, they may be *a contrario* binding upon everybody, *i.e.*, the EU institutions, the Member States and any individuals and entities within their jurisdiction. According to their definition, these decisions are *binding in entirety*.

The question is whether the unaddressed decisions can impose obligations, duties, tasks or restrictions on individuals similarly to regulations. Our reluctance results from the definition of the latter in art. 288(2) TFEU “[a] regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.” The cited definition of an unaddressed decision lacks the first sentence and the final disposition.

Concerning the capacity of these decisions to harmonise national laws, the answer should be the same as in the decisions addressed to all Member States.

Agreeing with both questions would render the unaddressed decisions the most potent instrument. One doubts that the authors of the Lisbon Treaty intended to establish such an instrument in addition to regulations and directives.⁹⁶

An analysis of the decisions - legislative acts, *i.e.* those adopted in the ordinary legislative procedure in 2009-2022 and the co-decision procedure in 1994-2009⁹⁷ – shows that the EU lawmakers addressed with “[t]his decision is addressed to the Member States” most of them to the Member States, *i.e.* all of them.

⁹⁴ M Whelanová, 'Quo vadis Europa? Loopholes in the EU law and Difficulties in the Implementation Process' (2016) *European Journal of Law Reform* 179.

⁹⁵ Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC.

⁹⁶ R Streinz, *Europarecht* cit. 182 concludes that the unaddressed decisions are binding exclusively upon EU institutions.

⁹⁷ Arts 289, 294 TFEU, and art. 189(b) TEC, renumbered as art. 251 by the Amsterdam Treaty.

The decision concerning “Europass” lacks this provision, but its substance does not allow another conclusion.⁹⁸ The resulting uncertainty is deplorable. Another debatable case is the above decision, which expresses the European Union's environmental programme.⁹⁹ It seems intentionally unaddressed, but its legal significance is little if other regulations and directives address this policy.

On the contrary, the decision specifying the control of Romania concerning its corrupt and inefficient judiciary and administration¹⁰⁰ is not “standardising” in reality. The Commission addressed the decision based on the 2006 Treaty on Accession (also Bulgaria) provision to the Member States. Still, its text stipulated particular obligations of the newcomer exclusively.¹⁰¹

The missing addressees in the Council decisions nominating individuals to the EU institutions and bodies cause little problems. Respecting the result is expected by everybody. On the contrary, one needs to consider this feature in the Council decisions specifying the position in negotiations on international treaties with other countries or international organisations and their approvals as binding upon the EU institutions and the Member States. Regarding CFSP decisions, primary law outlines the sincere cooperation of these Member States.¹⁰²

The practice supports theoretical conclusions. Nothing indicates that any unaddressed decision applies directly to individuals. Commentaries are also tacit about the possible failure to transpose these decisions similarly to directives.

The research did not identify any decision addressed explicitly to the Member States, individuals and entities under their jurisdictions, *i.e.* to everybody. The doctrine does not consider this possibility, either. Let us oppose this idea. Regulations serve this purpose.

Therefore, we may conclude that the European (Economic) Community or the European Union deploy “standardising” decisions in the agendas in which they established the Member States' cooperation while refraining from establishing rights and duties of individuals, either directly or through national laws.

⁹⁸ Decision (EU) 2018/646 of the European Parliament and of the Council of 18 April 2018 on a common framework for the provision of better services for skills and qualifications (Europass) and repealing Decision No 2241/2004/EC, art. 7 Member States' tasks. The repealed Decision 2241/2004/EC explicitly defines the Member States as addressees in its art. 19.

⁹⁹ Decision 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 and its predecessors.

¹⁰⁰ Commission Decision 2006/928/EC of 13 December 2006 establishing a mechanism for cooperation and verification of progress in Romania to address specific benchmarks in the areas of judicial reform and the fight against corruption, 56–57, special edition in Romanian 11, 051.

¹⁰¹ See art. 10 of Commission Decision 2006/928/EC, the Court of Justice invoked in joined cases C-83/19, C-127/19, C-195/19, C-291/19, C-355/19 and C-397/19 *Asociația “Forumul Judecătorilor din România” and others* ECLI:EU:C:2021:393 the obligation imposed on Romania, but did not clarified the tasks of other Member States. One may propose that these Member States shall actively require the compliance.

¹⁰² Arts 28(1), 28(2) TEU.

Arguing that “standardising” decisions should not harmonise national laws, supported by the limited evidence for the opposite and its criticism, does not exclude one similar phenomenon. These decisions expect the Member States to pursue activities they can hardly do without national laws. Therefore, they improve these laws if necessary or convenient. Regarding this, these decisions still resemble directives addressed by the EU lawmakers to the Member States.

SCBTHD exemplified this phenomenon well. It implied that the Member States monitored and suppressed contagious diseases.¹⁰³ For this purpose, national authorities resorted to mandatory testing, tracing contacts, quarantines and isolations. The Member States cannot impose these requirements and restrictions without laws specifying them.

Nonetheless, this phenomenon is not specific to “standardising” decisions. SCBTHR also relies on national epidemic surveillance. Among others, “Brussels I” and “Rome I” regulations imply that the Member States operate courts applying procedural rules and address contracts, respectively.¹⁰⁴

IX. IDENTIFIED REPLACEMENTS BY REGULATIONS

Replacing “standardising” decisions with regulations has become common in recent years. Regulations now stipulate the EU programmes supporting research.¹⁰⁵ The methodology for measuring greenhouse gas emissions has been subject to repeated recodifications.¹⁰⁶ One regulation supersedes, for the next decade, a decision applied in the

¹⁰³ Art. 1 Subject matter (1). This Decision lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning related to those activities, in order to coordinate and complement national policies. (2) This Decision aims to support cooperation and coordination between the Member States in order to improve the prevention and control of the spread of severe human diseases across the borders of the Member States, and to combat other serious cross-border threats to health in order to contribute to a high level of public health protection in the Union.

¹⁰⁴ Regulation 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast), and Regulation 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I).

¹⁰⁵ Regulation 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision 1982/2006/EC; Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe - the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013, replaced the 2013 Regulation.

¹⁰⁶ Regulation 525/2013 of the European Parliament and of the Council of 21 May 2013 on a mechanism for monitoring and reporting greenhouse gas emissions and for reporting other information at the national and the EU levels relevant to climate change and repealing decision 280/2004/EC, already absorbed by the Regulation (EU) 2018/1999 of the European Parliament and of the Council of 11 December 2018 on the Governance of the Energy Union and Climate Action, amending Regulations (EC) No 663/2009

previous decade in another framework related to this rapidly evolving policy.¹⁰⁷ Transforming may last three decades, as the case of standards for EC/EU statistics reveals.¹⁰⁸ A regulation started to address the exchange of information related to the trade in goods.¹⁰⁹ Codifying the EU space programme rules included standards for this specific task.¹¹⁰ The European Labour Authority absorbed an informal platform for combatting undeclared work.¹¹¹ Jürgen Bast started his treatise by mentioning the decision on the Erasmus students' exchange program,¹¹² which has just received its second regulation.¹¹³

and (EC) No 715/2009 of the European Parliament and of the Council, Directives 94/22/EC, 98/70/EC, 2009/31/EC, 2009/73/EC, 2010/31/EU, 2012/27/EU and 2013/30/EU of the European Parliament and of the Council, Council Directives 2009/119/EC and (EU) 2015/652 and repealing Regulation (EU) No 525/2013 of the European Parliament and of the Council.

¹⁰⁷ Regulation 2018/842 of the European Parliament and of the Council of 30 May 2018 on binding annual greenhouse gas emission reductions by Member States from 2021 to 2030 contributing to climate action to meet commitments under the Paris Agreement and amending Regulation 525/2013, 26-42, supersedes – without a formal repeal – Decision 406/2009/EC of the European Parliament and of the Council of 23 April 2009 on the effort of Member States to reduce their greenhouse gas emissions to meet the Community's greenhouse gas emission reduction commitments up to 2020, OJ L 140, 5. 6. 2009. We may discuss the significance of this approach.

¹⁰⁸ Regulation 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities; Council Regulation (EC) 322/97 of 17 February 1997 on Community Statistics, 1-7; and Council Decision 89/382/EEC of 16 June 1989 establishing a Committee on the Statistical Programmes of the European Communities.

¹⁰⁹ Regulation 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision 3052/95/EC; Decision 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community; Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State a repealing Regulation 764/2008, applies recently.

¹¹⁰ Regulation (EU) 2021/696 of the European Parliament and of the Council of 28 April 2021 establishing the Union Space Programme and the European Union Agency for the Space Programme and repealing Regulations (EU) No 912/2010, (EU) No 1285/2013 and (EU) No 377/2014 and Decision No 541/2014/EU and Decision 541/2014/EU of the European Parliament and of the Council of 16 April 2014 establishing a Framework for Space Surveillance and Tracking Support.

¹¹¹ Regulation (EU) 2019/1149 of the European Parliament and of the Council of 20 June 2019 establishing a European Labour Authority, amending Regulations (EC) No 883/2004, (EU) No 492/2011, and (EU) 2016/589 and repealing Decision (EU) 2016/344.

¹¹² Council Decision 87/327/EEC of 15 June 1987 adopting the European Community Action Scheme for the Mobility of University Students (Erasmus), extended by Decision 89/663/EEC until 1994.

¹¹³ Regulation (EU) 2021/817 of the European Parliament and of the Council of 20 May 2021 establishing Erasmus+: the Union Programme for education and training, youth and sport and repealing Regulation (EU) No 1288/2013, which repealed Regulation 1288/2013, which, in turn, consolidated the programmes specified by Decisions 1719/2006/EC, 1720/2006/EC and 1298/2008/EC and repealed them. To sum up, the EC/EU lawmakers adopted decisions for these programmes periodically.

It would be helpful to investigate whether “standardising” decisions enacted by the Council in various special legislative procedures also retreat because the following case is quite specific. The Court of Justice triggered¹¹⁴ the recast of rules concerning migration surveillance and checks of vessels¹¹⁵ after the European Parliament successfully challenged its bypassing by the Council.¹¹⁶

The survey has identified no countertrend, transforming a regulation into a decision. Transformations of directives into regulations are also a one-way tendency.¹¹⁷ The first instrument of secondary law has become the preferred one. However, there are also rare cases of their transformations in directives. This second instrument thus becomes the second option.

Directives replacing *framework decisions* of the former third pillar¹¹⁸ reflect the consolidation of the European Union as this instrument was quasi-directive. Amendments to the former with the latter sparked discussions due to their different theories.¹¹⁹

The transformation of a “standardising” decision into a directive specifying consular protection of unrepresented EU citizens outside the European Union¹²⁰ is exceptional. It is easy to explain this case with the amended competence provision requiring the former “before Lisbon” and the latter after.¹²¹

Let us scrutinise the transformation of SCBTHD to SCBTHR as a reform of epidemic cooperation in the European Union. Concerning the epidemic surveillance, the Member States blocked the empowerment of the EU institutions and agencies to impose restrictions on them or to require them to introduce these when SCBTHD was subject to negotiations a decade ago.¹²² An attempt to centralise the epidemic surveillance thus predated the instrument change.

¹¹⁴ C-355/10 *European Parliament v Council* ECLI:EU:C:2012:516.

¹¹⁵ Regulation 656/2014 of the European Parliament and of the Council of 15 May 2014 establishing rules for the surveillance of the external sea borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union.

¹¹⁶ Council Decision 2010/252/EU of 26 April 2010 supplementing the Schengen Borders Code as regards the surveillance of the sea external borders in the context of operational cooperation coordinated by the European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union.

¹¹⁷ F Křepelka, 'Transformations of Directives into Regulations' cit. 792.

¹¹⁸ Directive (EU) 2017/541 of the European Parliament and of the Council of 15 March 2017 on combating terrorism and replacing Council Framework Decision 2002/475/JHA.

¹¹⁹ H Satzger, 'Legal Effects of Directives Amending or Repealing Pre-Lisbon Framework Decisions' (2015) *New Journal of European Criminal Law* 528.

¹²⁰ Council Directive (EU) 2015/637 of 20 April 2015 on the coordination and cooperation measures to facilitate consular protection for unrepresented citizens of the Union in third countries, which replaced Decision of the Representatives of the Governments of the Member States meeting within the Council 95/553/EC of 19 December 1995 regarding protection for citizens of the European Union by diplomatic and consular representations.

¹²¹ Art. 23 TFEU and art. 20 TEC (post-Amsterdam numbering of articles), respectively.

¹²² Compare art. 12 SCBTHD to its initial proposal COM/2011/0866 final – 2011/0421 (COD).

The political and societal context differed from the deliberations on SCBTHD and the 1998 decision predating it. The threat of infections was not hypothetical due to the Covid-19 pandemic. Worldwide, people experienced contact tracing, mandatory testing, quarantines, isolations, suppressed contacts, prohibited activities, closed businesses and schools, and curtailed travel.

It is good to emphasise that SCBTHR does not centralise the epidemic responses. The Member States differed in their requirements and restrictions during the pandemic and changed them over two years. The willingness of people to quarantine themselves for numerous months gradually vanished, and experts diverged in their advice and recommendations.

Critical observers would ask whether more elaborate procedures and new institutions could stop such “communicable diseases” as Covid-19. But blaming SCBTHD for the pandemic would amount to scapegoating. Indeed, SCBTHR addresses the cooperation of the Member States whose national epidemic surveillance is a primary issue. One need not be an expert on public health after the Covid-19 pandemic to expect differences among the European countries. The evaluation of the effectiveness of this cooperation is thus tricky. A multidisciplinary approach would be necessary and beyond the expertise of legal experts.

Interestingly, the European Union established the European Centre for Prevention and Control of Diseases (ECDC) as its public health agency with a regulation eighteen years ago¹²³ according to the same competence.

Every decision and regulation this section mentions is a unique story deserving its legal, political and substantial analysis. Change of the instrument need not coincide with reforms of the substance. We dare to generalise solely about the detailedness of acts. New regulations are longer than the decisions replaced by them, as their pages in the Official Journal cited in the footnotes indicate.

X. EVALUATION OF REPLACEMENTS

EU legal scholars should check competence provisions before considering the substance and politics of the “standardising” decisions discussed here. The Lisbon Treaty allowed all instruments in most cases, thus enabling the preference for regulations. The cited decision on the EU’s “own” resources is an exception. However, the pre-Lisbon “standardising” decisions, including those replaced by regulations, could have relied upon similar competence provisions requiring this instrument.

Hurka and Steinebach conclude in their political analysis of the EU lawmaking that the recasts of directives and regulations often follow certain traditions. The European Commission proposes regulations if the previous ones were regulations as directives are

¹²³ Regulation 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control.

less effective. On the contrary, Member States avoid regulations as the more intrusive instruments.¹²⁴ The authors' findings may extend to “standardising” decisions, including SCBTHD as the 2013 recast of its 1998 predecessor.

It is time to add that traditions become eroded, especially during crises. The Covid-19 pandemic was such an event. Nonetheless, the preference for regulations predates it. The European Union has transformed three dozen directives into regulations during the last two decades.¹²⁵ Perhaps, the Member States have realised that detailed directives are challenging to transpose. Still, the process is unavoidable, as the Commission checks transposition and regularly sanctions failure in that respect, and undesirable legal effects appear. A similar tendency has emerged in decisions – legislative acts.

While deliberating on the substance of SCBTHR, the Council and the European Parliament did not question a change of the instrument.

Paradoxically, imposing requirements or restrictions on people is not what characterises SCBTHR. Namely, this regulation does not empower to impose quarantines, contact tracing, mandatory testing, isolations and lockdowns. Like the preceding decisions, it specifies the cooperation of the national and supranational public health authorities.

However, confirming this characteristic of SCBTHR would be careless without analysing all its provisions. Private providers – hospitals, ambulances and laboratories – would contribute to tackling eventual epidemics.¹²⁶ One may also question whether the cited case law would enable individuals to ask Member States for epidemic responses.

Nonetheless, the new instrument removes doubts, as regulations enable every possible arrangement. Such an analysis would thus be purely academic, only clarifying the hypothetical permissibility of the abandoned instrument.

As indicated, the feasibility of detailed directives is questionable.¹²⁷ Nonetheless, this instrument has a manifest *raison d'être*. The European Union and the Member States prefer national laws stipulating particular standards instead of uniform ones.

Doctrinal arguments for “standardising” decisions are weaker. We suggest considering them as an instrument establishing “mere” cooperation of the Member States, manifestly excluding direct or intermediated effects on individuals under their jurisdiction. “Standardising” decisions resemble international treaties considered binding exclusively to countries (states) as their contracting parties (dualism of international law and national laws), unlike regulations and directives applicable directly or indirectly to individuals, which resemble international treaties applied as such in national legal systems with privileged position (so-called incorporation) or through adjusted national laws (adoption) if the states decide for it.

¹²⁴ S Hurka and Y Steinebach, 'Legal Instrument Choice in the European Union' (2018) *JComMarSt* 278, 279.

¹²⁵ For an incomplete list of transformations, see F Křepelka, 'Transformations of Directives into Regulations' cit. 782 and 789-790.

¹²⁶ Art. 15 SCBTHR expects selected reference laboratories and stipulated requirements for them. Nonetheless, these laboratories would participate voluntarily in fulfilling government tasks.

¹²⁷ F Křepelka, 'Transformations of Directives into Regulations' cit. 793-794.

The explanatory memoranda accompanying the proposals of “standardising” decisions usually did not contain any explanations of the instrument choice. Retrospectively, we conclude that the Commission had no consistent approach concerning this subtype of decision when it proposed them in the previous decades. Their subsequent discontinuation seems to be a side-effect of the increasing preference for regulations instead of directives.¹²⁸ Let us admit that directives and “standardising” decisions share limitations.

The European Union does not reflect the third instrument in its legislative policies. Foremost, *the Interinstitutional Agreement on Better Lawmaking* requires an explanation of the instrument choice, distinguishing regulations and directives, but remains silent about (lawmaking with) decisions.¹²⁹ Similarly, initiatives aimed at improving EU legislation such as SLIM (*Simpler Legislation for the Internal Market*) since 1996,¹³⁰ *Small Business Act* since 2008,¹³¹ REFIT (*Regulatory Fitness and Performance Programme*) since 2012,¹³² *Better Regulation* since 2015¹³³ encompassing *Fit for Future Platform* since 2020¹³⁴ also lack any significant consideration of this instrument, despite the enormous length of some documents.¹³⁵

At the same time, one does not need to be a political scientist to estimate that “standardising” decisions could be helpful. A retrospective multidisciplinary analysis would be interesting to identify how often the European (Economic) Community and the European Union resorted to decisions when balancing at the edge of competence and expecting the Member States to refuse regulations and directives.

¹²⁸ Let us reiterate that Protocol n. 30 on the application of the principles of subsidiarity and proportionality in its original Amsterdam version stipulated with its para. 6: “[...] Other things being equal, directives should be preferred to regulations and framework directives to detailed measures”. The Lisbon Treaty dropped this preference, for discussion of its impact see F Křepelka, ‘Transformations of Directives into Regulations’ cit. 795-797.

¹²⁹ See *Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making*, IV. Legislative Instruments, para. 25.

¹³⁰ *Simpler Legislation for the Internal Market (SLIM): Extension to a Third Phase – Working document of the Commission Services SEC (98) 559*, 26. 03. 1996.

¹³¹ Communication COM/2008/0394 final from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions of 25 June 2008, “Think Small First” - a “Small Business Act” for Europe; Communication COM(204) final from the Commission to the Council and the European Parliament of 8 May 1996 - *Simpler Legislation for the Internal Market (SLIM): a Pilot Project*, and subsequent documents reflecting and evaluating this initiative.

¹³² Communication COM(2012) 746 final from the Commission to the European Parliament to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions of 12 December 2012, *Regulatory Fitness*.

¹³³ Communication COM(2015) 215 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions of 25 May 2015, *Better regulation for better results - An EU agenda*.

¹³⁴ Commission decision of 11 May 2020 establishing the *Fit for Future Platform* (2020/C 163/03), 1-7.

¹³⁵ Even the 612 pages-long (!) *Better Regulation Toolbox - July 2023 edition* compiled by the European Commission, available at commission.europa.eu does not go beyond summarising art. 288 and listing several examples.

Epidemic surveillance was one of these cases until recently. Art. 168(5) TFEU excludes harmonisation concerning healthcare. One may argue that *a fortiori* this provision prohibits unification. Nevertheless, the enactment of SCBTHD in 2013 and the preceding 1998 decision were without any problems as they specified cooperation. It seems that cautiousness materialised in the choice of the decision.

Despite little doctrinal attention, the limits of decisions are common knowledge. The Commission, the Council and the European Parliament respect them. The Court of Justice has identified no “standardising” decision imposing duties, restrictions and liabilities on individuals without due authorisation. The aforementioned decision on imported meat expecting harmonisation seems to be a sporadic deviation, now overcome.¹³⁶

Nonetheless, the increasingly complex provisions of the acts we discuss can affect individuals and private entities, including their claims and counterclaims. Regulations can impose duties, restrictions and liabilities on individuals. EU lawmakers need not care for allowed and excluded effects. Therefore, replacing “standardising” decisions with regulations is convenient.

But in fact, the burden need not increase in particular cases. The Commission, the European Parliament and the Council can refrain from imposing duties, restrictions and liabilities on individuals. The direct effect of regulations is their potential, not necessity.

In-depth analyses of cited regulations replacing “standardising” decisions would be needed to evaluate whether this instrument has been necessary. These analyses require familiarity with the substance, its contexts, origin and development.

As SCBTHR shows, “Choice of the instrument” paragraphs in explanatory memoranda accompanying their proposals simplify. Moreover, some explanations are doubtful. Arguments for the cited regulation establishing the EU space programme are misleading,¹³⁷ and these for establishing the European Labour Authority exaggerate the effects of the instrument.¹³⁸

¹³⁶ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin, has replaced the Commission Decision 777/2007.

¹³⁷ See Proposal for a Regulation establishing the space programme of the Union and the European Union Agency for the Space Programme COM/2018/447 final – 2018/0236 (COD), 6 June 2018: “Choice of the instrument: A Regulation [...] establishing the Programme is not only explicitly provided for by Article 189(2) TFEU, but also the preferred instrument for placing the Programme on a sustainable footing. For that choice of legal instrument ensures the uniformity and direct application which are required for the effective implementation of the Programme, while giving it all due visibility and providing it with the financial resources it needs for its implementation”; the cited TFEU article does not specify the legal instrument. We wonder whether the instrument provides financial resources.

¹³⁸ See Proposal for a Regulation COM/2018/0131 final of the European Parliament and of the Council of 13 March 2018 establishing a European Labour Authority: “Choice of the instrument – The proposed instrument is a regulation [...]. A regulation provides the legal certainty required for setting up the Authority, which could not be achieved by means of other legal instruments”.

Indeed, the sole reason for “standardising” decisions, as the third binding instrument of secondary law in its narrow sense, is to signal that these acts are obligatory exclusively for the Member States as their usual addressees.

XI. PERSPECTIVES AND LIMITS OF THE TENDENCY

This text is sympathetic to replacing “standardising decisions” with regulations. The latter instrument does not raise doubts about its applicability in complex relations encompassing individuals. The culture of recasts provides an opportunity for an instrument change. Let us identify prospective cases.

The new standard for electronic customs clearance did not use this opportunity¹³⁹ as one of the widely known regulations, the Customs Code, was addressing the customs administration for three decades.¹⁴⁰ Concerning the standard for surveillance of the goods subject to excises,¹⁴¹ its explanatory memorandum unnecessarily turned a tradition into an obligation as similar cooperation in this field has been subject to regulations for decades.¹⁴² Another debatable case is guidelines for the legislative policy concerning product standards.¹⁴³

There is no reason to object even to regulations specifying the rights and duties of every Member State or most of them with numbers (figures, amounts) or enumerating individuals and entities to whom measures apply, albeit these regulations are not

¹³⁹ Decision 70/2008/EC of the European Parliament and of the Council of 15 January 2008 on a paperless environment for customs and trade, as amended by Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union.

¹⁴⁰ Regulation (EU) 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (recast), is the second recast of custom procedures. The first codification was Council Regulation (EEC) 2913/92 of 12 October 1992 establishing the Community Customs Code.

¹⁴¹ Decision 2020/263 of the European Parliament and of the Council of 15 January 2020 on computerising the movement and surveillance of excise goods (recast). We read in the explanatory memorandum for its proposal: “The choice of instrument is fully in line with the current legal act in force. Since the proposal is a recast of Decision 1152/2003/EC it must be a proposal for a Decision”.

¹⁴² Council Regulation 904/2010 of 7 October 2010 on administrative cooperation and combating fraud in the field of value added tax.

¹⁴³ Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC. The citation of the choice of instrument explaining the policy: “The Commission has taken the option of splitting its proposal into two separate legal texts in order to take on board the consequences in legal terms of the contents of the proposals: [...] the Decision sets guidelines for the future legislator. For this purpose a sui generis decision is proposed, as was done in 1993 in this same area, in order to set out the common elements for the future, accompanied by guidelines for their implementation. Future sectoral legislation, new or revisions of existing legislation, should use these elements wherever possible to ensure coherence, simplification and to follow rules of better regulation”.

“standardising” (“normative”, “norm-setting”, or “general”). As mentioned, similar phenomena exist in countries and international organisations.

This text mentions the asylum seekers' quotas. Both instruments seem feasible from the doctrinal point of view. The Court of Justice refused objections to the two Council decisions, which are inherently non-legislative.¹⁴⁴ But one can hardly argue against an amending regulation if this instrument stipulates general competence. Regulations prescribing quotas for the Member States concerning agricultural products are frequent.¹⁴⁵ These figures result from various calculations but may be subject to bargaining. The European Union prefers figures before formulae.

As the Member States negotiate in the Council and enjoy privileged access to the Court, we do not learn about the character of these quotas and the calculations behind them. Therefore, we also consider the CFSP decision¹⁴⁶ and the related regulation listing sanctioned Russian officials and oligarchs after the aggression against Ukraine.¹⁴⁷ These people may oppose their inclusion before the General Court similarly to the decisions addressed to them.¹⁴⁸ One may describe both acts as packages of decisions adopted *en bloc* by the Council combining legislative and executive roles and enjoying political legitimacy instead of hypothetical burdensome administrative evaluation of these individuals resulting in actionable decisions.

Nonetheless, there are measures the decisions shall express, while regulations are unfeasible. As mentioned, decisions in national settings stand primarily for individual (single-case) acts. As state aid approvals and controls indicate, particular Member States may be their addressees in the supranational European Union. Similarly, the cited special supervision of Romania should also rely on this instrument, as it is country-specific.

XII. ENVISAGED REFORM OF SECONDARY LAW INSTRUMENTS

The founding treaties have been in force unchanged for the past thirteen years.¹⁴⁹ Unfortunately, this stability, contrasting with their frequent changes in the previous

¹⁴⁴ *Slovakia and Hungary v Council* cit.

¹⁴⁵ Among the recently applied, Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007, annex XII – national and regional quotas for sugar.

¹⁴⁶ Council Decision 2014/145/CFSP of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine, as amended by numerous Council implementing regulations expanding the list of sanctioned Russian officials and oligarchs.

¹⁴⁷ Council Regulation (EU) 269/2014 of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine, following the Decision 2014/145/CFSP cit.

¹⁴⁸ Among partially successful applicants case T-720/14 *Rotenberg v Council* ECLI:EU:T:2016:689.

¹⁴⁹ Besides treaties on the accession of Croatia (2013) and withdrawal of the United Kingdom (2020).

decades, is a deadlock caused by the crises. Several Member States and the European Parliament have recently called for their reforms, but others consider that hasty with other problems soaring. The Conference on the Future of Europe encompassing laypeople (2019-2022) may be an innovative impulse, but it cannot replace the unwillingness of the Member States as founding fathers.

The abolition of the veto right in the Council has become a debated issue. An adjustment of the European Union's healthcare competence is expectable after the Covid-19 pandemic. Nonetheless, no debates about other changes have started. Unsurprisingly, the Conference on the Future of Europe did not mention legal instruments beyond the calls for reviving the Constitution, which is sensitive.

Secondary law instruments deserve reform due to their overcomplexity.¹⁵⁰ Let us call for its discussion. The simplification envisaged by the Treaty establishing a Constitution for Europe may inspire.

CFSP decisions will undoubtedly remain non-legislative and non-justiciable expressions of the joint positions and joint actions – the echo of the former instruments¹⁵¹ and their recent definition – reflecting the political consensus of the Member States coordinating their foreign and security policy.

Approvals of international treaties and appointments of persons to institutions differ from administrative acts. Perhaps, one may distinguish these politically significant acts with the terms “appointment”, “mandate”, and “approval”. This delineation may also contribute to specifying the extent and limits of judicial review, as appointments¹⁵² and conclusions of international treaties¹⁵³ have been its object in borderline cases.

Similarly, the competition policy is prominent to disappear from the primary law. Nevertheless, other EU administrative agendas have emerged recently. Under these conditions, formulating principles for the administration could be more feasible than defining its results. In that respect, one may note that Stelkens called for the de-constitutionalisation of administrative instruments fifteen years ago.¹⁵⁴

¹⁵⁰ E Best, 'Legislative Procedures after Lisbon: Fewer, Simpler, Clearer?' (2008) *Maastricht Journal of European and Comparative Law* 85.

¹⁵¹ Arts 13, 28, 29 TEU (Maastricht version).

¹⁵² Among others, see a passionate discussion about the removing AG Eleanor Sharpston after the Brexit whose legal action the Court rejected to hear. For a fierce criticism, see DV Kochenov and G Butler, 'Independence of the Court of Justice of the European Union: Unchecked Member States Power after the Sharpston Affair' (2021) *ELJ* 262.

¹⁵³ Art. 218(11) TFEU enables ex-ante control of compliance of international treaties concluded on behalf of the European Union by the Court of Justice. See Briefing - European Court of Justice and international agreements (European Union, 2021) www.europarl.europa.eu.

¹⁵⁴ It was also proposed in respect to the then signed TECE, also U Stelkens, 'Die „Europäische Entscheidung“ als Handlungsform des direkten Unionsrechtsvollzugs nach dem Vertrag über eine Verfassung für Europa' cit. 95: "Notwendigkeit einer Dekonstitutionalisierung der Europäischen Verwaltungsrecht".

Let us realise the recent complexity. Contrary to *delegated* and *implementing* in derived acts,¹⁵⁵ the adjective *legislative* is not mandatory. Mentioning *regulations/directives – legislative acts* or simply *legislative regulations/directives* is uncommon as it sounds strange. *Decisions – legislative acts*, simply *legislative decisions*, are an oxymoron.

It is worth noting that the Treaty establishing a Constitution for Europe envisaged two legislative instruments only: European laws and European framework laws. European decisions shall be non-legislative acts.¹⁵⁶ The European Union does not need a specific legislative instrument with applicability restricted to the Member States. “Standardising” (“general”, “normative”, or “norm-setting”) decisions are redundant.

Existing terminology, *i.e.* regulation and directive, does not reflect their prominent position (direct effect and primacy, indirect effect) and democratic legitimacy. *European (framework) laws* as the legislative instruments envisaged by the Constitutional Treaty¹⁵⁷ faced no opposition and enjoyed acknowledgement also after its failure.¹⁵⁸

Indeed, this terminology is adequate. The quick explanation of regulations and directives to laypeople is to say they are European (framework) laws. The EU lawmakers have recently embraced this terminology in official short titles of several regulations.¹⁵⁹ Therefore, we suggest considering its revival.¹⁶⁰

With this terminological reform, European laws would be the preferred instrument instead of regulations. There is no reason to exclude those replacing “standardising” decisions.

XIII. CONCLUSIONS

The European Community/the European Union have adopted decisions specifying cooperation and programmes on spending their money, including partnerships with third

¹⁵⁵ Arts 290(3) and 291(4) TFEU in contrast to art. 289 TFEU.

¹⁵⁶ Citation of relevant sentences in the (unsuccessful) Constitutional Treaty. Arts I-33(1): “A European decision shall be a non-legislative act, binding in its entirety”; arts I-35 “(Non-legislative acts) (1). The European Council shall adopt European decisions in the cases provided for in the Constitution, (2) The Council and the Commission, in particular in the cases referred to in articles I-36 and I-37 [...] shall adopt European regulations and decisions, I-37 (Implementing acts):”(4). Union implementing acts shall take the form of European implementing regulations or European implementing decisions”.

¹⁵⁷ Arts I-33 TECE.

¹⁵⁸ J Ziller, *Separation of Powers in the European Union’s Intertwined System of Government a Treaty Based Analysis of the Use of Political Scientists and Constitutional Lawyers* (Il Politico 2008) 133, 144 “There is hardly any doubt that it has been the European Convention’s merit to start calling a spade a spade, and a law a law. [...] The Treaty [...] has therefore replaced the designations used since the Rome treaties, *i.e.* regulations and directives, by European laws and European framework laws”.

¹⁵⁹ Regulation 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance (Data Governance Act) and Regulation 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality (“European Climate Law”).

¹⁶⁰ For details and discussion, see F Křepelka, ‘Several Acts and One Law as an Impulse for Reviving European (Framework) Laws’ (2022) *Časopis pro právní vědu a praxi* 829.

countries or having a similar “standardising” content. The theory paid little attention to these decisions.

Recently, the European Parliament and the Council have replaced several of these “standardising” (“normative”, “norm-setting”, or “general”) decisions with regulations. This instrument enables duties and restrictions on individuals and private entities. These effects can result from increasingly complex frameworks. Therefore, the trend is laudable.

It may be helpful to generalise this tendency in the envisaged reform of the founding treaties. European laws are the appropriate terminology. Following the plain meaning of this term in legal settings, the decisions in EU law should be primarily acts of the European Union's expanding administration.