

THE STATISTICAL FRAMEWORK AMID THE WAVE OF THE EU DATA ECOSYSTEM REGULATION: THE WAY FORWARD?

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Abstract

In light of users' expectations for official statistics, the European Commission proposed an amendment of Regulation 223/2009, aiming to make 'European statistics timelier, more frequent, more detailed and cost-efficient as well as more responsive to urgent information demands in times of crises'. The revised Regulation seeks to achieve the vision of the European Statistical System (ESS) for the future of official statistics.

This initiative is aligned with the overall aim of the Commission's Data Strategy to leverage the potential of data for the economy and society by overcoming data access challenges. A common denominator is that society, as a whole, will benefit from the availability of more data that can help to address societal challenges. However, overlaps and diverse provisions seem to exist between statistical and other laws, such as the Data Governance Act (DGA), the Data Act and the forthcoming Regulation on European Health Data Space (EHDS). Potential national discrepancies add even more complexity.

My contribution aims to explore: whether the existing provisions of data governance and statistical framework mentioned above provide clear and effective rules on how data shall be processed by national statistical authorities; whether there are risks due to ambiguities; how these risks could be addressed. The analysis, with some references to the Greek Statistical Law is based on the examination of the provisions on: i) re-use of data held by the national statistical authorities (DGA), ii) the new roles of the European data governance system, iii) data altruism (DGA), iv) the access to privately held data (Data Act) and v) the secondary use of electronic health data (EHDS).

I. INTRODUCTION

1. Following its announcement for the “European strategy for data”, the European Commission (EC) put forward a series of legal texts, aiming to unlock the potential of data for the benefit of the economy and society, namely: the Data Governance Act¹ (DGA), the Data Act², the Regulation on the European Health Data Space (EHDS)³. In alignment with the EC's objective for increased data availability, the European Statistical System (ESS) identified the importance of harnessing the possibilities of digital transformation for the production of official statistics. In this way, the ESS could respond to the expectations of the users of official statistics for timelier, more frequent and more granular comparable information. To this aim, the EC, upon consultation with the European Statistical System Committee (ESSC)⁴, proposed the amendment of Regulation 223/2009⁵.

2. The revised text of the Regulation 223/2009, encompassing the older and the new rules, will not operate in a vacuum. First, data processing activities within the national statistical systems must comply with the provisions of the GDPR⁶ and national data protection law. Furthermore, the Regulations under the EC's Data Strategy (DGA, Data Act, EHDS) also set new rules. To untap the potential of data for the

official statistics and its users at EU level, legal certainty and harmonised procedures are of great importance. In addition, any rules should preserve and enhance the high quality of European Statistics.

3. My purpose is to explore whether the existing or forthcoming provisions of data governance and statistical framework mentioned above provide clear and effective rules on how data shall be processed by national statistical authorities or whether there are risks due to ambiguities and how these risks could be addressed. I will begin with the analysis of the provisions governing the re-use of data held by the national statistical authorities (DGA). Next, I will examine the impact of the new roles of the European data governance system and the rules on data altruism (DGA). I will continue with the implications of Data Act concerning the access to privately held data and finally I will touch upon the final text of EHDS. This puzzling exercise may indicate issues for consideration during the discussions on the national data governance rules and further implementation initiatives. Examples will be drawn from the Greek Statistical Law to illustrate the impact of national provisions.

II. RE-USE OF DATA HELD BY STATISTICAL AUTHORITIES – THE IMPACT OF DGA

4. According to the EC, DGA provisions of Chapter II regarding the re-use of data held by public sector bodies by third parties⁷ aimed to address the under-utilisation of data held by public sector bodies - including statistical offices- and prevent the emerging fragmentation and inconsistencies across sectors and across countries.⁸ Such fragmentation would increase transaction costs for re-users, thus discouraging them from harnessing the full potential of data. Thus, Chapter II of the DGA establishes conditions for the re-use of data subject to statistical confidentiality and other protected categories⁹ which cannot be characterised as open data. Art. 5 stipulates transparency obligations, technical and organisational measures such as pseudonymisation, aggregation or access in a secure processing environment. Art. 6 allows public sector bodies to charge transparent, non-discriminatory, proportionate and objectively justified fees for providing access to data, which cover the costs made by the public sector body. It also provides the possibility for online payments and reduced fees and discounts in case of re-use for non-commercial purposes. Art. 9 sets a time limit of two months for response to the re-user's request and establishes a right of redress against the public sector body's decision on the re-user's request. It also obliges Member States (MS) to adopt national provisions laying down a procedure for the review by an appropriate impartial body¹⁰ with the appropriate expertise.

5. In parallel with DGA provisions, the re-use of data subject to statistical confidentiality is already regulated by Regulation 223/2009. The ESS has acknowledged the importance of these data for the progress of scientific research.¹¹ More specifically, Art. 19, as in force, provides the possibility for National Statistical Institutes (NSIs) and Other National Authorities (ONAs) to disseminate public use files consisting of anonymised records (the statistical unit cannot be identified). Secondly, Art. 23, as in force, allows NSIs and ONAs to provide access to confidential data permitting indirect identification of the statistical units for researchers who carry out statistical analyses for scientific purposes. As a matter of fact, most, if not all, EU MS have enacted national laws and bylaws, which lay down conditions and the procedure for such re-use cases. Furthermore, the recently proposed amendment of the Regulation¹² also encompasses rules on the further use of data provided by private data holders (new Art. 17e) and the access of researchers to those data (amended Art. 23). Besides, the importance of strict protocols when access to confidential data is provided is also set out in the European Statistics Code of Practice¹³.

6. Since both the DGA and the EU or national statistical legislation contain rules on this subject, admittedly, there was a risk of overlap. However, according to Art. 1 of the DGA, its provisions are without prejudice to a) specific Union or national law regarding the access to or re-use of certain categories of data and b) the obligations of public sector bodies under Union or national law to allow the re-use of data or to requirements related to processing of non-personal data. Moreover, the same provision stipulates that

when sector-specific Union or national law (such as statistical) requires public sector bodies to comply with specific additional technical, administrative or organisational requirements, those provisions of that sector-specific Union or national law shall also apply provided that those requirements shall not be non-discriminatory, proportionate and objectively justified. The “without prejudice” rule is repeated in the introductory Article to Chapter II. Art. 3 stipulates that this Chapter is without prejudice to Union and national law on the protection of data subject to statistical confidentiality.

7. Recital 11 -although a non-binding provision- clarifies that DGA will have a complementary role when other laws apply. More importantly, Recital 3 specifies that DGA is without prejudice to Regulation 223/2009, since it is one of those sector-specific Union laws that regulate access to and re-use of data. Finally, it is noted both DGA and the Regulation 223/2009 do not oblige but simply allow (‘may’) MS to provide access to anonymised microdata or to statistical microdata for researchers. Therefore, MS are competent to decide whether data is made accessible for re-use as well as the purposes and scope of such access. It follows from all the aforementioned provisions that where there is a gap in EU and national statistical legislation, the conditions established in the DGA will have to be implemented as long as it has been decided that access to confidential data will be provided. Nevertheless, the national legislator can set the rules to cover this gap.

8. Admittedly, the fact that specific priority clauses have been inserted in some Articles of Chapter II causes some uncertainty, considering that the general provisions of Art. 1 and 3 cover all the provisions of Chapter II. In particular, the duty to impose a confidentiality obligation on the re-user (Art. 5 par. 5) applies “unless national law provides for specific safeguards on applicable confidentiality obligations relating to the re-use of data”¹⁴. In the same vein, the two-month limit of Art. 9 par. 1 for response to the requests applies unless the national law provides a shorter time restriction.

9. The question which remains to be addressed is whether EU and national statistical laws and the DGA can harmoniously co-exist and complement with each other with legal certainty. If we use the Greek statistical legal framework as an example, we observe that Law 3832/2010¹⁵ enables access to confidential microdata for researchers by all the agencies of the Hellenic Statistical System (Art. 8) as well as the availability of anonymised microdata (Art. 7). Furthermore, the Regulation on Statistical Obligations, which is binding legislation, establishes three conditions for access to indirectly identifiable data: a) submission of a request with a detailed research proposal, b) specific mention of the datasets to be accessed, the methods of analysing them, and the time needed for the research, c) the conclusion of a contract between the researcher, the research institution or the sponsor and the ELSS agency, which, inter alia, specifies the measures for respecting the confidentiality of statistical data and the sanctions in case of breach (‘national law’, Art. 5 par. 5 of the DGA). Consequently, the DGA will not affect the national mandate to establish the conditions for access, neither their substance nor the content of the confidentiality obligation of the re-users.

10. Interestingly, Article 17 of Law 3832/2010 lays down rules on the pricing policy for the data provided by ELSTAT while it also refers to the Regulation of on the Operation and Administration with regard to more detailed conditions. In this case, it cannot be determined with certainty whether the provisions about fees fall within the scope of national law concerning the protection of data subject to statistical confidentiality or sectoral organisational arrangements with regard to access to data, and, thus whether they will apply instead of DGA rules. In contrast to the above topics, neither the EU nor the Greek statistical law set a time limit for the response to the re-users request. It seems that national statistical authorities will have to abide by the relevant specific provision of DGA but there is some ambiguity as to this conclusion. It may also be difficult to allocate responsibilities for reviews to an impartial body¹⁶ with expertise in issues of statistical disclosure control.

11. Finally, the ‘without prejudice to national law’ approach leaves room for different rules among MS, especially considering that most -if not all- national statistical systems have already established rules and procedures to enable access to indirectly identifiable data, while protecting the statistical confidentiality. This may cast doubts on the necessity and the effectiveness of the additional harmonised framework for data access as regards the national statistical systems, as presented in the Impact Assessment Report for the DGA.

III. NEW ROLES IN THE EU DATA GOVERNANCE SYSTEM FOR PUBLIC SECTOR’S DATA

12. Furthermore, the DGA determines new roles with specific competences within the public sector. Firstly, competent bodies of Art. 7 will provide assistance and will contribute to standardisation and interoperability of the data. Secondly, Single Information Points of Art. 8 will ensure transparency and coordination of data requests. MS are free to decide which bodies or services within bodies will undertake these roles.¹⁷ In fact, some MS have already delegated the role of Art. 7 competent body to their National Statistical Institute¹⁸. In other MS, it seems that there is no intention either from the side of the governmental authority responsible for implementing this legislation or the national statistical authority to take on this role. Thirdly, the DGA’s European Data Innovation Board, the EC’s expert group designated¹⁹ to provide advice to the EC, propose guidance on Data Spaces and facilitate multinational cooperation shall consist of representatives of bodies with specific expertise, including national statistical offices.²⁰ Until now, Statistics Estonia has been nominated as a member of the European Data Innovation Board²¹.

13. Considering that MS can assign these roles to any public sector body and divide their tasks depending on their sector of expertise - as long as there are no limits by other EU legislation- diverse approaches among MS are likely to arise. This could adversely impact the EU statistical governance and cause confusion to data providers and users of European Statistics. However, the EC’s proposal for Regulation 223/2009²² aimed to mitigate the potential risks from different approaches in national data governance regimes. The new Art. 26a affirms that NSIs may assume at national level functions as laid down in the national data governance frameworks, including the tasks laid down in the DGA. Yet, the provision puts it clearly: the performance of these functions “shall be compatible with the exercise of the statistical functions performed in conformity with the statistical principles”. It was considered essential that the implementation of statistical principles and the corresponding quality framework will not be put into question, since they are the pillars for the trust in the high quality of official statistics. The ethical principles and the quality framework are key to maintaining the credibility of statistical producers and a trustworthy source of information in the modern economy and society.

14. In all cases, regardless of whether statistical authorities undertake a role established in the DGA or not, it is pertinent to consider the relevance of Art. 5a par. 2 of the Regulation 223/2009, as in force. In line with the principle of scientific independence and objectivity enshrined in Art. 338 of the TFEU²³, the head of NSI shall have the sole responsibility for deciding on processes, statistical methods, standards and procedures for European statistics developed, produced and disseminated by the NSI, shall act in an independent manner while performing their statistical tasks, and shall develop national guidelines, where this is necessary to ensure quality of all European statistics within their national statistical system and monitor and review their implementation.

IV. USE OF DATA PROVIDED BY DATA ALTRUISM ORGANISATIONS

15. Additionally, the DGA lays down requirements for data altruism organisations in order to increase trust in data altruism and facilitate data repositories for general interest purposes. Art. 2 (16) enumerates the production of official statistics as one of these general interest purposes for which data can be voluntarily provided. It is expected that this possibility will open up new opportunities by increasing data

availability for the purpose of official statistics. However, it can be argued that the voluntary character of data altruism contrasts with the basic principle of obligatory access to data by statistical authorities as stipulated in Principle 2 of the Code of Practice, through surveys, use of administrative records or re-use of privately held data. Notably, this principle has been implemented through laws in several MS and enables the compilation of accurate statistics in accordance with the statistical methodology.

16. Ambiguities also emerge because of Recital 50 of DGA, which highlights that, pursuant to Art. 5 par. 2 of GDPR, any further use for statistical purposes of data provided to data altruism organisations on the basis of consent should be considered compatible with the initial purposes. This means that it is not an a priori requirement for data altruism organisations to obtain data subjects' consent to allow re-use of data for the purpose of official statistics. As a result, data altruism organisations can legitimately provide access to data for the production of official statistics even without consent for this specific purpose. Moreover, processing of personal data for the production of official statistics should not use consent as a legal basis (Art. 6 par.1 a of GDPR) - on account of power imbalances- but instead, legal obligation (par. 1 c) and public task in the public interest (par.1e). In case the personal data belong to one of the special categories of Art. 9 (1) the legal basis for processing could be found in of Art. 9 par. 2 j (scientific, historical research and statistical purposes).

V. ACCESS TO PRIVATELY HELD DATA - THE IMPACT OF DATA ACT

17. Data Act ²⁴ aims to introduce new mechanisms for re-use by public sector bodies of data held by private entities in exceptional situations. The new data re-use arrangements are expected to maximise the benefits for society while minimising the burden on businesses. Despite the attempts to integrate provisions that could meet the aim of the ESS to ensure access to privately held data on a sustainable basis²⁵, the final scope of Art. 15 is even more restricted than it was initially proposed²⁶. Unless necessary to respond to a public emergency²⁷, only access to non-personal data is possible and on the condition that the public sector body will identify specific data, the lack of which prevents it from fulfilling its specific public task. In addition, the public body must have exhausted all other means at its disposal to obtain such data beforehand, including purchase of non-personal data on the market by offering market rates, use of existing obligations to make data available or the adoption of new legislation.²⁸ In the context of the interinstitutional negotiations, the Council managed to achieve the insertion of an exception from the requirement to exhaust all the means including the purchase on the market, when purchase of such data is not allowed by national law for the production of official statistics. Moreover, an exception from the general rules of compensation was finally introduced in Art. 20, according to which data holders shall not be entitled to compensation under the same circumstances.

18. The final Data Act provisions could not address the concerns of the ESS and the needs for the production of official statistics. Nonetheless, Art. 16²⁹ ensures that Data Act will not affect the obligations laid down in Union or national law for the purposes of reporting, complying with requests for access to information or demonstrating or verifying compliance with legal obligations. Importantly, Recital 67 explicitly mentions that this Regulation complements and is without prejudice to the Union and national law providing for access to and the use of data for statistical purposes, in particular Regulation (EC) No 223/2009 as well as national legal acts related to official statistics. Nevertheless, while some countries had enacted national statistical laws which allowed access to data held by private entities, such as Greece (Law 3832/2010, Art. 2 par.3), others had not. Yet, even in Greece, the law does not lay down a specific clear procedure with corresponding technical and organisational arrangements.

19. Considering the stricter conditions of Data Act, the EC, upon consultation with NSIs, proposed the introduction of new provisions (Art. 17b, 17c, 17e) to Regulation 223/2009, which could enable both NSIs and ONAs to get access to data of private data holders on a sustainable basis, without the time and other

restrictions of the Data Act. Pursuant to the new Art. 17b par.1, the new rules on access to privately held data shall be without prejudice to reporting obligations, data collections or any data access laid down in EU sectoral statistical legislation or to the obligation for data holders to make data available on the basis of an exceptional need in accordance with Data Act. Therefore, Data Act will only be used in public emergencies and exceptional circumstances. The new rules of Regulation 223/2009 aim to ensure a harmonised approach at EU level which would bring legal clarity and ensure fair treatment for private data holders who are active in multiple MS³⁰.

20. Contrary to Data Act limitations, the final revised text of Regulation 223/2009 (as of 13 March 2024)³¹ stipulates that the request which can be submitted only by the NSI (also on behalf of ONAs) may also concern personal data, which shall be specified in sectoral legislation, under specific circumstances. The principle of data minimisation (access only to data necessary for the development and production) should always be implemented, for instance through appropriate technical and organisational measures such as pseudonymisation. Importantly, the necessity is defined pursuant to specific methodological description for each statistical product.³² Moreover, contrary to Data Act which excludes access to data of micro and small enterprises, Art. 17b par. 6³³ also covers data held by such micro or small enterprises if they are of specific interest for official statistics because of their nature and volume at national level. In addition, Article 17b enshrines the free-of-charge principle for access to data. Compensation may be requested for specific processing services but, under no circumstances, compensation will be provided by the NSI where the national law stipulates a relevant prohibition³⁴. Furthermore, contrary to the Data Act, which clearly states that a public sector shall not make data obtained from private data holders available for re-use³⁵, neither on the basis of DGA nor the Open Data Directive, the new Art. 17 e and the amended Art. 23 enable further use of the privately held data.

VI. THE IMPACT OF THE REGULATION ON THE EUROPEAN HEALTH DATA SPACE

21. Lastly, the EHDS proposal³⁶, the first proposal of domain-specific common European data spaces, aims to promote the use of electronic health data and improve healthcare services (primary use) while enhancing control by the natural persons. It further aims to better achieve other purposes that would benefit society, such as research, innovation, policy-making and official statistics (secondary use) in a trusted and secure way that preserves privacy.

22. Pursuant to the definitions of the EHDS proposal, statistical authorities are likely to be involved in the secondary use of data either as data holders (y) or data users (z) (Art. 2). Further, although not in the initial proposal, the final consolidated text as adopted by the Parliament at its first reading³⁷ (of 24 April 2024) stipulates that the Regulation shall be without prejudice to the rules of Regulation 223/2009 (Art. 1 par. 3) regarding access to, sharing of or secondary use of electronic health data, or requirements related to the processing of data. Nevertheless, first, questions emerge with regard to the relationship with national statistical rules which might establish specific conditions and procedures or even cover other statistical bodies outside the ESS. Secondly, even though, according to the above priority clause, Regulation 223/2009 and the procedure foreseen therein shall apply to access to electronic health data, including administrative data and data held by private entities, the reference to official statistics as one of the purposes of secondary use covered by the EHDS remains in Art. 34. Finally, although the reading of the added provision indicates that the EHDS will complement the rules of the Regulation 223/2009, which will apply in their entirety, it is not clear whether this excludes the involvement of the health data access body (Art. 45-50 of EHDS) in all cases.

VII. CONCLUSION

23. As a result of the advancements of data technologies, the EU enacted new rules to facilitate data access and data sharing in order to unleash the potential of data for the economy and society, including for the production of official statistics. It can be argued that the references to official statistics in all data laws reflect its significance as a public good which contributes to improved decisions and policies. However, in view of the divergent objectives of EU and national legislators in terms of data laws, the proposed provisions may cause risks to the production of official statistics and the implementation of its quality framework.

24. At the same time, it is evident from the above analysis that, in 2024, national statistical authorities have to navigate through a complex array of legal provisions derived not only from targeted sectoral statistical laws. The DGA, the Data Act and the EHDS Proposal entail provisions, which pertain to statistical authorities as public sector bodies. At first sight, the ‘without prejudice’ provisions seem to keep the statistical framework intact. However, this requires specific rules on each specific matter. If there is a gap, it seems that ambiguity and legal uncertainty emerges. The possibility for diverse approaches among MS adds to the perplexity of the data governance framework for European Statistics.

25. Undoubtedly, the proliferation of EU data laws addressing data access challenges necessitates continuous monitoring and evaluation of the new rules. The revision of 223/2009 marks a crucial effort to establish a secure and sustainable legal framework for the future of the ESS. It sets the foundation for a sectoral data governance framework on official statistics aiming to achieve high quality of data. Considering the restrictive approach of Data Act provisions on access to privately held data and data sharing as well as the challenges of the new data governance functions of DGA, the Regulation 223/2009 demonstrates the vigilance of the ESS members so as to remain relevant in the data ecosystem. Additional rules on sectoral data spaces are expected soon³⁸. In the meantime, national initiatives on setting data governance rules are currently under development in many countries. National statistical authorities need to be on alert and consider the steps forward: adoption of new statistical law provisions, specific provisions added to data laws, clarification in the preamble or the explanatory memorandum, reliance on general interpretation rules (*lex specialis* etc) are some of the options.

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All views expressed are solely those of the individual author and do not necessarily reflect the views of the Hellenic Statistical Authority

¹ Regulation (EU) 2022/868 on European data governance and amending Regulation (EU) 2018/1724 [2022] L 152/1 (Data Governance Act)

² Regulation (EU) 2023/2854 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 [2023] (Data Act)

³ Commission, ‘Proposal for a Regulation on the European Health Data Space’ COM (2022) 197 final (EHDS Proposal)

⁴ The ESS Committee is composed of the representatives of the NSIs who are national specialists for statistics. It is chaired by the Commission (Eurostat). Council Regulation (EC) No 223/2009 of 11 March 2009 on European statistics [2009] OJ L 87/164, as in force (Reg 223/2009) art. 7 par. 2

⁵ Commission, ‘Proposal for a Regulation amending Regulation (EC) No 223/2009 on European statistics’ COM (2023) 402 final. The Commission proposed new rules regarding: i) the conditions and the procedure for access to privately held data by Eurostat and national statistical authorities (art. 17b-17d), ii) further uses of the data obtained (Art. 17e) iii) data sharing within the ESS (art. 17 f) iv) the decision-making power for the adoption of temporary statistical actions (art. 16a), v) new potential roles of NSIs within their national data ecosystem to promote data integration

and interoperability (art. 26a), vi) the development of experimental statistics (art. 17g) and vii) strengthened mechanism for access to administrative data (art. 17a).

⁶ Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [2016] OJ L119/1.

⁷The DGA does not apply to the exchange of data between public sector bodies purely in pursuit of their public tasks. Data Governance Act, art. 2 par. 2 & Recital 12

⁸ Commission, 'Impact Assessment Report Accompanying Proposal for the Data Governance Act' SWD (2020) 295 final

⁹ Data Governance Act, art. 3 § 1

¹⁰ Indicative examples of such bodies mentioned are: national competition authority, the relevant access-to-documents authority, the supervisory authority established in accordance with Regulation (EU) 2016/679 or a national judicial authority.

¹¹ Reg. 223/2009, Recital 26

¹² Commission, 'Proposal for a Regulation amending Regulation (EC) No 223/2009 on European statistics' COM (2023) 402 final. The Proposal was adopted on 10.7.2022. A political agreement on the final text was approved by the Council in February 2024 and by the European Parliament on 13 March 2024. The subsequent vote in EP of the text as finalised by the lawyer-linguists and approval in the Council will happen during the new legislative term.

¹³European Statistics Code of Practice [2017], indicators 5.6, 15.4

¹⁴ DGA, art. 5 par. 5

¹⁵Law 3832/2010, as in force https://www.statistics.gr/documents/20181/300673/Stat_Law3832_EN.pdf/de31bfc8-c4d4-4d39-aa5f-d4592d1c8330

¹⁶ Indicative examples of such bodies mentioned are: national competition authority, the relevant access-to-documents authority, the supervisory authority established in accordance with Regulation (EU) 2016/679 or a national judicial authority.

¹⁷ Data Governance Act, art. 7 par.1

¹⁸ NSIs as art. 7 DGA competent bodies: Statistics Denmark, Statistics Netherlands, the President of Bulgaria's National Statistical Institute (for re-use of statistical data), Statistics Finland, Lithuania's State Data Agency <https://ec.europa.eu/newsroom/dae/redirection/document/98966>

¹⁹ DGA, art. 29-30

²⁰ DGA, art. 29, recital 53

²¹<https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3903>

²² Commission, 'Proposal on the amendment of Regulation 223/2009', COM (2023) 402

²³ Treaty on the Functioning of the European Union (TFEU)

²⁴ Regulation (EU) 2023/2854 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act). Data Act was proposed on 23.2.2022 and was finally adopted on 13 December 2023. It entered into force on 11 January 2024. Provisions of Chapter V shall apply 12 September 2025.

²⁵European Statistical System (ESS) position paper on the future Data Act proposal [2021]

²⁶ Commission, 'Proposal for a Regulation on harmonised rules on fair access to and use of data' COM (2022) 68 final See also European Parliament, Doc No EP-PE_TC1-COD (2022)0047

²⁷'Public emergency' means an exceptional situation, limited in time, such as a public health emergency, an emergency resulting from natural disasters, a human-induced major disaster, including a major cybersecurity incident, negatively affecting the population of the Union or the whole or part of a Member State, with a risk of serious and lasting repercussions for living conditions or economic stability, financial stability, or the substantial and immediate degradation of economic assets in the Union or the relevant Member State and which is determined or officially declared in accordance with the relevant procedures under Union or national law. Data Act, art. 2 (29)

²⁸ Data Act, art. 15

²⁹ Data Act, art. 16

³⁰ Commission, 'Explanatory Memorandum to Proposal on the amendment of Regulation 223/2009', COM (2023) 402

³¹ Position of the European Parliament adopted at first reading on 13 March 2024 with a view to the adoption of Regulation (EU) 2024/... of the European Parliament and of the Council amending Regulation (EC) No 223/2009 on European statistics

³² *ibid*

³³ *ibid*

³⁴ *Ibid*, art. 17 par. 5

³⁵ Data Act, art. 17 par. 3

³⁶ Commission, 'Proposal for a Regulation on the European Health Data Space' COM (2022) 197 final (EHDS Proposal)

³⁷ European Parliament, Resolution on European Health Data Space (24 April 2024) Document No P9_TA(2024)0331

³⁸ Commission, 'Staff Working Document on Common European Data Spaces' SWD (2024) 21 final