



ORIGINAL PAPER

Accuracy of Information, Data and Health Resilience: An Analytical Study of the Regulation (EU) 2022/2371

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Abstract:

Objectives: The current study distinguishes the importance of social data and health security at the European Union (EU) and Member States (MS) levels in accordance with the legal provisions of Regulation (EU) 2022/2371 (2022). **Methodology:** Therefore, the study focuses on the conceptual and legal analysis aimed to: (1) identify the legal framework of cross-border threats facing health and social sectors; (2) determine the health processes and measures by underlying the causes leading to “serious cross-border threats to health” [Article 2(1) Regulation (EU) 2022/2371]; (3) identify the legal information of primary legal issues as defined within Article 3 of the Regulation (EU) 2022/2371] (e.g. “case definition”, “monitoring”, “health in all policies” (4) develop a research plan for the legal concepts, terms and theories regarding information systems, information and exchange. The research also develops a content analysis using the Word Counter tool aimed to evaluate the distribution of words for selected legal text. **Results and discussion:** The results of the research develop a multidimensional overview of the factors and “indicators for surveillance” in MS [Recital (2), Recital (6), Article 7(1), Article 13(11) Regulation (EU) 2022/2371]. **Conclusions:** Anchoring the research on information exchange, and personal data protection combined with health security and resilience extends the analytical framework of the Regulation (EU) 2022/2371 providing a proper understanding of the digital platform, early warning response [Article 18 Regulation (EU) 2022/2371], alert conditions [Article 19 Regulation (EU) 2022/2371], health risk assessment [Article 20 Regulation (EU) 2022/2371], coordination of policies and responses [Article 21 Regulation (EU) 2022/2371].

Keywords: *information exchange, personal data, health security, resilience, EU.*

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Introduction

The study comprehensively analyses the relationship between information exchange, personal data protection and health resilience within Regulation (EU) 2022/2371 (2022). Launched in 2022, the Regulation is enshrined within the principles of transparency [Recital (20) Regulation (EU) 2022/2371], independence and impartiality [Recital (30) Regulation (EU) 2022/2371], subsidiarity [Recital (41) Regulation (EU) 2022/2371] and proportionality [Recital (41) Regulation (EU) 2022/2371]. The linkage between information, data protection and health resilience is also captured by recent literature aimed at fostering cross-border integration and cooperation in the field of healthcare (Haist, Novotný, 2023: 124-142; Scola, 2016; Su, Richardson, Wen, Pagán, 2011: 859-876), but also to focus the role of information exchange, resilience and protection of personal data in times of crisis (Brousselle, Brunet-Jailly, Kennedy, Phillips, Quigley, Roberts, 2020: 369-408; Lenton, Boulton, Scheffer, 2022). Therefore, the current study emphasizes (a) the relevant historiography for the concepts of information exchange, health resilience and personal data; (b) the legal analysis of the Regulation (EU) 2022/2371 focused on “cross-border threats to health” and (c) the quantitative and qualitative analysis using the Word Counter research tool applied to the Regulation (EU) 2022/2371.

Materials and methods

The methodology of the study provides an in-depth overview of the thematic of research divided in *three* parts: (a) a literature review of the field; (b) the legal analysis of the key topics of the Regulation (EU) 2022/2371; (c) a quantitative and qualitative analysis of the Regulation (EU) 2022/2371 using the Word Counter keyword-based analytical and statistical tool (Lin, Lin, Wen, Chu, 2016; Vijayasathy, Gould, Gould, 2015: 476-493; Bhargava, D’Ignazio, 2015). Word Counter is a numerical online tool counting the number of words in a document used to analyze the keyword density for one word, two words or three words. The current study applies the keyword-based analytical and statistical tool of Word Counter for the text of the Regulation (EU) 2022/2371 with the aim to identify the multiple themes and patterns relevant for the information, health, data and resilience fields. The benefits of using the Word Counter tool are the analysis emphasizes that the research in the field validates the importance of some prominent topics (one, two or three words) for European Union documentation.

Literature review on information, ethical governance and health security

The main empirical question of the current research is whether legal provisions and legal concepts of the EU legislation [namely Regulation (EU) 2022/2371] are substantially connected and correlated with recent scientific advances and developments. Therefore, our study approaches two linkages related to (a) the conceptual and analytical research of cross-border medical care utilization and integration (Amuedo-Dorantes, Rivera-Garrido, Vall Castelló, 2022: 859-876; Cooke, 2022) and (b) the interface between ethical and institutional governance and medical research (Olimid, A.P., Olimid, D.A., Chen, 2018: 1305-1310; Nadalutti, 2020: 1377-1392; Olimid, A. P., Olimid, D. A., 2019: 729-735). Given both the important role of information exchange and health systems resilience, recent studies also highlight the need for social engagement and environmental sustainability (Wills, 2019; Olimid, D.A, Olimid, A.P., 2022a: 114- 121;

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Olimid, D.A., Olimid, A.P., 2022b: 122-131), public health emergency and security (Khan, O'Sullivan, Brown, Tracey, Gibson, Génèreux, Henry, Schwartz, 2018). Other findings investigate the association between the urban governance and resilience during COVID-19 (Hunter, 2021:115-125; Ringsmuth, Otto, van den Hurk, Lahn, Reyer, Carter, Magnuszewski, Monasterolo, Aerts, Benzie, Campiglio, Fronzek, Gaupp, Jarzabek, Klein, Knaepen, Mechler, Mysiak, Sillmann, Stuparu, West, 2022). Concerning the development of new legal provisions and scientific approaches, the literature also assesses the challenging tasks of international health security (Gostin, Katz, 2016: 264-313), the European Health Union (Gallina, 2023) and information security (Sohrabi Safa, Maple, Watson, Furnell, 2018: 238-245). A second area where the literature considered often necessary to identify the conceptual relationship between health security and resilience is the conceptualization and normative fundamentals of human security and the relationship between individual and community security (Kokki, Ammon, 2023; Rushton, 2011: 779-796; Stoeva, 2020).

Documenting health, information and resilience

The second part of the research follows the legal analysis and arise from the acknowledge of the: (1) cross-border threats facing health [Recital (29) and Recital (31) Regulation (EU) 2022/2371] and social areas, namely: “social partners” and “social services” [Recital (31) Regulation (EU) 2022/2371]; (2) health perspectives, processes and measures by underlying the emergencies causes leading to “serious cross-border threats to health” [Article 2(1) Regulation (EU) 2022/2371] and “public health emergency” [Recital (35) Regulation (EU) 2022/2371]; (3) identification of the diversity of approaches to legal information here including: “health data” [Recital (39) Regulation (EU) 2022/2371]; “health risk-assessment” [Recital (38) Regulation (EU) 2022/2371]; “information exchange” and consultation with MS [Recital (43) Regulation (EU) 2022/2371]; “response planning” [Recital (43) Regulation (EU) 2022/2371]; processing and protection of personal data [Recital (37), Recital (39), Recital (46), Article 18(2)(4), Article 27, Article 28 Regulation (EU) 2022/2371]. In this context, the stated purpose of Regulation (EU) 2022/2371 covers specific issues responding to public health actions and measures focusing on the cross-border threats to health sector as defined and categorized by Article 2(1)(a)-(e). Therefore, the legal framework provides specific objectives and definitions [Article 3 Regulation (EU) 2022/2371]. The definitions of the main legal concepts and terms provide detailed guidance of the “case definition” [Article 3(2) Regulation (EU) 2022/2371]; “communicable disease” [Article 3(3) Regulation (EU) 2022/2371]; “control tracing” [Article 3(4) and Article 13 Regulation (EU) 2022/2371]; “epidemiological surveillance” [Article 3(5) Regulation (EU) 2022/2371]; “public health measure” [Article 3(9) Regulation (EU) 2022/2371]; “medical countermeasures” [Article 3(10) Regulation (EU) 2022/2371] and “health system capacity” [Article 3(13) Regulation (EU) 2022/2371].

As noted above, the Regulation (EU) 2022/2371 develops a set of five specific findings regarding: (1) the institutional level for discussions, consultation and coordination between MS developed by the HSC (Health Security Committee) [Article 4 and Article 21 Regulation (EU) 2022/2371] and Joint Procurement Agreement [Article 12 Regulation (EU) 2022/2371]; (2) the planning and response level for cooperation and information exchange [Article 5 Regulation (EU) 2022/2371]; (3) MS preparedness actions and measures, EU governance and resources [Article 6-11 Regulation (EU) 2022/2371]; (4) digital platform rules and guidance [Article 14 Regulation (EU)

2022/2371]; (5) norms and procedures for Early Warning and Response System (EWRS) [Article 18 Regulation (EU) 2022/2371]. Accordingly, Regulation (EU) 2022/2371 develops an extended approach to the coordination of response at the HSC level requires three stages of analysis. *First*, the research observes the relation to the domain of information exchange [Article 21 Regulation (EU) 2022/2371], national responses and institutional engagement [Article 21(a) Regulation (EU) 2022/2371] and “temporary public health measures” [Article 22 Regulation (EU) 2022/2371]. *Second*, the Regulation (EU) 2022/2371 conducts an extensive approach to the EU public health emergency [Chapter 4 Regulation (EU) 2022/2371]. *Third*, the legal provisions describe the personal data protection regarding the EWRS functionality [Article 27 and Article 28 Regulation (EU) 2022/2371].

Results and discussions

The content analysis of Regulation (EU) 2022/2371 using the Word Counter tool is aimed to evaluate the distribution of words for selected legal texts. Furthermore, the Word Counter analysis emphasizes a total of 21.138 words for the Regulation (EU) 2022/2371. Table 1 shows a prominent presence of the words considered to be important for the theme of Regulation (EU) 2022/2371 namely: “health” (323 words); “border” (127); “response” (121); “data” (102); “threats” (87); “surveillance” (78); “information” (84); “threat” (53).

Table 1. Keyword density for one word

No.	Keyword	Density	%	No.	Keyword	Density	%
1.	<i>health</i>	323	4%	26.	<i>threat</i>	53	1 %
2.	<i>Union</i>	194	3%	27.	<i>procurement</i>	52	1 %
3.	<i>Regulation</i>	172	2%	28.	<i>bodies</i>	49	1 %
4.	<i>Commission</i>	169	2%	29.	<i>coordination</i>	47	1 %
5.	<i>article</i>	157	2%	30.	<i>joint</i>	47	1 %
6.	<i>Member</i>	152	2%	31.	<i>authorities</i>	45	1 %
7.	<i>European</i>	136	2%	32.	<i>agencies</i>	43	1 %
8.	<i>states</i>	135	2%	33.	<i>monitoring</i>	42	1 %
9.	<i>border</i>	127	2%	34.	<i>diseases</i>	41	1 %
10.	<i>response</i>	121	2%	35.	<i>emergency</i>	41	1 %
11.	<i>national</i>	102	1%	36.	<i>communicable</i>	40	1 %
12.	<i>data</i>	102	1%	37.	<i>assessment</i>	40	1 %
13.	<i>Council</i>	96	1%	38.	<i>procedure</i>	39	1 %
14.	<i>preparedness</i>	95	1%	39.	<i>order</i>	39	1 %
15.	<i>threats</i>	87	1%	40.	<i>risk</i>	39	1 %
16.	<i>Parliament</i>	84	1%	41.	<i>Committee</i>	38	1 %
17.	<i>information</i>	84	1%	42.	<i>countermeasures</i>	38	1 %
18.	<i>prevention</i>	80	1%	43.	<i>acts</i>	37	1 %
19.	<i>surveillance</i>	78	1%	44.	<i>network</i>	36	1 %
20.	<i>accordance</i>	66	1%	45.	<i>epidemiological</i>	36	1 %
21.	<i>measures</i>	61	1%	46.	<i>support</i>	36	1 %
22.	<i>medical</i>	59	1%	47.	<i>international</i>	35	1 %
23.	<i>HSC</i>	59	1%	48.	<i>activities</i>	35	0 %
24.	<i>ECDC</i>	57	1%	49.	<i>protection</i>	33	0 %
25.	<i>decision</i>	56	1%	50.	<i>systems</i>	33	0 %

Note: Table 1 displays keyword density of 1 word (selection).

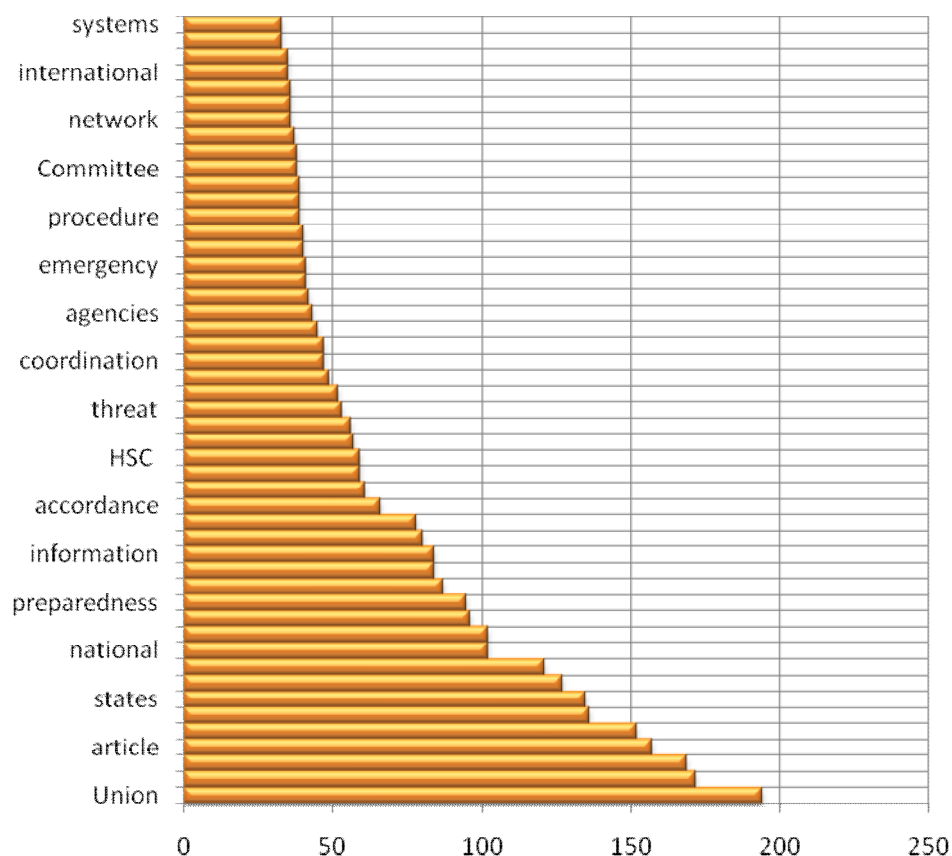
Data source: Authors’ own compilation based on the results of the context analysis of the Regulation (EU) 2022/2371 (<http://data.europa.eu/eli/reg/2022/2371/oj>) using the Word Counter tool.

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The most used terms (> 100 keywords) vary from “data” (102) to “health” (323) and tend to refer to sector terms [e.g. “health” (323); “border” (127); “national” (102); “medical” (59)] and institutional framework [e.g. “Commission” (169); “Member” (152); “Council” (96); “Parliament” (84); “HSC” (Health Security Committee) (59); “ECDC” (European Centre for Disease Prevention and Control) (57); “authorities” (45); “agencies” (43); “Committee” (38); “systems” (33); “surveillance” (78); “monitoring” (42); “procedure” (39); “network” (36); “support” (36);] (Table 1).

Graph 1 contains selected topics allowing for comparison of the keywords density for one word. Topics such as “systems”; “activities”; “support”; “network”; “countermeasures” and “procedure” provide information on institutional and functional indicators demanding coverage of effective measures and actions for the prevention of cross-border threats. Moreover, Graph 1 includes key topics used to estimate data preparedness and response planning. Other coverage concepts explain the prevalence of the topics in the area of institutional support and MS coordination (e.g. “prevention”, “coordination”, “Parliament”, “national”, “states”, “Union”).

Graph 1. Variations of the keyword density for one word



Data source: Authors’ own compilation based on the results of the context analysis of the Regulation (EU) 2022/2371 (<http://data.europa.eu/eli/reg/2022/2371/oj>) using the Word Counter tool

Table 2 indicates the frequency distribution of two words emphasizing the need for Regulation (EU) 2022/2371 to develop a planning and response road map for cross-border threats to the health suggesting a statistical development among the priorities in the EU and national policy agenda (e.g “cross-border” (124 words); “preparedness response (77); “border threats” (69); “threats health” (69); “border threat” (34); “competent authorities” (32); “response planning” (27); “national competent” (23); “Member State” (19); “response plans” (15); “acts adopted” (11).

Moreover, Table 2 states on focusing the key areas for cross-border cooperation and preparedness needed for policy and measures plans. Table 2 also shows the focus of the Regulation (EU) 2022/2371 tracing the information and trends of health resilience and data exchange.

Seven keywords, four from the institutional perspective [“health emergency” (23 words); “emergency Union” (16); “epidemiological surveillance” (35) “medical countermeasures” (36)] and three from a medical standpoint [“health emergencies” (13); “special health” (14); “communicable diseases” (28)] express the insights and patterns of the mechanisms of preparedness response.

This approach is followed by the legal provisions for data protection [“personal data” (28); “data protection” (10); “processing personal” (10)], information exchange [“network epidemiological” (15); “Member States” (133); “Member State” (19)] and knowledge on “risk assessment” (17 words), and “early warning” (20 words) (Table 2).

Table 2. Frequency distribution of two words

No.	Keywords	Density	%
1.	<i>Member States</i>	133	5 %
2.	<i>cross-border</i>	124	4 %
3.	<i>European Parliament</i>	84	3 %
4.	<i>preparedness response</i>	77	3 %
5.	<i>border threats</i>	69	3 %
6.	<i>threats health</i>	69	3 %
7.	<i>prevention preparedness</i>	59	2 %
8.	<i>joint procurement</i>	44	2 %
9.	<i>agencies bodies</i>	39	1 %
10.	<i>Union agencies</i>	38	1 %
11.	<i>medical countermeasures</i>	36	1 %
12.	<i>epidemiological surveillance</i>	35	1 %
13.	<i>border threat</i>	34	1 %
14.	<i>competent authorities</i>	32	1 %
15.	<i>personal data</i>	28	1 %
16.	<i>communicable diseases</i>	28	1 %
17.	<i>response planning</i>	27	1 %
18.	<i>advisory committee</i>	27	1 %
19.	<i>implementing acts</i>	25	1 %
20.	<i>national competent</i>	23	1 %
21.	<i>health emergency</i>	23	1 %

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22.	<i>article regulation</i>	23	1 %
23.	<i>early warning</i>	20	1 %
24.	<i>Member State</i>	19	1 %
25.	<i>reference laboratories</i>	18	1 %
26.	<i>risk assessment</i>	17	1 %
27.	<i>emergency Union</i>	16	1 %
28.	<i>network epidemiological</i>	15	1 %
29.	<i>response plans</i>	15	1 %
30.	<i>national prevention</i>	15	1 %
31.	<i>health measures</i>	15	1 %
32.	<i>procurement procedure</i>	14	1 %
33.	<i>health issues</i>	14	1 %
34.	<i>third countries</i>	14	1 %
35.	<i>special health</i>	14	1 %
36.	<i>digital platform</i>	14	1 %
37.	<i>European Union</i>	13	0 %
38.	<i>human origin</i>	13	0 %
39.	<i>health emergencies</i>	13	0 %
40.	<i>platform surveillance</i>	13	0 %
41.	<i>response plan</i>	12	0 %
42.	<i>international organisations</i>	11	0 %
43.	<i>communicable disease</i>	11	0 %
44.	<i>acts adopted</i>	11	0 %
45.	<i>monitoring early</i>	10	0 %
46.	<i>human health</i>	10	0 %
47.	<i>data protection</i>	10	0 %
48.	<i>processing personal</i>	10	0 %
49.	<i>examination procedure</i>	10	0 %

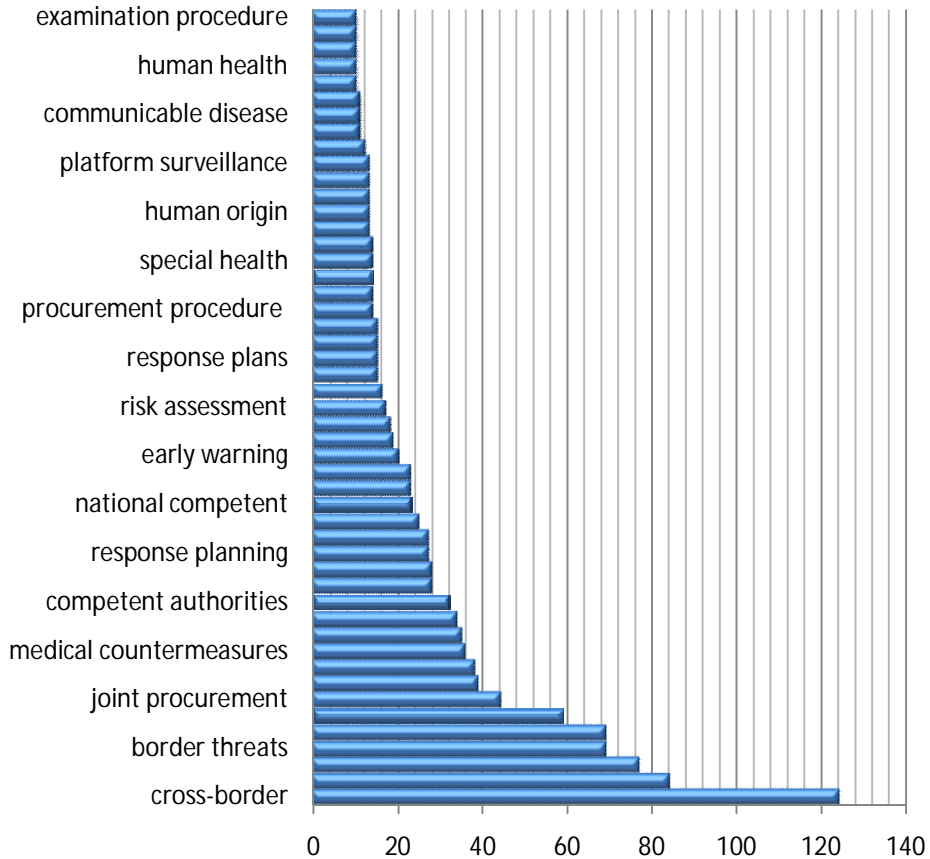
Note: Table 2 displays the Keyword density of two words (selection)

Data source: Authors' own compilation based on the results of the context analysis of the Regulation (EU) 2022/2371 (<http://data.europa.eu/eli/reg/2022/2371/oj>) using the Word Counter tool

Graph 2 entitled “Variations of the keyword density for two words” is relevant for the impact of four topics called to generate increased impact to institutional resilience and capacity [“response planning” (27); “monitoring early” (10); “platform surveillance” (13); “examination procedure” (10)]. Therefore, Graph 2 suggests that serious cross-border threats to health” [Article 2(1) Regulation (EU) 2022/2371] should frame a new action programme for “response plan”. These broad fundamental indicators include: (a) the need for institutional and capacity building [“network epidemiological (15)”; “national prevention” (15) and “platform surveillance” (13)]; (b) adaption of policy management and practices related to health sector [“joint procurement” (44); “procurement procedure” (14); “examination procedure” (10)]; (c) inclusion of

indicators demanding coordination at EU and MS levels [Recital (12) Recital (13) Recital (15), Recital (17) Regulation (EU) 2022/2371]. In this context, three keywords prioritize the health sector requirements for “epidemiological surveillance” [Chapter III Regulation (EU) 2022/2371] and “preparedness and response planning” [Chapter II Regulation (EU) 2022/2371], namely: “prevention preparedness” (59); “response planning” (27) and “health emergencies” (13)].

Graph 2. Variations of the keyword density for two words



Data source: Authors’ own compilation based on the results of the context analysis of the Regulation (EU) 2022/2371 (<http://data.europa.eu/eli/reg/2022/2371/oj>) using the Word Counter tool

Table 3 entitled “Frequency distribution of three words” shows three basic procedures and instruments designed to establish correlation between (a) the major components of “prevention, preparedness and response planning” [Chapter II Regulation (EU) 2022/2371] here including: “cross-border threats” (69 words); “prevention preparedness response” (58); “network epidemiological surveillance” (15); “national competent authorities” (23); (b) policy and programming calling for cooperation [Recital (30), Recital (38), Recital (39), Recital (40) Regulation (EU) 2022/2371] and

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“coordination of response” [Recital (33), Article 2(4), Article 21 Regulation (EU) 2022/2371]; “joint procurement procedure” (14); “Union prevention preparedness” (11); “monitoring early warning” (10); “joint procurement medical” (9); (c) “processing personal data” (10); “related special health” (13); “border threat health” (34); “health emergency Union” (16).

Table 3. Frequency distribution of three words

No.	Keywords	Density	%
1.	<i>European Parliament Council</i>	77	5 %
2.	<i>cross-border threats</i>	69	5 %
3.	<i>border threats health</i>	68	5 %
4.	<i>prevention preparedness response</i>	58	4 %
5.	<i>Union agencies bodies</i>	38	3 %
6.	<i>Regulation European Parliament</i>	35	2 %
7.	<i>cross-border threat</i>	34	2 %
8.	<i>border threat health</i>	34	2 %
9.	<i>preparedness response planning</i>	27	2 %
10.	<i>national competent authorities</i>	23	2 %
11.	<i>health emergency Union</i>	16	1 %
12.	<i>network epidemiological surveillance</i>	15	1 %
13.	<i>preparedness response plans</i>	15	1 %
14.	<i>national prevention preparedness</i>	15	1 %
15.	<i>joint procurement procedure</i>	14	1 %
16.	<i>substances human origin</i>	13	1 %
17.	<i>related special health</i>	13	1 %
18.	<i>digital platform surveillance</i>	13	1 %
19.	<i>special health issues</i>	12	1 %
20.	<i>preparedness response plan</i>	12	1 %
21.	<i>Member States Commission</i>	11	1 %
22.	<i>Union prevention preparedness</i>	11	1 %
23.	<i>monitoring early warning</i>	10	1 %
24.	<i>combating cross-border</i>	10	1 %
25.	<i>processing personal data</i>	10	1 %
26.	<i>joint procurement medical</i>	9	1 %

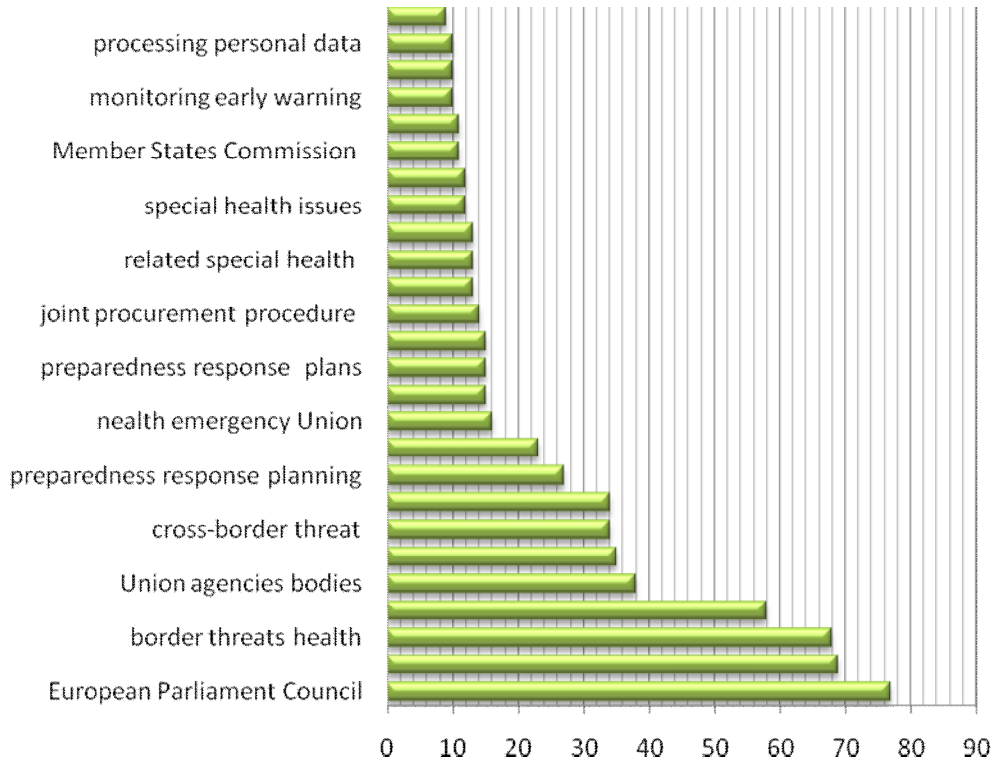
Note: Table 3 displays the Keyword density of three words (selection).

Data source: Authors’ own compilation based on the results of the context analysis of the Regulation (EU) 2022/2371 (<http://data.europa.eu/eli/reg/2022/2371/oj>) using the Word Counter tool

Graph 3 entitled “Variations of the keyword density for three words” shows the framework for formulated actions and key domains concluding the extent to which the legal provisions of the Regulation (EU) 2022/2371 are provided. Graph 3 also provides the institutional and functional priorities by outlining the need for a common action plan. In this context, the most used terms are “Union agencies bodies” (38 words) and “network epidemiological surveillance” (15). Furthermore, in this broad perspective, the “processing of personal data” [Recital (39), Recital (43), Recital (46), Article 27 and

Article 28 Regulation (EU) 2022/2371] undertakes principal activities involving responsibilities of MS [Article 27(1) Regulation (EU) 2022/2371].

Graph 3. Variations of the keyword density for three words



Conclusions

In conclusion, the study reveals the conceptual and analytical basis for the research of the Regulation (EU) 2022/2371 by enlightening the role of data and information exchange and health resilience. Moreover, the results of the research increase the relevance of the legal provisions to social and policy development. Then with institutional and functional linkages, the conceptual and analytical research provides operational guidance to fundamental keywords aimed to establish relevance among various domains of planning and implementation.

Authors' Contributions:

The authors contributed equally to this work.

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