13. EU public health law and policy – communicable diseases

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I. INTRODUCTION – SETTING THE AGENDA

The story of communicable diseases and their control is an old story of borders and the management of conflict across borders. Humans struggle to control diseases which breach the borders between people, States and species. In these struggles, the borders between States and institutions can help or hinder efforts to control diseases and preserve health. Governments can breach individual rights to privacy and autonomy in the name of public health,¹ individuals can undermine public health through their actions, and States or international organisations can interfere with health protection for all sorts of bureaucratic, political and legal reasons.

As a result, communicable disease control necessarily has a cross-cutting dimension² and cannot be limited to one policy or a single legal document only. On the Member State level, there is a long history of contests over borders, whether they take the form of argument about the border between privacy and public health surveillance or the form of arguments between States about quarantines and public health screening at borders.

The European Union (EU) is a relatively late entrant to this policy area and these issues. Its engagement involves strengthening some borders – such as those between Europe and the rest of the world, and responding to the weakening of others – such as those between Member States or those between human and animal health. It has largely avoided engagement in some of the thorniest problems of public health law because it lacks coercive


capabilities such as quarantine or distributive powers such as vaccination programmes, but the strength of its human rights law and its increasing role in setting norms of good practice for public health mean that it is increasingly, slowly, being drawn into the debates about privacy, coercion and proportionality that mark communicable disease control law in most States.

Certain communicable diseases such as influenza\(^3\) are a common annual phenomenon, while other examples amount to international challenges. The BSE (bovine spongiform encephalopathy) crisis not only touched upon the EU’s agricultural policy, but also concerned consumer safety, the environment and last but not least, public health.\(^4\) Hazards passed onto humans such as BSE, e-coli, salmonella or listerias require appropriate rules in the field of food law. Communicable diseases can be transmitted via animals (e.g., BSE, Zika virus) or via humans (e.g., Ebola virus or HIV/AIDS), resulting in possible questions of stigmatisation, discrimination, compulsory blood testing or, on the contrary, prohibition of blood donation, also affecting issues of human tissues or organs.

The cross-cutting nature of communicable disease control, combined with the limited Treaty bases for EU action, means that communicable disease control relates to virtually all possible kinds of legal questions\(^5\). They range from discrimination (e.g., in the case of HIV/AIDS), to human rights (e.g., bodily integrity in the context of forced testing, or property rights in the case of slaughtered animals), free movement (entry to a territory, as well as expulsion), criminal or non-contractual liability (e.g., the prohibition of the import of BSE contaminated meat), or sophisticated questions about the preconditions under which precautionary measures may lawfully be taken, that is to say, which probable degree of risk has to exist. This cross-cutting nature of communicable disease control can be seen through the EU legal lens of ‘positive’ or ‘negative’ integration, where in the former EU harmonisation measures are aiming at a high level of health protection,\(^6\) whereas in the latter situation restrictions on the free movement of goods, persons etc. can be justified based on public health\(^7\) considerations.

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\(^4\) This cross-cutting dimension is also reflected by Commission, ‘Decision on establishing Scientific Committees in the field of public health, consumer safety and the environment’ C(2015) 5383 final.

\(^5\) To be dealt with in section 3 of this chapter.

\(^6\) Consolidated version of the Treaty on the Functioning of the European Union [2016] OJ C202/47 (TFEU), Article 114(3) (this also holds true for safety, environmental protection and consumer protection).

\(^7\) TFEU, Articles 36, 45(3) and 52 (in connection with Article 62).

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From a policy perspective, communicable disease control involves, among others, questions of surveillance (monitoring populations for diseases), sharing of data and best practice, microbiology (identifying pathogens), communication with both public health sectors and the general public, joint procurement (of vaccines or medicines) as well as research funding.\(^8\)

The focus of our chapter is on communicable diseases,\(^9\) which is a subset of infectious diseases.\(^10\) In 2013, the term 'communicable diseases' was defined in the following way:

'communicable disease' means an infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the contagious agent.\(^11\)

These two notions of direct and indirect exposure highlight the fact that the ultimate objective is to safeguard human health, whereas animals can play an important role in an indirect way.\(^12\) This is strongly reflected by a recent Regulation on transmissible animal diseases.\(^13\)

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\(^8\) On citizen participation see ML Flear, “Supra-stewardship”: a tool for citizen participation in European Union pandemic preparedness planning” (2011) 62(5) Northern Ireland Legal Quarterly 677; see also Chapter 6 in this book.

\(^9\) The Commission has identified prevention of communicable diseases as one of the priorities in its current work programme: Commission, Implementing Decision concerning the work programme for 2016 in the framework of the third Programme of the Union’s action in the field of health (2014–2020) [etc.] C(2016) 1158 final (plus annexes); see also ‘Call for applications 2016 – Third Programme of the Union’s action in the field of health’ [2016] OJ C84/8.


\(^11\) A third term sometimes used is the one of ‘transmissible diseases’; Case T-333/10 ATC ECLI:EU:T:2013:451, para 173.


\(^13\) Although that is true for a lot of cases examined in that regard, nevertheless the increasing importance attributed to animal welfare (now TFEU Article 13) has to be emphasised, even if it is not our focus in this chapter; see M Frischhut, “EU? Short for “Ethical” Union?: The Role of Ethics in European Union Law” (2015) 75(3) Heidelberg Journal of International Law 531, 556–7.

A major justification for communicable disease control policies is also security, both against themselves, and against bioterrorism, such as the Anthrax attacks in the United States (US) in 2001. Cross-border health threats include the problem of antimicrobial resistance, bio-toxins, threats from chemical products or even from environmental events (e.g., volcanic eruptions).

The chapter presents the historic development of EU communicable disease control law and policy since the 1990s, using the lens of European integration theory to explain why it is a case of some relatively common dynamics in European integration. It is a story of a developing network, institutional entrepreneurs, agenda-setting and alternative specification in policy debates. We highlight key milestones and challenges. These are further explained in an elaboration of the status quo of EU communicable disease control, which also deals with some selected key issues of this cross-cutting challenge from both a policy and law perspective. Finally, we address possible future directions of travel.

II. HISTORIC DEVELOPMENT

International cooperation in communicable disease control has a much longer history than does the EU. The reason is simple: due to movement of people, animals or products, diseases do cross borders, and always have (see Figure 13.1).

Even a costly disruption of trade and movement, such as blanket quarantine, will frequently fail. Protection against communicable diseases therefore needs a measure of international coordination and cooperation


16 On the history of EU health law see Chapter 1 in this book.
including data-sharing and resources, and policymakers have frequently risen to the challenge of cooperating.

The basic logic of EU communicable disease control policy has been one characterised by neo-functionalists. Neo-functionalism is a theory of European integration, rather than a theory of European policymaking or Europeanisation. It explains the development of new EU supranational competencies, often despite initial Member State reluctance. Neo-functionalists are attuned to two ways in which European integration breeds further integration. First, there is what we might call the route of social spillover, in which more interaction creates common problems and solutions. In the case of communicable disease control, cross-border outbreaks within the EU are a shared problem that seems to call for a shared solution. The second route is what we might call the political route, in which European institutions shape political agendas and policy alternatives to create more integration. Politicians at the EU and national level, seeking to make a mark in the eyes of their constituents, are offered attractive, integrating, policy solutions. Much of EU health policy (much of EU policy) has been a response to the CJEU’s agenda-setting moves.

The EU was a relatively late entrant to this world. The key institution for cross-border cooperation on communicable diseases since the Second World War was the World Health Organisation (WHO), while the EU remained largely sidelined from communicable disease control for most of its history. Figure 13.2 summarises the timeline.

The 1980s saw two major communicable disease crises. The EU institutions were involved in tackling the challenges of the spread of HIV/AIDS in the mid-1980s, with the first European programme (Europe against AIDS). The other major communicable disease challenge was mainly related to animals, the BSE crisis, though with links to new variant Creutzfeldt–Jakob disease (nvCJD). As a result, Member States were willing to transfer competences for public health to the EU level in 1992, and the Maastricht Treaty tasked the EU with ‘prevention of diseases, in particular the major health scourges’. The first EU agency that was able to have an indirect relevance (in case of air and waterborne communicable diseases) for communicable disease control, the European Environment Agency (EEA), became operational in 1994.

Decision 2119/98/EC created a framework for EU coordination of surveillance and epidemiology, including the work necessary to standardise case definitions and surveillance methods so that data from different Member States would be mutually intelligible (it is worth underlining that decades of international cooperation had failed to achieve this). In the wake of this decision, the Commission established an early warning and response system (EWRS) for communicable disease control, and listed

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20 This abbreviation refers to the Court of Justice of the EU in the sense of TEU (Consolidated version of the Treaty on European Union [2016] OJ C202/13 Article 19(1), which comprises not only the Court of Justice (CJ), but also the General Court (GC; when in the following reference is made to the GC, this should be understood as also comprising the former Court of First Instance). See also Chapter 3 in this book.

21 SA Scheingold, The Rule of Law in European Integration: the Path of the Schuman Plan (Yale University Press 1965); AS Sweet, The Judicial Construction of Europe (OUP 2004); KJ Alter, Establishing the Supremacy of European Law (OUP 2001).


23 For more details see Hervey and McHale (n 22) 336–48.


the communicable diseases to be covered by epidemiological surveillance in the EU network pursuant to Decision 2119/98/EC.  

On 28 October 2001, immediately after the attacks in the US, the Council created a Health Security Committee, a then informal coordination and cooperation body made up of high-level national and Commission representatives. The Health Security Committee was a very limited step for European integration, but it created a forum for high-level coordination within the EU separate from other bodies such as the WHO or, in some cases, NATO.

Anthrax attacks in the US in 2001 revived bioterror concerns, and were followed closely by SARS (severe acute respiratory syndrome), the very model of an emerging infectious disease. These events put communicable disease control on political agendas, and concerns about pandemic influenza and viral haemorrhagic fevers (e.g., Ebola) kept the topic there. The 2003 advent of SARS, with its speedy global dispersion, led to the Commission presenting a proposal for a EU public health agency.

The proposal passed the Council and Parliament on its first reading, a sign of urgency and consensus, and became law in spring 2004 as Regulation 851/2004. The board of the new organisation, sited in Stockholm, named it the European Centre for Disease Control and Prevention (ECDC), an EU agency. This form of the agency, one that was common and even fashionable in the EU at the time, offered a tested and apparently agreeable solution that fitted with the globally popular idea of ‘national public health institutes’ for central coordination of public health responses. In the EU context, an independent agency could offer flexibility and stable resources yet, unlike the Commission, could be constrained by a board and a mandate.

Communicable diseases often move through the food supply, and a series of scandals, most prominently the BSE crisis, increased interest in matching EU regulation of food safety to the increasingly European and integrated market for food and animals. The result was the creation of the European Food Safety Authority (EFSA), together with the introduction of some general principles and requirements for food law. Those principles included identification of emerging risks, as well as a rapid alert system. In the same context of food safety, Regulation (EC) 882/2004 aims at ensuring proper checks on food and animal feed.

As the Anthrax attacks and SARS had put communicable disease control on political agendas, concerns about pandemic influenza and viral haemorrhagic fevers (e.g., Ebola) kept the topic there. Internationally, it meant the adoption of the revised International Health Regulations (IHR) of 2005, one of the world’s most-adopted legal instruments, and one which commits countries to information-sharing, capacity-building and a flexible definition of public health events that relies on their international importance.

More recently, Decision 1082/2013 has enlarged the scope of EU communicable diseases law and policy to other threats (e.g., biological or chemical agents or environmental events), though lack of interest in revising the EURATOM treaty means that there is less of a formal base for cooperation on nuclear threats. The EU has now shifted more to an

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30 Now formalised due to Decision on Cross-border Threats, Article 17.

31 Top-rank EU medical officials also had their own meeting, and it had become increasingly professionalised over the years (eg, members stopped bringing their spouses) and mingled with the other networks and forums.


35 Food Law Regulation, Articles 34 and 35; see also part III,iii.e.


"all-hazards' approach\textsuperscript{39} which addresses serious cross-border threats of any origin.

III. STATE-OF-THE-ART OF COMMUNICABLE DISEASE CONTROL

III.i Health Threats – the All-hazards Approach

Despite what might be seen as a bad taste left over from H\textsubscript{1}N\textsubscript{1}, the EU nonetheless moved forward into this new direction,\textsuperscript{40} the incorporation of communicable disease control into a new category of 'health threats'. In the jargon of health security,\textsuperscript{41} as noted above, this marks the transition of the EU to an 'all-hazards approach' that is equally responsive to disease outbreaks, environmental threats (e.g., a chemical plant disaster), new communicable diseases due to climate change\textsuperscript{42} and bioterrorism.

The shift to an all-hazards approach, and the language of health security, very clearly came from the US. The US has long had a much higher level of securitisation of its public health thinking and became especially security-conscious after September 2001.\textsuperscript{43} The complex of concepts – all-hazards, biosecurity and public health – was necessarily somewhat unstable, as there is no reason, for example, that an all-hazards approach need be bound up with a greater role for security bureaucracies and approaches, or that the specific field of 'emergency management' should develop in all Member States. Nor is it clear that public health, with its focus on diagnosis, tracking and human rights is a good fit with the more paramilitary, active, style often associated


\textsuperscript{40} de Ruijter A, The Expansion of EU Power in the Field of Human Health (Oxford University Press 2017) (forthcoming); Decision on Cross-border Threats.


with the developing world of emergency management. In the EU, this is an interesting challenge as the EU, an essentially civilian organisation, adopts elements of a broader security framework that is alien to many of its Member States, puts it in close contact with very different security bureaucracies such as NATO, and starts to develop a role and perhaps capacities outside traditional definitions of public health or EU competencies.

III.ii Players and Principles

Communicable disease control involves different players, both at EU (European Commission, ECDC, Health Security Committee), international (WHO) and at national level. Apart from ECDC, there are also other agencies involved in communicable disease control (Table 13.1).45

From its 2004 start, ECDC was given the mission of centralising much of the ongoing work, such as the EPIET (European Programme for Intervention Epidemiology Training) training programme and the disease-specific surveillance networks, and making itself the hub of a more coherent, Europeanised, communicable disease control infrastructure.

ECDC’s functions, then, are common ones in the world of communicable disease control. They are, broadly, surveillance (monitoring populations for diseases), microbiology (identifying pathogens), communication with public health sectors (and directed at the general public) and support for responses by those tasked with risk management.46 The list of diseases that receive Europe-wide surveillance is set by an EU committee47 rather than ECDC alone. It also engages in a wide range of capacity-building activities such as EPIET and cross-border epidemiology, and surveillance collaborations such as EPINORTH, which covers the Baltic including Russia. This list of functions is not so different from many public health agencies in the Member States, particularly north-western Europe.

Since ECDC is an EU agency rather than a national agency, it relies heavily on a network of national ‘competent bodies’, each of which is responsible for the bulk of the work of risk assessment and support. The ECDC’s role is to coordinate, in many senses: to promote common definitions and procedures in different countries, to standardise information and promote its easy transfer, to build capacity in countries with weaker public health infrastructures, to facilitate networks that will transfer capacity and expertise between countries, to manage understandings of new threats and to approximate understandings of what a communicable disease control agency should look like. There are a variety of ways to do this. For example, the ECDC commissioned research from academics at the London School of Hygiene and Tropical Medicine mapping the very large discrepancies between good practice and actual practice in many EU States’ pandemic influenza plans.48 This research made a case for more action and that such action should be directed towards goals shared across Europe.49

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Table 13.1 Key agencies involved in communicable disease control

<table>
<thead>
<tr>
<th>Agency</th>
<th>Objective</th>
<th>Established</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>European Environment Agency (EEA)</td>
<td>Environmental protection and improvement (important for air and waterborne communicable diseases)</td>
<td>1990</td>
<td>Copenhagen (Denmark)</td>
</tr>
<tr>
<td>European Medicines Agency (EMA)</td>
<td>Approval of medicinal products for human or animal use</td>
<td>1995</td>
<td>London (UK)</td>
</tr>
<tr>
<td>European Food Safety Authority (EFSA)</td>
<td>Scientific advice and information on risks in food chain</td>
<td>2002</td>
<td>Parma (Italy)</td>
</tr>
<tr>
<td>European Centre for Disease Prevention and Control (ECDC)</td>
<td>Defence against infectious diseases</td>
<td>2004</td>
<td>Stockholm (Sweden)</td>
</tr>
<tr>
<td>Consumers, Health, Agriculture, and Food Executive Agency (CHAFEA)</td>
<td>Administers health, consumer and safer food programmes</td>
<td>2005</td>
<td>Luxembourg</td>
</tr>
</tbody>
</table>

45 The indicated date refers to the legal act having established this agency (respectively predecessors).
46 See also M McKee, TK Hervey and A Gilmore, ‘Chapter 5: Public health policies’ in E Mossialos and others (eds), Health Systems Governance in Europe: The Role of EU Law and Policy (CUP 2010) 253.
47 See Decision on Case Definitions.

The European Commission, then, is charged with EU risk management. Risk management is a very broad category comprising everything that might be done to manage a threat or respond to an event – from slaughtering animals to closing schools to evacuating European nationals abroad to purchasing vaccines. It is in risk management and response that the EU faces its biggest challenges. The EU has very weak Treaty powers and Member States have deeply conflicting incentives and responses. Most recently, the EU found it very difficult to coordinate responses to Ebola in West Africa, and that was an issue on which Member States had largely similar incentives. The EU might be effective at making policy decisions about which diseases should have shared reporting, but it is less effective at deploying Member States' resources and making policies for them. This should not surprise us.

Its relations with the rest of the EU institutions follow a principle of separation between risk assessment and risk management.50 This separation is common in both EU policy (where it reflected the lessons policymakers drew from the new variant Creutzfeldt–Jakob disease, aka vCJD or 'mad cow', episode) and internationally since the 1980s. It creates a science-focused risk assessment function that can, in principle, offer advice and raise concerns even if they are politically inconvenient. Separating risk management responsibilities and assigning them to general government then is thought to have several advantages.51 It separates science from decision-making, which might free scientists. It locates accountability where it will end up anyway, with elected politicians. It gives risk management responsibility to general government, where it will end up anyway in any large-scale policy issue or crisis. It would be frankly unrealistic to imagine that the EU, let alone an EU agency, could force Member States to act against their will in a major public health crisis, so the separation at least keeps ECDC clear of much political peril.

This separation can also be found in the CJEU's case-law.52 According to the General Court, the first step, that is to say risk assessment, has to be 'carried out as thoroughly as possible on the basis of scientific advice founded on the [trinity] principles of excellence, transparency and independence [and is therefore] an important procedural guarantee whose purpose is to ensure the scientific objectivity of the measures adopted and preclude any arbitrary measures'.53

As the General Court has emphasised, risk assessment, 'includes for the competent public authority, in this instance the [EU] institutions, a two-fold task, whose components are complementary and may overlap but, by reason of their different roles, must not be confused. Risk assessment involves, first, determining what level of risk is deemed unacceptable and, second, conducting a scientific assessment of the risks.'54

- With regard to the first task of risk assessment, the EU institutions have to take into account international law (e.g., of the WTO)55 when determining the level of protection which they deem appropriate.56 While it is clear that determining the level of risk has to be done on a case-by-case basis, the EU institutions have to take into account 'the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge'.57

50 On the different phases in case of pandemics, see Fleur (n 22) 153-4.
53 Case T-13/99 Pfizer ECLI:EU:T:2002:209, [2002] ECR II-3305, para 172. Transparency has also been stressed in Council Conclusions Precautionary Principle (n 51) point 14; see also Hervey and McHale (n 22) 363, 365. Decision on Cross-border Threats, Recital 17 also mentions those principles, while adding impartiality. Those principles also figure in the Food Law Regulation.
54 Alpharma (n 52) para 162.
55 For the global health perspective see Chapter 18 in this book.
56 Alpharma (n 52) para 163. The level of risk has been described as 'the critical probability threshold for adverse effects on human health and for the seriousness of those possible effects – which in their judgment is no longer acceptable for society and above which it is necessary, in the interests of protecting human health, to take preventive measures in spite of any existing scientific uncertainty' (para 164). For a broader perspective on the topic of risk see HW Micklitz and T Tridimas (eds), Risk and EU Law (Edward Elgar 2015); A-M Farrell, 'Risk, Legitimacy, and EU Regulation of Health Technologies' in ML Fleur and others (eds), European Law and New Health Technologies (OUP 2013).
57 Alpharma (n 52) para 166. R Martin, 'The Exercise of Public Health Powers in Cases of Infectious Disease: Human Rights Implications' (2006) 14(1) Medical Law Review 132, 142 emphasised the importance of criteria for determination of whether conditions are liable to become a public health risk.
With regard to the second aspect of risk assessment, this scientific assessment has to be entrusted to experts, who will then provide the scientific advice. This shall ensure that EU institutions take decisions 'in the light of the best scientific information available and that they are based on the most recent results of international research'. Again, this expertise has to adhere to the 'trinity'—principles of excellence, independence and transparency. As full risk assessment might require long and detailed scientific research, if 'essential', the institutions may nevertheless take preventive measures, even at very short notice. The institution then has the tricky obligation to either wait (until the results of more detailed scientific research become available) or to act on the basis of the scientific information already available. The institution acts on the safe side, if the scientific expertise adheres to the aforementioned criteria, and if the institution itself is 'given sufficiently reliable and cogent information to allow it to understand the ramifications of the scientific question raised and decide upon a policy in full knowledge of the facts'. If the EU institution adheres to those principles, then the burden of proof shifts to the company etc. questioning those measures.

Preventive measures taken based on the precautionary principle will be assessed by the courts at the time when the measure was taken, or in other words, courts do not assess the efficacy of a measure retrospectively.

In order that it comes full circle, this second aspect of risk assessment then should enable the EU institution 'to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materialising', that is to say the second step, risk management.

As we have seen, several players are involved in risk assessment and risk management of communicable disease control. While the principles those players have to apply (excellence, transparency, independence, etc.) are clear in theory, applying them to concrete examples of communicable disease control remains challenging, and political goals unrelated to technical public health inevitably play a big role in individual and organisational actions.

III.iii Selected Communicable Disease Control Measures

III.iii.a Precautionary measures

It is obvious that for a new communicable disease threat, whether it is BSE or Zika, the possibility of the EU taking precautionary measures plays a key role. The precautionary principle, a 'general principle of EU law', and is not defined in the EU Treaties, though it is in secondary legislation. In assessing the probability of the feared harm arising, something more than a mere theoretical hypothesis, and at least a possibility, or a likelihood, is necessary. The EU institutions may not choose a 'zero-risk' policy. But they may exercise precaution. In other words, there is no requirement on the EU to provide 'conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality', before taking regulatory action to counter the probable risk.

The precautionary principle applies 'where there is uncertainty as to the existence or extent of risks to human health'. This principle also has to be seen in the context of the EU's duty to promote a high level of

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58 Alpharma (n 52) para 170.
59 ibid para 170.
60 ibid para 172. See also Food Law Regulation, articles 37 (independence) and 38 (transparency), and n 53.
61 Alpharma (n 52) para 173.
62 Alpharma (n 52) para 174.
63 Alpharma (n 52) para 175.
64 Pfizer (n 53) para 164.
65 ibid para 144; see also Case C-601/11 P France v Commission ECLI:EU:C:2013:465, para 136 ('the level of protection of human health is tightly correlated to the level of risk deemed acceptable for society, which depends, in turn, on the scientific knowledge available at a given moment').
66 Case C-101/12 Schaible ECLI:EU:C:2013:661, para 50.
protection in the fields of human health, 76 consumer protection, 77 and the environment, 78 as well as in the context of sustainable development 79 and the common agricultural policy. 80 In those contexts, 'the [EU] institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent'. 81

The European Group on Ethics (EGE) 82 has claimed the precautionary principle is 'the expression of prudence as a genuine ethical virtue', and that the attendant risk assessment is a moral duty, stressing that, in the event of damages, individuals are entitled to 'fair reparation'. 83 However, as we will see below, this may be the EU's moral or ethical position, but it has not been translated into practical legal effects in terms of legal liability for harm from communicable diseases (or communicable disease control measures).

Notwithstanding the European Group on Ethics view, and even though the EU is associated with a precautionary approach to risk, the consequence of not following such a principle in terms of legal accountability is not clear-cut. Certainly a failure to adopt precautionary measures has not been a successful ground for judicial censure by the CJEU. On the contrary, the CJEU grants broad discretion to the relevant actors at EU or national level when taking measures and therefore limits the level of judicial scrutiny.

That is true for public health with regard to national measures in the context of the fundamental freedoms 84 and for EU-level measures when dealing with communicable disease control. The EU legislature has broad discretion in areas involving political, economic or social choices, where complex assessments must be undertaken. 85 In terms of sectoral policies affected, that is not only the case for agriculture (as in the case of BSE, where both national authorities and EU institutions were criticised for their responses), 86 but also for other fields, such as social and employment policy. 87 The EU legislature has discretion as to the objectives to be pursued, the means of action, and as to the determination of the level of risk deemed unacceptable for society. It also has discretion in terms of determining the factual basis for its action. 88 The concept of scientific 'fact' being politically determined is familiar from the science and society literature. 89

Where the CJEU has exerted some measure of control is by seeking to ensure that measures held to be valid in EU law must adhere to the scientific state-of-the-art, 90 and must refer to the most recent, 91 though well-established, 92 scientific knowledge or opinion. 93

Like the aforementioned principles, the precautionary principle is clearer in theory than when it has to be applied to a concrete potential health threat. Although it is the most commonly cited principle in the cases where the CJEU has dealt with communicable diseases, the broad discretion granted might make it less appealing to be used as an argument when legally challenging both measures taken by the EU institutions, as well as those not taken.

III.iib Vaccination

Annieke de Ruijter has written persuasively about the challenges that the EU faces in coordinating risk management and the predictable informal mechanisms that EU policymakers have used to coordinate risk management and their response. The following two paragraphs are based on

76 TFEU, Articles 9, 114(3) and 168(1). See also France v Commission (n 75) para 66.
77 TFEU, Articles 114(3) and 169(1).
78 TFEU, Articles 3(3), 114(3) and 191(2) (explicitly mentioning 'the precautionary principle').
79 Council Conclusions Precautionary Principle (n 51) Recitals A and D.
80 France v Commission (n 75) para 60.
81 ibid para 61.
84 Joined Cases C-570/07 and 571/07 Blanco Pérez and Chao Gómez ECLI:EU:C:2010:300, [2010] ECR I-4629, para 44: 'health and life of human rank foremost among the assets and interests protected by the Treaty'.
85 Schäible (n 66) para 47.
86 Hervey and McHale (n 22) 349 (UK government), 356–7 (Commission).
88 Alpharma (n 52) paras 177–9.
91 Case C-528/13 Léger ECLI:EU:C:2015:288, para 63.
93 Pillbox 38 (n 75) para 116 ('serious scientific information alleging the existence of potential risks to human health').
EU was able to create a vehicle for joint purchasing.100 The existence of such a procedure does not necessarily overcome discrepancies between the priorities and financial means of the different EU-Member States, but it does start to link more core public health activities in the Member States to the EU.

As it happened, the H1N1 pandemic was not as frightening as had been imagined. Debate about it quickly became acrimonious, with critics arguing that the commercial interests of the pharmaceutical companies had influenced the declaration of a pandemic, and WHO responding that severity was unknown at the time of the declaration and was not one of the criteria for a pandemic anyway. Wealthier EU Member States, meanwhile, had their own debates about what to do with unused vaccine.

Vaccination can be an issue both in communicable diseases transmitted directly via humans, or indirectly via animals.101 Communicable disease control measures can also be confronted with people refusing to get vaccinated. Recently, the CJEU had to deal with the question if EU law entails a right not to be treated. This case was about a mother refusing to vaccinate her child, which under Slovakian law resulted in a fine of €100 (of a maximum possible amount of €331). The CJEU stated that Article 168 TFEU entails no obligation at all to vaccinate minors and consequently declared itself not to have jurisdiction for this preliminary ruling question.102 Although vaccination can be a key tool for fighting communicable diseases, the CJEU did not provide substantive clarification on this important question whether there is a right not to be vaccinated.103

96 European Centre for Disease Control and Prevention (ECDC), 'Influenza surveillance in a pandemic' (Working Group Paper, 2007).
97 The available drugs merely reduce its duration and severity. This did not stop them becoming an object of fascination for policymakers and the public, who struggled for scarce supplies.
100 Decision on Cross-border Threats, Article 5; see also Commission, 'Pandemic (H1N1) 2009' COM (2009) 481 final, Chapter 7; Commission, 'Joint procurement of vaccine against influenza A(H1N1)' (Staff Working Document) SEC (2009) 1188 final; and Commission, 'Statement from the European Commission on Article 7(3) of the Joint Procurement Agreement to procure medical countermeasures pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council' [2014] OJ C185/33.
101 Jipjes (n 92).
102 In a similar way, the CJEU excluded its jurisdiction concerning the interpretation of the Charter of Fundamental Rights of the European Union [2016] OJ C202/389 (CFREU) (in this case: Article 33, family life; and Article 35, healthcare), by referring to the limitations provided in CFREU Article 51(1); Case C-459/13 Stříbřek ECLI:EU:C:2014:2120, paras 21–6.
103 CFREU Article 3 (right to the physical integrity) has not been an issue in this case. According to S Michalowski, 'Article 3 – Right to the Integrity of the Person' in S Peers and others (eds), The EU Charter of Fundamental Rights: A Commentary (Hart 2014) 39, 46, 'healthy behaviour can be encouraged, but not
Consequently, it is for national law to decide if compulsory vaccination is legal.

III.iii.c Food law and traceability

Food safety and animal health are as critical to communicable disease control as the core activities of ECDC. A large proportion of outbreaks involve the food supply which is highly integrated across Europe, and most human communicable diseases start out as zoonoses (animal diseases). The scale and importance of the EU internal market in food and animals, and the major role that the EU plays in market regulation, consumer safety and agriculture, all point to an inevitable EU role in food safety and animal health. As the BSE crisis proved, even a non-decision has effects: the lack of EU level regulation in an integrated market amounted to a policy that enabled the spread of the disease.

As mentioned above, the BSE crisis led to new rules on food and feed law, the Food Law Regulation, which also emphasises the separation of the three interconnected components of risk analysis, that is to say, risk assessment, risk management and risk communication. The Regulation also establishes a rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed. The broad solution that the EU has adopted, along with much of the world, is to focus on traceability. This defines the problem of food safety, in large part, as being one of information about how and where problematic foods entered the food safety system. It directly addresses problems such as that identified in inquiries into BSE, namely that European markets in animals and animal products had far outpaced regulators' ability to figure out what was in those markets. It also responds to direct concerns such as the need to identify unsafe foods and remove them from the market, and also makes it more possible to pin accountability on unscrupulous actors who introduce unsafe foods or commit fraud in food supply chains. For these reasons, EU law and policy emphasises traceability, both of animals imposed on the individual who chooses not to adopt it. See also ‘A jab in time’ The Economist (London, 26 March–1 April 2016) 53–4.

104 See now: Animal Health Regulation.
105 A nondecision is when politics forecloses even discussing a topic and making a formal decision. P Bachrach and MS Baratz, 'The Two Faces of Power' (1962) 56(4) American Political Science Review 947.
106 Food Law Regulation, Recital 17. The precautionary principle (Article 7) has already been mentioned (see at n 70). See also Chapter 16 in this book.
107 ibid, Article 50(2).
108 The Food Law Regulation emphasises the necessity ‘to consider all aspects of the food production chain as a continuum’ (Recital 12); on the ‘farm to table’ as well as of products. This can especially be guaranteed by electronic means of identification, as this improves the effectiveness of the fight against infectious diseases ‘since it ensures greater reliability and speed of data communication’. For food and feed, comprehensive systems of traceability have been emphasised for enabling ‘targeted and accurate withdrawals’. 109

III.iii.d Freedom of movement

The connection between diseases, borders and mobility is a connection many have made in different ways, whether they call for cross-border cooperation to defeat border-jumping diseases or reinforced borders and quarantines to block them. Infectious diseases in case of humans can restrict freedom of movement, both inbound and outbound.

III.iii.d.1 Inbound situations

The EU Citizens' Directive limits such inbound restrictions on the freedom of movement to, first, ‘diseases with epidemic potential as defined by the relevant instruments of the [WHO]’, such as Ebola. The second limitation refers to ‘other infectious diseases or contagious parasitic diseases if they are the subject of protection (or ‘farm to fork’) principle, see Commission, ‘White Paper on Food Safety' COM (1999) 719.

109 Schable (n 66) para 39 (traceability of animals in the context of foot-and-mouth disease); Case C-1/00 Commission v France ECJ:EU:C:2001:687, [2001] ECR I-9089, para 113 (traceability of products in the context of BSE). See also Food Law Regulation, Recitals 28 and 29, Article 18, where traceability has been defined in Article 3(15) as follows: ‘traceability’ means 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. See also Animal Health Regulation, parts 4 and 5.
110 Food Law Regulation, Recital 28.
111 In case of products (food, feed, animals, meat, blood, etc.), restrictions can be justified based on TFEU Article 36. See also McKee, Hervey and Gilmore (n 40) 237–8, 249–50.
112 See also Decision on Cross-border Threats, Recital 21.
114 WHO, IHR (n 37) Article 1 defines a ‘public health emergency of international concern’ (PHEIC), and Article 12 provides for the procedure of determination of a PHEIC (see also Annex 2); see also Article 57(3). Reference to those provisions is made in Decision on Cross-border Threats, Recitals 6 and 12, Article 10, and especially Article 12 (recognition of emergency situations).
provisions applying to nationals of the host Member State', that is to say requiring non-discrimination in relation to a Member State's own citizens. Within three months after the date of arrival, Member States can require persons to undergo medical examinations only in exceptional cases and free of charge. After those three months, expulsions cannot be based on diseases. In other words, public health-related reasons can only restrict the entry and short-term residence of EU citizens and family members.

Concerning the refusal of application for residence of third-country nationals (TCN) who are long-term resident (or their family members), similar rules apply. Although slightly different in wording, and details, they also refer to the relevant applicable instruments of the WHO.

In this context, the EU relies on the expertise of the WHO. The WHO's decision on a 'public health emergency of international concern' (PHEIC), is taken based on advice from the Emergency Committee and other experts. In case of the Zika virus, this decision was taken based on the following criteria: health risk to other countries through international spread; necessity of a coordinated response; and implications beyond the affected country. However, the relationship of the EU and the WHO is not restricted to the EU referring to the WHO, the EU also cooperates with the WHO, the World Bank, and other bodies in the context of global health governance, also comprising the Global Health Security Initiative. This question of inter-organisational relationships might be managed effectively but is not going to go away; and there is a longstanding question mark over the relationship between the EU and the WHO.

### III.iii.d.2 Outbound situations

The European Court of Human Rights had to deal with communicable diseases and human rights issues, but rather from an outbound perspective, that is to say, expulsion of foreigners. Aliens who are subject to expulsion cannot in principle claim any entitlement to remain in the territory. However, in very exceptional cases, such an expulsion can amount to 'inhuman or degrading treatment' (ECtHR Article 3). While even a significant reduction in life expectancy has been

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116 Citizens' Directive, Article 29(2) and (3). In addition, Article 27(1) explicitly excludes economic ends to be invoked in that regard.


119 In case of Zika v PHEIC, a PHEIC has been declared on 1 February 2016, and the continuation of a PHEIC on 1 March 2016. As of 29 March 2016, Ebola has not longer been seen as a PHEIC, and Zika as of 18 November 2016.

120 D Heymann and others, 'Zika virus and microcephaly: Why is this situation a PHEIC?' (2016) 387(10020) The Lancet 719.

121 TFEU Article 168(3).


123 On global health see also Chapter 18 in this book.


126 S Guignier, 'The EU’s role(s) in European public health: the interdependence of roles within a saturated space of international organizations' in O Elgström and M Smith (eds), The European Union's Roles in International Politics (Routledge 2006); S Guignier, 'The EU and the health dimension of globalization: playing the World Health Organization card' in J Orbie and L Tortell (eds), The European Union and the Social Dimension of Globalization (Routledge 2009); DM Fox, 'Commentary: The governance of disease control in Europe' (2012) 37 (6) Journal of Health Politics, Policy, and Law 1121. In practice, the European region of WHO has mostly focused its attention in this area on the former Soviet Union and south-east Europe, where there is no rival like the ECDC, no necessary affection for the EU among local politicians and a set of pressing communicable disease problems. This pragmatic division of labour might be quite stable if the political leadership of the EU and the WHO want it to be stable. There is also a broader question about the relationship between the EU institutions and the US approach, which is typically more focused on security and less prone to work through WHO or international organisations. The US has been developing a 'Global health security agenda' with cooperation from some Member States, such as the UK. The place of this initiative, its eventual institutionalisation and its implications for EU communicable disease control remain to be seen.

127 On this topic see also JH Carens, The Ethics of Immigration (OUP 2015) 178.

128 Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended) (signed 4 November 1950, entered into force 3 September 1953) CETS 5 (ECtHR) Article 5(1)(e) (right to liberty and security) allows for 'the lawful detention of persons for the prevention of the spreading of infectious diseases'. In Enhorn v Sweden App No 56329/00 (ECtHR, 25 January 2005) the ECtHR has balanced the interest of the
seen to be under this threshold, this 'high' (sic)\textsuperscript{129} threshold would be reached if an 'applicant was critically ill and appeared to be close to death, could not be guaranteed any nursing or medical care in his country of origin and had no family there willing or able to care for him or provide him with even a basic level of food, shelter or social support'.\textsuperscript{130} This case-law refers not only to HIV, but to 'any serious, naturally occurring physical [...] illness'.\textsuperscript{131}

This reasoning has also been confirmed by the CJEU, whereas in the very exceptional cases in which the removal of a TCN suffering a serious illness to a country where appropriate treatment is not available, Member States cannot proceed with such removal,\textsuperscript{112} and also might need to provide emergency healthcare and essential treatment of illness.\textsuperscript{110}

\textbf{III.iv Liability for Harm}

In the context of indirect measures relating to animals, there have been several cases alleging the non-contractual liability of the EU in the context of communicable disease control measures, such as for TSE,\textsuperscript{134} avian influenza\textsuperscript{135} and BSE (including both damages to traders,\textsuperscript{136} as well as persons who died).\textsuperscript{137} The heirs of French people who died due to nCD in France were also not successful in attempts to claim compensation of damages based on an alleged principle of solidarity.\textsuperscript{138} None of these legal claims have been successful, despite the European Group on Ethics' view that reparation should be given as the moral aspect of the precautionary principle.

The legal reason for the lack of liability is mainly because the link of causality has not been established.\textsuperscript{139} The lack of causal link arises because the problem primarily was not caused by the EU itself, but rather by the Member States,\textsuperscript{140} acting according to their national competences.\textsuperscript{141}

\textbf{III.v Fundamental Rights}

A legal perspective on communicable disease control must necessarily also include discussion of fundamental human rights.\textsuperscript{142} Due to the cross-cutting dimension of communicable disease control, the potential linkages to human rights are vast. Here we highlight only some selected aspects.

So far, in CJEU communicable disease control case-law, several rights have been alleged, both as general principles of EU law,\textsuperscript{143} and more recently as EU Charter-based rights. That was the case for the right to business activity (CFREU Article 16), the right to property (CFREU Article 17), the right to equality (CFREU Article 20)\textsuperscript{144} and the right to health (CFREU Article 35). Several other rights could be relevant in communicable disease control, such as, for example, CFREU Article 2 (right to life), Article 3 (right to integrity), Article 6 (right to liberty and security), Article 7 (right to private and family life) and Article 8 (protection of personnel data).\textsuperscript{145}

While it has been emphasised that certain provisions might seek to attain a double objective, that is to say, both the completion of the internal market as well as health protection,\textsuperscript{146} case-law has emphasised that the protection

\begin{itemize}
\item \textsuperscript{129} \textit{Abad Pérez} (n 136) para 108.
\item \textsuperscript{130} \textit{ibid} paras 119, 124 ('systematic failures in the implementation of the [EU] rules'), 130 ('tardy transposition of the [EU] rules'), etc.
\item \textsuperscript{131} \textit{UK v Commission} (n 71) para 76 (48% of slaughterhouses were failing to comply fully with the statutory requirements). For a similar criticism with regard to Ebola in the context of the WHO, \textit{IHR} (n 37), see Rodier, Hofmann and Alutis (n 115) 30.
\item \textsuperscript{132} See further Chapters 4 and 19 in this book.
\item \textsuperscript{133} \textit{Joined Cases C-20/00 and C-64/00} \textit{Booker ECLI:EU:C:2003:397}, [2003] ECR I-7411, paras 65–6.
\item \textsuperscript{134} \textit{Scharfe} (n 66) paras 76–7, 87, 92 (alleged discrimination against keepers of sheep and goats as compared to keepers of cattle and pigs).
\item \textsuperscript{135} See also Table 19.1 in Chapter 19 in this book.
\item \textsuperscript{136} \textit{Booker} (n 143) para 73.
\end{itemize}
of human health ‘must take precedence over economic considerations’.\(^{147}\) Recently, this has been emphasised as follows:

It should be borne in mind, however, that the protection of human health has considerably greater importance in the value system under EU law than such essentially economic interests (see Articles 9 TFEU, 114(3) TFEU and 168(3) TFEU and the second sentence of Article 35 of the Charter of Fundamental Rights), with the result that health protection may justify even substantial negative economic consequences for certain economic operators.\(^{148}\)

In the context of the non-contractual liability of the EU, the General Court has emphasised the social function of fundamental rights, such as the right to property, which are not absolute rights.\(^{149}\) Therefore, due to the broad discretion enjoyed by EU institutions in the field of agricultural policy, for example the destruction of fish stocks infected by viral haemorrhagic septicemia and infectious salmon anaemia does not require compensation to be paid in all circumstances and does not constitute disproportionate and intolerable interference impairing the very substance of the right to property (CFREU Article 17).\(^{150}\) This social function has also been emphasised in the context of the freedom to conduct a business (CFREU Article 16), where the General Court has also referred to CFREU Article 52(1) (limitations of CFREU rights).\(^{151}\)

While most of the CJEU cases related to communicable diseases were about animals (especially the BSE crisis), the CJEU recently had to deal with a case of alleged discrimination against gay men due to their exclusion from blood donation.\(^{152}\) This case was also, but not only, about HIV\(^{153}\) which has been referred to as ‘the greatest health scourge of modern times’.\(^{154}\) The CJEU was asked to analyse whether this constitutes discrimination based on sexual orientation, as prohibited by CFREU Article 21. Although the CJEU finally left it to the national court to ascertain if there are effective techniques for detecting HIV in order to avoid transmission to recipients,\(^{155}\) it emphasised the objective of ensuring a high level of human health protection – as recognised in TFEU Article 168 and CFREU Article 35 2nd sentence – which can justify a permanent deferral from blood donation.\(^{156}\) In reaching its decisions, the CJEU had a close look at the specific epidemiological situation in France, and also stressed the need to consider ‘scientific and technical progress’.\(^{157}\)

Contrary to the question whether there is an EU-based right not to be treated,\(^{158}\) the question could arise whether EU law could be used to claim access to resources (both in general, but of course also in the context of communicable diseases). Although CFREU Article 35 is generally seen as a right and not only as a principle,\(^{159}\) it refers to national laws and practices, and is sometimes only seen as a negative right (against interference).\(^{160}\) Therefore it is difficult to deduct an EU-based right of access to resources, unless one follows a minimum core approach,\(^{161}\) which can be the case in life-threatening situations.\(^{162}\) It is more likely that the CJEU will continue to rise in the incidence of HIV/AIDS in Greece’. In general, for accounts of the relationship between austerity and health: Frischlut and Fahy (n 90); and SA Burgard, JA Ailshire and L Kalousouva, ‘The Great Recession and Health: People, Populations, and Disparities’ (2013) 650 The ANNALS of the American Academy of Political and Social Science 194.

\(^{147}\) *UK v Commission* (n 71) paras 91–2; *ATC* (n 11) para 188 (emphasising the ‘social function’ of the economic rights enshrined in the CFREU); *Alpharma* (n 52) paras 356 and 364; *Pfizer* (n 53) para 456. Seeing public health not as an end in itself, but rather as a way of maintaining the functioning of the internal market: *Fleiz* (n 22) 164.

\(^{148}\) *Case C-358/14 Poland v European Parliament and Council* ECLI:EU:C:2015:848, Opinion of Advocate General Kokott, para 130.

\(^{149}\) *Booker* (n 143) para 68. See also *Pfizer* (n 53) para 457; *ATC* (n 11) para 188.

\(^{150}\) *Booker* (n 143) paras 85–6.

\(^{151}\) *Schaible* (n 66) para 27.

\(^{152}\) On blood safety and HIV, see also Hervey and McHale (n 22) 343–8; Hervey and McHale (n 51) 349–52. For a related issue in this context see R Andorno, ‘The right not to know does not apply to HIV testing’ (2016) 42(2) *Journal of Medical Ethics* 104.

\(^{153}\) As regards the impact of the financial crisis on healthcare and more specifically HIV, see ME Salomon, ‘Of Austerity, Human Rights and International Institutions’ (2015) 21(4) *European Law Journal* 521, 535 mentions a 200%

\(^{154}\) *Pfizer* (n 53) para 340 (in the context of a case concerning the transfer of resistance to antibiotics from animals to humans).

\(^{155}\) *Léger* (n 91) para 63 (also – but not only – with regard to the so-called ‘window period’, paras 62 and 67).

\(^{156}\) ibid para 57. The CJ has also emphasised the need to interpret secondary law in line with those fundamental rights (para 41), and elaborated on the already mentioned (n 151) CFREU Article 52(1) (paras 51–69).


\(^{158}\) See at n 102.

\(^{159}\) TK Hervey and JV McHale, ‘Article 35 – The Right to Health Care’ in S Peers and others (n 103) 967.

\(^{160}\) Frischlut and Fahy (n 90) 55–6.

\(^{161}\) See the overview in Hervey and McHale (n 159) 958 (and 954).

\(^{162}\) Frischlut and Fahy (n 90) 57. While a move of the CJEU towards requiring MS to provide certain treatment etc. based on CFREU Article 35 in situations other than life-threatening ones is not very likely, there is no doubt about the
with the approach of ‘rules for rights’, in which it obliges Member States to adhere to standards of EU law in defining rights but does not enunciate substantive social rights.\(^{163}\)

**IV. CONCLUSIONS AND DIRECTIONS OF TRAVEL**

It is always challenging to deal with unpredictable risky future events. However, unlike examples such as new technologies\(^{164}\) where quite often reference is then made to non-legal concepts such as ethics,\(^{165}\) this does not apply for the legal handling of communicable diseases cases.

With regard to EU legislation, we will see whether the Decision on Cross-border Threats in the future will prove to have been ‘a solid framework to tackle future public health crises similar to the Ebola outbreak’, as the Council states it desires.\(^{166}\)

In a similar way as we can observe an increasing number of CJEU cases dealing with the CFREU in general (since the entry into force of the Lisbon Treaty), the direction of travel for communicable diseases will most likely involve an increasing number of cases concerning human rights. The fact that communicable disease-threats such as the Zika virus can also result in discussions about abortion is one example that could barely have been envisaged before.\(^{167}\)

Another direction of travel will concern the relationship of law and science. In a similar way as we have seen it in the context of patient mobility,\(^{168}\) stem-cell patentability\(^{169}\) or e-cigarettes,\(^{170}\) it will remain a challenge for the CJEU and other EU institutions\(^{171}\) to deal with the scientific state-of-the-art (determined by hopefully independent scientists) and derive the appropriate legal conclusions.

This leads us to the precautionary principle. Although in the CJEU case-law dealing with communicable diseases, it has been the principle most widely covered, in the end it was not successfully used when challenging measures of EU institutions (e.g., in claiming damages). However, challenges not only occur in the former-mentioned internal perspective, but also in an external one. Having been qualified as a ‘general principle of EU law’ (i.e. primary EU law) by the General Court, it could play an interesting role in relation to interpretation of trade deals with the US (especially TTIP).

The development of communicable disease control in the EU is a case of broader dynamics of European integration. It shows how social and political spills over, mediated through the shaping of the EU political agenda and policy alternatives, can lead to further integration. From this point of view, the striking thing is how well the old neo-functionalists theories work, given that we are in a much more contentious and disputed EU. Equally, it presents an interesting case study, which we have barely developed, in how the thickets of law on EU action and public health in Member States accommodate and integrate with the new and increasingly coherent EU policy actors.

It is easy to look at some aspect of new governance or soft law, observe that it does not really govern or is not really like law, and dismiss it. If we evaluate new governance and soft law in the same terms as hierarchical formal governance and hard law, we are bound to find it wanting, at most something to do when hard law is unavailable. That is very much the case for the institutions and policies that we have discussed here: technical epidemiology does not seem much like an exercise of power and the ECDC is, on paper, effectively powerless. But an appreciation of the work of new governance will put much of the focus on two other aspects: its relationship to hierarchy and its constitutive function. First, there is its relationship to hierarchy. As much of the EU health literature, and much other EU literature, shows, new governance often works best in the shadow of hierarchy. That means the operation of the formal mechanisms would be unattractive to participants and can be avoided through effective use of informal mechanisms.\(^{172}\) Even more importantly in the case of communicable

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\(^{163}\) See Chapter 8 in this book.

\(^{164}\) Frischkut (n 13) 531.


\(^{166}\) ‘To breed, or not to breed’ The Economist (London, 30 January – 5 February 2016) 39, 40.

\(^{167}\) Smits and Peerbooms (n 90) paras 94 and 97.

\(^{168}\) International Stem Cell (n 90) para 33.

\(^{169}\) Pillbox 38 (n 75) para 51.

\(^{170}\) Although this example is not about communicable diseases, we can perfectly observe this in the current discussion on glyphosate; ‘Fog of uncertainty’ The Economist (London, 5–11 March 2016) 23.

disease control, we see the role of new governance in its constitutive function – as part of the development of norms and expectations. In this function, actors develop rules, norms and practices that can be the basis for later hardening of law. Without soft mechanisms like disease-specific surveillance networks, the informal Health Security Committee, or research projects intended to harmonise epidemiological practices, it is unlikely that a European alternative would have been a plausible or functional space for communicable disease control. In other words, the case of communicable disease control in Europe is interesting in part because it shows how very soft law, such as standards enunciated by academic networks, can become harder law, such as policies of an agency such as ECDC, and can then compel action not through hierarchy but through authority.

Communicable disease control might seem boring and well established in this age of antibiotics, vaccines and sewers. But a quick glance at cinemas or news headlines shows the fascination and fear of diseases in particular diseases from abroad. They cross borders, prompting calls for international collaboration and fear of foreigners. The EU, a global actor and an integrated internal market, is inevitably involved in blurring and crossing borders, whether it is animals and people crossing borders between Member States, zoonoses breaching the species barrier somewhere in the food system and becoming human diseases, or diseases from abroad circulating into the European space and becoming more or less real threats to Europe’s safety and health. Over time, this inevitability has been filtered through politics, law and chance to create an increasingly impressive EU role in managing the EU’s internal market and maintaining its political and species borders with the outside world. History suggests that the EU did not have to develop an effective role but it has nonetheless started to do so, but history also suggests that a topic so fraught with fear, complexity, and potential human rights abuses and panic will also continue to be a difficult area for politics and law.

14. EU public health law and policy – tobacco

Alberto Alemanno*

I. INTRODUCTION

Despite its increasing public rejection and reduced social acceptance, smoking remains the single largest cause of preventable death and disease in the European Union, accounting for 650,000 deaths each year – representing more than 15 per cent of all deaths in the EU.

In addition, more than 13 million people in the 28 countries of the EU suffer from smoking-related diseases. However, for more than a decade smoking prevalence has been on the decline, reflecting a broader trend of reduction in smoking prevalence among industrialised countries that may be observed since the 1980s.

This chapter offers a detailed legal and policy analysis of how EU tobacco control contributed to this result, by focusing on the constitutional debate surrounding the genesis, evolution and latest developments of EU regulatory action. By focusing on some of the most far-reaching and already controversial measures contained in the 2014 Tobacco Products Directive, in particular packaging standardisation, it also identifies future regulatory developments. In particular, the chapter illustrates how most of the policies aimed at de-normalising tobacco today, as epitomised by plain packaging, rely on ‘nudging’ approaches via behavioural change rather than via the provision of information, it cannot be ruled out that

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2 ibid.

3 ibid; the EU smoking prevalence remains high – as compared to other industrialised countries – with an average of around 29%. While southern European countries see the greatest proportion of smokers, specifically Greece, where the proportion of smokers exceeds 40%, in the northern Member States of Sweden and Finland the proportion of smokers is the lowest at 16% and 21% respectively.

4 WA Bogart, Permit But Discourage, Regulating Excessive Consumption (OUP 2011).
This important series presents a comprehensive analysis of the latest thinking, research and practice across the field of European Law. Organised by theme, the series provides detailed coverage of major topics whilst also creating a focus on emerging areas deserving special attention. Each volume is edited by leading experts and includes specially-commissioned chapters from distinguished academics as well as perspectives from practice, providing a rigorous and structured analysis of the area in question. With an international outlook, focus on current issues, and a substantive analysis of the law, these Handbooks are intended to contribute to current debate as well as providing authoritative and informative coverage.

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RESEARCH HANDBOOK ON EU Health Law and Policy

The steady expansion of the European Union’s involvement in health over the past 20 years has been accelerated by recent events. This Handbook offers an up-to-date analytical overview of the most important topics in EU health law and policy. It outlines, as far as possible, the direction of travel for each topic and suggests research agendas for the future.

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