The Role of the European Court of Justice in the Europeanization of Communicable Disease Control: Driver or Irrelevance?

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Abstract What role(s) does the European Court of Justice (ECJ) play in the Europeanization of communicable disease control? Drawing on a review of the ECJ's case law, especially but not exclusively in public health fields, from the 1950s to 2009, this article argues that the ECJ's past and present role in the Europeanization of communicable disease control is neither that of a driver nor that of an irrelevance. Instead, the ECJ has been responsible for four important elements of the environment that over time led to the Europeanization of communicable disease control in general and the establishment of the European Centre for Disease Prevention and Control in particular: (1) the European Union itself has responsibility for public health; (2) agencies are a constitutionally permissible institutional arrangement in the EU; (3) EU legislation that inter alia protects public health is mandatory and justiciable; and (4) such EU legislation may not be undermined by liberalizing internal market law. A fifth idea, "mainstreaming" public health, could play a role in the future.

What role(s) does the European Court of Justice (ECJ) play in the Europeanization of communicable disease control? Standard legal accounts of the process of European integration place the ECJ very much in the driver's seat (see, e.g., Stein 1981; Cappelletti et al. 1986; Weiler 1991). In areas such as the internal market and competition policy, and also in health care (see, e.g., Hervey and McHale 2004; Gekiere, Baeten, and

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Palm 2010; Palm and Glinos 2010), the ECJ's activism in carving out the constitutional contours of European Union (EU) law is portrayed as playing a central role in creating the conditions for further Europeanization of policies, whether through the adoption of EU-level legislation or through the creation of EU-level administrative or (quasi)-regulatory bodies. In these accounts the Europeanization process is essentially seen as a process of integration through law, and the ECJ is seen as a key driver of that process.

But the story of the Europeanization of communicable disease control, and the creation of the European Centre for Disease Prevention and Control (ECDC), has not been told that way. There are no legal accounts of the ECDC. There are no obvious judgments of the ECJ that change the landscape in ways that explain the ECDC's establishment.[1] Regarding the ECDC, case law does not explain why the governments of the member states turned to EU institutions to solve a particular problem, itself caused or highlighted by litigation before the ECJ. Instead, the story of the ECDC is told as a gradual process of European Commission–supported networking of national authorities and expert groups (of varying strengths), each in a specific (vertical) communicable disease area (Steffen 2012), which were eventually brought together in a horizontal institutional arrangement (the ECDC), responding to specific, high-profile communicable disease incidents or problems: anthrax (2001) in the context of global security threats, and severe acute respiratory syndrome (2002–2003) in the context of global economic threats (McKee, Hervey, and Gilmore 2010; Greer 2012; Elliott, Jones, and Greer 2012). Perhaps the ECJ is irrelevant in this area of EU policy.

This article argues that the ECJ is neither the driver nor an irrelevance in the Europeanization of communicable disease control. Instead, it seeks to show that the ECJ's activities formed an important part of the institutional context that made the development of EU communicable disease control, and in particular the establishment of the ECDC, possible. The argument made here is that without the ECJ, one of the key features of the Europeanization of communicable disease control in general, and the creation of the ECDC in particular, would be missing.

1. Examples of such cases in other areas include Case 120/78, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon)*, 1979 ECR 649, on the internal market; Cases 142 and 156/84, *British American Tobacco and R J Reynolds Industries v Commission*, 1987 ECR 4487, on mergers and acquisitions; Cases 209–213/84, *Criminal Proceedings against Lucas Asjes and others, Andrew Gray and others, Jacques Maillot and others and Léo Ludwig and others (Nouvelles Frontières)*, 1986 ECR 1425, on air transport liberalization (Armstrong and Bulmer 1998: 149–51, 95–96, 177–78, respectively); and Case C-158/96, *Kohll v Union des Caisses de Maladie*, 1998 ECR I-1931, on health care services.

The article draws on a review of the ECJ's case law, especially but not exclusively that in public health fields concerning communicable disease, from the inception of the European Economic Community (EEC) in the 1950s to 2009. Using Eur-lex, the EU's official free access database of EU law, to screen the whole of the ECJ's jurisprudence, I selected some eighty decided cases for analysis, in the areas of food safety (food additives, bacteria/microorganisms, pesticides), delegation of powers in the EU (coal and steel, transport), enforcement of EU law (trade law and the common agricultural policy), and environmental protection (air and water quality). A literature review and review of relevant EU legislation and policy documents form the basis for the discussion of the political developments in EU communicable disease control.

Europeanization and the Role of Law

The term *Europeanization* has several overlapping meanings (Olsen 2002). In political science scholarship, Europeanization usually denotes the EU's influence on domestic policies and politics (Ladrech 1994; Bache and Jordan 2006: 30; Bulmer 2007; Bulmer and Radaelli 2005; Caporaso 2007). Metaphors of downloading and uploading (Börzel and Risse 2000; Börzel 2005; Goetz 2005), fit and misfit (Héritier 2001; Bache and Jordan 2006), and reorientation (Bache and Jordan 2006: 30; Bache 2008: 9) suggest national policy changes resulting from the power or influence of EU political or administrative processes or institutions. In this article, *Europeanization* has a different meaning (Olsen 2002; Bulmer 2007): it denotes the processes by which a particular policy area (communicable disease control) became part of EU responsibility and activity. In other words, I ask how the EU "got into" communicable disease control, and what roles — if any — the ECJ played in that process.

In the Europeanization literature, variants of new institutionalism are central (Bache et al. 2011). Institutionalism is also a particularly appropriate frame of analysis of Europeanization when the focus is on legal institutions (Armstrong and Bulmer 1998). Respect for the institution of the rule of law itself, and the habit of legal compliance, provides an explanation of domestic change following legal pronouncements from EU institutions. So, for instance, governments of member states implement EU legislation (even if it is inconvenient to do so or if they opposed it in Council) simply because it is law. And the governments of member states comply with ECJ rulings because the ECJ is recognized as a court (indeed, a constitutional court of sorts) in national legal systems (in particular by national constitutional courts).

Moreover, the nature of EU law — in particular its direct effect and supremacy[2] — means that the law penetrates national legal orders more effectively than the law of other international organizations. EU law confers rights on individuals that are enforceable in their domestic courts: these rights (essentially the right to trade freely across borders) are thus upheld by national courts, in litigation involving private actors (usually traders), without the ECJ (or any other European institution) having to be directly involved. Moreover, the ECJ's position is protected in the relationships between it and national courts through an institution promoting dialogue and mutual respect (for an example, see the discussion in Krisch 2008): the preliminary reference procedure.[3] Finally, the ECJ enjoys an important protection from the "rough and tumble" of Europeanization processes, because its quotidian activities are not always subject to scrutiny by the media, elected parliaments, or civil society. Much of the ECJ's case law is in areas of low political salience. To a large extent, the ECJ has therefore been able to operate below the radar of the contested politics of Europeanization and build up incrementally to positions that are relatively unassailable, precisely because they have been reached over time through a series of politically uncontested steps.

The ECJ's "creation" of EU law is thus an important dynamic of Europeanization. Formally speaking, the ECJ — in common with all courts — may only interpret the written texts of the law, not make the law. However, through the legal fiction of *interpretation* of these texts, the ECJ has effectively made EU law in a wide range of policy areas (Stein 1981; Weiler 1991). If a court makes surprising and significant changes in an individual legal case — for instance, by applying a preexisting legal principle to an unexpected new area — this can contribute to a sudden move of a policy area to Europeanization. (Greer [2008, 2009] has argued that the ECJ's case law on health care services is such an example.) But in general court-made law tends to follow a pattern of incremental change. The legal devices of applying and distinguishing previous cases to determine the *ratio decidendi* (the legal proposition for which a decided case stands) and elucidating legal principles from a series of related cases operate to constrain courts from making sweeping changes in individual court decisions. However, smaller, incremental changes are inherent in the process

2. Cases 26/62, *Van Gend en Loos*, 1963 ECR 1 (direct effect), and 6/64, *Costa v ENEL*, 1964 ECR 585 (supremacy).

3. This procedure allows national courts to refer to the ECJ on questions of validity or interpretation of EU law. Any national court may do so; national courts of last resort (e.g., the UK Supreme Court) are obliged to do so. See European Union 2007b: Article 267.

of judicial lawmaking as legal rules are developed through the process of deciding (and distinguishing) similar (and different) cases. We can therefore track the significance of legal principles (developed by the ECJ through case law) as explaining opportunities for Europeanization, and constraints on such opportunities, over longer periods of time. The ECJ's role contributes to what is feasible or what at a particular point in time becomes feasible, in terms of Europeanization processes.

The following discussion analyzes the ECJ's jurisprudence on four elements of the environment in which the Europeanization of communicable disease control, and the eventual creation of the ECDC, has taken place: (1) the EU itself has responsibility for public health; (2) agencies are a constitutionally permissible institutional arrangement in the EU; (3) EU legislation that inter alia protects public health is mandatory and justiciable; and (4) such EU legislation may not be undermined by liberalizing internal market law.

ECJ Support for Europeanization of Communicable Disease Control

Public Health Protection as a Matter of EU Responsibility

The earliest examples of ECJ decisions on public health in EU law are in the early to mid-1970s. In several cases involving national laws blocking "parallel imports" of pharmaceuticals[4] and cases involving charges for Italian sanitary inspections of imports of beef and veal[5] and raw cowhides moving between France and Italy,[6] the ECJ began to develop its jurisprudence on the place of public health in the EU. These extremely low-profile cases concerned the proper balance between, on the one hand, the benefits of a single European market in products and the corresponding imperatives of EU free movement law, and, on the other, the need to protect the health of humans, animals, and plants in that emergent single market. The ECJ's interpretation of its jurisdiction is that the treaty establishing the EEC gave the ECJ responsibility for determining the proper balance between these competing interests. The ECJ does so through interpreting and applying the treaty rules on free movement of the factors of produc-

4. Cases 15/74, *Centrafarm and de Peijper v Sterling Drug*, 1974 ECR 1147; 16/74 *Centrafarm and de Peijper v Winthrop*, 1974 ECR 1183; and 104/75 *De Peijper*, 1976 ECR I-613.

5. Case 29/72, *Marimex* 1972 ECR 1309.

6. Case 87/75, *Besciani* 1976 ECR 129.

tion, and the exceptions to those rules set out in the treaty, to the effect that the free movement rules "shall not preclude prohibitions or restrictions on imports . . . justified on grounds of . . . the protection of health and life of humans, animals or plants" (EEC 1957: Article 36) or on public health (Articles 48 [3] and 56 [1]).

The ECJ made one of its earliest rhetorical moves in these cases. In 1976, in a case on parallel imports of pharmaceuticals, the ECJ asserted for the first time that "health and life of humans rank first among the property or interests protected by [the treaty]."[7] This idea is not made explicit in the EEC Treaty. The ECJ could easily have interpreted the treaty as simply leaving the protection of health and life of humans to *national* law and policy. The concept that human health is protected in EU law can therefore properly be seen as a piece of court-made law through the ECJ's interpretative jurisdiction. Having made this move as a matter of rhetoric, in that particular case the ECJ then went on to find that the national rules at issue were not "necessary" to protect that interest. The ECJ then reasserted the principle in several subsequent cases, embedding it in its jurisprudence.[8]

By the early 1990s, when the BSE crisis was looming,[9] the ECJ was able to assert that the high ranking of protecting human health and life was already an established principle of EU law, not only in cases involving free movement of pharmaceuticals but also in those involving preservatives and food additives, although not consistently in the free movement of feedstuffs.[10] Indeed, playing catch-up with the jurisprudence, the member states included a statement to the effect that the EC shared responsibility for human health protection in the amended EC Treaty, following the Treaty of Maastricht, agreed in 1992.[11] In July 1996 the president of the Court of First Instance (now called the General Court) was faced with a claim to the effect that the EU legislation banning the export of British

7. Case 104/75, *De Peijper*, para. 15.

8. Explicitly in Cases 215/87, *Schumacher*, 1989 ECR 617; C-347/89, *Freistaat Bayern v Eurim-Pharm GmbH*, 1991 ECR I-1747; C-62/90, *Commission v Germany (Private Medicines Imports)*, 1992 ECR I-2575; C-320/93, *Ortscheit,* 1994 ECR I-5243, para. 16.

9. The BSE crisis was a moment of high political salience in the development of EU public health policy (Vos 2000b; Westlake 1996; Krapohl 2003).

10. Cases 215/87, *Schumacher*; C-347/89, *Freistaat Bayern v Eurim-Pharm GmbH*; and C-62/90, *Commission v Germany (Private Medicines Imports)* (pharmaceuticals); Case C-42/90, *Bellon*, 1990 ECR I-4863 (preservatives and food additives); and Case C-39/90, *Denkavit Futtermittel*, 1991 ECR I-3069 (feedstuffs), which does not mention this concept.

11. Article 3(o) of the Treaty Establishing the European Community (as amended by the Treaty of Maastricht, which entered into force in November 1993): "The activities of the Community shall include . . . a contribution to the attainment of a high level of health protection" (European Communities 2002: 40–41).

beef should be temporarily suspended until the Court could hear a claim in judicial review against the legislation. He was easily able to assert that "the requirements linked to the protection of public health must unquestionably be given more weight than commercial or economic interests, in conformity with the Treaty's objectives of ensuring a high level of protection of human health and with the fundamental principles of Community law in that area."[12] The idea that public health protection — including communicable disease control — is part of the EU's obligations ("protected by the Treaty") and not just an obligation of the member states (and an exception to or excluded from the scope of application of EU law) was firmly embedded in the *acquis communautaire*.

During this period, the ECJ's jurisprudence can therefore be seen as part of the overall circumstances that allowed the refocusing of EU food policy (including the development of the European Food Safety Authority [EFSA]) that took place in the late 1990s and early 2000s (Vos 2000a; Westlake 1996; Krapohl 2003). The ECJ's role is not the driver of the process (there is no case or group of cases that we could point to as key in this process of change). Instead, the ECJ's contribution is in creating part of the environment that made creation of the EFSA feasible. Once this environment — in the sense of the idea of EU responsibility for public health protection — was established in principle, it could be extended to areas of communicable disease control beyond food law. We might include the creation of the European Environment Agency (1993) and the significant body of EU environmental law and policy, and the creation of EU law and policy on human blood and tissue regulation. We might also include the creation of the ECDC (2004).

Agencies as Constitutionally Permissible in the EU

Communicable disease policy in the EU is centered on the activities of several different EU agencies. The EFSA deals with food-borne communicable diseases; the European Environment Agency handles water- and airborne communicable diseases; and the European Medicines Agency oversees the marketing authorization of medicines that might be used to treat or prevent the spread of communicable diseases. The ECDC deals

12. Case T-76/96–R, *The National Farmers Union, International Traders Ferry Ltd, UK Genetics, RS & EM Wright Ltd and Prosper De Mulder Ltd v European Commission*, 1996 ECR II-815, para. 103.

with the remaining areas of communicable disease policy, to the extent that there is EU law or policy in those areas. EU legislation covers communicable diseases transmitted through blood (Directive 2002/98/EC), human tissue (Directive 2004/23/EC), and organs (Directive 2010/45/EU). EU policy covers viral diseases such as avian or seasonal influenza (COM[2005] 607 final, COM[2009] 353 final, Council Recommendation 2009/1019/EU); H1N1, swine flu (EMEA et al. 2009); HIV/AIDS (COM[2005] 654 final); and antibiotic resistance (European Community 1999). EU agencies, which differ significantly from their US counterparts in that they generally lack independent rule-making, adjudication, or enforcement powers (Majone 2002), have existed since the 1970s. Many more EU agencies were created during the 1990s as a response to the burgeoning powers and responsibilities of the European Commission so that the member states' governments could both "get the technical out of politics" (Shapiro 1997) and maintain control over EU-level policy making. Without agencies, it is difficult to imagine how communicable disease policy could possibly have been Europeanized.

Yet the original constitutional settlement, in terms of the separation of powers between governmental-type institutions in the EEC, made no provision for the European Commission to delegate tasks to other bodies. Both the literal text of the EEC treaty (each institution "shall act within the limits of the powers conferred upon it by this Treaty" [EEC 1957: Article 4 (1)]) and the principle of conferred competence (Treaty on European Union, Article 5; Treaty on the Functioning of the European Union, Articles 1–6 [European Union 2007a, 2007b]), which is crucial to the constitutional legitimacy of the EU (Weatherill 2004; Craig 2004), imply no delegatory powers. The ECJ ruled in a 1958 case involving coal and steel[13] that the "High Authority" (the precursor institution to the European Commission) could not lawfully delegate discretionary powers or responsibility for making policy choices. So litigation could be used to challenge the delegation of powers in the EU to independent or quasi-independent bodies. However, the European Commission is simply not large enough to support the kinds of regulatory practice, information gathering, data analysis, rule making, and executive application necessary to govern most areas of complex policy.[14] If successful, therefore, such litigation could

13. Case 9/56, *Meroni No 1*, 1957–58 ECR 133, p. 151. See also Cases 10/56, *Meroni No 2*, 1957–58 ECR 157, and 98/80, *Romano*, 1981 ECR 1241; and Chamon 2011.

14. Indeed, in 2003 it decentralized the one area in which it did carry out that kind of detailed policy making, antitrust, and control of concentrations. See Regulation 1/2003/EC (European Communities 2003) on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty Establishing the European Community (European Communities 2002).

effectively block the development in practice of detailed EU-level regulation in many areas. For instance, the ECJ heard an (unsuccessful) challenge to the ERASMUS student mobility program in the 1980s,[15] in part to the effect that the EU did not have the power to create institutional arrangements involving delegation of some decisions to national universities. Without the ability to devolve some powers in running the ERASMUS program, student mobility would not in practice be supportable by the EU. Yet even in its 1958 *Meroni* decisions, the ECJ left the door open for further development of this line of case law, in that it implied that delegation is permitted for tasks that do not involve the autonomous exercise of discretion, as long as some power to scrutinize decisions remains with the delegating authority.[16] In a series of subsequent decisions, the ECJ has moved ever farther away from a literal textual interpretation of the legal position on delegation of powers.

The next step was taken in *Köster*,[17] involving delegation by the European Commission, via the management committee procedure (now consolidated in Regulation 182/2011/EU), of powers to determine import and export licenses for cereals. The ECJ held that even though the text of the Treaty Establishing the European Economic Community (EEC 1957: Article 155) suggested otherwise, such delegation was lawful under EU law.[18] The European Parliament also challenged the original EU legislation formalizing such comitology procedures,[19] which the ECJ held inadmissible. These cases were crucial to the continued development of the comitology process (Andenas and Türk 2000; Harlow 2002), whereby the European Commission's decisions are effectively taken by a committee composed of national civil servants (Regulation 182/2011/EU). Comitology was in many ways the 1970s and 1980s precursor to the agency arrangements of the 1990s (de Búrca 1999; Vos 2000a). The ECJ's reasoning in comitology cases is that executive acts can be delegated to another body without upsetting the institutional balance created by the treaty, part of the EU's constitutional legitimacy. Legislative acts may not be so delegated. But of course the distinction in practice between executive and legislative is highly indeterminate.

A series of competition policy cases (mainly in the field of transport) followed from the mid-1990s on, in the context of whether the member

15. Case 242/87, *Commission v Council (ERASMUS)*, 1989 ECR 1425.

16. Case 9/56, *Meroni No 1*, p. 152.

17. Case 25/70, *Köster*, 1970 ECR 1161.

18. This principle does not apply to legislative acts; see Case 119/77, *Nippon Seiko v Council and Commission*, 1979 ECR 1303.

19. Decision 87/373/EC, in Case 302/87, *Parliament v Council (Comitology),* 1988 ECR 5615.

states could delegate their responsibilities for complying with EU competition law to private bodies.[20] In these cases the ECJ essentially permitted delegation as long as the delegator retained control. Again, the concept of control can be interpreted flexibly to include the possibility of oversight rather than operational control. The ECJ's scrutiny was light, and in only one of the cases did the ECJ find unlawful delegation.[21] The ECJ's jurisprudence paved the way for the debate about delegated powers to be overtaken by the debate on good governance (COM[2001] 428 final).

The ECJ's jurisprudence on delegation thus relies both on control remaining with the delegating authority of the ability (in theory if not in practice) to substitute its decision for that of the delegate, and on the distinction between executive acts and lawmaking acts. But the flexibility of these distinctions, applied in the context of agencies that coordinate actions of nationally based networks rather than take regulatory decisions per se, allows the EU to establish agencies without their existence being challenged by litigation. No litigation has been brought to challenge the validity of the enabling act of any of the EU agencies concerned with communicable disease control. Indeed, legislation often now mandates the consultation of EU agencies.[22] This body of court-made law therefore forms the second element of the environment within which EU communicable disease control could be developed: part of the Europeanization process leading to the ECDC.

EU Public Health Legislation Is Mandatory and Justiciable

As noted above, EU law and policy on communicable diseases is currently scattered across different areas of EU law and policy. In terms of air- and waterborne communicable diseases, the relevant EU law is environmental law. EU environmental law encompasses a significant body of detailed legislation, in terms of both Framework Directives, which set general priorities and principles, and detailed Daughter Directives, with details of

20. Cases C-185/91, *Reiff*, 1993 ECR I-5801; C-153/93, *Delta Schiffahrts*, 1994 ECR I-2517; 96/94, *Centro Servizi Spediporto*, 1995 ECR I-2883; C-140–2/94, *DIP v Comune di Bassano del Grappa*, 1995 ECR I-3257; C-35/96, *Commission v Italy (Customs Agents)*, 1998 ECR I-3851; C-38/97, *Autotransporti Librandi*, 1998 ECR I-5955; and C-35/99, *Arduino*, 2002 ECR I-1529.

21. Case C-35/96, *Commission v Italy (Customs Agents)*, concerning setting customs tariffs by customs agents.

22. See, for instance, the legislation on additives in animal feed at issue in Case T-13/99, *Pfizer v Council*, 2002 ECR II-3305.

substance (Bell and McGillivray 2006). Environmental law is consistently an area in which member state compliance is slow and deficient (see most recently COM[2011] 588 final). The constitutional qualities of EU law, in particular its direct effect (enforceability before national courts by individuals) as developed by the ECJ, have a role to play in terms of securing Europeanization processes, in the sense of policy compliance at the national level. But the ECJ has held that much of EU environmental law is not directly effective, because the provisions of Framework Directives are insufficiently precise and clear to confer enforceable rights on individuals.[23] A more important role has been the ECJ's approach to litigation brought by the European Commission against a defaulting member state, under the procedure now found in Article 258 of the Treaty on the Functioning of the European Union (TFEU) (European Union 2007b).

The text of that provision (originally Article 169 in the Treaty Establishing the European Economic Community [EEC 1957]) simply says that if the European Commission considers that a member state has failed to fulfill an obligation in EU law, it may bring that state before the ECJ. The text says nothing about the approach the ECJ is to take in these cases. To what extent may the ECJ take into account any explanation given by the defaulting member state? Such states may have many reasons for not complying with EU law, not all of which involve a deliberate governmental departure from EU obligations, particularly in areas such as environmental law, including lack of supporting infrastructure, lack of capacity, lack of parliamentary time, lack of enforcement authorities, and so on. If the ECJ is sympathetic to the real context within which noncompliance litigation is brought by the European Commission, the effect is to diminish in practice the mandatory quality of the relevant legal obligation.

The ECJ's approach has consistently been quite the opposite (Schermers and Waelbroeck 1992: 297–305). Defenses that would apply in ordinary international law — the member state agreed to the obligation only with a reservation,[24] national sovereignty or autonomy was compromised,[25]

23. Case C-236/92, *Comitato di Coordinamento per la Difesa della Cavana v Regione Lombardia*, 1994 ECR I-483. But see Case C-237/07, *Dieter Janecek v Freistaat Bayern*, 2008 ECR I-6221, para. 38, where the ECJ held that "where the failure to observe the measures required by directives which relate to air quality and drinking water, and which are designed to protect public health, could endanger human health, the persons concerned must be in a position to rely on the mandatory rules included in those directives."

24. Cases 38/69, *Commission v Italy (Lead and Zinc)*, 1097 ECR 55; 39/72, *Commission v Italy (Premiums for Slaughtering Cows)*, 1973 ECR 115; and 92/79, *Commission v Italy (Sulphur)*, 1980 ECR 1121.

25. Cases 6 and 11/69, *Commission v France (Rediscount Rate)*, 1969 ECR 540.

local remedies had not been exhausted,[26] or the EU itself, or other member states, failed to comply with their corresponding obligations[27]—had all been consistently rejected by the ECJ in a series of cases during the 1950s–1970s. Indeed, the ECJ stresses that EU law is a new legal order, not part of ordinary international law. In addition, the ECJ firmly rejected a suggestion that the Commission would have to show fault or at least inertia or opposition on the part of the defaulting member state.[28] Again, these cases were in low-profile areas, such as trade law and the common agricultural policy. But the principles they established remained valid and relevant when the ECJ decided cases involving failures to implement elements of the EU's environmental policy, with implications for public health.

So, for instance, throughout the 1980s and 1990s and into the 2000s, the ECJ was faced with a series of European Commission challenges to deficient national implementation of the EU's drinking water directives. The ECJ found that merely altering administrative practices,[29] incomplete, fragmentary legislation,[30] or entering into contracts with water companies[31] were not sufficient to comply with EU law. It rejected defenses advanced by member states, including administrative difficulties, financial difficulties,[32] and having taken all practical steps to comply.[33] Even where the ECJ found that the emergency situation exemption in the EU legislation is present, the ECJ both interpreted the exemption narrowly[34] and stressed the obligation for the national authorities to provide information,[35] thus adding a transparency dimension to compliance. The same

26. Cases 31/69, *Commission v Italy (Export Rebates)*, 1970 ECR 32; 102/79, *Commission v Belgium (Vehicles directives)*, 1980 ECR 1487; and 29/84, *Commission v Germany (Nurses)*, 1985 ECR 1661.

27. Cases 90 and 91/63, *Commission v Luxembourg and Belgium*, 1964 ECR 631, para. 10; 52 and 55/65, *Germany v Commission (Customs Duties)*, 1966 ECR 159; and 52/75, *Commission v Italy (Vegetable Seed)*, 1976 ECR 283.

28. Cases 7/71, *Commission v France (Euratom)*, 1971 ECR 1034, AG Opinion; 301/81, *Commission v Belgium (Credit Institutions)*, 1983 ECR 477; and 322/82, *Commission v France (Fruit and Vegetables No 2)*, 1983 ECR 3700.

29. Case 97/81, *Commission v Netherlands (Water Quality)*, 1982 ECR 1819.

30. Cases C-266/99, *Commission v France (Water Quality)*, 2001 ECR I-1981; and C-396/01, *Commission v Ireland (Water Quality No 2)*, 2004 ECR I-2315.

31. Case C-340/96, *Commission v UK (Water Quality No 2)*, 1999 ECR I-2023.

32. Case C-42/89, *Commission v Belgium (Water Quality)*, 1990 ECR I-2821.

33. Cases C-337/89, *Commission v UK (Water Quality No 1)*, 1992 ECR I-6103; C-316/00, *Commission v Ireland (Water Quality No 1)*, 2002 ECR I-10527; and C-198/97, *Commission v Germany (Water Quality No 2)*, 1999 ECR I-3257.

34. Case 228/87, *Criminal Proceedings against X*, 1988 ECR 5099.

35. Case C-237/90, *Commission v Germany (Water Quality No 1)*, 1992 ECR I-5973.

approach may be seen in the ECJ's case law on air quality.[36] This is consistent with its earlier line of case law on the mandatory nature of obligations in EU law.

At first glance this element of the ECJ's jurisprudence seems to have little to do with the ECDC. Unlike the European Environment Agency, the ECDC does not operate in the context of a detailed body of EU legislation. However, member states are under some obligations, according to both the legislation pertaining to the European Commission's networks that are precursors to the ECDC (see, e.g., Decision 2000/96/EC, Article 6; Decision 2000/57/EC, Article 3; Decision 2119/98/EC, Article 6) and the legislation setting up the ECDC itself (Regulation 851/2004/EC). These are relatively weak reporting requirements (Regulation 851/2004/EC, Article 4). The fact that the obligation currently extends only to "available" information weakens it further: there is at present no obligation on member states to collect information in a particular form or of a particular nature that would assist the ECDC. However, those member states that may have a distaste or disdain for the ECDC because they have their own more powerful and well-resourced communicable disease control body (Elliott, Jones, and Greer 2012) could be constrained (at least if the Commission seeks to enforce their obligations in EU law) from failing to comply with these obligations because of the ECJ's approach to noncompliance with EU legislation. This is probably even more the case with member states that lack the capacity to feed effectively into the ECDC's work, where the ECJ has been clear that such lack of capacity is never an excuse for noncompliance with mandatory EU law. The ECJ's approach to EU legislation that protects public health—that it is both justiciable if the requirements for direct effect are met and mandatory in the special nature of EU law—can therefore be said to form a third part of the environment within which the Europeanization of communicable disease law and policy is taking place.

EU Public Health Legislation May Not Be Undermined by Liberalizing Internal Market Law

In addition to supporting the mandatory and justiciable nature of EU public health legislation, the ECJ's jurisprudence also protects it from the

36. Cases C-13/90, *Commission v France*, 1991 ECR I-4327; C-14/90, *Commission v France,* 1991 ECR I-4331; C-64/90, *Commission v France*, 1991 ECR I-4335; C-417/99, *Commission v Spain (Air Quality)*, 2001 ECR I-6015; C-60/01, *Commission v France (Waste Incineration)*, 2002 ECR I-5679; and C-320/03, *Commission v Austria (Air Quality)*, 2005 ECR 9871.

application of potentially liberalizing (and therefore undermining) internal market rules. This is an important element of the environment for the Europeanization of communicable disease control, because without it the liberalizing law of the EU's internal market would override any restrictive measures that the EU or the member states adopt that seek to control communicable disease. In its early jurisprudence, before the EU had developed its own legislation to protect public health, the ECJ simply took the approach that public health protection was not a matter for EU law. The ECJ recognized that public health protection — including protection against communicable diseases — was for national administrations. Particularly in its earlier jurisprudence, the ECJ allowed member states a wide margin of discretion. As the ECJ put it in a case in the early 1990s involving national rules restricting the sale of medicinal products to pharmacies, echoing earlier cases dating back to the 1970s,[37] "It is for the Member States, under the limits imposed by the Treaty, to decide what degree of protection [for human health] they intend to assure and in particular how strict the checks to be carried out are to be."[38]

However, this legal principle alone would have completely countermanded the ECJ's drive to create a single European market in goods. If member states could adopt any national policies they wished simply by invoking the grounds, however spurious, of human health protection, the single market would be easily thwarted by protectionist national rules. Alongside this legal principle, therefore, the ECJ developed a legal principle that allowed it control over national health protection policies. National regulation is permitted in EU law, subject to the proviso that such regulation is *proportionate* to the aims of the internal market.[39]

Thus the ECJ has always scrutinized national regulations that ban or inhibit trade on grounds of health protection to ensure they are not simply disguised rules protecting national markets. The court uses the legal test of proportionality to decide these cases. Many cases involve restrictions on the free movement of food within the EU. The classic example involves litigation in the early 1980s on UK rules inhibiting the import of turkeys (a key component of the traditional British Christmas dinner) in November and December on the spurious ground that there was a risk of spreading

37. Cases 104/75, *De Peijper*; 174/82, *Sandoz*, 1983 ECR 2445; 227/82, *Criminal Proceedings against Leendert van Bennekom*, 1983 ECR 3883; 97/83, *Melkunie*, 1984 ECR 2367; 247/84, *Motte*, 1985 ECR 3887; and 304/84, *Muller*, 1986 ECR 1511.

38. Case C-62/90, *Commission v Germany (Private Medicines Imports)*, para. 10.

39. Cases 272/80, *Biologische Producten*, 1981 ECR 3227; 266 and 267/87, *R v Royal Pharmaceutical Society of Great Britain, ex parte Association of Pharmaceutical Importers*, 1989 ECR 1295; C-60/89 *Monteil,* 1991 ECR I-1547; and 293/94, *Brandsma*, 1996 ECR 3159.

Newcastle disease (a disease of poultry, which results in only short-term viral symptoms in humans). The ECJ held that the UK's ban was a disproportionate response.[40] Around the same time the court gave short shrift to German beer purity rules and Italian pasta purity rules,[41] finding that the supposed danger to health had not been shown. This approach continued: for instance, in the 2000s Italy has failed to show more than a purely hypothetical risk to human health from genetically modified foodstuffs[42] and has failed to show a risk from foodstuffs marketed to sportspeople.[43] In order to satisfy the proportionality test, some scientific data linking the risk of harm to human health must be advanced by the member state seeking to derogate from EU law.[44]

The proportionality test provides a legal device of great flexibility. Stronger or weaker versions of proportionality are available (Sauter 2008). In the weakest version, a measure that is prima facie suitable to protect health and is not manifestly disproportionate is permissible. In the strictest version, only the least restrictive ways of protecting health are permissible, and the relevant body must show that no other imaginable measure could achieve that objective with a lesser detrimental effect to free trade. From the beginning of the 1970s into the mid-1980s, the ECJ was applying a weaker version of the proportionality test to its scrutiny of human health protection measures.

This is seen, for instance, in cases involving national rules designed to protect against the risks to human health from pesticides in food.[45] The ECJ stresses that pesticides are harmful to human health, that harmonized EU law on pesticides is incomplete, and that therefore different member states may adopt different approaches without breaching EU law. In *Mirepoix*,[46] the ECJ explained, "In so far as the relevant Community rules do not cover certain pesticides, the Member States may regulate the presence of residues of those pesticides on foodstuffs in a way which var-

40. Case 40/82, *Commission v UK (Turkeys)*, 1984 ECR 283.

41. Cases 178/84, *Commission v Germany (Beer Purity)*, 1987 ECR 1227 (German beer purity); and 90/86, *Zoni*, 1988 ECR 4285 (Italian pasta purity).

42. Case C-236/01, *Monsanto*, 2003 ECR I-8105.

43. Case C-270/02, *Commission v Italy (Sports Food)*, 2004 ECR I-1559.

44. See also Cases 216/84, *Commission v France (Milk Powder)*, 1988 ECR 793; 274/87, *Commission v Germany (Meat Products)*, 1989 ECR 229 (food with lower nutritional value than food already on the market is not a threat to human health); C-24/00, *Commission v France (Added Nutrients)*, 2004 ECR I-1277; C-41/02, *Commission v Netherlands (Added Vitamins)*, 2004 ECR I-11375; and C-192/01, *Commission v Denmark (Added Vitamins)*, 2003 ECR I-9693.

45. Cases 94/83, *Criminal Proceedings against Albert Heijn BV*, 1984 ECR 3263; and 54/85, *Ministère public against Xavier Mirepoix*, 1986 ECR 1067.

46. Case 54/85, *Mirepoix*, para. 15.

ies from one country to another according to the climatic conditions, the normal diet of the population and their state of health." Likewise, in a case involving the prohibition of certain levels of active coliform bacteria and active micro-organisms in milk products, the ECJ readily accepted that a real danger to public health was present and that therefore a member state could lawfully inhibit free trade.[47]

The weaker version of proportionality also applied in cases where the science was less clear. So in 1975, in a case involving an inspection system to protect plant health, the ECJ held that the different treatment of imported and domestic products does not breach EU law as long as effective measures prevent the distribution of contaminated domestic products and there is *reason to believe* that there is a risk of harmful organisms spreading without inspection of imported products.[48] There was no need to *prove* the risk; it was enough to show that it was reasonable for the national administration to believe it existed. This softer version of proportionality was also found in cases in the early 1980s concerning the addition of vitamins and other additives to food.[49] The ECJ held that where there were scientific uncertainties, member states could determine the degree of regulation to protect public health. The ECJ reasoned:

> In view on the one hand of scientific uncertainties and on the other of the fact that the harmfulness of vitamins depends on the quantity absorbed with the whole nutrition of a person *it is not possible to say with certainty whether any food to which vitamins have been added is harmful or not.*
>
> *Scientific research does not appear to be sufficiently advanced to be able to determine with certainty* the critical quantities and the precise effects.[50]

Similar reasoning is found in *Eyssen*:

> It is indeed accepted that the increasingly widespread use of that substance, not only in milk but also in numerous preserved products, has revealed *the need, both at national level in certain countries and at international level, to study the problem of the risk* which the consumption of products containing the substance presents, or may present, to human health . . . although *those studies have not as yet enabled*

47. Case 97/83, *Melkunie.*

48. Case 4/75, *Rewe-Zentralefinanz Gmbh v Landwirtschaftskammer*, para. 8.

49. Cases 174/82, *Sandoz* (vitamins); and 53/80, *Officier van Justitie v Koninklijke Kaasfabriek Eyssen BV*, 1981 ECR 409 (other additives).

50. Case 174/82, *Sandoz*, paras. 10 and 11 (emphasis added).

> *absolutely certain conclusions to be drawn* regarding the maximum quantity of nisin which a person may consume daily without serious risk to his health.[51]

This approach continued into the mid-1980s.[52]

The softer version of proportionality supports the position that although the EU and its member states share competence for protecting public health, essentially the member states hold primary responsibility. The ECJ's jurisprudence here supports a highly circumscribed EU public health competence. Given that, the implication is that there is no particular need to develop a dense system of EU-level public health institutional mechanisms or capacities.

But piece by piece, from the mid-1960s on, the EU did develop its regulatory capacity on some sources of risk to human health, in particular in the food chain. These activities related to the common agricultural policy, an area that was originally seen as separate from internal market law, which is the policy context for the ECJ's case law discussed above. In 1964 the Commission set up "a panel of veterinary experts" to recommend whether infected bovines or swine could lawfully be prohibited entry into a member state (Directive 64/432/EEC, Article 10). The Standing Committee on Foodstuffs was set up in 1969 (Council Decision 69/414/EEC). These bodies now form part of the Standing Committee on the Food Chain and Animal Health (Regulation 178/2002/EC*, as amended)* within the EFSA. Originally deciding on matters that seem only technical (e.g., whether a particular additive counts as a color for the purposes of EU legislation [Directive 94/36/EC] or whether additives are being used in accordance with EU legislation [Directive 95/2/EC]), over time these comitology procedures built up a body of EU-level decisions about the risk to human health of various food additives and hazards (including toxins and biological hazards such as bacterial pathogens/zoonotic agents).[53] For instance, in 2002 the European Commission adopted a decision that the additive Konjac E425 was no longer authorized in products marketed in the EU (Holland and Pope 2004: 55–56). Originally following decisions taken by member states, the EU began to develop its own idea of tolerable (and intolerable) levels of risk concerning human health within the food chain. The ECJ's jurisprudence on the locus for public health

51. Case 53/80, *Eyssen*, para. 13 (emphasis added).

52. See Cases 247/84, *Motte*; and 304/84, *Muller.*

53. Any bacterium, virus, or parasite that is likely to cause a zoonosis (i.e., a disease or infection transmitted from animals to humans). This includes brucellosis, salmonella, listeria, rabies, and tuberculosis.

decision making (the soft version of proportionality, supporting member state responsibility) did not act as a constraint on the Europeanization process here.

However, perhaps responding to these developments but certainly supporting their continued proliferation, by the early 1990s the ECJ began to modify its jurisprudence in this field by adding a procedural dimension to its application of proportionality. In a series of cases involving the addition of sorbic acid, the nutrient L-carnitine, and the nutrient coenzyme Q10,[54] the ECJ was asked to assess whether a procedure requiring a national marketing authorization was permissible in EU law. The ECJ continued to assert rhetorically that "it is of course left to Member States to decide the level of protection to life and health of humans they wish to provide, in the absence of harmonization and where there is scientific uncertainty."[55] However, the ECJ's position moved toward a stricter version of proportionality by scrutinizing the transparency, speed, and accessibility of the national marketing authorization procedures at issue.

The evolution of this line of case law again suggests the ECJ in a role that supports the Europeanization of communicable disease control. To underpin EU development of greater regulatory and administrative controls over food that might pose hazards to human health, a stricter application of the proportionality principle to national measures that impeded free trade became necessary. Through a virtuous circle of mutual reinforcement, this further justified the need to develop EU regulatory structures through which "EU" public health protection standards could then be articulated. As the EU developed its own scientific knowledge (such knowledge being not only scientifically but also socially and politically constructed; Jasanoff 2005) through the proliferation and deepening of the remit of EU scientific committees and agencies, so the ECJ was able to develop an increasingly suspect position toward nationally determined versions of hazard. Because of its inherent flexibility, the legal principle of proportionality did not impede but instead supported the path to development of EU-level regulation.

In addition to developing its regulatory and administrative public health capacity, especially in food law, during the 1990s and 2000s, the EU also adopted a significant body of public health legislation. The framework for this legislation encompasses the common agricultural policy, the inter-

54. Cases C-42/90, *Bellon* (sorbic acid); C-24/00, *Commission v France* (L-carnitine); and C-95/01, *Greenham and Abel*, 2004 ECR I-1333 (coenzyme Q10).

55. Case C-95/01, *Greenham and Abel*, para. 37.

nal market, and EU consumer protection policy. During this time, as the density of EU legislation increased, the incidence of litigation based on internal market law decreased and (significantly for the purposes of this article) the chances of success in such litigation declined. Again looking at litigation on food additives, in the 1980s and 1990s the ECJ decided a steady stream of cases involving challenges to national laws restricting the use of food additives on the basis that they infringed treaty-based internal market law.[56] But by 2005 the ECJ was deciding cases by reference only to the EU legislation and not engaging with possible infringements of the treaty per se.[57] The approach of looking to EU legislation rather than the treaty became increasingly embedded in the ECJ's response to this kind of litigation to the extent that by 2009 it had become the standard approach. A 2009 case concerning a challenge to the use of the term *low-sugar jam* provides an example.[58] Given that the effect of the national law was to inhibit the marketing in Germany of jam lawfully produced in Austria (a classic infringement of internal market law in terms of the ECJ's treaty-based case law), the ECJ could have characterized the national law as a potential breach of treaty-based internal market law. That would then have required, through the proportionality test, balancing national approaches to public health protection with free trade in the internal market. Instead, the ECJ decided the case solely by reference to EU food additive legislation. From the ECJ's point of view, the place of public health regulation had become EU level. EU legislation was increasingly occupying the field and therefore determining what levels of risk to human health were (and were not) acceptable. Implicitly, then, according to the ECJ, EU treaty rules — which essentially operate to liberalize markets — could not undermine this determination of acceptable risk to human health by the EU legislature. This ECJ case law provides the fourth example of an element of the environment supporting the Europeanization of communicable disease control.

Conclusion

The European Court of Justice was not the driver in the process of Europeanization of communicable disease control. However, as this article has

56. Cases 53/80 *Eyssen*; 195/84, *Denkavit Futtermittel*, 1985 ECR 3181; 247/84, *Motte*; 176/84, *Commission v Greece (Law on Beer)*, 1987 ECR 1193; 178/84, *Commission v Germany (Beer Purity)*; and 29/87, *Dansk Denkavit*, 1988 ECR 2965.

57. See Case C-145/02, *Denkavit Futtermittel*, 2005 ECR 51.

58. Case C-366/08, *Darbo*, 2009 ECR I-8439.

shown, neither was the ECJ irrelevant. The ECJ's activities provide part of the answer to the question of why the EU's role in public health developed as it has. The ECJ played an important part in creating the environment in which the gradual Europeanization of communicable disease control has taken place and continues to take place. First and most important, the ECJ's jurisprudence established from early on that although member states have responsibility for public health protection (and especially where bacteria cross borders may choose to fulfill that responsibility using the institutions of ordinary international law), that protection is also (constitutionally) a responsibility of the EU itself. Second, where EU public health protection activity has manifested itself in administrative arrangements, as some of the other articles in this issue have shown (Grant; Elliott, Jones, and Greer), it was necessary for the effective development of Europeanized disease control that this was done through EU agencies. This is how the EU, with its distinctive powers, politics, and law, copes with carrying out its role in communicable disease control. The ECJ's understanding of institutional balance in the EU, and specifically of the role of the European Commission, created (or at least sustained) an environment where the establishment of EU-level agencies became and remained feasible, without the threat of litigation undermining their activities, tasks, or very existence. Third, where EU public health protection manifests itself in legislative activity, the ECJ's jurisprudence ensured greater effectiveness by promoting compliance with EU legislative obligations. Such obligations are mandatory and justiciable even where national specificities make compliance inconvenient or very difficult. Fourth, the ECJ's jurisprudence also protects EU public health legislation from potentially liberalizing internal market rules that are found in the treaties.

Looking to the future, there is a fifth possible area in which the ECJ could support the further Europeanization of communicable disease control, in particular by the ECDC. Communicable disease control is currently a policy category that is scattered across many different EU policy "silos," each with its own institutional arrangements, policy dynamics, priorities, and received wisdom. This article has mainly discussed EU food law and policy (which itself falls within the common agricultural policy, EU trade policy, and consumer protection policy) and EU environmental policy. Other areas include pharmaceuticals and medical devices policy; policy on blood, organs, and human tissue; and ECDC monitoring and surveillance activities. It seems unlikely that the ECDC could replace or subsume institutions such as the EFSA, which is among the most embedded and powerful of the EU agencies (Vos and Wendler

2006). But if communicable disease control is to become a unitary policy in its own right under EU institutional arrangements, and if the ECDC is to become the hub for those institutional arrangements (Elliott, Jones, and Greer 2012), one possibility that might support the process is the concept of "mainstreaming" (see Merkel 2010). Mainstreaming has both a policy and a legal meaning. The ECJ could develop the legal idea that public health protection must be mainstreamed across all EU policies. To do so it could rely on provisions in the post-Lisbon treaties, especially the Treaty on the Functioning of the European Union: "In defining and implementing its policies and activities, the Union shall take into account requirements linked to . . . protection of human health" (European Union 2007b: Article 9).[59] This court-led development, particularly if it fed into policy understandings of the meaning of mainstreaming and hence into adjustment of the responsibilities of different EU institutions, might assist (but no more than assist, as other factors would also have to come into play) the further Europeanization of communicable disease control.

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59. The ECJ has referred to this provision in interpreting EU legislation in Cases C-197/08, *Commission v France (Cigarette Retail Prices)*, 2010 ECR I-1599; C-198/08, *Commission v Austria (Cigarette Retail Prices)*, 2010 ECR I-1645; and C-221/08, *Commission v Ireland (Cigarette Retail Prices)*, 2010 ECR I-1669.

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