

Food Safety Regulation in the European Union: Toward an Unavoidable Centralization of Regulatory Powers

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ABSTRACT

As the threat of foodborne illnesses is becoming increasingly obvious, the future of the European Union (EU) is becoming clearer. The study of food safety regulation in the EU sheds light on the future of the European regulatory system as a whole. Looking at the evolution of the European Union and the EU institutions, and how food safety has been regulated over the years, one can predict a centralization of regulatory powers in the EU. Despite the fact that the present decentralized system is not able to prevent food scares, the centralization of food safety regulatory powers in the EU has been both supported and criticized. However, an analysis of the present food safety measures in the EU demonstrates that the movement toward centralization has already begun. Today's de facto centralization will eventually lead to tomorrow's de jure centralization.

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I. INTRODUCTION

In October 2004, two eagles, smuggled from Thailand, were transported on a plane and arrived in Belgium, despite the ban on imports of birds from countries that faced bird flu outbreaks.¹ The birds were inspected and tested positive for Influenza A virus subtype H5N1, commonly known as “bird flu.”² In February 2006, the virus was detected in France, Germany, Greece, and Italy. Birds at a turkey farm in the department of Ain in France were found to be infected with the bird flu virus in approximately the same area where a wild duck was found dead from the same disease.³ In Germany, a cat died from the virus, becoming the first European Union mammal to succumb to avian flu.⁴ Avian flu was also detected in dead swans in Greece, Bulgaria, and Italy.⁵ In January 2007, a farm in Hungary was infected with the virus; as a result, 3000 geese were slaughtered.⁶ In February 2007, turkeys on a commercial farm in England owned by one of Europe’s largest poultry

1. *Bird Flu Sparks Belgian Manhunt*, BBC NEWS, Oct. 24, 2004, <http://news.bbc.co.uk/2/hi/europe/3948597.stm> (last visited Apr. 2, 2008).

2. *See id.*

3. *See Bird Flu on Turkey Farm Alarms French Officials*, N.Y. TIMES, Feb. 25, 2006, at A3.

4. *German Cat Gets Deadly Bird Flu*, BBC NEWS, Feb. 28, 2006, <http://news.bbc.co.uk/v2/hi/europe/4758632.stm> (last visited Apr. 2, 2008).

5. Maria Sanminiatielli, *Avian Flu Discovered in Wild Swans in Italy, Greece, Bulgaria*, WASH. POST, Feb. 12, 2006, at A25.

6. *EU Lab Confirms Hungary Bird Flu*, BBC NEWS, Jan. 29, 2007, <http://news.bbc.co.uk/2/hi/europe/6310029.stm>.

producers were found infected with the H5N1 strain of bird flu.⁷ Even if bird flu is not currently a threat to human beings, some fear the virus might mutate and endanger human lives.⁸

These incidents are merely a sample of the numerous similar occurrences of hazards that do not recognize national borders which have happened over the past years in the Member States of the European Union (EU). Given the way food safety is regulated in the EU, each country essentially bears the responsibility to address the problem. Council Directive 2005/94/EC of December 20, 2005, on Community Measures for the Control of Avian Influenza was enacted in order to create measures for Member States to deal with sudden outbreaks of bird flu.⁹ However, Member States were not required to implement it until July 1, 2007.¹⁰ In the meantime, more bird flu outbreaks occurred and endangered not only the country primarily touched with the virus, but also any other country where goods can freely travel with little or no inspections.¹¹ These events demonstrate how decentralized the EU is in terms of food safety regulation and raise the question of whether a centralized system would have prevented the spread of avian influenza.

This article will focus on the food safety regulation system in the EU by looking at how centralization of food regulatory powers is a necessary step to protect the public health as well as the future of the EU in a more general sense. It will show how food regulation in the EU reflects the most fundamental controversies that are also seen in the international arena, and it will demonstrate how centralization of risk assessment and risk management is not only preferable, but is unavoidable.

This article will first present an analysis of the issue of centralization of powers for food safety regulation purposes, addressing the historical developments of food safety regulation in the EU, analyzing the various arguments that have been made in favor of centralization, and considering the “single food agency debate” occurring in the United States. Then the article will take a more practical approach by discussing why a centralized power in Europe is difficult to attain. Finally, the article will predict and demonstrate how centralized power will eventually develop. This article will discuss the current state of de facto centralization, characterized by a tendency toward uniformity of principles and standards, and then show how this will eventually lead to an official and recognized de jure centralization. However, centralization will not actually happen until future EU constituents recognize that in order to remain competitive in the global market, centralization of food safety regulatory powers in the EU is essential.

II. AN ANALYSIS OF CENTRALIZATION OF FOOD SAFETY REGULATORY POWERS: TODAY’S EUROPEAN UNION IS NOT READY FOR AN OFFICIAL CENTRALIZATION OF ITS FOOD SAFETY REGULATORY SYSTEM

Centralization of food safety regulation is an issue greatly debated both in the EU and other countries. Proponents and opponents debate on whether centralization is necessary

7. Alan Cowell, *Deadly Bird Flu Confirmed in British Turkeys*, N.Y. TIMES, Feb. 4, 2007, at A16.

8. Donald G. McNeil, Jr., *Scientists Hope Vigilance Stymies Avian Flu Mutations*, N.Y. TIMES, Mar. 27, 2007, at F1.

9. Council Directive 2005/94, On Community Measures for the Control of Avian Influenza and Repealing Directive 92/40/EEC, art. 1, 2006 O.J. (L 10) 16, 46 (EC).

10. *Id.* art. 67.

11. *See supra* notes 3–7 (discussing the spread of avian flu in 2006).

and whether it would be beneficial. While noting the advantages brought by a more centralized system, the EU is not ready for an official centralization of food regulation, given the institutional, political, economic, and social obstacles that it is facing at the present time.

To understand how the EU has reached its present point, it is important to understand how food safety regulation in the EU has evolved throughout history.

A. *Historical Evolution of Food Safety Regulation in the EU*

The Treaty of Rome, signed in 1957, is the fundamental treaty of the European Community (EC). It did not provide any guidance for food regulation because a major objective for the EC was freedom of movement of foodstuffs.¹²

Recognizing the need to harmonize laws, the EC issued compositional directives in the 1970s. These directives created standards of composition for certain foodstuffs.¹³ The standards allowed some ingredients and prohibited others that did not meet the requirements set by the Commission.¹⁴ It is important to keep in mind that the goal of those directives at that time was to guarantee the free movement of food within the European Common Market, rather than to advance consumer health.¹⁵ The directives applied only to particular ingredients, including sugars, jams, chocolate products, and preserved milks.¹⁶ Ultimately, however, this formula failed because the differing culinary cultures of the Member States prevented them from agreeing on the adoption of those ingredients' requirements.¹⁷ The fact that the Treaty of Rome required unanimity in order to adopt directives made any decision difficult to reach.¹⁸

In 1985, the EC came up with a new approach. Instead of trying to harmonize all of the food regulations, it decided to use labeling to indicate the differences in composition and production methods, allowing consumers to make an informed decision.¹⁹ It adopted the principle of mutual recognition, requiring a Member State to allow the free circulation of goods produced in conformity to equivalent standards of other Member States.²⁰ This mutual recognition principle was established by the *Cassis de Dijon* case, in which a German law prohibited the marketing of liqueurs below a certain alcoholic strength.²¹ As a result of this prohibition, plaintiff, a German importer of liquor, could not market his liquor that contained less alcohol.²² Given the fact that the importer was able to sell the liquor in France, which did not have this limitation, the European Court of Justice held that since plaintiff's liquor contained less alcohol than what the German law allowed, the justification of its prohibition could not be in the public interest and therefore could not stand.²³ Thus,

12. Kaarin Goodburn, *Introduction: The Development of EU Food Law*, EU FOOD L. 1, 1 (Kaarin Goodburn ed., 2001).

13. Alberto Alemanno, *Food Safety and the Single European Market*, in WHAT'S THE BEEF? THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY 237, 240 (Christopher Ansell & David Vogel eds., 2006).

14. *Id.*

15. *Id.*

16. Goodburn, *supra* note 12, at 1.

17. Alemanno, *supra* note 13, at 241.

18. *Id.* at 240–41.

19. *Id.* at 241.

20. *Id.*

21. Case 120/78, *Rewe-Zentral AG v. Bundesmonopolverwaltung für Branntwein*, 1979 E.C.R. 649, 660 [hereinafter *Cassis de Dijon*].

22. *Id.* at 660–61.

23. *Id.* at 664.

the Court held that the German law impeded on the principles of free circulation of goods and introduced the principle of mutual recognition.²⁴ This principle led to a horizontal, as opposed to vertical, harmonization of food standards.

In 1987, the Single European Act replaced the unanimity requirement with a qualified majority in the Council.²⁵ As a result, the European Community adopted additional regulations, but avoided adopting too many of them for fear of jeopardizing the single market goal and culinary culture.²⁶

Food scares of the mid-1990s such as the bovine spongiform encephalopathy (BSE) crisis and the dioxin contamination in Belgium affected the public's trust in the EU food safety regulation system.²⁷ These events yielded a series of new determinations and recommendations regarding the need for reform. In 1997, the European Commission issued a Green Paper concluding that the current food legislation fell short of meeting the "needs of consumers, producers, and manufacturers of food products."²⁸ In 1999, three professors issued a report to the Director-General calling for: a new system for risk assessment based on the principles of excellence, transparency, and independence; the creation of a food and public health agency; and increased cooperation among Member States.²⁹ In 2000, recognizing the need for measures to deal with foodstuffs "from farm to table," the Commission determined that an independent European food authority would be the best way to ensure food safety.³⁰

Accordingly, in 2002, the Council of the EU and the European Parliament adopted Regulation (EC) No. 178/2002, presenting the principles of food law and creating the European Food Safety Authority (EFSA).³¹ Prior to the creation of the EFSA, EU policy had been aimed at eliminating trade barriers within the European market and its goal was economic success rather than safety assurance.³² To accomplish this goal, each Member State had regulated its own foodstuffs. In contrast, the EFSA is an independent agency that provides scientific advice to Member States and EU institutions. It gathers data to help anticipate risks and issues opinions on matters relating to human nutrition, animal welfare, plant health, and genetically modified organisms.³³ The EFSA gives scientific assessments but does not handle any of the risk management. Instead, the EU institutions and the Member States themselves are responsible for risk management, a division of authority that poses an obstacle to greater centralization.

24. Alemanno, *supra* note 13, at 241.

25. *Id.* at 242.

26. *Id.*

27. Winn S. Collins, *The Commission's Delegation Dilemma: Is the European Food Safety Authority an Independent or an Accountable Agency?*, 10 U.C. DAVIS J. INT'L L. & POL'Y 277, 281 (2004).

28. *Id.* at 282.

29. *Id.* at 283–84.

30. *Commission White Paper on Food Safety*, at 3, COM (1999) 719 final (Jan. 12, 2000).

31. Council Regulation 178/2002, Laying Down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, art. 1, 2002 O.J. (L 31) 1, 6.

32. *See* Alemanno, *supra* note 13, at 240, 248.

33. Council Regulation 178/2002, *supra* note 31, art. 22.

B. *A Centralized Power Is Better Than a Decentralized Power When It Comes to Food Safety*

Centralization presents a number of advantages with respect to both the economy and social attitudes toward food safety regulation in the EU. Centralization of the power to regulate food safety is in the best interest of consumers, companies, and countries. In light of the debate over centralization in the United States, where the food regulatory system is already more centralized than in the EU, it is clear that centralization is the most efficient approach to meet consumer, national, and corporate interests.

1. *Decentralization Encourages Member States to Use Public Health Concerns as a Competitive Tool Against One Another*

Decentralization encourages Member States to use their domestic policies as a competitive tool.³⁴ By having different standards, countries that could be working together instead use regulations to gain a competitive economic advantage. Member States and producers, for example, create distinctions between products in order to have the upper hand in the market.³⁵ The labeling process, which will be discussed in more detail in Section III, enables countries to identify where products come from, thus aiding consumers in making informed decisions regarding their choices in groceries. For example, when a food scare occurs in one Member State, other Member States might use that to their advantage by telling consumers that their products are safer.³⁶

One might argue that this is healthy competition and that countries have a duty to inform consumers of the safety of products, including identifying the location of the product's origin and production. Competition is allowed within the EU and is deemed a protected practice as long as businesses follow certain rules.³⁷ However, competition between businesses based on economic variables is quite different from competition based on public health issues. In a union of countries where products can circulate freely, competition based on food safety standards will not help improve the trust that consumers have in the EU food system. Rather, people will likely recognize the economic motive of using public health as a competitive tool and become cynical about the actual merits of the system.

Not only do Member States compete through varying food safety policies, but also in the varying ways they each implement EU regulations and directives.³⁸ For example, EU regulations and directives provide an implementation deadline to Member States.³⁹ Naturally, some countries are more able than others to implement a policy in a short period of time. However, in an environment of free circulation of goods, those discrepancies create economic incentives where public good should be the priority.

34. Ladina Caduff & Thomas Bernauer, *Managing Risk and Regulation in European Food Safety Governance*, 23 REV. POL'Y RES. 153, 156 (2006) [hereinafter *Managing Risk*].

35. Thomas Bernauer & Ladina Caduff, *Food Safety and the Structure of the European Food Industry*, in WHAT'S THE BEEF? THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY, *supra* note 13, at 81, 83 [hereinafter *Food Safety*].

36. *Managing Risk*, *supra* note 34, at 156.

37. Patrick Closson, Note, *Penalty Shot: The European Union's Application of Competition Law to the Bosman Ruling*, 21 B.C. INT'L & COMP. L. REV. 167, 168-71 (1998).

38. *Food Safety*, *supra* note 35, at 84.

39. See Council Directive 2005/94, *supra* note 9, art. 67.

These distinctions not only represent the individualism of competing countries in the EU, but they also likely reinforce individual consumers' nationalist sentiments at the expense of developing a stronger, more cohesive "European" outlook.

2. Centralization Improves Consumer Trust

Despite the changes in EU food safety regulation, such as the creation of the EFSA, the lack of consistency between countries has hindered any improvement in consumer trust.⁴⁰ Ignited by the food scares of the 1990s,⁴¹ consumer surveys conducted over the past several years show how skeptical consumers are of the European food safety and regulatory systems.⁴² The levels of trust vary, however, among Member States. The Northern countries such as Denmark are more trusting of their national food regulatory systems than are Southern countries, such as Italy and Portugal.⁴³ Germans tend to have less trust in food items than the British.⁴⁴

Furthermore, the high volume of imports causes concern among European consumers over the origin and safety of their foods.⁴⁵ Contrary to the United States, where ninety percent of food consumption is produced domestically, EU Member States import about half of their total food supply from other EU Member States.⁴⁶

In addition, whenever countries do not reach a consensus about food safety regulation, consumers are faced with a plurality of opinions instead of one leading decision. They are thus more likely to wonder whether their own country is acting in the public's best interest or is pursuing another goal. This uncertainty reflects consumers' lack of confidence in their respective governments.

Centralizing risk assessment and risk management processes, however, would likely result in more certainty, and therefore, increased trust. Consumers are skeptical about their national food system because they have experienced food scares, and they question their government's ability to prevent further problems. A centralized system at the European level would act as an extra shield of protection for consumers by reducing national competition based on food safety.

3. Centralization Reduces Business Uncertainty

With centralization of regulatory powers, all Member States would be subject to identical standards and the uniform enforcement of those regulations.⁴⁷ As a result, food businesses would have more of an incentive to trade, knowing exactly what to expect in the foreign country.⁴⁸ Moreover, small businesses would be better able to compete with larger

40. See Thomas Bernauer & Ladina Caduff, *European Food Safety: Multilevel Governance, Re-Nationalization, or Centralization?* 6-7 (Ctr. for Comp. and Int'l Stud., Working Paper No. 3, 2004) [hereinafter *European Food Safety*].

41. *Id.* at 7.

42. *Id.* See also Unni Kjaernes et al., *Contestation over Food Safety: The Significance of Consumer Trust*, in *WHAT'S THE BEEF? THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY*, *supra* note 13, at 61, 63.

43. Kjaernes, *supra* note 42, at 76-77.

44. *Id.* at 77.

45. See *European Food Safety*, *supra* note 40, at 8.

46. *Managing Risk*, *supra* note 34, at 155.

47. See *European Food Safety*, *supra* note 40, at 19.

48. *Id.*

companies in the European market because the regulatory system would be more stable.⁴⁹ Large companies already have more resources to adapt to the differing regulations in Member States. With a more centralized system, smaller companies might not face barriers to entry with regulations that are too expensive for them to implement.

4. Even Slightly Decentralized Systems Are Not Perfect: The Single Food Agency Debate in the United States

The issue of centralization of food regulatory powers has not only arisen in the EU. Other countries that have a more centralized system than the EU's also see a push for even greater centralization. The United States, for example, has been facing calls for potential reform of its food agencies. Given the various food scares of the past decade, Americans have questioned the effectiveness of their current system.⁵⁰ The issue is whether, instead of having two food agencies overseeing different aspects of food, there should be a single agency with the authority over all foodstuffs. This section demonstrates that, even with an already quite centralized system like that found in the United States, the question persists of whether to consolidate it even further.

i. Overview of the U.S. Food Regulatory System

The American food safety regulatory system is far more centralized than the European system. The issue of adulteration became a national issue in 1848 when Congress passed the Drug Importation Act, requiring inspection by the U.S. Customs Service to prevent the entry of adulterated drugs from abroad.⁵¹ In 1862, in order to address the issue of adulterated food, the Chemical Division of the United States Department of Agriculture (USDA) was established and then renamed the Bureau of Chemistry.⁵² This Bureau of Chemistry was the precursor to today's Food and Drug Administration (FDA).⁵³

After 1880, several food and drug bills were introduced to Congress, but it was not until 1906 that a major piece of legislation was passed. The Food and Drugs Act was enacted in June 1906 and prohibited interstate commerce of misbranded and adulterated foods, drinks, and drugs.⁵⁴ This law was in part a reaction to Upton Sinclair's book, *The Jungle*, which exposed unsanitary conditions in meatpacking plants.⁵⁵ This book also led to the 1907 Federal Meat Inspection Act, which authorized meat inspections and the condemnation of meat products unfit for human consumption.⁵⁶

In 1938, the Food and Drugs Act was preempted by the Federal Food, Drug, and Cosmetic Act (FDCA). This Act focuses on food misbranding and adulteration and serves

49. *Id.*

50. See, e.g., *Federal Food Safety and Security System: Fundamental Restructuring Is Needed to Address Fragmentation and Overlap: Hearing Before the Subcomm. on Civil Serv. and Agency Org.*, 108th Cong. 1–2 (2004) (statement of Lawrence Dyckman, Director, Natural Resources and Environment, Gen. Accounting Office).

51. Debra D. Burke & Anderson P. Page, *Regulating the Dietary Supplements Industry: Something Still Needs to Change*, 1 HASTINGS BUS. L.J. 119, 122 (2005).

52. James Robert Dean, Jr., *FDA at War: Securing the Food That Secured Victory*, 53 FOOD & DRUG L.J. 453, 455 (1998); Sue McGrath, Student Article, *Only a Matter of Time: Lessons Unlearned at the Food and Drug Administration Keep Americans at Risk*, 60 FOOD & DRUG L.J. 603, 603–04 (2005).

53. Dean, *supra* note 52.

54. Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, § 1, 52 Stat. 1040 (codified as amended at 21 U.S.C. § 301 *et seq.* (2000)).

55. *Id.*

56. Peter Barton Hutt, *Food Law & Policy: An Essay*, 1 J. FOOD L. & POL'Y 1, 6 (2005).

as the basic framework for food regulation by the FDA and the USDA.⁵⁷ This legislation created food standards, mandated inspections of factories, and provided for the issuance of court injunctions in addition to the already existing seizure and prosecution remedies.⁵⁸ Since 1938, the FDCA has been amended a number of times and additional supporting laws have been enacted relating to food safety, security threats, and nutrition. Additionally, this federal framework is supplemented by state laws.

The USDA and the FDA are the main actors in food regulation in the United States. These two federal agencies encompass all phases of the food regulatory system: they evaluate, investigate, regulate, inspect, and sanction. The USDA oversees the safety of meat, poultry, and some egg products, while the FDA regulates all other foodstuffs, such as whole eggs, seafood, fruits, vegetables, grain products, and milk.⁵⁹ As discussed previously, the European system differs: authority is not only divided among various countries, but those countries also have flexibility both in the way they control their food safety regulations and in the way they implement EU regulations and directives. This difference comes in part from the fact that the United States is a federal state and the EU is not. However, even in a centralized system like the United States, some argue that the USDA and the FDA should consolidate into one single food agency.⁶⁰

ii. The Present U.S. System Does Not Prevent Food Scares

Despite a centralized regulatory scheme with a statutory mandate to regulate and enforce, food scares have not been eradicated within the United States. In September 2006, the FDA issued a warning against contaminated bagged spinach.⁶¹ Despite this warning, the *E. coli* bacteria caused the deaths of three people.⁶² Then, in February 2007, jars of peanut butter containing salmonella were recalled after almost three hundred people became ill.⁶³ In March 2007, a massive recall of cat and dog food was issued, but not before thousands of pets suffered kidney failure, leaving at least sixteen of them dead.⁶⁴ A month later, the problem had still not been solved.⁶⁵

Given the already centralized nature of the American system, how can we expect that a decentralized system like the EU's would work better? In other words, if such a centralized system does not work all the time, how can the EU's completely decentralized system be efficient at all?

57. 21 U.S.C. § 301 *et seq.* (2000).

58. 21 U.S.C. § 332 (2000).

59. U.S. GEN. ACCOUNTING OFFICE, FEDERAL FOOD SAFETY AND SECURITY SYSTEM: FUNDAMENTAL RESTRUCTURING IS NEEDED TO ADDRESS FRAGMENTATION AND OVERLAP 3 (2004) [hereinafter GAO Report], available at <http://www.gao.gov/new.items/d04588t.pdf>.

60. Stuart M. Pape et al., *Food Security Would Be Compromised by Combining the Food and Drug Administration and the U.S. Department of Agriculture Into a Single Food Agency*, 59 FOOD & DRUG L.J. 405, 406 (2004).

61. Gardiner Harris, *F.D.A. Warns Against Eating Bag Spinach*, N.Y. TIMES, Sept. 15, 2006, at A14.

62. Libby Sander, *Nebraska Woman's Death Brings to 3 Those Attributed to Spinach*, N.Y. TIMES, Oct. 7, 2006, at A16.

63. *Peanut Butter Is Recalled As 300 Fall Ill*, N.Y. TIMES, Feb. 16, 2007, at A19.

64. Sarah Abruzzese, *Tainted Pet Food Is Said to Be Still on Shelves*, N.Y. TIMES, Apr. 13, 2007, at A12.

65. *Id.*

iii. The U.S.'s Single Food Agency Debate

The issue of whether the United States should combine FDA and USDA functions into a single food agency has been debated for several years.⁶⁶ Both sides rely in part on arguments reflecting efficiency and practicality. The opponents of a single food safety agency argue that the agencies already have so many intrinsic problems that, if they were to merge, food safety risks would increase rather than decrease.⁶⁷ They claim that consolidation would take too much time, would be very costly, and there would be regulatory gaps during the implementation period, thereby undermining the primary goal of safety.⁶⁸ Furthermore, they point out that the FDA and the USDA have two different philosophies and each has its own expertise proper to specific areas of the food system.⁶⁹ Moreover, they argue that since the food agencies already have to resort to the help of other agencies such as intelligence agencies and research organizations, creating a single food agency will not stop the need to work with other groups in a decentralized fashion.⁷⁰

On the other hand, proponents of a single food agency argue that because different agencies are involved in food regulation and have different types of jurisdiction over different parts of the food supply, there are inconsistencies in the application of regulations.⁷¹ For example, when Food Safety Inspection Service inspectors (who work for the USDA) notice serious violations of USDA regulations, those inspectors can remove their inspection services immediately.⁷² This in turn forces the plant to stop operating, because foodstuffs under the USDA's jurisdiction must have a USDA inspector present to inspect and approve the food products before they are sold to consumers.⁷³ However, some products under the FDA's jurisdiction are treated differently. For example, despite the fact that new food additives require prior FDA approval, cosmetics and dietary supplements can be marketed without it. The regulatory limbo starts when a food product contains a dietary supplement, such as orange juice with calcium—what happens then?⁷⁴

Another argument for consideration is that the multiple jurisdictions create gaps, overlaps, and duplicative efforts, which in turn undermine the efficiency of both agencies.⁷⁵ Proponents argue that having two agencies inspecting one facility is not efficient because those agencies supervise in different ways. A recent GAO report raises the issue that there are food-processing facilities which, due to the types of ingredients their products contain, are subject to both FDA and USDA regulations.⁷⁶ Thus, in sandwich or canned soups facilities, for instance, USDA inspectors must inspect the soups or sandwiches containing meat or poultry while FDA inspectors inspect the other products.⁷⁷ If the agencies ever issued recommendations that could not be reconciled, facility owners would find it very difficult to comply. Moreover, the overlap causes an inefficient use of funding and

66. Pape et al., *supra* note 60, at 405.

67. *Id.* at 406.

68. *Id.* at 413.

69. *Id.* at 414.

70. *Id.* at 416.

71. Timothy M. Hammonds, *It Is Time to Designate a Single Food Safety Agency*, 59 FOOD & DRUG L.J. 427, 427 (2004).

72. GAO Report, *supra* note 59, at 6.

73. *Id.*

74. See Dana Ziker, *Regulating Functional Foods: Pre- and Post-Market Strategy*, 2002 DUKE L. & TECH REV. 24, 24 (2002), available at http://www.law.duke.edu/journals/dltr/articles/pdf/2002DLTR_0024.pdf.

75. Hammonds, *supra* note 71, at 428.

76. GAO Report, *supra* note 59, at 5–6.

77. *Id.* at 6.

inspectors. With a single food agency, the standards would likely be more uniform, which would avoid the potential confusion caused by jurisdictional fragmentation.

Furthermore, proponents of consolidation argue that the dual regulation system creates rivalries between agencies and funding disparities that do not reflect food safety priorities.⁷⁸ The funding received by the USDA and FDA is not proportionate to the amount of foodstuffs each agency regulates. In 2003, while the FDA oversaw seventy-nine percent of foodstuffs, it received forty percent of the budget spent on food safety oversight.⁷⁹ In addition, the funding these agencies receive is “disproportionate to the percentage of food borne illnesses linked to the food products they regulate.”⁸⁰ This inequality in funding encourages each agency to fight for turf and authority so that it can enhance its budget.⁸¹

Similarly, those in favor of centralizing food safety regulatory bodies in Europe claim that it would accelerate the inspection process, limit business uncertainties, and preserve consumer confidence.⁸² Just as the loss of consumer confidence in the EU forced changes in its regulatory system, the same thing is likely to take place in the U.S. if food scares continue. Having one agency in control of the whole food safety system would eliminate jurisdictional inefficiencies and inconsistencies, resulting in a more secure public and less burdensome regulations.

Over the years, the EU has realized that greater centralization would be necessary to eliminate barriers and promote free trade. But having also been through the food scares of the 1990s, the EU has realized that consistency is necessary for countries to safely trade foodstuffs. Accordingly, the EU adopted a more centralized risk assessment mechanism. The question is whether or not it will be effective.

C. *Today's EU Is Not Ready for an Official Centralization of Its Food Safety Regulatory System*

In an abstract world, many might concur with the idea that a centralized system more efficiently ensures the safety of our food.⁸³ However, individuals are influenced by markets, by politics, by culture, and by the fear of giving up national identities. Personal biases are reflected in the institutions of individual nations, which in turns renders the combined regulatory process more complex. Opponents of centralization have noted various obstacles that legitimately demonstrate how the EU is not ready for centralization.

Member States are not obligated to follow EFSA's issued recommendations. Making EFSA's recommendations mandatory would create tension as countries fear centralization will infringe on their sovereignty. The obstacles that impede further progress toward centralization come not only from the institutions themselves, but also from politics, economics, and society as a whole.

78. Hammonds, *supra* note 71, at 430.

79. GAO Report, *supra* note 59, at 8.

80. *Id.* at 9.

81. Hammonds, *supra* note 71, at 430.

82. *Food Safety*, *supra* note 35, at 94–95.

83. See generally *Managing Risk*, *supra* note 34, at 165; *Food Safety*, *supra* note 35, at 94; Peter Shears et al., *The European Food Safety Authority: Towards Coherence in Food Safety Policy and Practice*, 106 BRIT. FOOD J. 336, 336 (2004).

1. Institutional Obstacles to Centralization

While EFSA is able to exert influence over Member States, it cannot impose its opinions on them.⁸⁴ In fact, the Regulation lays out duties only to cooperate with each other. EFSA is to “serve as point of reference . . . [and] shall act in close cooperation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.”⁸⁵ “The Authority, Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.”⁸⁶ Article 22(6) provides that “[t]he Authority shall provide scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission.” Although Member States must “take into account” EFSA’s opinions in establishing their own regulations,⁸⁷ when EFSA’s opinion conflicts with a member state’s opinion or with the opinion of another EU scientific body, Article 30 provides that EFSA, again, has to cooperate with the other party to try to resolve the disagreement or to issue a public document identifying the disagreement.

From those articles, we can infer that EFSA’s opinions must be taken into consideration in establishing policies regarding food safety. However, the Regulation never expressly provides that EFSA has the authority to make its opinions binding.

2. Political Obstacles to Centralization

Disagreements among Member States prior to the creation of EFSA were not uncommon. For instance, in 1996, after the BSE crisis in the United Kingdom, the EU banned trade in British beef.⁸⁸ However, when the ban was lifted four years later France refused to permit imports of British beef because of lingering safety concerns.⁸⁹ In spite of many tests performed by the EU indicating the beef was safe, France, based on its own national experts, argued that it still posed risks. The European Commission brought the case to the European Court of Justice, which ruled against France.⁹⁰ However, France refused to comply with the ruling and did not lift the ban until the Commission threatened to issue penalties against the country.⁹¹ This fight between Member States did not help consumers to feel safe within the EU as a whole.

The creation of EFSA brought a more centralized approach to food safety and established a more unified policy. Yet, those who oppose centralization rightfully claim that at the present time the Member States do not sufficiently support the EU institutions to permit total centralization of food regulatory powers.⁹² Moreover, some claim that with centralization, EU recommendations will always be considered correct, and Member States will no longer have an individual say in how to govern their own countries. In other words, Member States fear losing some of their sovereignty and risking abuse on the part of EU

84. Council Regulation 178/2002, *supra* note 31, art. 29.

85. *Id.* art. 22(7).

86. *Id.* art. 22(8).

87. *Id.* art. 6(3).

88. *See* Commission Decision 96/239/EC, Emergency Measures to Protect Against Bovine Spongiform Encephalopathy art. 1, 1996 O.J. (L 78) 47.

89. Shears et al., *supra* note 83, at 338.

90. Case C-1/00, *Comm’n of the European Cmtys v. French Republic*, 2001 E.C.R. I-09989, para. 142.

91. Shears et al., *supra* note 83, at 339.

92. *European Food Safety*, *supra* note 40, at 20.

regulators.⁹³ This is a legitimate argument, as this concern over sovereignty comes into play whenever nations come together to create an international agreement, or any time they make any other international decision.

Nevertheless, despite EFSA's lack of official authority, Member States take EFSA's recommendations seriously, as EU countries perceive them as somewhat of a limitation on state action.⁹⁴

3. Economic Obstacles to Centralization

Opponents to centralization note that it will require an extensive budget because it requires giving EFSA more authority, including enforcement powers.⁹⁵ The European Commission is unlikely to obtain those resources at the moment.⁹⁶ Moreover, given the current economic state in the EU, centralization would allow companies from richer countries to be more able to adapt and compete than companies in poorer countries.⁹⁷ If everyone had to implement the same food standards, the poorer firms would have much more difficulty doing so.⁹⁸

4. Social Obstacles to Centralization

Cultural and national pride is embedded in EU constituents' lives. To date, the EU is composed of twenty-seven countries, and its constituents are extremely culturally diverse. Culture plays a role in food regulation because each country has culinary traditions that focus on specific products. As a result, countries will enact regulations based on criteria that facilitate, or that do not overly restrict the production of these favorite products.⁹⁹ Some question the impact of local tastes on food safety regulation, in part arguing that those disagreements are not unique to Europe.¹⁰⁰ It is true that culture is a major contributor to divergences of opinion not only at the EU level, but also at a more global level. Culture no longer plays as significant a role in the regulatory process as it did several years ago. This does not undermine the idea that culture does play a role in the way Member States decide to regulate their foodstuffs. EU constituents that are attached to their culinary traditions, such as the non-pasteurization of cheeses, will have difficulties supporting a more centralized system, in which some traditions would inevitably be lost for health reasons.

Other cultural aspects that are unrelated to food can also be obstacles to centralization. Just as countries often fear losing some of their sovereignty in international negotiations, EU countries can experience the same scare. A supranational authority, with the power to

93. See *id.* at 19–20; Ed Randall, *Not That Soft or Informal: A Response to Eberlein and Grande's Account of Regulatory Governance in the EU with Special Reference to the European Food Safety Authority (EFSA)*, 13 J. EUR. PUB. POL'Y 402, 412 (2006).

94. Alemanno, *supra* note 13, at 250–51.

95. Cf. *European Food Safety*, *supra* note 40, at 20; Randall, *supra* note 93, at 412.

96. Randall, *supra* note 93, at 412.

97. See *European Food Safety*, *supra* note 40, at 19.

98. See *id.*

99. See Frans van Waarden, *Taste, Traditions, Transactions, and Trust: The Public and Private Regulation of Food*, in WHAT'S THE BEEF? THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY, *supra* note 13, at 35, 38–39.

100. Laurie Buonanno, *The Creation of the European Food Safety Authority*, in WHAT'S THE BEEF? THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY, *supra* note 13, at 259, 276.

subject individual governments to a higher power, would probably forever modify national institutions.

Despite these obstacles, the EU has managed to enact food safety policies, speaking more and more frequently with one voice. The trend that we have seen over the years where countries went from being completely independent to increasingly unified Member States suggests that this movement toward more uniformity will eventually lead to centralization. However, questions remain over whether centralization will ever occur.¹⁰¹ As the next section will argue, despite current resistance to it, centralization is inevitable.

III. TOWARD AN INEVITABLE CENTRALIZATION OF REGULATORY POWERS

Centralization is not only possible, it is unavoidable. However, it is probably not the kind of centralization one would expect, and such an official change will most likely not occur immediately. The first thought that comes to mind when the word “centralization” is mentioned is one of an official regrouping of agencies or powers under a single entity that is able to create laws, implement them, and enforce them through sanctions on violators. Yet there are other forms of centralization that happen in a more progressive manner. This section will argue that as the EU is on its way toward an official centralization of its food safety regulatory system, it is first encountering an intermediary stage of development where the goal is harmonization of standards.

EFSA aims to develop similar and adoptable principles, general standards and ideas that each Member State can implement on its own. The way that the EU currently works does not allow for anything more. However, this creates its own form of centralization. When general standards apply to everyone, even if regulatory and enforcement powers are not officially centralized, centralization occurs automatically around those principles. This is *de facto* centralization, and it is what the EU is experiencing right now. Some scholars have already referred to the uneven *de facto* standards that the EU Member States are following in order to have a more harmonized system.¹⁰² Even though these *de facto* standards are unevenly implemented in the Member States, they nevertheless create harmonization. As such, they represent a form of unofficial centralization that will eventually evolve into an official one. In other words, the movement toward official centralization is already happening today.

De facto centralization can be observed in the trend toward uniformity of principles and standards that is happening today (as discussed below through the Hazard Analysis and Critical Control points (HACCP), labeling, and even the Common Agricultural Policy (CAP)¹⁰³ and which ends up constituting a form of centralization as everyone works under similar standards. This *de facto* centralization serves as an intermediary step that will eventually lead to an official, *de jure* centralization.

Uniformity of practices and principles provide a sort of centralization that is a middle ground, an intermediate step toward a *de jure* centralization that will eventually occur. The various EU standards indicate signs of centralization, such as notions of traceability and labeling, the crisis management system, the HACCP system, and the Common Agricultural Policy.

101. See *Managing Risk*, *supra* note 34, at 165; *European Food Safety*, *supra* note 40, at 21; see generally Shears et al., *supra* note 83.

102. *European Food Safety*, *supra* note 40, at 7.

103. See *infra* Sec 3(c) (Hygiene Rules); 3(b)(2) (Labeling); 3(e) (The Common Agricultural Policy).

A. EFSA's Risk Assessment Responsibility

As previously discussed, EFSA handles risk assessment and therefore one of its functions is to give all of the Member States a scientific evaluation of food safety issues.¹⁰⁴ Its assessments results in a harmonization of the very definition of food scares and emergencies. This assessment and its effects form part of the de facto centralization phase the EU is currently experiencing.

B. Traceability and Labeling

Traceability and labeling are probably the biggest part of the harmonization of standards and principles that the EU has undertaken in the realm of food safety regulation in order to allow the recording of the entire “from farm to fork” system.¹⁰⁵ The EU aims to provide consumers with information about products in order for them to make informed choices.¹⁰⁶

1. Traceability

Traceability in the EU, which has primarily been a reaction to the BSE crisis that occurred in the mid-1990s, has the main objective of consumer protection.¹⁰⁷ A 2002 regulation established the general principles and requirements of food law, the EFSA, and procedures in matters of food safety.¹⁰⁸ It also introduced the principle of traceability, defining it as “the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.”¹⁰⁹ It is a process to be “established at all stages of production, processing and distribution.”¹¹⁰ The concept of traceability requires food and feed operators to be able to identify where their foodstuffs came from before entering the operator’s facility, and where the foodstuffs went after leaving the operator’s facility.¹¹¹ Thanks to this process, whenever a food safety issue arises, the source of the problem can quickly be identified and appropriate measures can be taken efficiently.

2. Labeling

Adequate labeling is also required in order to facilitate traceability.¹¹² In 2000, the EU adopted a directive that approximated the laws of the Member States relating to the labeling,

104. Council Regulation 178/2002, *supra* note 31, arts. 23(a), (b).

105. See Food Safety: From the Farm to the Fork, http://ec.europa.eu/food/index_en.htm (last visited Mar. 24, 2008).

106. Council Regulation 178/2002, *supra* note 31, art. 8.

107. Coralie Angélique Bonnin, Student Article, *La Traçabilité: Outil Commun à l'Union Européenne et au Canada pour Garantir la Sécurité Alimentaire [Traceability: Tool Proper to the European Union and Canada to Ensure Food Safety]*, 45 CAHIERS DE DROIT 563, 567 (2004) (Can.).

108. Council Regulation 178/2002, *supra* note 31.

109. *Id.* art. 3(15).

110. *Id.* art. 18(1).

111. *Id.* arts. 18(2), (3).

112. *Id.* art. 18(4).

presentation, and advertising of foodstuffs.¹¹³ Despite the fact that Member States are allowed to enact additional labeling laws as long as they are not inconsistent with EU law,¹¹⁴ this directive led to more uniform standards that made it easier for foods to circulate freely while preserving consumers' immediate access to information about their food. Labeling is defined as "any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff,"¹¹⁵ and the directive applies to foodstuffs that are supplied to the ultimate consumers as well as to "restaurants, hospitals, canteens and other similar mass caterers."¹¹⁶ In addition to regulations concerning labeling to address food safety issues, the EU, like the United States, has a system for the labeling of nutrition information, as well as health and nutrition claims. As a presentation of food labeling in the EU could be the subject of an entire article, the following subparts are merely examples of labeling regulations for particular products.

i. Labeling of Genetically Modified Organisms

The main regulations that involve traceability concern genetically modified organisms (GMOs). The EU is very careful about GMOs and has in place regulations to ensure consumers know which products contain GMOs. Regulations No. 1829/2003 and No. 1830/2003 cover traceability and labeling of products containing GMOs. In short, these regulations require labeling of food products consisting of or containing genetically modified organisms.¹¹⁷

The EU regulates the release of GMOs into the environment in different ways, depending on whether the release is for the purpose of scientific experiment or of eventual consumption.¹¹⁸ In order to release GMOs into the environment for experimental purposes, one must obtain written consent from the Member States where the experimental release will occur.¹¹⁹ The consent will be issued based on an assessment of the risks posed by the GMO to the environment and human health.¹²⁰ The decision is made exclusively by the Member States, and is therefore, a solely national determination.

The procedure is a little different for GMOs to be placed on the market because, by being on the market, the GMO will be subject to free circulation and will therefore be able to reach many other Member States' constituents. A 2003 regulation dictates the procedure to obtain authorizations for placing food or feed products containing GMOs or produced from or containing ingredients produced from GMOs, on the market for sale, distribution, or other types of transfers.¹²¹ The person or company wanting to place a GMO product or product containing GMOs on the market needs to request an authorization from the

113. Council Directive 2000/13, art. 1, On the Approximation of the Laws of the Member States Relating to the Labelling, Presentation and Advertising of Foodstuffs, 2000 O.J. (L 109) 29, 30.

114. DEBRA HOLLAND & HELEN POPE, EU FOOD LAW AND POLICY 32 (2004).

115. Council Directive 2000/13, *supra* note 113, art. 1(3)(a).

116. *Id.* arts. 1(1) & (2).

117. Council Regulation 1829/2003, On Genetically Modified Food and Feed, art. 1(c), 2003 O.J. (L 268) 1, 6; *see* Council Regulation No. 1830/2003, Concerning the Traceability and Labelling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC, pmb. (1), 2003 O.J. (L 268) 24, 24.

118. Council Directive 2001/18, On the Deliberate Release Into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC, art. 1, 2001 O.J. (L 106) 1, 4.

119. *Id.* art. 6(8).

120. *Id.* art. 6(2)(b).

121. Council Regulation 1829/2003, *supra* note 117, art. 3(1).

appropriate and “competent” national authority. This authority will then forward the request to the European Food Safety Authority (EFSA), which in turn will inform the other Member States as well as the European Commission of the application along with any other supplementary information.¹²² The request for authorization of GMOs or food containing GMOs must contain a report on the risks associated with the product as well as a scientifically detailed description of the GMO product.¹²³ For authorizations of GMO products on the market, the EFSA can recommend that the Commission modify, suspend, or revoke the authorizations.¹²⁴

Once the EFSA authorizes the product, labeling requirements come into play. Pre-packaged products that contain GMOs must bear a label stating “[t]his product contains genetically modified organisms” or “[t]his product contains genetically modified [name of organism(s)].”¹²⁵ Non pre-packaged products that are offered to the final consumer must have the same label appear “on, or in connection with, the display of the product.”¹²⁶ Those requirements apply even if the final product does not contain DNA or protein resulting from the genetic modification.¹²⁷

An exemption applies to some types of unintentional contaminations. Given the fact that products that are not genetically modified may be accidentally contaminated by GMOs during processes such as transport or processing, those products that contain ingredients produced from GMOs in a proportion equal or less than 0.9% of the total ingredients are exempt from traceability and labeling requirements as long as the presence of genetically modified material is “adventitious or technically unavoidable.”¹²⁸

Member States are in charge of inspections and testing and have the authority to decide the penalties in case of infringement.¹²⁹ However, to facilitate a coordinated approach, the European Commission can provide guidance as to the kind of sampling and testing to be used.¹³⁰

ii. Labeling of Beef and Beef Products

Operators are required “to label beef at all stages of marketing.”¹³¹ Labels must communicate the link between the meat and the animal through codes or numbers designating the slaughterhouse and the cutting hall where the animal was slaughtered, and the country where the slaughtering took place.¹³² The label must also indicate the country of birth of the animal and all the countries where fattening took place.¹³³ However, if the animal was reared in a country for thirty days or less, that country does not have to be

122. *Id.* art. 5(2) at 7.

123. *Id.* art. 5(5) at 8, Council Regulation 2001/18, *supra* note 118, art. 6.

124. Council Regulation 1829/2003, *supra* note 117, art. 10(2).

125. Council Regulation 1830/2003, *supra* note 117, art. 4(6)(a).

126. *Id.* art. 4(6)(b).

127. Council Regulation 1829/2003, *supra* note 117, pmbl. (21).

128. *Id.* arts. 12(2), 24(2).

129. *Id.* art. 45; Council Regulation 1830/2003, art. 9(1).

130. Council Regulation No. 1830/2003, art. 9(2).

131. Council Regulation 1760/2000, Establishing a System for the Identification and Registration of Bovine Animals and Regarding the Labelling of Beef and Beef Products and Repealing Council Regulation (EC) No 820/97, art. 11, 2000 O.J. (L 204) 1, 6.

132. *Id.* art. 13(2).

133. *Id.* art. 13(5).

indicated, as long as the animal was reared in another country for more than thirty days.¹³⁴ If an operator wants to indicate any additional information on the labels, he or she must send a request “to the competent authority of the Member State where production or sale of the beef in question takes place.”¹³⁵

These examples of GMO labeling and beef labeling confirm the general principle that Member States are responsible for enforcing food law, ensuring that the provisions are respected and the requirements are met.¹³⁶ Therefore, the Member States still play a significant role in how the food safety policies are implemented. Nevertheless, EU agencies such as the EFSA and the EC have a more overarching function to make sure Member States follow the same standards in similar ways. The Commission, through the Food and Veterinary Office, which is part of the Directorate-General for Health and Consumer Protection, is responsible for ensuring that European food safety regulations are respected, implemented, and enforced. Therefore, through this system, EU countries work on similar standards, and it likewise contributes to the de facto centralization phenomenon.

C. *Hygiene Rules*

The EU also has in place common hygiene rules to ensure the safety of foodstuffs.¹³⁷ Various regulations cover the safety of foodstuffs in food businesses from initial production to the final sale to consumers; unprocessed and processed products of animal origin;¹³⁸ official controls on products of animal origin intended for human consumption;¹³⁹ and official controls performed to ensure the verification of compliance with feed and food law, animal health, and animal welfare rules.¹⁴⁰

Food business operators are responsible for ensuring the safety of their foods at all stages of production that are under their control.¹⁴¹ They are required to put in place a procedure based on HACCP, a proactive control system created to ensure food safety by controlling all stages of production.¹⁴² It has seven principles: (1) identification of “any hazards that must be prevented, eliminated or reduced to acceptable levels;” (2) identification of the critical control points at the step(s) at which control “to prevent or eliminate a hazard or to reduce it to acceptable levels;” (3) establishment of “critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;” (4) establishment and implementation of “effective monitoring procedures at critical control points;” (5) establishment of “corrective actions when monitoring indicates that a critical control point is not under control;” (6) establishment of “procedures, which shall be carried out regularly, to

134. Commission Regulation (EC) No. 1825/2000, Laying Down Detailed Rules for the Application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council As Regards the Labelling of Beef and Beef Products, art. 3, 2000 O.J. (L 216) 8, 10.

135. Regulation 1760/2000, *supra* note 131, art. 16(1).

136. Council Regulation 178/2002, *supra* note 31, art. 17(2).

137. *See generally* Corrigendum to Regulation 852/2004, On the Hygiene of Foodstuffs, 2004 O.J. (L 226) 3; Corrigendum to Regulation 853/2004, Laying Down Specific Hygiene Rules for Food of Animal Origin, 2004 O.J. (L 226) 22; Corrigendum to Regulation 854/2004, Laying Down Specific Rules for the Organisation of Official Controls on Products of Animal Origin Intended for Human Consumption, 2004 O.J. (L 226) 83; Corrigendum to Regulation 882/2004, On Official Controls Performed to Ensure the Verification of Compliance with Feed and Food Law, Animal Health and Animal Welfare Rules, 2004 O.J. (L 191) 1.

138. Corrigendum to Regulation 853/2004, *supra* note 137.

139. Corrigendum to Regulation 854/2004, *supra* note 137.

140. Corrigendum to Regulation 882/2004, *supra* note 137.

141. *See* Corrigendum to Regulation 852/2004, *supra* note 137, art. 3.

142. *Id.* art. 5(1).

verify that [measures (1) to (5)] are working effectively;” and (7) establishment of “documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in [provisions (1) to (6)].”¹⁴³

Member States are in charge of maintaining controls of the hygiene of foodstuffs through the adoption of record keeping and registration requirements.¹⁴⁴ The record keeping and registration requirements entered into effect on January 1, 2006 and replaced an earlier directive which had not provided for record keeping.¹⁴⁵

Member States and the Commission, with the assistance of the Standing Committee on the Food Chain and Animal Health, can each issue guides to good practice for hygiene and for the application of HACCP principles for food business operators to use if they so desire.¹⁴⁶ Yet, despite the fact that the use of the guides is voluntary, food business operators still must implement some form of processes based on the HACCP principles.

D. *The Crisis Management System*

The EU has procedures to deal with crises both before and after they occur. If Member States are unable to eradicate the risks some food or feed pose to human health, then the EU Commission takes action.

1. The Rapid Alert System for Food and Feed

EU regulations provide for a system to disseminate information when a Member State discovers a problem that poses a potential risk to human health. Chapter IV of Regulation (EC) No. 178/2002 lays out a procedure for a Rapid Alert System for Food and Feed (RASFF). Its purpose is effective “notification of a direct or indirect risk to human health deriving from food or feed.”¹⁴⁷ This process involves the Member States, the Commission, as well as the EFSA. Whenever one party has information about a serious direct or indirect risk to human health deriving from food or feed, this information must be transmitted to the Commission, which will then transmit the information to the other members.¹⁴⁸ Member States have an obligation to notify the Commission of any measures they adopt that require rapid action and that force the withdrawal from the market, or the recall, of food or feed to protect human health. The Commission also requires notification for measures that limit or impose conditions on the placing on the market or use of food or feed on account of a serious risk to human health requiring rapid action, or measures of rejection of containers of food or feed due to a direct or indirect risk to human health.¹⁴⁹

143. *Id.* art. 5(2).

144. *Id.* arts. 2, 6.

145. *Id.* arts. 17–18; Council Regulation 852/2004, which came into effect on January 1, 2006, replaced EC Directive 93/43.

146. Corrigendum to Regulation 852/2004, *supra* note 137, art. 7.

147. Council Regulation 178/2002, *supra* note 31, art. 50(1).

148. Bernd M.J. van der Meulen & Annelies A. Freriks, *Millefeuille: The Emergence of a Multi-Layered Controls System in the European Food Sector*, 2 *UTRECHT L. REV.* 156, 171 (2006).

149. Council Regulation 178/2002, *supra* note 31, art. 50(3).

2. Emergencies

If the risk to health is serious and likely to occur, and if the Member State cannot contain it efficiently, the Commission, pursuant to the procedure laid out in Article 5 of Decision 1999/468/EC, can take different measures, depending on whether the problematic product is in a Member State or a third party country.¹⁵⁰ If the food or feed comes from a Member State, the Commission can suspend the placing on the market or the use of the food or feed, set up specific conditions to be met, or take any other measures that it deems appropriate.¹⁵¹ As for food or feed coming from a third party country, the Commission can decide to suspend imports either from the part of the third party country involved, or from the whole third party country, where appropriate; it can also set up specific conditions for the food or feed to meet, or it can take any other appropriate measure.¹⁵² Only when the Commission does not act accordingly can the Member State adopt measures by itself.¹⁵³

3. Crisis Management

The Commission has a plan for crisis management for the risks to human health derived from food or feed that could not be eradicated by the emergency measures previously mentioned.¹⁵⁴ The Commission must notify the Member States and the EFSA, and create a crisis unit that will gather and analyze information to find ways to prevent, eliminate, or reduce the risk. EFSA is to provide scientific and technical assistance whenever necessary.¹⁵⁵

E. *The Common Agricultural Policy*

The CAP has had an influence on the evolution of the European Community's food law.¹⁵⁶ The CAP was provided for in the Treaty of Rome, the founding document of the European Community. The objectives of the CAP were initially listed in Article 39 of the Treaty Establishing the European Economic Community, which is now Article 33 of the Treaty Establishing the European Community. Those goals are to increase agricultural productivity through technical progress; to provide a fair standard of living for the agricultural community, stabilize markets, guarantee supplies; and to make sure retail prices are reasonable.¹⁵⁷ Because the original CAP did not anticipate the problem of harmonizing countries' different production methods, when the common market developed, there were disparities in income within and among Member States.¹⁵⁸ Until the 1990s, the most important component of the CAP was the market and price policy.¹⁵⁹ However, the

150. *Id.* arts. 53(1), 58(2).

151. *Id.* art. 53(1)(a).

152. *Id.* art. 53(1)(b).

153. *Id.* art. 54(1).

154. Council Regulation 178/2002, *supra* note 31, art. 55.

155. *Id.* arts. 56, 57.

156. Alemanno, *supra* note 13, at 239.

157. Consolidated Version of the Treaty Establishing the European Community art. 33, Dec. 24, 2002, 2002 O.J. (C325) 48.

158. MARJOLEINE HENNIS, GLOBALIZATION AND EUROPEAN INTEGRATION: THE CHANGING ROLE OF FARMERS IN THE COMMON AGRICULTURAL POLICY 41 (2005).

159. *Id.* at 42.

regulations shifted to focus closely on consumers after the food scares of the mid-1990s.¹⁶⁰ In June 2003, a CAP reform established a cross-compliance obligation, requiring farmers to meet their obligations regarding public, animal, and plant health; the environment; and animal welfare, in order to receive their single payment.¹⁶¹ This single farm payment is unrelated to production and is allocated only if the farmer respects the environmental, food safety, and animal welfare standards.¹⁶²

Despite the existence of regulations providing risk assessment, traceability, labeling, hygiene rules, crisis management, and even incentives to respect health norms, scholars have noted the divergence between national and European-level regulation.¹⁶³ Disagreements create inconsistencies among the Member States' policies.¹⁶⁴ However, it is unlikely that those problems will cause the EU to step back in its progress and stop using processes such as HACCP, labeling, and other common standards. Those processes may need to be reviewed or improved. However, the fundamental idea of harmonization and similarities in processes will remain. Since the creation of the European Community fifty years ago, nations continue to grow closer. Thus, the tendency to continue to unite seems to be the logical outcome. Furthermore, as nations come together globally, the natural inclination seems to suggest that EU Member States will come together as well.

IV. CONCLUSION

The EU food safety regulatory system faces challenges. A centralization of regulatory powers would bring a more homogeneous type of regulation where Member States would let European institutions oversee both risk assessment and risk management. This centralization is difficult to achieve because political, economic, and social obstacles make Member States reluctant to give up part of their sovereignty. However, the direction of reforms within the past decade anticipates the future official centralization of regulatory powers.

In the EU, diplomacy prevails over authority. Despite all of its virtues, diplomacy is a slow process, especially because the EU is faced with twenty-seven visions and ideologies. It takes time for people and nations to reach a consensus. In the context of food safety regulations, this problem has to do with the fact that agriculture is seen as a way of life more than a business. History and culture are intertwined with agriculture, which makes it hard to make concessions and reach a compromise.

Food safety regulations often concern a cultural aspect which, mixed with politics and economics, becomes an overwhelming obstacle. In addition, countries also fear the loss of independence and sovereignty. The debate over food safety regulation in the EU raises a bigger issue, one concerning Europe's future in general. Centralization would improve consumer trust and make it easier for businesses. Furthermore, if policies are implemented evenly throughout the whole EU, foodborne illnesses will more likely be prevented. Even in the United States, which has a system that is more centralized than the EU's, a debate over

160. *Id.* at 61.

161. Council Regulation 1782/2003, Establishing Common Rules for Direct Support Schemes Under the Common Agricultural Policy and Establishing Certain Support Schemes for Farmers, arts. 3, 4, 2003 O.J. (L 270) 1, 8.

162. *Id.*

163. See generally WHAT'S THE BEEF? THE CONTESTED GOVERNANCE OF EUROPEAN FOOD SAFETY, *supra* note 13 (collection of scholarly articles discussing the various levels and methods of regulation of food safety in European countries).

164. *Id.*

further centralization is under way. Some argue that politics, economy, and even society conspire to oppose centralization. However, this reluctance comes from today's generation, and all of this will change as globalization makes nations closer to each other. Today's generations may not be ready to be part of an entirely centralized system. The cultural aspect and national pride are very deeply embedded in the European way of life. The "Europeanization" of the EU will be increasingly a part of the new generation's cultural upbringing, and globalization will drive this movement. It is only when these new generations feel truly "European" that they will allow centralization.

The decentralization of food safety regulatory powers demonstrates a reluctance to make the EU a true union. Yet, the creation of European institutions proves that Member States are willing to move toward common principles of legality and ethics. Before, Member States had total authority over whatever occurred within their borders. Today, some laws have been enacted to allow EU entities to supervise Member States' actions and to assist whenever an emergency situation arises. The harmonization of standards that the EU is experiencing today is simply half of the process necessary to have a true, official, and de jure centralization of food safety regulatory powers.

In other words, centralization will happen eventually. Today, de facto centralization is occurring. Tomorrow, as globalization ceases to be a new phenomenon to new generations, the EU will go on to the next phase of its evolution: an inevitable official centralization of food safety regulation, along with the likely centralization in other areas of regulation as well.