The origins of food safety regulation and the different models in food risk control systems: the cases of Italy, Poland, Serbia and Austria (Draft-long abstract)

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1. The origins of food safety regulation and competent authorities

In a current scenario characterised by an uncertain and constant discussion on finding the new oil for humanity (such as data), there is no doubt that food has always been our fuel. Hopefully, it will remain as such. However, it is well known that this same fuel can sometimes be fatal. It is not uncommon to hear about catching bacterial infections or the spread of diseases transmitted by eating certain types of food. This goes back to ancient years. It is believed that Alexander the Great died because of Salmonella typhi[1].
In ancient Egypt, there was already attentiveness to food preservation[2]. For instance, Egyptians developed the silo to store grain and maintain it in a good state of conservation[3].

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[1] Cunha, B. A. (2004). *The death of Alexander the Great: malaria or typhoid fever? Infectious Disease Clinics of North America*, 18(1), 53–63. https://doi.org/10.1016/s0891-5520(03)00090-4
[2] Ikram S. (2008). *Meat Preservation in Ancient Egypt, in: Selin H. (eds) Encyclopaedia of the History of Science, Technology, and Medicine in Non-Western Cultures*. Springer, Dordrecht. https://doi.org/10.1007/978-1-4020-4425-0_8752
[3] Bardonová, M. (2019), *Grain Storage in Ancient Egypt (2500-1650 BC), Typology and socio-economic implications,* PhD dissertation, Charles University, Czech Institute of Egyptology: https://dspace.cuni.cz/bitstream/handle/20.500.11956/106470/140073202.pdf?sequence=1

Romans used the salting process[4]. All this a long time before the refrigeration era[5], the discovery of germs and parasites' presence in food[6], or pasteurisation[7].
If food safety issues were already an ancient concern, the origins of regulation lead even further back, in its broader definition. It can be said that regulatory measures were introduced as soon as human activities developed in economic ones[8]. Indeed, regulations are considered crucial for the stability of economies and societies: creating a framework that allows the protection of rights and safety of citizens[9].
In 2000 BC, based on the book of Leviticus[10], Moses introduced laws, such as the washing of clothes and bathing after animal sacrifices, as protection for citizens from food diseases. The Code of Hammurabi dates as far back as 3000 BC[11], the Arthashastra in India dates back to 400 BC. The latter also contains a reference to food adulteration[12]. Moreover, in ancient Egypt, magistrates had the task of controlling the healthiness of food and drink to avoid fraud[13]. Romans had the *Edili Curuli* : inspectors that oversaw foodstuffs on the market, including inspecting food shops and checking meat[14]. Augustus then entrusted this task to a magistracy: the Prefetti dell'annona[15].
Later on, in the late 12th century, the shift of population in Western Europe, from rural to urban settings, required an improvement in regulation and increased food safety controls[16] – obviously regarding what was deemed to be "safe". For instance, with the statutes of the so-called *Beccai*[17] and the *Magistrato di Sanità* in Florence.
However, it is between 1800 and 1900, with growing populations in cities, and foreign trade leading to an increase in the spread of food diseases and food poisoning (ex. typhoid

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[4] Villegas Becerril, A. (2021). *Culinary Aspects of Ancient Rome: Ars Cibaria*, Cambridge Scholars Publisher, p. 19.
[5] See: Rezeneck, S. (1954). *Refrigeration in America. By Oscar Edward Anderson Jr*, (Published for the University of Cincinnati.) Princeton: Princeton University Press, 1953. Pp. ix, 344. The Journal of Economic History, 14(1), 76–77. https://doi.org/10.1017/s0022050700063762
[6] See: History of Microorganisms in Food. (2005). Modern Food Microbiology, 3–9. https://doi.org/10.1007/0-387-23413-6_1
[7] Birch, B. (1988). *Louis Pasteur: The Scientist who Discovered the Cause of Infectious Disease and Invented Pasteurization*, United States, G. Stevens.
[8] Di Porto, F. (2011), *Regolazione del rischio, informazione e certezza giuridica*, in *Rivista di diritto alimentare*, Anno V, N. 4, p. 2
[9] OECD (2011), *Regulatory Policy and Governance: Supporting Economic Growth and Serving the Public Interest*, OECD Publishing, Paris, https://doi.org/10.1787/9789264116573-en.
[10] Book of Leviticus, 15:13; 13:46.
[11] Ross, J. C. (2004). A History of the Ancient Near East, ca. 3000–323 BC. Marc Van De Mieroop. *Bulletin of the American Schools of Oriental Research*, *334*, 77–78. https://doi.org/10.2307/4150110
[12] El Mahi, T. (2013). *Food customs and cultural taboos*, in *Sudanese journal of paediatrics*, *13*(1), pp. 90–95.
[13] Cammeo, F.; Vitta, C. (1905), "Sanità Pubblica", in V. E. Orlando (ed.), Primo trattato completo di diritto amministrativo italiano, Part II, Vol. 4 (Milan: Società Editrice Libraria, 1905), at p. 217.
[14] Civera, T.; Julini, M. (2008), *Dal naso alle nanotecnologie: evoluzione millenaria delle metodologie ispettive,* abstract della relazione presentata al convegno di Alimentazione, igiene e società tra passato e presente, Università di Torino, Facoltà di Medicina Veterinaria, Torino, 21-22 novembre 2008, p.1.
[15] Civera, T.; Julini, M. (2008).
[16] Blanc, F.; Cola, G. (2017*). Inspections, risks and circumstances. Historical development, diversity of structures and practices in food safety*, in *Studi Parlamentari e di politica costituzionale*, Anno 50- N. 197- 3-4 trimestre, p. 51
[17] Giuliani, M. (2006), *Le Arti Fiorentine*, Firenze, Scramasax.

fever, diarrhoea, dysentery)[18], along with better scientific knowledge[19], that the modern approach to food safety had origin.

Britain introduced the First Public Health Act in 1848[20]. The *ratio* was economic: improvements in health would lead to fewer people seeking poor relief[21]. The latter was followed by the Adulteration of Food and Drink Act[22] in 1860 (Britain) and by the Sale of Food and Drugs Act[23] of 1875, considered the "foundation of modern food legislation"[24].

It followed the formation of the US Department of Agriculture (USDA), containing the Division of Chemistry, that in 1906 became the Food and Drug Administration; the Pure Food and Drug Act and Federal Meal Inspection Act (USA) in 1906; the Food, Drug, and Cosmetic Act in 1938 (USA). Leading to the Codex Alimentarius in 1963[25], the HACCP[26], and the EEC and EU, which strongly affected the food safety regulations in the European Countries. The majority of them had general and poor implemented regulations. Here as well, a food safety crisis was crucial for the regulatory development: the "mad cow disease"[27]. Thus, a decade of collaboration concerning the objectives of the Common Agricultural Policy, the growth of the Internal Market, and the goal of a high level of protection of human health and safety led to the need for an integrated approach[28] between the Member States. The latter through the Regulation (EC) n. 178/2002 (primarily presented in the White Paper on Food Safety) and the European Food Safety Authority (EFSA) set-up.

Food safety was characterized by different approaches at European level (being actually still an ongoing development).

In Italy, the food safety system development began with a need for harmonisation. As well known, the peninsula's territories were deeply fragmented before 1861. The central

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[18] Cirillo, V. J. (2000). *Fever and Reform: The Typhoid Epidemic in the Spanish-American War*, in *Journal of the History of Medicine and Allied Sciences*, *55*(4), 363–397. https://doi.org/10.1093/jhmas/55.4.363 ; Kazanjian, P. (2018). The Short-Lived Epidemic of Botulism From Commercially Canned Foods in the United States, 1919 to 1925. *Annals of Internal Medicine*, *168*(8), 579. https://doi.org/10.7326/m17-2853.; Neiderud C. J. (2015). How urbanization affects the epidemiology of emerging infectious diseases. *Infection ecology & epidemiology*, *5*, 27060. https://doi.org/10.3402/iee.v5.27060

[19] For instance, the first isolation of Salmonella happened in 1880 after a food poisoning outbreak: Food safety: thinking globally acting locally. (2006). Regno Unito: Emerald Group Publishing, p. 7.

[20] See: https://www.parliament.uk/about/living-heritage/transformingsociety/towncountry/towns/tyne-and-wear-case-study/about-the-group/public-administration/the-1848-public-health-act/

[21] *Ibid.*

[22] Curran, R. E. (1951). *British Food and Drug Law —A History*, in *Food, Drug, Cosmetic Law Journal*, *6*(4), 247–268. http://www.jstor.org/stable/26654525

[23] Ibid.

[24] Thompson, K. (1995), The Law of Food and Drink, Shawn & Sons Ltd.

[25] FAO and WHO, 'Origins of the Codex Alimentarius' in Understanding the Codex Alimentarius (1999), ISBN 92-5-104248-9.

[26] To deepen the HACCP history: Weinroth, M. D., Belk, A. D., & Belk, K. E. (2018). History, development, and current status of food safety systems worldwide. *Animal frontiers: the review magazine of animal agriculture*, *8*(4), 9–15. https://doi.org/10.1093/af/vfy016

[27] Aldy, J.E.; Viscusi, W.K., Risk Regulation Lessons from Mad Cows, Foundation and Trends in Microeconomics, vol 8, no 4, pp 231–313.

[28] FAO/WHO, *Global forum of food safety regulators*, The general principles of food law in the European union and the European food safety authority (2002): http://www.fao.org/3/ab508e/ab508e.pdf

administration was entitled to the Ministry of Interior and locally to the prefectures[29]. The first food safety legislation was the "*Organisation of health care and administration*"[30]. Then, the Superior Health Council was established as a technical consultive organ of General Direction on Public health inside the Ministry of Interior[31].
Legislative activity had difficulties getting off the ground except in emergency cases with epidemics, endemics and epizootics[32] , and executive power in food safety was actually in the hands of the local administrations[33].
Later on, with the "new unified law on health"[34], there was a more precise organisation. The central body remained the General Directorate of Health, still under the Ministry of the Interior, supported by the Superior Health Council and the Research Institutes. The peripheral bodies were the Prefect, the Provincial Health Council, the provincial doctor, the local laboratories of hygiene and prevention, the metropolitan, border and airport health officers, the mayor and the health officer. The latter until the establishment of the High Commission for Hygiene and Sanitation[35], abolishing the General Directorate of Health. Finally, on 13 March 1958, the Ministry of Health was established, which was created to implement Article 32 of the Constitution fully[36].
It is essential to understand that food safety was not a primary necessity between the early 1960s and the mid-1980s. More importance was given to food security: the urgency of quantity prevailed over quality. The right to food has long been a category of criminal interest, being part of a more general right to health and public hygiene[37]. There was no emphasis on risk prevention.
On the opposite, food safety is now acquiring relevance in terms of public economic law, and the preventive approach has become the focus of its regulation[38].
The Law n. 283 of 30 April 1962 and its implementing regulation (Presidential Decree No 327/1980) are considered a fundamental Italian milestone in food safety, being a rather complex regulatory text of an administrative nature, but with critical criminal inserts. It was intended to regulate the entire cycle of food products, from preparation to

[29] Bottari, C. (2015), La sicurezza alimentare. Italy, Maggioli Editore, p. 47
[30] (Royal Decree No. 2248 of 20 March 1865).
[31] Gueze, R. (1962), *Lineamenti storici del ministero degli interni*, in *Amministrazione civile*, V (1961), n. 47-51, pp. 195-218; Franze, G. (1962), *L'ordinamento costituzionale amministrativo dell'interno*. La pubblica sicurezza, Rome.
[32] For instance, Giovanni Lazza, Minister of Interior, presented (twice) a Sanitary Code piece of legislation on 1870 that was not even discussed in the Parliament: Peruta, F. D. (1980), *Sanita' pubblica e legislazione sanitaria dall'Unita' a Crispi,* in *Studi Storici*, *21*(4), 713–759.
http://www.jstor.org/stable/20564843
[33] Bottari, C. (2015), *La sicurezza alimentare.* Italy, Maggioli Editore, p. 47.
[34] Royal Decree no. 1265 of 27 July 1934
[35] DL No 417 of 12 July 1945
[36] The Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the poor. Nobody may be forcefully submitted to medical treatment except as regulated by law. That law may in no case violate the limits imposed by the respect for the human being.
[37] Bevilacqua, D. (2012). *La sicurezza alimentare negli ordinamenti giuridici ultrastatali*, Giuffrè editore, Milano, p.12.
[38] Costato, L. (2017). *Diritto al cibo e Global Food Security: la perdurante assenza di un'adeguata risposta europea*, in *Rivista di diritto alimentare*, Anno XI/4, ottobre-dicembre, p. 20.

distribution. It still remains in force, albeit strongly amended. It is now obsolete because it was adopted in an outdated economic and production context and scientific knowledge. In particular, concerning the offences highlighted in article 5, the widespread practice in the Courts was to penalise companies even in the case of conduct that does not constitute a danger to human health or damage to consumers.

Legislative decree no. 27/2021, which covers the rules of broadest and most relevant interest to operators, implementing Regulation (EU) No 625/2017, and reformed the system of official controls on food, feed, animal health and animal welfare, attempted to repeal art. 5 and the criminal offences on food safety. Thus, overcoming the outdated provision.

However, the Italian government, with a last-minute Legislative decree no. 42/2021 avoided the repealing effect of all the penal and administrative provisions of Law No 283 of 30 April 1962. Hence, the obsolete coexistence of two different approaches still remains in place.

The globalisation and Europeanisation of food safety regulation is now a multi-layered matter, depending on the diversity of interests involved: safety, freedom of trade, economic development and environmental protection[39].

Therefore, it can be said that Italian national administrative Law is an integrated law conforming to norms of international origin, but of an administrative nature, capable of binding the authorities of the territory to which it belongs[40].

The global complexity of food safety led to the idea of having to regulate respecting local needs without affecting global ones, giving decision-making powers to the centre without taking them away too much from the periphery.

Such a situation has been defined as "*organisational disorder*"[41], in which the command-and-control system based on random inspection has shown to be ineffective and a public regulation failure.

As the fragmented constituting history of Italy impacted its current food safety system, Poland has been deeply affected by its historical events. Despite some initial attempts of food safety laws in the middle ages and in the Polish-Lithuanian Commonwealth, it is well known that Poland disappeared for 123 years[42]. Thus, because of the partition, Austrian, German and Russian laws were in force until the establishment of the Polish National Institute of Public Health - National Institute of Hygiene in 1918[43], and the Decree of the President of the Republic of Poland in 1928, on "*Supervision of food articles and usable goods*"[44]. The latter, also revised in 1970, was characterised by a majority of criminal sanctions. The

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[39] Fiorenza, C.; Fiorenza, F. (2002). *La disciplina italiana della sicurezza alimentare*, in S. Cassese (edited by), *Per un'autorità nazionale della sicurezza alimentare*, Milano, il Sole 24 ore, 2002, p.25.

[40] Cassese, S. (2005). *Il diritto amministrativo globale. Una introduzione*, in *Rivista trimestrale di diritto pubblico*, n. 2, p.236.

[41] Bevilaqua, D. (2012).

[42] Brudnicka, J. (2016). *Geopolitical position of Poland - from time of partitions to the independence,* in *Securitologia*, *23*(1), 87–102. https://doi.org/10.5604/01.3001.0009.2971

[43] Balinska, M. A. (1996). *The National Institute of Hygiene and Public Health in Poland 1918–1939,* in *Social History of Medicine*, *9*(3), 427–445. https://doi.org/10.1093/shm/9.3.427

[44] Korzycka-Iwanow, M. (2011). *Practical development of rural law in the EU, in States and Regions and in the WTO*, Individual Report Poland, XXVI European Congress and Colloquium of Agricultural Law, Bucharest, 21-24 September 2011.

gradual liberation of the country following WW2 resulted in the resumption of activities performed by sanitary supervision structures, and the Public Health – National Institute of Hygiene was re-established[45].
The communist period was distinguished by the above-mentioned revised Law of 1970, which was poorly implemented and characterised by the communist firm reliance on administrative and penal sanctions[46].
The radical economic alteration at the end of the polish communist era and the EU's access required a reorganisation the food safety law and administration system. A functionally diversified system was in place, and the other Member States brought along the coordination problem[47]. The transformation to a market-based economy required the rethinking of traditional regulatory approaches[48].
The UKIE was established, an interministerial task force, to put down the polish food safety strategy. For instance, the latter led to the return of sanitary inspections to a vertical subordination and State structures[49]. In 2001, the Law of 1970 was replaced by a new Act on the health conditions of food and nutrition with the primary goal to align Polish legislation as wholly as possible with EU law. Such process continued until 2006, with the Polish Law on the safety of food nutrition[50]. This Act defines the requirements for food and feeds safety assurance in line with Regulation No. 178/2002, finally introducing the scientific risk analysis approach (risk assessment, management and communication) that was still lacking.
The most important current government authorities controlling food safety are the Chief Sanitary Inspectorate and the Chief Veterinary Inspectorate. Furthermore, specific competencies are recognised by the Ministry of Finance (border control of foodstuffs), the President of the Office of Competition and Consumer Protection (Trade controls)[51].
The Austrian history was more stable concerning food safety, which is also shown by the present administrative situation (par. 5). During the Austrian-Hungary era, the first Food Act was published (1897)[52]. A collection of standards and product descriptions were developed in the "Codex Alimentarius Austriacus" in the following years[53]. The latter

[45] Panteli, D., Sagan, A., Busse, R. (2017), *Poland Health system review*, in *Health Systems in Transition*, Vol. 13 No. 8 2011; M. L. Grabowsi, B. Kosinska, Jozef P. Knap, Evolution of sanitary-epidemiological service in Poland in the years 1944-2014, Postepy High Med Dosw ; 71: 915-920.
[46] Zurek, K. (2011). *European Food Regulation after Enlargement: Facing the Challenges of Diversity*, Martinus Nijhoff.
[47] Abels, G; Kobusch, A (2010). *Regulation of food safety in the EU: Changing patterns of multi-level governance*, Paper presented at the Conference of the ECPR Standing Group on Regulatory Governance, June 17-19, 2010, University College Dublin, p. 15.
[48] Majone, G., Surdej, A. (2006). *Regulatory Agencies in Economic Governance. The Polish Case in a Comparative Perspective,* in *KICES Working Papers*, No 5.
[49]Korzycka-Iwanow, M. (2006). *Poland's Food Safety Law of 2006: Has the Legislator "learnt" to implement EU Regulations?,* in *European Food and Feed Law Review*, *1*(6), 348–354. http://www.jstor.org/stable/24325136
[50] Korzycka-Iwanow, M. (2006).
[51] Bundesinstitut fur Risikobewertung (2021), *EU Food Safety Alamanac*, p. 20-
[52] Koßdorff, K. (2006). *The new Austrian Food Safety and Consumer Protection Act: "Lebensmittelsicherheits- und Verbraucherschutzgesetz – LMSVG*", in *European Food and Feed Law Review*, *1*(5), 286–294. http://www.jstor.org/stable/90008301
[53] Codex alimentarius Austriacus. (1917). Austria: K. K. Hof- und Staatsdruckerei.

lacked legal force, but it was used by the courts to determine identity standards for specific foods.
Following a period of German influence, a new Food Act entered into force in 1975. Relevant attention was given to food freshness and consumer's health, being a modern approach for those times[54].
The need for harmonisation demanded by the EC led to a new food act. Previously as a draft in 2004, and then entered into force in 2006 as the Austrian Law on Food Safety and Consumer Protection[55]. Amended in 2009, such piece is the transposition of EU laws into Austrian Law and the national Agency's set-up source. The competent Authority is the Austrian Agency for Health and Food Safety, established in 2002.
The previously mentioned law oversees sanitation guidelines throughout the natural way of life, from the essential creation site to the end buyer. Prerequisites are set up for food items, consumable water, objects of utility, and beauty care products.
As for the other cases, the peculiarities of the Austrian food safety system will be highlighted in the following paragraphs.
Another peculiar and deeply EU influenced history is the one of Serbia. During the First Serbian Principality and Grand principality, between the 8th and 13th centuries, there was a common law system[56]. Hence, it is difficult to trace any reference to food safety, or food laws in general. Later on, with the Dušan's Code, there was some basic reference to food security, but not food safety[57]. Equally, it is not easy to find something more than food security measures in the Kingdom of Serbia era[58]. During its history, Serbia has undergone several state borders, socio-economic and political variations. Obviously, this led to a bit of attention to some matters, as food safety. However, this is not the case of the Yugoslavia period. Indeed, it is possible to find relevant legislation concerning food safety and a constantly increasing attention to the scientific aspects of the subject. In 1946, a Health supervision agency was established, and it was in charge of sanitary inspections. Food safety controls were organised according to the Basic Law on Sanitary Inspection, passed in the spring of 1948, as the first law relating to this type of inspection. Later on, in 1956, a second law on sanitary inspection passed, and the health inspection agency was entrusted to supervise the implementation of regulations and health promotion measures. Indeed, health inspections were mandatory in all the communes of Yugoslavia.
Following the SFRY Constitution of 1963[59], a third Basic Law on Health inspection passed (1965), which prescribed the organisation, position and tasks of health inspection. Furthermore, with the constitutional amendments of 1971, the task of health inspections passed from federal to the mainly provincial level. On 1978, the Yugoslav Act Regulating the Wholesomeness of Foodstuffs and Items in General Use Act (Yugoslav Food

[54] Koßdorff, K. (2006). The new Austrian Food Safety and Consumer Protection Act: "Lebensmittelsicherheits- und Verbraucherschutzgesetz – LMSVG." *European Food and Feed Law Review*, *1*(5), 286–294. http://www.jstor.org/stable/90008301
[55] Koßdorff, K. (2006).
[56] Serbs in European Civilization. (1993). Serbia: Nova.
[57] Ibid.
[58] From 1882 to 1918.
[59] Lapenna, I. (1969). *The Yugoslav Constitution of 1963*, in *The International and Comparative Law Quarterly*, *18*(2), 469–471. http://www.jstor.org/stable/757536

Wholesomeness Act)[60] passed. As evidenced of the work on the field in such years, nineteen[61] implementing regulations were adopted based on the mentioned above act. Those concerned: sampling methods and sample quantities, analysis parameters and acceptability criteria, analytical methods and performers of analysis for foodstuffs, including drinking water and items in general use.
The competent authorities were as follows. The Government, the Ministries of Health, Social Policy, Agriculture, Trade and Economics were entrusted with the enforcement measures. The central institution for the coordination on food safety matters was the Ministry of Health. The Ministry of Agriculture was entrusted for preparing food quality standards, which were also based on the standards of Codex Alimentarius Commission, and enforcing protection from infectious diseases[62]. For import and export the Federal trade inspection service was tasked, together with the Federal sanitary inspection service and Federal veterinary and fito sanitary inspection service.
It is also interesting to examine the food safety risk assessment system of the Yugoslavic period, in light of what will be represented in par. 6. Indeed, an annual food safety monitoring programme was established as a part of the Federal Statistical Health Program[63]. All the competent authorities had to gather and send the inspection's results to the district Public Health Institute. The Federal Institute of Public Health collected the data for the whole country. Through this statistical system, it was divided into a specific division of 22 types of foods. The quality standard parameters of inspections also included microbiological and chemical analysis.
However, the legislation mentioned above and the following one were highly based on criminal and administrative sanctions, because of the political ideology.
However, the attention on the food safety concerns was also highlighted by the adoption, in 1996, of the conclusion that the food safety legislation of the country would be adjusted to the proposals of the EU White Paper 1995. Following the independence, the Serbian application to enter the EU in 2009 profoundly influenced the food safety system in Serbia. The central Law on the subject is indeed the Food Safety law of 2009[64], amended in 2019, which prescribes the rules on food and feed safety, responsibilities of food and feed business operators, the rapid alert system, emergency measures and crisis management. This Law is harmonised with Regulation (EC) No. 178/2002. Other relevant regulations are the regulation on control and certification in organic production and methods of the organic output (2020), the Law on spirit drinks (2015), and the Law on the health safety status of foodstuffs and general use items (2011)[65].

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[60] Official Gazette of the Socialist Federal Republic of Yugoslavia No. 55/78 and 58/85
[61] For more details: Bosnjak, D. (2007). *Changes in Food Safety Legislation*, in *European Food and Feed Law Review*, *2*(3), 146–152: http://www.jstor.org/stable/90008420
[62] Official Gazette of the Socialist Federal Republic of Yugoslavia n. 43/86).
[63] Brooks, M. R., Berg, R. L., Savićević, M. (1976). *Health Care in Yugoslavia and the United States*. Stati Uniti: National Institute[s] of Health, p. 30
[64] Food Safety Law was adopted by the National Parliament of the Republic of Serbia on May 29, 2009 and published in the Official Gazette of the Republic of Serbia No. 41/09.
[65] FAO Country Profile Serbia: http://www.fao.org/faolex/country-profiles/general-profile/en/?iso3=SRB

The improvement process of the food safety system in Serbia following the EU recommendations is still ongoing, and it will be better highlighted in par. 6.

2. Risk assessment, risk management, and risk communication

An already stated increased scientific knowledge on the origin of food-borne diseases and the growing attention to consumers health protection led to critical attention to food-related risks. Regulating risk has become a central part of institutions' tasks[66]. Food safety can not be excluded, and risk regulation in the subject shifted to be a vital issue mostly worldwide.

It is not easy to identify food-related risks and feasibly organise a regulatory intervention. Thus, regulators need to effectively protect food risks through developed food safety systems, being based on risk analysis. The European approach went from a market-oriented regulation to integrated governance based on risk to achieve this goal thanks to the bovine spongiform encephalopathy (mad cow) outbreak[67].

The BSE crisis shaped the public debate about risks in the food chain and the role of science in effectively responding to them[68]. The attitude of the European public and growing anxiety about the possible consequences of this maladministration led to a political and regulatory review. The changing character of the agro-food chain and the role of science in the policy-making process made society equally interested in these risks, and created expectations on scientific experts to provide information necessary to limit the impact of both types of risk. BSE can thus be considered the culmination of the transition from modernity to post-modernity[69]. Thus, requiring the 'risk' to be managed by public authorities, and citizens to expect a risk science-based analysis behind their food consumption.

The public authority is indeed called upon to intervene and reduce the risks by guaranteeing certainty.

The pace of sociological and technological innovation is inevitably accompanied by regulation to manage the risks it creates[70].

Indeed, the presence of risk can be the justifying basis for intervening to regulate an activity, a process or a product[71].

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[66] Van der Heijden, Jeroen. (2019). *Risk Governance and Risk-Based Regulation: A Review of the International Academic Literature*. SSRN Electronic Journal. 10.2139/ssrn.3406998.

[67] Aldy, Joseph. (2013). *Risk Regulation Lessons from Mad Cows. Foundations and Trends®*, in *Microeconomics*. 8. 231-313. 10.1561/0700000046; Weimer, M. (2019). *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology*. Regno Unito: OUP Oxford.; Focker, M., et al (2021). *Interactions between risk assessors and risk managers during three major food incidents in Europe*, in *Journal of Food Science*, Volume 86, Issue 8, p. 3611-3627.

[68] Focker, M; et. al. (2021).

[69] Szajkowska, A. (2012). Regulating food law: Risk analysis and the precautionary principle as general principles of EU food law, Wageningen University.

[70] Giddens. A (1990) *The Consequences of Modernity*, Standford University Press.

[71] Di Porto, F. (2011), *Regolazione del rischio, informazione e certezza giuridica*, Rivista di diritto alimentare, Anno V, N. 4, p. 35

Procedures such as risk analysis help the regulator assess the need to regulate, select the type of risk regulation, and, therefore, measure the pre-existing impact of the effectiveness of the response to be given[72].
It becomes thus possible to determine the necessity of the intervention and identify the minimum threshold that such an intervention justifies.[73]
In a broader organisational setting, it is reflected in decision-making systems and methods that organise administrative exercises and send supervisory assets, based on an evaluation of the risk that firms posture to the regulator's targets[74]. Risks are identified, their level is assessed, a decision is taken as to how much risk reduction is needed, and a piece of legislation is introduced accordingly[75].
In Babylon, specific figures were entitled to provide advice in risky, uncertain or essential decisions in life[76]. Nowadays, risk analysis is divided into three main components, risk assessment, risk management and risk communication[77].
Risk assessment is a scientific-based process characterised by: 1) hazard identification; 2) hazard characterisation; 3) exposure assessment; and 4) risk characterisation[78].
Risk management is «a secondary process of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant to consumers' health protection and the promotion of fair-trade practices, and, if needed, selecting appropriate prevention and control options»[79]. Risk assessment may also involve judgments and choices that are not entirely scientific, and risk managers need a sound understanding of the scientific approaches used by risk assessors. Risk management ought to be thought-about because the management or mitigation step of risk assessment. Risk management requires 1) identification of the problem, 2) definition of a risk profile, 3) goal description, 4) identification and definition of the tolerable risk, and 5) risk communication concerning the tasks mentioned above[80].
Lastly, risk communication is «the exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions»[81]. Complex food safety regimes are today in place worldwide.

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[72] Di Porto, F. (2011).
[73] De Benedetto, M; Martelli, M, Rangone, N, *La qualità delle regole*, Il mulino, 2011, p. 57
[74] Black, J. 'Risk Based Regulation: Choices, Practices and Lessons Being Learned' in *Risk and Regulatory Policy: Improving the Governance of Risk* (OECD, 2010).
[75] Black, J. (2010).
[76] Rifkin, E., Bouwer, E., Sheff, B. (2007). *The Illusion of Certainty: Health Benefits and Risks.* Netherlands, Springer US, p. 20.
[77] Codex Alimentarius Commission, *Definitions of Risk Analysis Terms Related to Food Safety,* page 45.
[78] FAO/WHO, Food safety Risk Analysis, Part 1: An overview and framework manaual provisional edition, Rome, June 2005.
[79] Codex Alimentarius Commission, *Definitions of Risk Analysis Terms Related to Food Safety,* page 45.
[80] FAO/WHO, *Global Forum of Food safety Regulators, Ensuring efficient communication and interaction between food safety risk assessors and risk managers*, Marrakesh, Morocco, 28-30 January 2002.
[81] Codex Alimentarius Commission, *Definitions of Risk Analysis Terms Related to Food Safety,* page 45.

A European Parliament study (2000)[82] distinguishes food safety systems, considering the administrative separation between risk assessment and risk management.
Regarding the EU White Paper, the study highlights that the separation between risk assessment and risk management matches science and policy respectively.
Following what highlighted in the same study, the White Paper expresses the significance of isolating the science of risk assessment from the political dimensions of risk management policy deliberations.
At the same time, the closest possible linkage must be established between risk assessment, risk management, and risk communication[83] for the risk analysis efficiency.
Moreover, the study represents as it would be desirable if there were a more systematic attempt to define the relationships amongst the levels of food risk management (ex. local, regional, national).
Thus, an analysis of different food safety systems could be based on regulatory approaches in separating risk assessment and management. To this, the handling of the risk communication element and the relationship defined between the different administrative levels can be added.
To conduct risk analysis, it is essential to separate the scientific integrity of the risk assessment process and avoid political influence that would undermine the objectivity and trust on the outcomes. Separation of risk management and risk assessment helps to ensure that assessments are not biased by risk managers[84].
Analysing and understanding countries' food safety risk analysis systems is essential to comprehend their development in the subject. Italy, Poland, Austria, and Serbia all have interesting peculiarities in their food safety system development, differentiated by their past history, and attempitngly harmonised by EU.

3. Italy

In Italy, risk assessment and risk management are considered to be institutionally separated[85]. The latter could actually be a questionable division. The historical fragmentation of Italy indeed led to a particular sharing of competence between State and Regions. The Italian Constitution confers exclusive competencies on the Central Authorities for some matters and shared competencies between State and Regions on others. Indeed, Italian Regions are entrusted for planning, coordinating, managing, authorising and verifying food safety inspections on their territories. The, the so-called "Permanent Conference State-Regions" coordinates the work between Central Authority and Regions. However, the Italian Ministry of Health deals with orientation and planning on issues of public health, veterinary health, food hygiene and safety, and actually

[82] Trichpoulou, A, (2000). European Policy on Food Safety Study: https://www.europarl.europa.eu/stoa/en/document/DG-4-JOIN_ET(2000)292026
[83] Food Standards Agency (2000), *Government Supports Establishment of a European food Authority*, London, 1 June, Press Release 2000/0015, p. 1: http://www.fao.org/3/a0822e/a0822e01.pdf
[84] FAO/WHO, *Global Forum of Food safety Regulators, Ensuring efficient communication and interaction between food safety risk assessors and risk managers*, Marrakesh, Morocco, 28-30 January 2002.
[85] Bundesinstitut fur Risikobewertung (2021). *EU Food Safety Alamanac*, p. 69.

incorporates risk assessment, risk management and risk communication under its supervision. This raises doubts on the actual division between the scientific and political dimensions. Concerning risk assessments, those should normally be published on the internet. The Ministry of Health is organised in a General Secretariat and 12 Directorates-General. For instance, the Directorate-General for animal health and veterinary healthful merchandise is answerable for framing national programs for animal diseases by guaranteeing effective controls on food safety issues. Moreover, the Directorate-General for Collegial bodies for health protection, being the responsible one for food safety risk assessment, is the national EFSA focal point and central point for the Food Safety National Committee. Furthermore, it is responsible for the coordination and planning of actions aimed at assessing risks in the food chain and the activities of the Committee of Consumers and Producers Associations. As in many other States, the Ministry of Agriculture, Foodstuff and Forestry Policies is also between the food safety organs. In Italy, it is responsible for the coordination of activities related to the quality of agricultural products and food. Hence, it includes risk management and risk communication duties. Particular importance is given to the National Institute of Health. The latter is a technical and scientific public body of the Italian National Health Service, under the remit of the Ministry of Health. As the main task, it supervises the Italian National Health Service laboratories and stages corroboratory analyses. It carries out consultations and supports inspections and quality controls upon request at central or local level. Thus, it has risk assessment duties. There are ten officially ones called the Istituti Zooprofilattici Sperimentali - National Reference Centers concerning the laboratories supervised. As already mentioned, a permanent cooperation between Regions and Central Authority is ensured by the Permanent Conference between State, Regions and Autonomous Provinces. Regions and Local Health Units (e.g., ASLs) are competent authorities for food safety under the Legislative Decree n. 193/2007. Those are structured into Regional Public Health Services, divided into Regional Veterinary Service, which is responsible for food of animal origin, animal health and welfare and feed safety, and the Regional Food Hygiene and Nutrition Service. The latter is accountable for product of non- animal origin, food supplements and food contact materials. Moreover, Local Health Units are present in each Region and act as public bodies responsible for the organisation and management of all public health facilities at local level. The Local Health Units have managerial, administrative, financial, and technical autonomy. Moreover, they are organised in sanitary districts, prevention departments, and hospital services. However, it is important to state that the faculty to perform inspections at the local level still remains for the Ministry of Health by carrying out audit activity through the sectorial offices of the Directorates-General. Furthermore, police forces are also included in a food safety inspection. The NAS (the Food Law Enforcement Department) is a special unit, which should operate under the supervision and direction of the Ministry of Health. It carries out controls on its own initiative or upon request by the Ministry. All the above, it might potentially lead to a poor division of responsibilities between bodies and an easy risk of duplications of inspections and lack of sharing between competent authorities. The general coordination between such a fragmented division of responsibilities is in the hands of the Directorate-General for food hygiene and safety and nutrition of the Ministry of Health, through the four-year plan and the Annual Report. The MANCP describes

Member States' strategy for efficient inspections and preservation by operators. The tasks of the MANCP are taken on together with the the National Institute of Health), the Experimental Zooprophylactic Institutes, the Ministry of Agricultural, Food and Forestry Policies, the Ministry of Environment, the regions and autonomous provinces, the Customs Agency, the Food Law Enforcement Department, the State Forestry Corps, the port authorities, and the Ministry of Finance's Police Force. The MANCP ensures effective controls and allocates resources in areas at high risk, where the maximum impact is expected. Risk communication is also fulfilled by the publication of the annual report published on the MOH website, and it provides an overall evaluation of the official controls and audit system. Interestingly, a study[86] based on 30 sentences issued from 2012 to 2019 by Regional Administrative Courts and Council of State rulings, highlights critical issues in the official control activity. The final measure issued by the Competent Authority represents the decisive moment of the official control activity[87]. The measures should be issued by correctly assessing the risk connected to the case at hand and in compliance with the general legal principles that support official administrative activities. The analysis of cases in the study, scrutinised by the administrative judiciary, reveal a general criticism of the work of the local Competent Authorities, especially where the extreme measure of closure of the activity was applied[88]. The case law emphasises the widespread incorrect application of the legislation on food hygiene, and the violation of the principle of proportionality, which ought to regulate the wide discretion of the authority. From a technical and hygienic point of view, except for very few cases, the assessment of non-compliance - mainly of a structural nature- and therefore the related risk assessment, does not appear to be fully carried out by the control body[89].

4. Poland

Despite the fragmentation, a growing institutional differentiation of risk assessment and risk management is developing. Governmental Food safety measures are based upon risk assessments studies (Law on Food Safety – 2006), but the final decision on the legality of governmental measures rests with the courts[90].

The Ministry of Health is responsible for public health policy and food safety. The Ministry prepares draft legislation on food hygiene, chemical residues, contaminants and import of foods of non-animal origin.

The Chief Sanitary Inspectorate (GIS) answers to the Ministry of Health and it is the EFSA focal point. It is considered the competent authority for food safety in Poland.

Differently from the previously mentioned cases, Poland's EFSA focal point has not risk assessment duties, but risk management ones. It cooperates with the Ministry of Agriculture and the Ministry of Environment.

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[86] Rossi, A., et al. (2020), *Official controls on food safety: Competent Authority measures*, in *Italian Journal of food* safety, Volume 9:8607, 2020, p.10.

[87] Rossi, A, et al. (2020), p. 12.

[88] Rossi, A, et al. (2020, p. 14.

[89] Rossi, A, et al. (2020), p. 16.

[90]Bundesinstitut fur Risikobewertung (2021). *EU Food Safety Alamanac*, p. 70.

Moreover, the GIS coordinates and supervises the State Sanitary Inspectorates (PIS). The latter are entrusted for official controls on food safety.
GIS risk management decisions follow the scientific risk assessments of the National Food and Nutrition Institute, and the National Institute of Public Health.
The Ministry of Agriculture and Rural Development has risk management duties as in other MS. It is responsible for agricultural policy and the safety of food of animal origin and prepares draft legislation in subjects of its competence. The risk management tasks are based on scientific risk assessments prepared by the National Veterinary Research Institute.
The Customs Service at the Ministry of Finance is also a competent authority with risk management duties. It is entrusted with food border control.
Furthermore, the Office of Competition and Consumer Protection (risk management tasks) goal is to protect the consumer's interests and ensure free and fair competition within a free market.
The National Institute of Public Health prepares scientific risk assessments on food additives, biological risks, added chemical substances, and drinking water. On a different note, the National Veterinary Research Institute prepares scientific risk assessments on feed, residues of veterinary medicinal products.
As in all MS, the regional and local levels is of first-rate importance. In Poland, the division is as follows: 16 regions (voivodships), 379 districts (powiats) and 2,478 local authorities (gminas). At the district and local levels, specialists of the GIS and MRiRW are responsible for enacting food laws and carrying out food inspections.
Risk assessments are not published. This is a critical issue. Risk communication is an essential part of risk analysis. It is necessary to define the intervention, explain the risk assessment, and develop the best risk management decision. All the previous work (assessment and management) might lose importance without correct risk communication handling.
Moreover, the risk managers must balance their duties and assess the effectiveness of their decisions' impact. The reliability of risk assessment is obviously crucial for risk managers. At the same time, a bad risk management might turn the risk assessment job to be useless. In addition, risk communication is needed to helping risk managers understand the potential impact of their different decisions and to assess how effective their choices would be. A proper risk communication might not constantly improve trust, but inadequate risk communication and poorly developed messages will almost certainly harm the work done and the civil society perception[91].

5. Austria

The competent authority for risk assessment is the Austrian Agency for Health and Food Safety (AGES), which also identifies risks and issues recommendations. It replies to specific consultations, carries out veterinary examinations, and deals with food and infectious disease. Austria is considered to be the sole Member State having all the federal

[91] Maxim, L, et al. (2021). *Techincal assistance in the field of risk communication, scientific report*, EFSA Journal 2021; 19(4):6574.

competencies in various areas upon one unique public body[92]. Indeed, the old 19 federal agencies specialised in health issues were all unified in the AGES. This is a relevant example of integration and coordination to allow better communication between competent authorities and consumers' protection. Moreover, such an organisation grants a high efficiency and transparency of the administration. The innovative organisation of AGES, including, as stated many former federal agencies, also allows a high representation of members of the same Agency in the EFSA panels. The latter gives more relevance to its role and reflects the better coordination. To this, it must be included a higher efficiency and transparency. The Agency is also the EFSA Focal Point and RASFF Contact Point. AGES was apparently structured following the EFSA ideal. Other administrations and local authorities use AGES risk assessments as the foundation for their management measures. Food inspections and risk management are entrusted to the supervision and coordination of the Federal Office for Food Safety at regional and local levels. The Office is, however always part of the AGES. The same Agency includes 60 National Reference Laboratories. However, AGES answers both to the Ministry of Health and the Ministry of Agriculture, Forestry, Environment and Water Management. The Ministry of Health is also responsible for coordinating state food inspections and can issue national regulations in the area of food safety. It has risk management and risk communication duties. On a slightly different note, the Federal Ministry of Agriculture, Regions and Tourism is responsible for agricultural policy and food safety during primary food production. It prepares draft legislation in feed and groundwater based on scientific risk assessments conducted by the AGES. Thus, both the Ministries, as in other MS, have as well risk management and risk communication duties.

6. Serbia

The analysis of the food safety system in Serbia is of first interest because of the particular history and the status of candidate-EU Country. Indeed, despite long-time attention to the EU food safety system development and recommendations[93], it still presents relevant differences between the other Countries. For instance, a non-clear division between risk assessment and risk management tasks[94], the importance of the latter separation has been already stated. The Ministry of Agriculture, Forestry and Water Management and the Ministry of Health share the responsibility concerning the risk management tasks. The first is entrusted with draft legislation in food and feed safety and animal and plant health matters. The second in public health, potable water, diet supplements, novel food and packaging materials. Thus, the Ministry of Agriculture is of paramount importance, which is also the EFSA focal point. Both the Ministries form the Expert Council for Risk assessment in Food Safety to provide risk assessments upon request. The Ministry of Agriculture is also the competent authority for policy and legislation on the enforcement of laws on food safety. Furthermore, the Veterinary Directorate has risk management and risk communications tasks. It also has the responsibility of carrying out official controls

[92] Bundesinstitut fur Risikobewertung (2021). *EU Food Safety Alamanac*, p. 12.
[93] See par. 1.
[94] Bundesinstitut fur Risikobewertung (2021). *EU Food Safety Alamanac*, p. 143.

on holdings and establishments. Veterinary local institutes support the work of the Veterinary Directorate, together with the National Reference Laboratory for Veterinary medicinal products and other designated state and private laboratories for official testing's tasks. A special directorate, the Plant Protection Directorate, is the competent authority for phytosanitary concerns. It has risk management and risk communication duties and monitors the implementation of laws and enforcement of official controls in the qualified areas. The Ministry of Health also includes the Sector for Inspection Supervision (SIS), the Department for Sanitary Inspection that carries out official controls within designated food safety tasks and in the case of food outbreak/epidemiology investigations. Public health institutes are tasked with the official testing of food and water.

7. Final remarks

The above-represented cases show as historical events influenced the food safety system development. In States with a fragmented territories history (Italy, Poland), the result is a share of competencies between various levels of government, and more relevant, across several different competent authorities, including a strong law enforcement presence. The latter might have as an outcome: an increasing potential duplication of inspections, a lack of understanding of the competent authority by the civil society, and relevant administrative burdens.

Moreover, such division might lead to an extreme difficulty in reforming the system (as in the missed repeal of criminal food sanctions in Italy), since too many institutions have a say on the matter and different laying interests. The presence of criminal food sanctions and relevant tasks given to law enforcement bodies (Italy, Poland) is also probably the result of history. For instance, as already represented, in Italy food safety tasks were initially entrusted to the Ministry of Interior.

Countries with a more stable history (Austria) had the opportunity to strictly follow the EU recommendations and properly restructure their food safety system. Indeed, Austria shows a clear distinction between tasks and increased attention to the food safety matter. This, along with a potential most assertive international representation under a sole public body.

In all the above-mentioned cases, regulation of food safety has changed profoundly from market-oriented or also state-led command-and-control approaches to responsive and scientific and risk-based ones. The latter, particularly in light of Europeanization of food policy across the EU Member States (or candidates). Concerning EU candidates, the Serbian food safety system development shows as, despite an actual food safety history in the Yugoslavia period with attention also to risk assessment tasks, evolving towards a division of risk analysis tasks and reforming the structural approach to food safety is not a simple road.

Transparency remains an issue. Risk communication is developed through internet publication (this does not mean that it is enough) in some countries; in others, this does not happen. The civil society should have automatic and easy access to all studies concerning risk assessment. As already stated, (par. 4 concerning Poland), the lack of fulfilling this task might decrease the importance of the risk assessment and risk management work. Furthermore, without a proper risk communication, citizens' trust in

Institutions can not increase. Therefore, there is a need for improvement and simplification of the communication with the public audience.

However, as risk management and risk assessment do need a proper risk communication, the latter requires a good balance between risk managers and risk assessors. This could be achieved by a central agency supervising the work for each State. Central does not mean a lack of decentralisation at state, regional and local levels. It does mean an agency that can take decisions and organise the system properly, without influences from, for instance, two different Ministries.