

# 3 *EU regulatory agencies and health protection*

GOVIN PERMANAND AND ELLEN VOS

## 1. Introduction

The challenges involved in the governance of the European Union's (EU) internal market, as well as the need for closer collaboration between Member States, have seen EU policy-makers increasingly turn to executive or regulatory agencies outside the Commission structure.<sup>1</sup> These agencies are entrusted to execute a wide range of tasks from simple information collection and dissemination, to the adoption of decisions that are binding on all Member States.<sup>2</sup> Seen within the context of the need for reform of the Commission and the general striving of the Community institutions for better law-making based on principles of good governance, it is not surprising that, in the new millennium, the resort to European-level agencies is more popular than ever. Moreover, as the EU's competences in social affairs continue to develop, the Commission's use of agencies has further spread into health-related areas. We have thus witnessed a mushrooming of agencies such as the European Medicines Agency,

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<sup>1</sup> Although the European Community represents the first pillar of the European Union's Treaty structure, for simplicity's sake we use the terms EU and Community interchangeably in this Chapter.

<sup>2</sup> See, in general, E. Chiti, 'The emergence of a Community administration: the case of European agencies', *Common Market Law Review* 37 (2000), 309–43; E. Vos, 'Reforming the European Commission: what role to play for EU agencies?', *Common Market Law Review* 37 (2000), 1113–34; M. Everson *et al.*, 'The role of specialised agencies in decentralising EU governance', Report presented to the Commission (2000), [http://ec.europa.eu/governance/areas/group6/contribution\\_En.pdf](http://ec.europa.eu/governance/areas/group6/contribution_En.pdf); S. Frank, *A new model for European medical device regulation – a comparative legal analysis in the EU and the USA* (Groningen: Europa Law, 2003); D. Geradin and N. Petit, 'The development of agencies at EU and national levels: conceptual analysis and proposals for reform', Jean Monnet Working Paper No. 01/04 (2004).

the European Agency for Safety and Health at Work, the European Monitoring Centre for Drugs and Drug Addiction, the European Food Safety Authority, the European Aviation Safety Agency, the European Maritime Agency, the European Centre for Disease Prevention and Control and, most recently, the European Chemicals Agency. These agencies do not work to similar remits and do not exercise the same degrees of authority. But many have an impact on the way the Community protects the health of its citizens, and they shift the coordination of specialized, technical and scientific expertise to the European level.

More recently, agencies have been seen as a constitutive element within the so-called 'new modes of governance' (NMG) approach to the making and enforcing of rules at EU level. The NMG debate focuses on the shift away from the traditional 'Community method' of regulation to embrace softer, more responsive and reflexive modes, with the incremental and consensus-generating approach of the open method of coordination (OMC) best conforming to this ideal.<sup>3</sup> But the increase in agency numbers, even if seen from this softer perspective, raises a number of concerns. As the European agencies are, for the most part, decentralized networks of variegated national level players and answerable to the Commission, they are neither sufficiently independent nor powerful to act as regulators in the traditional sense. At the same time, with agencies created to bolster better governance in the EU, to address areas of collective action, as well as to provide scientific guidance, it is clear that their sphere(s) of influence are growing. Moreover, the Commission's relationship to them is often one of dependence. This, in turn, raises questions about agency accountability, their relationship with the Member States, and the extent to which further discretionary powers could be given to them, were the Treaties or secondary legislation to allow this.

This chapter examines two agencies with a particularly important role to play in human health and safety protection, and thus impacting on Member State health care systems: the European Medicines Agency (EMA) and the European Food Safety Authority

<sup>3</sup> See D. Trubek and L. Trubek, 'Hard and soft law in the construction of social Europe: the role of the open method of co-ordination', *European Law Journal* 11 (2005), 343–64. See also Chapter 4 in this volume.

(EFSA).<sup>4</sup> Another agency that would be relevant for the study of health (care) is the European Centre for Disease Prevention and Control (ECDC). However, given our focus on policy and regulation (and primarily as they apply to the single European market (SEM)), rather than public health per se, the ECDC falls outside our coverage here.<sup>5</sup>

These medicines and foodstuffs agencies are particularly interesting as they are examples par excellence of softer, more responsive and reflexive modes of governance, and may be indicative of, if not instructive for, the development of new governance patterns for health protection in the EU. Moreover, because of the decisive role they play in the re-regulation of health issues at the EU level – as will be shown – and foremost in the context of the internal market, both agencies have an impact on national health systems, even if not an immediate or ostensibly direct one.

To this end, the chapter first looks at the development of European agencies in general, in order to understand the reasons behind and rationale for their proliferation. It then briefly profiles the development of EU competences in health, and the extensive activities of European legislators to regulate the pharmaceuticals and food safety arenas on health grounds, although as part of the EU's internal market policy. These activities have been undertaken particularly in response to the potential threats to health (and health care) that the deregulatory initiatives of the 1980s may otherwise have had.<sup>6</sup> We see that, in both domains, therefore, the EU has extensive legislative powers to determine which products or substances may be considered 'safe' and may obtain a marketing authorization within the SEM.<sup>7</sup> In this, the European Commission relies to a great extent on the technical and scientific expertise of the agencies to serve both its health protection and internal market goals, which in turn affects Member State health care systems. The chapter thus examines the roles of both agencies and addresses specific questions relating to their risk assessment mandates, composition, independence and accountability, and the extent of their influence. Some observations on the use of European agencies in general, and with regard to the EMEA and

<sup>4</sup> Although the EMEA is also responsible for veterinary medicinal products, and the EFSA also for animal health, we consider their roles only in respect of human health protection.

<sup>5</sup> See Chapter 5 in this volume.

<sup>6</sup> See Chapter 5 in this volume.

<sup>7</sup> The 'regulatory pathway', as Leigh Hancher puts it. See Chapter 15 in this volume.

EFSA specifically, and their potential impact on health protection and national health systems, are provided by way of conclusion.

## 2. European agencies as a new mode of governance

Agencies have been created within the Community's institutional framework since the 1970s. A strong Commission push saw many agencies set up during the 1990s given the single market programme, and in the 2000s we observe renewed interest (also as part of the NMG approach). This latter wave can in large part be put down to the bovine spongiform encephalopathy (BSE) crisis of 1996 and the subsequent need to regain the trust of the general public, stakeholders and regulators in EU decision-making involving health protection. Inquests into the BSE crisis and its handling made it clear that the Commission had been ill-equipped to deal with the various elements involved in regulating the foodstuffs sector, and that it lacked the expertise and organizational infrastructure to deal with highly technical questions and/or crises more generally. It was felt that independent (scientific) expertise and authority was needed to inform policy-making – for instance, in terms of divesting the science from the politics – and to enable proper risk analysis activities. There was also much domestic level interest in specialized agencies at the time, and a growing confidence in this decentralized approach based on the American tradition of independent statutory agencies.<sup>8</sup>

### A. Delegating to European agencies

Stemming from this, there is now a considerable (and growing) literature on the emergence and operation of agencies in the European national and Community frames. While we are unable to review this here, it is noteworthy, even if only in passing, that principal-agent analysis<sup>9</sup>

<sup>8</sup> M. Thatcher, 'Delegation to independent regulatory agencies: pressures, functions and contextual mediation', *West European Politics* 25 (2002), 125–47.

<sup>9</sup> See, for example, M. Thatcher and A. Stone Sweet, 'Theory and practice of delegation to non-majoritarian institutions', *West European Politics* 25 (2002), 1–22; P. Magnette, 'The politics of regulation in the European Union', in D. Geradin, R. Muñoz and N. Petit (eds.), *Regulation through agencies in the EU: a new paradigm of European governance* (Cheltenham: Edward Elgar, 2005).

(including a multi-principals view),<sup>10</sup> and historical institutionalism<sup>11</sup> are widely used as explanatory approaches in the political science literature. They generally focus on the ‘why’ from the Community macro perspective, while additional meso-level considerations on the part of policy-makers are often concerned with ensuring the credibility of decision-making (and decision-makers),<sup>12</sup> promoting market efficiency and fairness, addressing the delegation problem,<sup>13</sup> and serving the public interest more widely. Agencies also have been seen as a progression of the wider ‘privatisation, liberalisation, welfare reform and deregulation’ agenda of European governments since the late 1970s.<sup>14</sup>

Notwithstanding the validity of the different theoretical lenses – which we cannot explore here – in practical terms, the EU agencies have been created on numerous grounds, but mainly in response to an increased demand for information, expert advice and coordination at the Community level, as well as the need to lessen the Commission’s workload and its search for more efficient and effective decision-making. Further, the resort to agencies is generally favoured by the Member States. First, they perceive benefits from collective action in given policy domains, along with improved governance, but are at the same time unwilling to strengthen the Commission. Second, the EU agencies are generally networks functioning to a ‘hub and spoke’ model,<sup>15</sup> which directly involves national level counterparts.

<sup>10</sup> R. Dehousse, ‘Delegation of powers in the European Union: the need for a multi-principals model’. Draft Discussion Paper Connex 2–3, Centre d’études européennes de Sciences Po, 12 November 2006, [www.arena.uio.no/events/LondonPapers06/DEHOUSSE.pdf](http://www.arena.uio.no/events/LondonPapers06/DEHOUSSE.pdf).

<sup>11</sup> See, for example, T. Christensen and P. Lægreid, ‘Regulatory agencies – the challenge of balancing agency autonomy and political control’, *Governance: An International Journal of Policy, Administration and Institutions* 20 (2001), 499–520; S. Krapohl, ‘Thalidomide, BSE and the single market: an historical-institutionalist approach to regulatory regimes in the European Union’, *European Journal of Political Research* 46 (2007), 25–46.

<sup>12</sup> See, for example, S. Krapohl, ‘Credible commitment in non-independent regulatory agencies: a comparative analysis of the European agencies for pharmaceuticals and foodstuffs’, *European Law Journal* 10 (2004), 518–38.

<sup>13</sup> See, for example, G. Majone, ‘Delegation of regulatory powers in a mixed polity’, *European Law Journal* 8 (2002), 319–39.

<sup>14</sup> G. Majone, ‘The agency model: the growth of regulation and regulatory institutions in the European Union’, *European Institute of Public Administration (EIPAScope)* 3 (1997), 1–6.

<sup>15</sup> R. Dehousse, ‘Regulation by networks in the European Community: the role of European agencies’, *Journal of European Public Policy* 4 (1997), 246–61.

While not having a single designation (e.g., ‘agency’, ‘office’, ‘centre’, ‘authority’ or ‘foundation’), the European agencies can at their simplest be defined as bodies that, in addition to the European institutions, operate within the EC or EU realm in order to fulfil specific tasks, and which have an independent administrative structure.<sup>16</sup> Other characteristics depend on the type of body and policy domain. They are often based on existing (scientific) committees and, in some cases, have been designed to replace this comitology structure. The agencies generally support the Community institutions and national authorities in identifying, preparing and evaluating specific policy measures and guidelines. Only a handful have been given any concrete decision-making powers,<sup>17</sup> however, and, particularly for legal and political science analysts, even these do not amount to independent regulatory agencies in the traditional sense. Numerous typologies of agencies have been attempted<sup>18</sup> – and the Commission has often changed its own categories – but a simple classification of the agencies can be based on the following factors: the pillars of the EU; the legal basis for establishing the agency; their organizational structure; and the functions and nature of the agencies’ powers.

### *B. Classification according to function*

European agencies are thus situated across policy domains and, at the time of writing, there are currently twenty-eight spanning the three pillars of the EU (including one undergoing final preparations). There are twenty-two agencies in the first pillar (European Communities) – including the EMEA and EFSA – three within the second pillar (Common Foreign and Security Policy), and three set up under the third pillar (Police and Judicial Cooperation in Criminal Matters). A listing of all the European agencies within the three pillars, and a brief outline of their purpose, can be found in Table 3.1. Listing these agencies helps to convey a sense of the scope of agency work in the EU, not to mention their proliferation since early 2000. Furthermore, it is clear that

<sup>16</sup> European Commission, ‘Operating framework for the European agencies’, COM (2002) 718 final, 11 December 2002.

<sup>17</sup> That the agencies can be granted strictly circumscribed executive powers subject to Commission-imposed constraints is a result of the ‘Meroni doctrine’ based on the ECJ’s ruling in Case 9/56, *Meroni v. High Authority* [1958] ECR 133.

<sup>18</sup> See, for instance, Geradin and Petit, ‘The development of agencies’, above n.2.

many of these will, even if indirectly, have an impact on health matters within the EU frame, as well as on the Member States' health care systems and policy-making priorities. The (growing) number of the agencies also suggests their acceptance among the Member States within the context of less top-down and more NMG-oriented approaches at EU level. Agencies are regarded as softer modes of regulatory governance than the use of hard law, and their envisaged independence fosters a sense of credibility.

Towards externalizing management tasks, there is a fourth category of agency outside the pillars.<sup>19</sup> Governed by a separate legal framework,<sup>20</sup> 'executive agencies' are established to execute certain tasks relating to the management of one or more Community programmes. They are established for a fixed period and are located within the Commission, either in Brussels or Luxembourg. There are currently six such offices: the Education, Audiovisual and Culture Executive Agency; the European Research Council Executive Agency; the Executive Agency for Competitiveness and Innovation; The Research Executive Agency; the Trans-European Transport Network Executive Agency; and the Executive Agency for Health and Consumers (EAHC). The latter was set up in 2005 under the auspices of the Commission's Directorate-General for Health and Consumer Protection (DG SANCO) to manage the EU's multi-annual public health programmes (1 January 2003 to 31 December 2007<sup>21</sup> and 1 January 2008 to 31 December 2013), and its mandate expires in December 2015.<sup>22</sup> As an executive rather than a regulatory agency, a detailed discussion of the EAHC falls outside the scope of this chapter.

<sup>19</sup> Since 2009, there is an additional separate category of two agencies relating to the European Atomic Energy Community Treaty (EURATOM).

<sup>20</sup> Council Regulation 58/2003/EC laying down the statute for executive agencies to be entrusted with certain tasks in the management of Community programmes, OJ 2003 No. L11/1.

<sup>21</sup> European Parliament and Council Decision 1786/2002/EC adopting a programme of Community action in the field of public health (2003–2008), OJ 2002 No. L271/1. European Parliament and Council Decision establishing a second programme of Community action in the field of health (2008–2013), OJ 2007 No. L301/3. The programmes focus on health information, health threats and health determinants. The agency was initially called the Public Health Executive Agency.

<sup>22</sup> Commission Decision 2008/544/EC amending Decision 2004/858/EC in order to transform the Executive Agency for the Public Health Programme into the Executive Agency for Health and Consumers, OJ 2008 No. L173/27, Article 1 (2).

**Table 3.1. Agencies of the EU**

Agencies of the first pillar: Community agencies					
Name	Acronym	Established*	Location	Profile	Web site
European Centre for the Development of Vocational Training	Cedefop	1975 <sup>23</sup>	Thessaloniki, Greece	Cedefop is the European Union's reference centre for vocational education and training and supports vocational training of professionals and the development and improvement of vocational training measures throughout Europe.	www.cedefop.europa.eu
European Foundation for the Improvement of Living and Working Conditions	EUROFOUND	1975 <sup>24</sup>	Dublin, Ireland	EUROFOUND analyses living and working conditions and issues guidelines and recommendations for social policy decision-makers.	www.eurofound.europa.eu
European Training Foundation	ETF	1990 <sup>25</sup>	Turin, Italy	The ETF supports vocational training reform in the partner countries and translates EU policy into practical training and labour market instruments for non-EU countries.	www.etf.europa.eu



**Table 3.1. (cont.)**

Agencies of the first pillar: Community agencies					
Name	Acronym	Established*	Location	Profile	Web site
European Medicines Agency	EMA	1993 <sup>26</sup>	London, United Kingdom	The EMA's main responsibility is the protection of human and animal health; it endeavours to ensure optimum evaluation and supervision of medicines in Europe.	<a href="http://www.emea.europa.eu">www.emea.europa.eu</a>
Office for Harmonization in the Internal Market (Trade Marks and Designs)	OHIM	1993 <sup>27</sup>	Alicante, Spain	OHIM administers Community trade-marks and designs, which guarantee their owners uniform legal protection applicable in all Member States of the European Union.	<a href="http://oami.europa.eu">http://oami.europa.eu</a>
European Environment Agency	EEA	1994 <sup>28</sup>	Copenhagen, Denmark	The EEA provides information on the state of Europe's environment. It is also open to non-EU countries with similar aims.	<a href="http://www.eea.europa.eu">www.eea.europa.eu</a>
European Agency for Safety and Health at Work	EU-OSHA	1994 <sup>29</sup>	Bilbao, Spain	EU-OSHA acts as a catalyst for developing, collecting, analysing and disseminating information	<a href="http://www.osha.europa.eu">www.osha.europa.eu</a>

Translation Centre for the Bodies of the European Union	CdT	1994 <sup>30</sup>	Luxembourg	that is intended to make workplaces in Europe safer, healthier and more productive. CdT meets the translation needs of the decentralized Community agencies.	www.cdt.europa.eu
Community Plant Variety Office	CPVO	1995 <sup>31</sup>	Angers, France	CPVO grants industrial property rights for plant varieties that apply throughout the Community.	www.cpvo.europa.eu
European Monitoring Centre for Drugs and Drug Addiction	EMCDDA	1995 <sup>32</sup>	Lisbon, Portugal	The EMCDDA collects and disseminates 'objective, reliable and comparable information' on drugs and drug addiction in Europe.	www.emcdda.europa.eu
European Food Safety Authority	EFSA	2002 <sup>33</sup>	Parma, Italy	EFSA provides independent scientific advice and clear communication on existing and emerging risks in the field of food and feed safety.	www.efsa.europa.eu
European Aviation Safety Agency	EASA	2002 <sup>34</sup>	Cologne, Germany	EASA's task is to create uniform safety standards for the safety of aviation.	www.easa.europa.eu

**Table 3.1. (cont.)**

Agencies of the first pillar: Community agencies						
Name	Acronym	Established*	Location	Profile	Web site	
European Maritime Safety Agency	EMSA	2003 <sup>35</sup>	Lisbon, Portugal	EMSA provides technical and scientific advice to the Commission in the field of maritime safety and prevention of pollution by ships, and provides support in developing new legislation.	<a href="http://www.emsa.europa.eu">www.emsa.europa.eu</a>	
European Network and Information Security Agency	ENISA	2004 <sup>36</sup>	Heraklion, Greece	ENISA's task is to support and advise the Commission and Member States in matters of information security.	<a href="http://www.enisa.europa.eu">www.enisa.europa.eu</a>	
European Centre for Disease Prevention and Control	ECDC	2004 <sup>37</sup>	Solna, Sweden	ECDC's task is to coordinate action to monitor and combat epidemics at the European level.	<a href="http://www.ecdc.europa.eu">www.ecdc.europa.eu</a>	
European Railway Agency	ERA	2004 <sup>38</sup>	Valenciennes and Lille, France	The ERA reinforces railway safety and interoperability throughout Europe.	<a href="http://www.era.europa.eu">www.era.europa.eu</a>	

European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union	Frontex	2004 <sup>39</sup>	Warsaw, Poland	Frontex coordinates the Member States' operational management in ensuring the security of the EU's external borders. It provides assistance in training border guards, conducts risk analyses, monitors relevant research and, if necessary, assists Member States in circumstances requiring increased technical and operational assistance at borders.	www.frontex.europa.eu
European Global Navigation Satellite Systems Supervisory Authority	GSA	2004 <sup>40</sup>	Brussels, Belgium	GSA took over from the Galileo Joint Undertakings, and manages all public interests related to European global satellite navigation system programmes. Objectives include laying of foundations for a fully sustainable and economically viable Galileo system.	www.gsa.europa.eu
Community Fisheries Control Agency	CFCA	2005 <sup>41</sup>	Vigo, Spain	CFCA organizes the operational coordination of fisheries control and inspection activities by the Member States, and assists them in complying with the Common	www.cfca.europa.eu

**Table 3.1. (cont.)**

Name	Acronym	Established*	Location	Profile	Web site
European Chemicals Agency	ECHA	2006 <sup>42</sup>	Helsinki, Finland	EU Fisheries Policy in order to ensure its effective and uniform application. ECHA manages the registration, evaluation, authorization and restriction processes for chemical substances, in order to ensure consistency across the European Union.	www.echa.europa.eu
European Fundamental Rights Agency	FRA	2007 <sup>43</sup>	Vienna, Austria	FRA builds on the European Monitoring Centre on Racism and Xenophobia and provides assistance and expertise on fundamental rights when implementing community law, and supports the EU institutions and Member States in taking measures and formulating appropriate courses of action	www.fra.europa.eu

European Institute for Gender Equality	EIGE	2007 <sup>44</sup>	Vilnius, Lithuania	EIGE aims to strengthen the promotion of gender equality, including gender mainstreaming in all Community and resulting national policies, to fight against gender discrimination and to raise awareness of gender equality through technical assistance to the Community institutions and national authorities.	<a href="http://ec.europa.eu/social/main.jsp?catId=732&amp;langId=en">http://ec.europa.eu/social/main.jsp?catId=732&amp;langId=en</a>
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#### Agencies of the second pillar: Common Foreign and Security Policy (CFSP)

Name	Acronym	Established*	Location	Profile	Web site
European Union Satellite Centre	EUSC	2001 <sup>45</sup>	Torrejón de Ardoz, Spain	The EUSC analyses information from satellite imagery in support of Union decision-making in the field of the CFSP. It thereby strengthens both the CFSP and the European Security and Defence Policy, particularly with regard to crisis monitoring and conflict prevention. The Centre also conducts research and development projects.	<a href="http://www.eusc.europa.eu">www.eusc.europa.eu</a>

**Table 3.1. (cont.)**

Agencies of the second pillar: Common Foreign and Security Policy (CFSP)						
Name	Acronym	Established*	Location	Profile	Web site	
European Union Institute for Security Studies	ISS	2002 <sup>46</sup>	Paris, France	ISS promotes the EU's security interests. It contributes to the CFSP through research and debate on security and defence issues, forward-looking analysis for the Council and High Representative of the EU, and the development of a transatlantic dialogue on all security issues with the EU, the United States and Canada.	<a href="http://www.iss.europa.eu">www.iss.europa.eu</a>	
European Defence Agency	EDA	2004 <sup>47</sup>	Brussels, Belgium	The EDA's task is to improve defence and crisis management capabilities under the European Security and Defence Policy.	<a href="http://www.eda.europa.eu">www.eda.europa.eu</a>	

### Agencies of the third pillar: police and judicial cooperation in criminal matters

Name	Acronym	Established*	Location	Profile	Web site
European Police College	Cepol	2000 <sup>48</sup>	Hook, United Kingdom	<p>task of facilitating effective, close cooperation between the Member States in preventing and combating international organized crime.</p> <p>Cepol organizes training for police officers to provide information on different police systems and cross-border police work. Its aim is to support the national police forces, particularly in the fight against cross-border crime. From 2006 onwards, Cepol has become an EU agency having separate legal personality.</p>	<p>www.cepol.eu</p>



European Union's Judicial Cooperation Unit	Eurojust	2002 <sup>49</sup>	The Hague, the Netherlands	Eurojust assists the Member States, in particular, with the inves- tigation and prosecution of serious cross-border and organized crime. Emphasis is placed on improving the competent authorities' coordination of cooperation and fostering cooperation in criminal justice throughout Europe.	www.eurojust- europa.eu
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<sup>49</sup> Year of establishment under legislation, not date of first operations.

<sup>23</sup> Council Regulation 337/75/EEC establishing a European Centre for the Development of Vocational Training, OJ 1975 No. L39/1.

<sup>24</sup> Council Regulation 1365/75/EEC on the creation of a European foundation for the improvement of living and working conditions, OJ 1975 No. L139/1.

<sup>25</sup> Council Regulation 1360/90/EEC establishing a European Training Foundation, OJ 1990 No. L131/1, as amended by Council Regulation 2063/94/EC amending Regulation 1360/90/EEC establishing a European Training Foundation, OJ 1994 No. L216/9; Council Regulation 1572/98/EC amending Regulation 1360/90/EEC establishing a European Training Foundation, OJ 1998 No. L206/1; and Council Regulation 2666/00/EC on assistance for Albania, Bosnia and Herzegovina, Croatia, the Federal Republic of Yugoslavia and the Former Yugoslav Republic of Macedonia, repealing Regulation 1628/96/EC and amending Regulations 3906/89/EEC and 1360/90/EEC and Decisions 97/256/EC and 1999/311/EC, OJ 2000 No. L306/1.

- <sup>26</sup> Council Regulation 2309/93/EEC laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ 1993 No. L214/1.
- <sup>27</sup> Council Regulation 40/94/EC on the Community trade mark, OJ 1994 No. L11/1.
- <sup>28</sup> Council Regulation 2062/94/EC establishing a European Agency for Safety and Health at Work, OJ 1994 No. L216/1; Council Regulation 1643/95/EC amending Regulation 2062/94/EC establishing a European Agency for Safety and Health at Work, OJ 1995 No. L156/1.
- <sup>30</sup> Council Regulation 2965/94/EC setting up a Translation Centre for bodies of the European Union, OJ 1994 No. L314/1; Council Regulation 2610/95/EC amending Regulation 2965/94/EC setting up a Translation Centre for bodies of the European Union, OJ 1995 No. L268/1.
- <sup>31</sup> Council Regulation 2100/94/EC on Community plant variety rights, OJ 1994 No. L227/1; Council Regulation 2506/95/EC amending Regulation 2100/94/EC on Community plant variety rights, OJ 1995 No. L258/3.
- <sup>32</sup> Council Regulation 302/93/EEC on the establishment of a European Monitoring Centre for Drugs and Drug Addiction, OJ 1993 No. L36/1; Council Regulation 3294/94/EC amending Regulation 302/93/EEC on the establishment of the European Monitoring Centre for Drugs and Drug Addiction, OJ 1994 No. L341/7.
- <sup>33</sup> European Parliament and Council Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 No. L031/1.
- <sup>34</sup> European Parliament and Council Regulation 1592/2002/EC on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, OJ 2002 No. L240/1.
- <sup>35</sup> European Parliament and Council Regulation 1406/2002/EC establishing a European Maritime Safety Agency, OJ 2002 No. L208/1.
- <sup>36</sup> European Parliament and Council Regulation 460/2004/EC establishing the European Network and Information Security Agency, OJ 2004 No. L77/1.
- <sup>37</sup> European Parliament and Council Regulation 851/2004/EC establishing a European Centre for Disease Prevention and Control, OJ 2004 No. L142/1.
- <sup>38</sup> European Parliament and Council Regulation 881/2004/EC establishing a European Railway Agency (Agency Regulation), OJ 2004 No. L220/3.
- <sup>39</sup> Council Regulation 2007/2004/EC establishing a European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union, OJ 2004 No. L349/1; European Parliament and Council

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### Notes to Table 3.1. (cont.)

Regulation 863/2007/EC establishing a mechanism for the creation of Rapid Border Intervention Teams and amending Council Regulation 2007/2004/EC as regards that mechanism and regulating the tasks and powers of guest officers, OJ 2007 No. L199/30.

- <sup>40</sup> Council Regulation 1321/2004/EC on the establishment of structures for the management of the European satellite radionavigation programmes, OJ 2004 No. L246/1.
- <sup>41</sup> Council Regulation 768/2005/EC establishing a Community Fisheries Control Agency and amending Regulation 2847/93/EEC establishing a control system applicable to the common fisheries policy, OJ 2005 No. L128/1.
- <sup>42</sup> European Parliament and Council Regulation 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation 793/93/EEC and Commission Regulation 1488/94/EC as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ 2006 No. L396/1.
- <sup>43</sup> Council Regulation 168/2007/EC establishing a European Union Agency for Fundamental Rights, OJ 2007 No. L53/1.
- <sup>44</sup> European Parliament and Council Regulation 1922/2006/EC on establishing a European Institute for Gender Equality, OJ 2006 No. L403/9.
- <sup>45</sup> Council Joint Action 2001/555/CSFP on the establishment of a European Union Satellite Centre, OJ 2001 No. L200/5.
- <sup>46</sup> Council Joint Action 2001/554/CSFP on the establishment of a European Union Institute for Security Studies, OJ 2001 No. L200/1.
- <sup>47</sup> Council Joint Action 2004/551/CFSP on the establishment of the European Defence Agency, OJ 2004 No. L245/17.
- <sup>48</sup> Council Act drawing up the Convention based on Article K.3 of the Treaty on European Union, on the establishment of a European Police Office (Europol Convention), OJ 1995 No. C 316/1.
- <sup>49</sup> Council Decision 2002/187/JHA setting up Eurojust with a view to reinforcing the fight against serious crime, OJ 2002 No. L63/1.

For the purpose of this chapter, we regard regulatory agencies as broader than in the American sense, and consider them to be independent legal entities created by secondary legislation in order to help regulate a particular sector at the European level, and to help implement a particular Community policy regime. These agencies thus play an active role in exercising executive powers at the EU level. We thus closely link to the usage that is common in the 'Brussels circuit'.<sup>50</sup> A regulatory agency in the EU context has the following characteristics: it is created by a (European Parliament and) Council act; it has its own domestic legal personality; it comprises autonomous management bodies; it exercises financial independence; and it operates to a set of well-defined missions and tasks.<sup>51</sup>

Most of the agencies are mandated to collect and disseminate information and otherwise have merely advisory powers. This is also true of the health-oriented agencies: the European Drugs and Drug Addiction Monitoring Centre, which has the provision and supervision of information, along with creating and coordinating relevant networks, as its main tasks; the European Medicines Agency, which issues expert opinions on the market access of new drugs in the EU and monitors their post-approval safety; and the European Food Safety Authority, which is mandated to collate data and information and to provide well-informed, independent scientific opinions on food safety issues. Indeed, the EMEA and EFSA, which are otherwise regarded as strong agencies because of their risk analysis and recommendation-issuing

<sup>50</sup> See European Commission, 'Draft interinstitutional agreement on the operating framework for the European regulatory agencies', COM (2005) 59 final, 25 February 2005, p. 5; European Commission, 'European agencies – the way forward', COM (2008) 135 final; and SEC (2008) 323, 11 March 2008.

<sup>51</sup> A conceptualization proposal was tabled by the Commission's Legal Service, SEC (2001) 340, cited in A. Quero, 'Report by the working group 3a. Establishing a framework for decisionmaking regulatory agencies', SG/8597/01EN, Preparation of the White Paper on Governance Work – Improving the Exercise of Executive Responsibilities, June 2001. The EU's web site has a dedicated 'Agencies of the EU' page ([http://europa.eu/agencies/index\\_En.htm](http://europa.eu/agencies/index_En.htm)), which defines a Community agency as 'a body governed by European public law; it is distinct from the Community Institutions (Council, Parliament, Commission, etc.) and has its own legal personality. It is set up by an act of secondary legislation in order to accomplish a very specific technical, scientific or managerial task, in the framework of the European Union's "first pillar".'

roles in sensitive and often highly technical policy domains (versus the more information gathering and dissemination roles of other agencies) – not to mention their underlying aim to protect the public from harm – do not take legally binding decisions. Both provide scientific advice to the Commission on the basis of which it then adopts and delivers a decision.

It is a function of the Commission's lack of technical and specialized expertise, as well as its inability to keep pace across a multitude of policy areas, that EU regulatory agencies are being developed in such numbers. Given public interest concerns, and the often scientific nature of policies involving health considerations, it is perhaps unsurprising that European agencies exist in the medicines and foodstuffs domains. On the other hand, with health policy a comparatively weak area of Community competence, and one that the Member States are especially sensitive about, perhaps it is a surprise that the EU has been able to set up agencies for medicine control and food safety. In order to help us understand why the two agencies were created and what they mean for health protection and national health systems in general, a brief overview of the 'Europeanization' of health protection is provided in the next section.

### **3. Europeanization of health protection and the emergence of 'health agencies'**

Social concerns – and health-specific issues in particular – were not among the initial designs in respect of the original 1951 Treaty of Paris.<sup>52</sup> But, in establishing the European Atomic Energy Community, the 1957 Treaty of Rome included a specific chapter on health and safety at work. This, in turn, led to initial European worker safety standards for protection against ionizing radiation and was subsequently extended to the wider population. The Treaty also established the European Economic Community, which aimed to promote economic growth, develop closer ties and raise living standards among the signatory countries. It was recognized that the Community's common economic interests would be served by improved social interests

<sup>52</sup> Article 55 of the 1951 Treaty of Paris made allowances for Member States' research and cooperation over the health and safety of workers in the coal and steel industries.

as well. This unintentional – or at least unspecified – spread of Community competence from one policy domain to another (in this case, from economic to social affairs), primarily via the need to serve the requirements of the internal market, has been dubbed ‘spillover’ in the European political science literature.

Chapter 5 of this volume considers the history and scope of EU public health competences in detail. But it is worth highlighting here several important developments that contributed to the thinking on, and eventual emergence of, health protection as an area for agency authority.

### A. Health protection and the treaties

The 1986 Single European Act (SEA) set out progress towards a ‘single European market’ by 1992 as an institutional corollary of the Commission’s 1985 programme on a new approach to technical harmonization and standards, which in essence announced a de-regulatory operation.<sup>53</sup> Spillover meant that health matters would now be pursued within this broader and primarily economic, market-serving context, despite it already being accepted that a single market would directly impact on a range of health (care) issues.<sup>54</sup> Even if it was not as explicit as some might have hoped,<sup>55</sup> the SEA thus established the legal basis for the single market to take consumer health protection requirements into consideration.

The 1992 Maastricht Treaty then sought to formally entrench public health protection as a constituent element in all areas of Community policy under a new Article 129.<sup>56</sup> The Treaty also

<sup>53</sup> European Commission, ‘Technical harmonisation and standards, a new approach’, COM (85) 19 final, 31 January 1985; European Commission, ‘Completion of the internal market’, White Paper, COM (85) 310 final, 14 June 1986.

<sup>54</sup> See M. Cadreau, ‘An economic analysis of the impacts of the health systems of the European single market’, in J. Kyriopoulos, A. Sissouras and J. Philalithes (eds.), *Health systems and the challenge of Europe after 1992* (Athens: Lambrakis Press, 1991); C. Altenstetter, ‘Health care in the European Community’, in G. Hermans, A. F. Casparie and J. H. Paelinck (eds.), *Health care in Europe after 1992* (Leiden: Dartmouth, 1992).

<sup>55</sup> See, for instance, G. Robertson, ‘A social Europe: progress through partnership’, *European Business Journal* 4 (1992), 10–6; P. Curwen, ‘Social policy in the European Community in light of the Maastricht Treaty’, *European Business Journal* 4 (1992), 17–26.

<sup>56</sup> The rhetoric proved stronger than the implementation, and Article 129 EC was criticized for being a simple statement of an objective, and one that was

introduced Article 3(b), the subsidiarity provision, whereby policy decisions were to be taken at the level most appropriate to their implementation. The aim was to ensure a transparent legislative process, which ensured that not all policy would be set in Brussels, but it in essence meant a Treaty-based veto on Commission involvement in those affairs over which the Member States wished to retain autonomy. Yet, while health is generally considered to be such an area, and health care and health services (provision, financing, organization) particularly so, subsidiarity has not in fact impeded the Commission from gradually acquiring a greater health protection role than envisaged. Viewed from a broad perspective, therefore, the Community has actually developed itself into a 'leader' with regard to ensuring product safety (especially in medicines and foodstuffs), albeit mainly driven by its internal market aspirations.

The revision of Article 129, which was replaced by Article 152 in the 1997 Treaty of Amsterdam, meant that a high level of human health protection was now to be ensured in the definition and implementation of all Community policies and activities. As this was defined primarily in terms of 'the fight against the major health scourges' (and in the immediate aftermath of the BSE crisis), it was, however, seen as a missed opportunity to consolidate public health within the Community's competences.

Further Europeanization has come in large part via rulings of the European Court of Justice (ECJ), and specifically in relation to free movement issues.<sup>57</sup> We see this not only in respect of free movement of persons, such as patient mobility, health insurance and the reimbursement of medical costs, but also in respect of free movement of goods, such as product safety. By allowing Member States to create or maintain barriers to trade that were justified to protect public health, the Court forced the Community institutions to undertake Community action on these issues to remove trade barriers. While it is clear, therefore, that the EU's shift into the health domain was largely driven by the development of economic interests, spillover cannot on its own

ill-defined in practical terms, as no details or measures on how to achieve it were set out.

<sup>57</sup> See, for instance, E. Mossialos and M. McKee, 'Is a European health care policy emerging?', *British Medical Journal* 323 (2001), 248; M. McKee and E. Mossialos, 'Health policy and European law: closing the gaps', *Public Health* 120 (2006), Supp: 16–20; T. Hervey, 'EU law and national health policies: problem or opportunity?', *Health Economics, Policy and Law* 2 (2007), 1–6, who also question the direction EU of health care competences.

explain the Community's – in particular, the Commission's – involvement in medicines and food safety and the creation of the EMEA and EFSA.<sup>58</sup> For that, we observe that both agencies can trace their origins to a crisis in the respective policy domain.

### *B. The 'European' dimension to health protection in pharmaceuticals and foodstuffs*

The thalidomide tragedy of the 1950s was the sharpest possible wake-up call regarding the need to regulate medicines. In Europe, this was heightened given the transnational dimension of an emerging free market. The result was the establishment of strict regulatory measures and regimes at the national and Community levels, both with regard to the grounds for granting a medicine market access and for post-approval follow-up. It was a similar situation for foodstuffs. Despite a host of food scares during the 1980s and 1990s (e.g., e-coli, salmonella, dioxins), it was not until the BSE crisis in 1996 that the Commission recognized the need for an integrated and systematic approach to regulating foodstuffs and food safety within the EU, ultimately leading to the creation of EFSA. That said, food issues have been on the EU agenda since the 1960s in respect of cross-border agricultural trade and a 'European trading environment that fostered transnational society in the production, distribution and consumption of food'.<sup>59</sup> Without detailing the histories of European medicines and foodstuffs/food safety regulation, a few milestones are noteworthy in respect of our interest in the EU's risk analysis role and eventual establishment of the EMEA and EFSA.<sup>60</sup>

<sup>58</sup> For a discussion on the merits and failings of a neo-functionalist explanation of how health became an area of Community competence, see E. Mossialos and G. Permanand, 'Public health in the European Union: making it relevant', London School of Economics (LSE) Health Discussion Paper 17 (2000).

<sup>59</sup> E. Randall, 'Not that soft or informal: a response to Eberlein and Grande's account of regulatory governance in the EU with special reference to the European Food Safety Authority (EFSA)', *Journal of European Public Policy* 13 (2006), 402–19.

<sup>60</sup> For detailed reviews of these histories see, respectively, G. Permanand, *EU pharmaceutical regulation: the politics of policy-making* (Manchester: Manchester University Press, 2006); and E. Vos and F. Wendler, 'Food safety regulation at the EU level', in E. Vos and F. Wendler (eds.), *Food safety regulation in Europe* (Antwerp: Intersentia, 2006).



For the pharmaceutical sector, the first milestone came in the aftermath of the thalidomide tragedy, when, in keeping with the proliferation of national medicine laws and regulations, the European Economic Community instituted its own legislation in 1965.<sup>61</sup> The first piece of Community legislation in the pharmaceuticals field, Directive 65/65/EEC, defined a medicinal product within the European market context and stipulated rules regarding the development and manufacture of medicines in the Community, along with initial guidelines for post-market monitoring. Importantly, it established safety, efficacy and therapeutic benefit as the sole grounds for marketing approval. These criteria form the basis of the EMEA's mandate today.

A second milestone was the 1975 establishment of a 'mutual recognition' procedure<sup>62</sup> and the Committee for Proprietary Medicinal Products (CPMP).<sup>63</sup> With the Commission's attention on removing trade barriers between Member States, the aim was to speed up marketing applications for new medicines and to alleviate the burden of applications being made separately to each national authority. The Committee was to act as the single authorization and arbitration body for the Community market. The mutual recognition idea was perhaps good in theory but not in practice. The Member States remained unmoved by the procedure and turned to the public health exception in the free movement rules (formerly Article 36 EC, now Article 30 EC) to object to medicines being made available in their markets without their own assessment. In an effort to address such failings, the Commission introduced the 'multistate' procedure in 1983.<sup>64</sup> This saw the minimum number of countries to which authorization could be extended drop from five to two. While the number of applications submitted via the

<sup>61</sup> Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ 1965 No. L22/369.

<sup>62</sup> Council Directive 75/318/EEC on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products, OJ 1975 No. L147/1.

<sup>63</sup> Second Council Directive 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, OJ 1975 No. L147/13.

<sup>64</sup> Council Directive 83/570/EEC amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, OJ 1983 No. L332/1.

new procedure was higher than for mutual recognition, it proved cumbersome and was not favoured by the industry. Companies preferred the national route as being easier to negotiate and often for reasons related to the marketing and pricing of their medicines.

The 1986 SEA and the vision of a single market by 1992 is a third milestone. For, as part of this direction, the Commission introduced the 'concertation' procedure in 1987.<sup>65</sup> This applied only to biotechnologically-developed and other high technology products, but again with a view to speeding up the authorization process. Additionally, the so-called 'Transparency Directive', which obliged the Member States to adopt verifiable criteria vis-à-vis their pricing of medicines and their inclusion in national health insurance systems, was agreed in 1989.<sup>66</sup> Further legislation pertaining to, *inter alia*, good manufacturing practice, labelling, patent protection, advertising and sales promotion, and wholesale distribution<sup>67</sup> all followed within this free movement context.

In 1993 came the fourth milestone, with legislation creating the European Agency for the Evaluation of Medicinal Products (now the European Medicines Agency). Opened in 1995, and subsuming the CPMP, the EMEA was to provide scientific advice on all applications for marketing authorization within the Community, and

<sup>65</sup> Council Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology, OJ 1987 No. L15/38.

<sup>66</sup> Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems, OJ 1989 No. L40/8.

<sup>67</sup> Commission Directive 91/356/EEC laying down the principles and guidelines of good manufacturing practice for medicinal products for human use, OJ 1991 No. L193/30; Council Directive 92/27/EEC on the labelling of medicinal products for human use and on package leaflets, OJ 1992 No. L113/8; Council Regulation 1768/92/EEC concerning the creation of a supplementary protection certificate for medicinal products, OJ 1992 No. L182/1; Council Directive 92/26/EEC concerning the classification for the supply of medicinal products for human use, OJ 1992 No. L113/5; Council Directive 92/25/EEC on the wholesale distribution of medicinal products for human use, OJ 1992 No. L113/1. See, further, L. Hancher, *Regulating for competition. government, law, and the pharmaceutical industry in the United Kingdom and France* (Oxford: Clarendon Press, 1990); L. Hancher, 'The European pharmaceutical market: problems of partial harmonisation', *European Law Review* 15 (1990), 9–33; and L. Hancher, 'Creating the internal market for pharmaceutical medicines – an Echternach jumping procession?', *Common Market Law Review* 28 (1991), 821–53.

was empowered with a new centralized procedure<sup>68</sup> under which all applications were made directly to the agency, but with the Commission still adopting the final and binding decision. Importantly, the new regime was not intended to affect the powers of the Member States to set the prices of medicines or to include them in the scope of national health systems or social security schemes.<sup>69</sup> This remains the case today. The EMEA is nonetheless regarded as a success in having minimized the administrative burden of new applications and expedited the authorization of new medicines in the EU, even if it is not clear that this has translated into quicker access for patients. Revised legislation strengthening the operations of the agency, which came into force in 2005,<sup>70</sup> has since sought to build on this success.

In the food sector too, we can discern several milestones in the Europeanization process. Until the 1986 BSE crisis, the Commission had used its comitology structure to reconcile tensions between food safety issues and sensitivities at the national level, and free trade and market harmonization goals at the European level. Rules and policies were created on a piecemeal basis, and sometimes via jurisprudence through the ECJ. From 1974, the Commission had a risk assessment body to which it could turn for advice on public health concerns in the area of food consumption: the Scientific Committee for Food (SCF).<sup>71</sup> More importantly than the Commission simply having a consultative body is that the SCF was able to raise issues with the Commission on its own accord. In matters of risk management, the Commission had already created the Standing Committee on Foodstuffs (StCF) in 1969, and it considered all foodstuffs-related questions that fell within the Commission's competences. Not only could the StCF raise issues itself, but the Member States could themselves seek advice from the Committee directly. To deal specifically with crises, the Commission established a rapid-response unit within the Directorate-General for Agriculture and Rural Development (DG Agriculture) in 1984.

<sup>68</sup> Council Directive 93/39/EEC amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products, OJ 1993 No. L214/22.

<sup>69</sup> Article 1, European Parliament and Council Regulation 726/2004/EC laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 No. L136/1.

<sup>70</sup> *Ibid.*

<sup>71</sup> The Scientific Veterinary Committee (SVC) was also established.

The Commission and the Member States were satisfied with this committee arrangement until the BSE crisis exposed its failings. BSE was not simply an ‘accident’, but rather the consequence of intensive farming practices exacerbated by poor institutional management and regulation. Given that StCF discussions had perhaps become more collegial than rigorous,<sup>72</sup> and British interests – which had dominated the relevant scientific committee, the Scientific Veterinary Committee – had downplayed the risks of BSE for humans,<sup>73</sup> the need for a structured and systematic approach was a recommendation of the European Parliament’s 1997 Medina Ortega report into the handling of the crisis.<sup>74</sup> The scientific committees were thus combined and absorbed within the Consumer Affairs Directorate-General of the Commission (now the Directorate General for Health and Consumers, DG SANCO). At the same time, the Food and Veterinary Office (FVO) was set up as part of DG SANCO, though located in Ireland, and a broader intersectoral and intrasectoral integration of food safety policy resulted.<sup>75</sup> As the Medina Ortega report had concluded that public health interests had been subverted in favour of producer and economic interests, public health protection in respect of foodstuffs was now high on the Commission agenda and on its way to becoming a European, rather than Member State, matter.<sup>76</sup>

In the following years, a recipe for a new Community approach was designed.<sup>77</sup> The so-called ‘from farm to fork’ precept (i.e., introducing

<sup>72</sup> Vos and Wendler, *Food safety regulation*, above n.60.

<sup>73</sup> Krapohl, ‘Thalidomide, BSE and the single market’, above n.12.

<sup>74</sup> European Parliament, ‘Report on the alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and the national courts’, A4-0020/97/a, PE 220.544/Fin/A, 7 February 1997.

<sup>75</sup> T. Ugland and F. Veggeland, ‘Experiments in food safety policy integration in the European Union’, *Journal of Common Market Studies* 44 (2006), 607–24.

<sup>76</sup> The BSE crisis is also seen as having promoted European health ministers into a ‘knee jerk’ political revision of (old) Article 129 EC, resulting in the somewhat rushed (current) Article 152 EC. Health ministers were under pressure to show not only how such a crisis could be prevented in the long term, but also how it would be addressed in the short term. See, for instance, H. Stein, ‘The Treaty of Amsterdam and Article 129: a second chance for public health in Europe?’, *Eurohealth* 3 (1997), 4–8.

<sup>77</sup> European Commission, ‘General principles of food law in the European Union’, Green Paper, COM (97) 176 final, 30 April 1997; European Commission, ‘Food safety’, White Paper, COM (99) 719 final, 12 January 2000.

traceability) became a key plank in the efforts to re-establish consumer confidence. In turn, it resulted in 2002 in the adoption of the 'General Food Law'.<sup>78</sup> This sought to address safety concerns in tandem with internal market requirements, and with risk analysis at its heart – thus going beyond public health protection to covering wider consumer issues as well (e.g., labelling). Procedures and standards for ensuring safe foods within the EU were also set down. These paved the way for the eventual creation of EFSA as a centralized body, and one which would work in a transparent and accountable fashion towards rebuilding confidence and protecting public health. This, at least, is the view of those involved, for not all commentators would agree. Giandomenico Majone, who has long championed the regulatory agency model at EU level, said of the White Paper on food safety's vision for a food agency: 'once more bureaucratic inertia and vested interests, at national and European levels, have prevented the emergence of much needed institutional innovation'.<sup>79</sup> Others have simply summed up the creation of EFSA as a 'political, rather than science-based solution',<sup>80</sup> since the final agency model did not include any regulatory powers (only risk assessment and risk communication), and would not therefore help in streamlining approvals and market authorization as many industry leaders and policy-makers had hoped.

### C. *Balancing single market priorities*

Despite the attention paid to health protection, it remains clear that the role of the single market in both domains should not be understated. In pharmaceuticals, the Commission, since its first piece of legislation in 1965, has sought to achieve some harmonization of Member State markets, and there is now a raft of legislation.<sup>81</sup> Nevertheless, the Member States have consistently blocked Commission initiatives

<sup>78</sup> European Parliament and Council Regulation 178/2002/EC laying down the principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002 No. L31/1.

<sup>79</sup> G. Majone, 'The politics of regulation and European regulatory institutions', in J. Hayward and A. Menon (eds.), *Governing Europe* (Oxford: Oxford University Press, 2003).

<sup>80</sup> L. Buoninno, S. Zablutney and R. Keefer, 'Politics versus science in the making of a new regulatory regime for food in Europe', *European Integration Online Papers* 5 (2001), 1.

<sup>81</sup> For a full listing, see EudraLex Volume 1, <http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/homev1.htm>.

towards market integration, often turning to the subsidiarity principle. We see this primarily in respect of pricing and reimbursement, where, after accepting the impossibility of top-down harmonization, the Commission has sought greater alignment of Member State policies. The Commission's view is that a more harmonized market is in the interests of both consumers and producers (not to mention Member States and the EU as well). But the prospect of harmonized prices and loss of Member State autonomy in respect of health care spending under a single market remain taboo to many national policy-makers. Yet, we have the EMEA, which, in issuing recommendations on marketing authorizations, is not only one of the EU's most powerful agencies, but has a direct impact on national health care decisions.

A similar situation exists for foodstuffs. Although the market is perhaps more harmonized than for medicines, it still does not represent a single market per se. And, while the health complexities of pharmaceutical regulation were recognized from the outset, for foodstuffs this recognition became clearer only as more legislation was introduced. This includes both horizontal and vertical legislation, such as that relating to additives or food agents, or specific food categories such as chocolate and honey. As with medicines, the number of individual legislative instruments for foodstuffs is considerable. However, unlike for drugs, where internal market imperatives followed the need to regulate on health grounds, initial foodstuffs regulation was concerned with overcoming barriers to trade and promoting the free movement of products, with the health protection element developing later in the wake of a number of food scares. It is something of an irony that, at the time EU pharmaceutical regulation was being consolidated, EU foodstuffs regulation was subject to a complete re-assessment.

Their respective health protection impetuses notwithstanding, the Commission clearly views EFSA and the EMEA as instruments of the internal market. The Commission has often regarded national food safety provisions as barriers to trade, and has seen various harmonization initiatives be rejected by Member States. We see this even in respect of the BSE crisis, which revealed that some Member States may have been taking advantage of the EU's pre-existing administrative (cum regulatory) structure to forward their own interests.<sup>82</sup>

<sup>82</sup> See G. Majone, 'The credibility crisis of Community regulation', *Journal of Common Market Studies* 38 (2000), 273–302.

Additionally, a number of Member States that had opposed earlier Commission efforts to promote harmonization within the sector simply banned British beef outright.<sup>83</sup> The same applies for pharmaceuticals pre-EMEA. The Member States did not otherwise accept the mutual recognition concept in practice, and generally cited public health concerns as grounds for not accepting other countries' medicines in their own markets. That this was actually in order to protect domestic industry or to discriminate against the reimbursement of imported products is generally acknowledged. So, although each has a health crisis as its spur, the end result for both agencies is that their mandates cover not just health protection via the application of strict regulatory criteria in accordance with scientific expertise, but also ensuring that the free movement of products in their respective sectors is enabled to the highest degree possible.

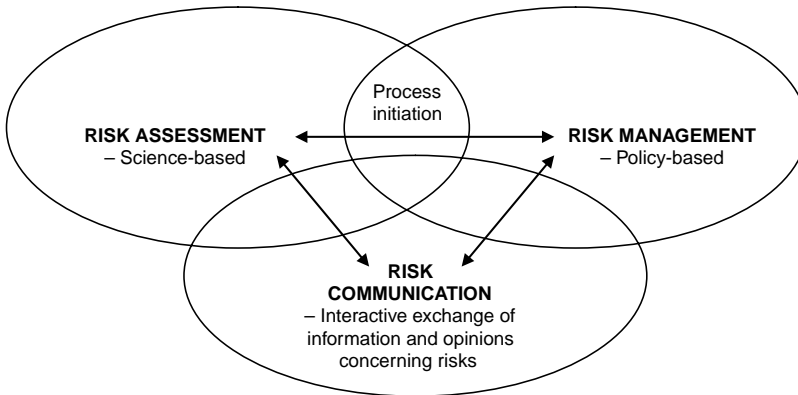
#### **4. Health (care), the European Medicines Agency and the European Food Safety Authority**

Comparing the regulation of medicines and foodstuffs in the EU necessarily highlights some differences, but there are certain similarities to consider in view of the aims and functions of EMEA and EFSA.

In both arenas, not only must the products be accessible and safe to consume, but consumers can expect to be informed where this is not the case and protected when it is. This implies a commitment to risk analysis, comprising the distinct elements of risk assessment, risk communication and risk management (see Figure 3.1). There are also informational asymmetries that characterize both sectors, and that regulators can help to mitigate through improved communication and greater operational transparency. At the EU level, regulation is also concerned with standard policies and guidelines within the single market.

A background point to be borne in mind is that one of the main differences between the two sectors lies in the timing of regulatory intervention. For medicines, notwithstanding that most national agencies have a role in pharmacovigilance, the emphasis is on pre-market regulation. Since Directive 65/65/EEC, quality, safety and efficacy are

<sup>83</sup> When it became clear just how considerable the spread (and threat) of BSE was – not to mention the lack of accountability that was revealed – a consensus emerged that common European policies were in the Member States' interest, in turn contributing to consensus over the formation of EFSA.



**Figure 3.1 Risk analysis**

Source: [www.who.int/foodsafety/micro/riskanalysis/en/](http://www.who.int/foodsafety/micro/riskanalysis/en/)

the sole approval criteria for new medicines, with the assessment of applications representing the main element of the EMEA's work. For foodstuffs, the considerable fragmentation of the market precludes much *ex ante* testing and the focus is thus post-market. While pharmaceutical regulation has involved public authorities, foodstuffs have generally relied on self-regulation by producers and retailers; governments are usually involved in setting content requirements, limits and labelling laws. As the growing number of national food safety agencies in Europe shows, this is changing – in part because of food scares, but also because of increasing levels of production, high technology approaches to farming, the considerable use of additives and chemicals in food, along with the potential opportunities and threats raised by globalization. We thus see an increasing trend towards pre-market control and the setting into place of authorization procedures.

### *A. Core functions and the politics of scientific advice*

The EMEA began operations in 1995, replacing the Community's earlier approval mechanisms. The crux of its role lies in assessing marketing authorization applications for new medicinal products via either a centralized or decentralized procedure. The former represents the mandatory application route for certain products<sup>84</sup> and involves the

<sup>84</sup> Centralized approval is required for biotechnology-derived products, orphan drugs, products containing a new active substance not previously authorized



relevant committee delivering an opinion. There is a Committee for Medicinal Products for Human Use (CHMP), a Committee for Orphan Medicinal Products (COMP), a Committee on Herbal Medicinal Products (HMPC) and, since 2007, a Paediatric Committee (PDCO). Following a committee opinion, the Commission then issues a formal EU-wide decision (the Standing Committee on Medicinal Products for Human Use has an important say on behalf of the Member States). Applications are subject to two assessments undertaken by Member State medicines agencies acting as rapporteurs. The latter, essentially a mutual recognition procedure, involves one Member State granting a product a licence, after which multiple national authorizations can be issued without the need for separate applications. This is the process for conventional products and allows Member States to register a formal objection.<sup>85</sup> Should a manufacturer seek to launch a product in only one Member State, the application is simply made to the national agency concerned (the relevant EMEA committee is called upon only if adjudication becomes necessary).

Among other tasks, the EMEA provides scientific advice and incentives to help stimulate the development of new medicines, and works towards developing best practice for medicines evaluation and supervision in Europe. Pharmacovigilance is part of the agency's mandate and, since 2005, it has maintained the public access 'Eudravigilance' database, which is a network and management system for reporting and evaluating suspected adverse reactions during the development and post-approval phases of medicines (it also operates a Europe-wide clinical trials database). The agency has a role in undertaking inspections, either through its own capacity or by coordinating Member State activities in this direction. With national medicines agencies directly involved in the EMEA regime – the above-

in the EU, and medicines for the treatment of HIV/AIDS, cancer, diabetes or neurodegenerative disorders. By 2009, this will be extended to antiretrovirals and medicines designed to treat autoimmune and other immunological diseases. It is voluntary for other 'innovative' products. The definition of 'innovative' is not clear, but will cover drugs 'of major interest from the point of view of public health and in particular from the point of view of therapeutic innovation'. See Article 14(9), European Parliament and Council Regulation 726/2004/EC laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 No. L136/1.

<sup>85</sup> Member States may object and appeal on public health grounds, and the EMEA has a protocol in place to consider such instances.

mentioned ‘hub and spoke’ model – the regulation of medicines thus remains a joint EU–Member State competence.

EFSA opened its doors in 2002 and, similarly to the EMEA, was designed to integrate and replace the Community’s existing regulatory functions, which had failed over the BSE crisis. It may therefore be argued that it was a political rather than health crisis that led to the creation of EFSA,<sup>86</sup> but we may also differentiate the initial health crisis from the subsequent political scandal. EFSA’s primary tasks are four-fold: the provision of scientific advice and information, including issuing expert opinions and carrying out safety or risk assessments, along with technical support to the Community in respect of policy and legislation; collating and analysing information and data towards risk characterization and monitoring; to promote and facilitate the development of shared risk assessment approaches in the EU; and communicating risks in respect of the various elements of its mandate. The communication element of EFSA’s role is paramount given the agency’s origins in the BSE crisis and the need to engender confidence among consumers. EFSA is thus mandated to communicate directly to the public.

Comparable to the EMEA’s committees, EFSA has a series of area-specific scientific panels that undertake the risk assessments behind its opinions.<sup>87</sup> These opinions are forwarded to the Commission, which adopts a decision after receiving a favourable opinion from the Standing Committee on the Food Chain and Animal Health, composed of Member States representatives.<sup>88</sup> A further similarity is that EFSA does not supplant national agencies, although it does engage with them more directly than the EMEA. Both the EMEA and EFSA rely on national agencies for the scientific work behind their

<sup>86</sup> C. Clergeau, ‘European food safety policies: between a single market and a political crisis’, in M. Steffen (ed.), *Health governance in Europe: issues, challenges and theories* (London: Routledge, 2005).

<sup>87</sup> There are nine scientific panels: (a) additives, flavourings, processing aids and materials in contact with food; (b) animal health and welfare; (c) biological hazards; (d) contaminants in the food chain; (e) additives and products used in animal feed; (f) genetically modified organisms; (g) dietetic products, nutrition and allergies; (h) plant protection products or substances and their residues; and (i) plant health. At the time of writing, preparations are underway to split the first panel into two separate units.

<sup>88</sup> Should an unfavourable opinion be delivered, or in the absence of an opinion, the Commission’s draft decision is sent to the Council, which may adopt a decision.

evaluations. EFSA's role here has been seen as that of *primus inter pares*, as it coordinates national agencies' efforts, often in specific areas.<sup>89</sup> However, in view of its dependence on the national agencies as built into its organizational structure through its Advisory Forum, and partly due to a lack of resources, the importance of the Member States' agencies for EFSA's scientific work is likely to increase. It is important to note that, given its strong communication focus, just like the EMEA, EFSA does not assume responsibility for Community or Member State food safety legislation. Moreover, it is not in charge of labelling, inspections or other food safety controls. Risk assessment and communication are the core of EFSA's mandate; risk management falls to the Commission and Member States.

The question of agenda-setting (and marketing authorization) is one where the two agencies differ. Unlike the EMEA, which requires an applicant product to begin its scientific evaluation and risk assessment work, EFSA is dependent on the Commission to essentially 'invite' it into a particular policy issue. Yet, the agency can also initiate an opinion on its own initiative, and thereby try to put the issue on the EU's decision-making agenda. In identifying the policy issues and controlling the policy space, the Commission thus remains the agenda-setter in the foodstuffs arena. This is not the case for medicines, where the Commission is not involved until the EMEA opinion has been sent.

Both agencies are committed to delivering the 'best possible' scientific advice, the former in respect of the safety, quality and efficacy of medicines, the latter in terms of risk assessments vis-à-vis foodstuffs. This shifting of the risk assessment function away from the Member States to the relevant scientific committee or panel represents a Europeanization of the science in both sectors and a commensurate depoliticization of the health protection function. That said, both sectors remain highly political, and foodstuffs especially so. It is therefore interesting to observe that, due to the increasing importance of science in these sectors, and the 'scientification' of politics, there is again high potential for a politicization of the science. This was the case in the pre-BSE food regulation era and, ironically perhaps, a phenomenon that post-BSE legislation and EFSA have sought to combat.

For instance, in 2006, EFSA's Deputy Executive Director stated that the agency feels the influence of national politics, and that it

<sup>89</sup> Vos and Wendler, *Food safety regulation*, above n.60.

has ‘sometimes [come] under pressure from the Commission to make or give a decision in a certain way’.<sup>90</sup> This is due to the fact that EFSA opinions form the basis of Commission decisions and are thus discussed by the college of Commissioners and, at times, put to a vote in the Council of Ministers. The politics of the Commission’s discussions is evident in the case of two genetically modified (GM) maize lines, Bt11 and 1507.<sup>91</sup> Despite EFSA’s view that they were safe, then Agriculture Commissioner Stavros Dimas opposed their approval in 2007. Other Commissioners were in favour and discussions – irrespective of the science – thus continued. As for EFSA’s exposure to national politics, with qualified majority voting required in the Council, the Member States can effectively block one another. Moreover, it means under comitology procedures that they can collectively impede the Commission’s draft decisions despite these being based on EFSA’s scientific opinion, as has occurred in many cases of GM authorizations. At the same time, it is interesting to observe that the Member States may in fact use scientific arguments during the comitology process in their attempts to block the Commission’s draft authorizations, which are based on EFSA’s opinions. Faced with a request to look at these arguments, EFSA has often declined to do so in detail, and considers these arguments to be often more political than scientific. It is something of a paradox, then, that as EFSA seeks to keep scientific risk evaluation independent, by separating assessment from management, the science itself is becoming politicized as the health protection function is taken away from Member States.

For the EMEA, the politics are perhaps less immediate, but the fact that the opinions delivered by the CHMP are generally accepted by the Commission leads to two lines of thinking. First, that this may be an indication of the strength of the science (and/or the Commission’s lack of capacity to validate it). Indeed, the Committee’s opinions are delivered as finished documents in the expectation that the Commission can issue them as they are and without undue delay. Second, that this reflects the acceptability of the position to the Member States. For, unlike in the case of EFSA’s opinions, where the (panels of the

<sup>90</sup> H. Koeter, as interviewed in A. El Amin, ‘EU’s food agency battles attempts to hijack science’, *Food Quality News*, 21 September 2006, [www.foodqualitynews.com/news/ng.asp?id=70720-efsa-health-claims-antibiotics](http://www.foodqualitynews.com/news/ng.asp?id=70720-efsa-health-claims-antibiotics).

<sup>91</sup> GMOs are authorized at the EU level based on EFSA’s risk evaluation, although no GM crops have been approved in the EU since 1998.

Standing Committee on the Food Chain and Animal Health convenes to discuss every proposal, the Medicines Standing Committee is given thirty days to respond in writing to an opinion, with the proposal accepted if no response is received. The Committee's members are, in the main, from the same regulatory authority as the CHMP (or other evaluation committee) members. Ellen Vos thus ascribes the Commission's general policy of endorsement to the fact that a normative or 'nationally-flavoured' element is taken to be implicit within the assessments delivered by the Committee (and the Commission would rather not contradict the Member States).<sup>92</sup> This contributes to the contention that the Member States view the EMEA's opinions as more credible than those of EFSA and that, as a result, the latter will not become as strong or successful as the former.<sup>93</sup> In this manner, we can interpret the reinforcement of the role of Member States within and around EFSA as the Commission's and EFSA's attempt to overcome the decisional deadlock on matters surrounding genetically modified organisms (GMOs).

The fact that neither agency has the executive power to regulate in the manner of an independent regulatory agency such as the United States Food and Drug Administration (FDA) is in large part due to the political and institutional constraints surrounding the comparative roles and interests of the Commission and Member States in the health (care) arena, and the policy-making architecture of the EU polity itself.<sup>94</sup> Furthermore, the political interests at the national and supranational levels, far less the strength of producer interests within both policy domains, have also helped to ensure that power remains fractured. For EFSA, there are thus calls for increased centralization in order to decrease uncertainties, foster efficiency and increase consumer confidence.<sup>95</sup>

<sup>92</sup> E. Vos, 'European administrative reform and agencies', European University Institute Working Papers No. RSC 2000/31 (2000).

<sup>93</sup> Krapohl, 'Credible commitment', above n.12 .

<sup>94</sup> This relates to the imbalance or constitutional asymmetry between the Commission's economic and social policy competences, and has been shown to have had an effect on the EMEA's mandate and wider EU regime for pharmaceutical regulation. See G. Permanand and E. Mossialos, 'Constitutional asymmetry and pharmaceutical policy-making in the European Union', *Journal of European Public Policy* 12 (2005), 687–709.

<sup>95</sup> L. Caduff and T. Bernauer, 'Managing risk and regulation in European food safety governance', *Review of Policy Research* 23 (2006), 153–67.

## B. Good governance

Given the increasing public health impact of their roles, their aims to ensure public confidence and their impact on national health care priorities, it is therefore essential that EFSA and EMEA be independent, accountable and transparent in exercising (regulatory) authority. Furthermore, given the softer approach to regulation and policy-making espoused by new modes of governance thinking, a participatory approach – in so far as is possible – is also deemed to be a positive element. These are among the EU's own principles of good governance,<sup>96</sup> and tie into the Commission's Communication on the operating framework for the European agencies.<sup>97</sup> However, while these are stated objectives, questions remain over both agencies' commitment to these considerations.

## Independence

(Independent) regulatory agencies are to be above any interference from government or producers – or indeed from any other interested party. And while this may be the optimal view, in theory if not in practice, Scott notes that the Commission 'formula for the EU regulatory agencies' does not actually even aspire towards this: '[it] appears to represent, simultaneously, an embracing of the agency model, and a rejection of its development along the lines of the independent regulatory agency'.<sup>98</sup> Indeed, it may be argued that, given their various aspects of direct involvement in the agencies' work, the Commission, the European Parliament, the Member States and the industry all have some degree of influence.

All agencies are linked to the Commission via the relevant Directorate-General. For EFSA, this is DG SANCO (responsible for health and consumer protection); for the EMEA, it is the Directorate-General for Enterprise and Industry (responsible for industrial policy). Although the EMEA's institutional setting stems from its origins in the single market programme, it may legitimately be asked why the

<sup>96</sup> European Commission, 'European governance', White Paper, COM (2001) 428 final, 25 July 2001.

<sup>97</sup> European Commission, 'Operating framework', above n.16.

<sup>98</sup> C. Scott, 'Agencies for European regulatory governance: a regimes approach', in Geradin, Muñoz and Petit (eds.), *Regulation through agencies*, above n.9.

agency is linked to the 'business' arm of the Commission rather than the 'health' arm. This is especially the case in view of the concerns over the intertwining of business and health interests as raised by the Medina Ortega report on the BSE crisis. Indeed, several commentators, including several Members of the European Parliament (MEP), have raised queries in this direction.<sup>99</sup> That said, it should equally be acknowledged that a lack of expertise and capacity regarding the medicines sector more widely (e.g., industrial policy concerns or pricing and reimbursement issues) would seem to preclude DG SANCO from being solely responsible. This duality is in fact expressed in the composition of EMEA's management board, which has two Commission members, Heinz Zourek, acting Director-General of DG Industry, and Andrzej Ryś, Director of Public Health and Risk Assessment in DG SANCO. For EFSA, the Commission has one representative on the Board, the current Director-General of DG SANCO, Robert Madelin.

The Commission's links to the agencies via its representatives in the management boards are important, as these bodies oversee activities and are charged with the important tasks of agreeing the budget and choosing the executive director. It is noteworthy that, while both agencies are supposed to work at arm's length from the Commission, separating risk assessment from risk management, it is clear that there is a strong interface between the agencies and the Commission. In the case of EFSA, there is a 'grey zone' between the agency and the Commission in which they closely interact and where the separation is, in practice, not upheld in a clear-cut way. Moreover, several specific legislative acts assign the Commission the competence to review EFSA acts (e.g., regarding pesticides residues and GM food and feed). Furthermore, we can note how, by arguing that their acts are not mentioned in Article 230 EC, both agencies try to avoid such reviews by hiding behind the Commission. For instance, in a recent case where the EMEA had rejected an application for a variation to a marketing authorization, the Court of First Instance dismissed the applicant's appeal (directed against EMEA itself) on the basis that the EMEA

<sup>99</sup> See, for instance, S. Garattini and V. Bertele, 'Adjusting Europe's drug regulation to public health needs', *Lancet* 358 (2001), 64-7; and selected MEPs' letter to European Parliament in February 2002, [www.haiweb.org/campaign/DTCA/MariaNegristatementDTCA\\_files/lettertoeu.htm](http://www.haiweb.org/campaign/DTCA/MariaNegristatementDTCA_files/lettertoeu.htm).

was not listed among the institutions mentioned in Article 230 EC. However, it ruled that, as the EMEA had only been endowed with advisory powers, the EMEA's refusal must be deemed as emanating from the Commission itself and would hence be reviewable.<sup>100</sup> This kind of case-law may lead to the strange situation of the Commission being held responsible for acts<sup>101</sup> for which the legislator had clearly conferred responsibility on EMEA.<sup>102</sup>

The influence of Member States on the agencies' activities is clearer in the case of EMEA, given that its management board comprises one representative from each Member State. While such national representation does not, at first sight, seem compatible with an agency whose science is supposed to be above national interests, it is of course not the board that adopts EMEA's scientific opinions. That

<sup>100</sup> Case T-133/03, *Schering-Plough Ltd v. Commission and EMEA* (Order of CFI of 05.12.2007). The Court ruled that '[i]n so far as Regulation EC No. 2309/93 [laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJ 1993 No. L214/1] provides for only advisory powers for the EMEA, the refusal referred to in Article 5(4) of Commission Regulation EC No. 542/95 [concerning the examination of variations to the terms of a marketing authorization falling within the scope of Council Regulation 2309/93/EEC, OJ 1995 No. L55/15] must be deemed to emanate from the Commission itself. Since the contested measure is imputable to the Commission, it may be the subject of an action directed against that institution. It follows that the action must be dismissed as inadmissible in so far as it is directed against the EMEA'. See paras. 22 and 23. See also Case T-123/00, *Thomae v. Commission* [2002] ECR II-5193.

<sup>101</sup> In the case at stake, Case T-133/03, *Schering-Plough*, above n.100, the CFI nevertheless ruled that there was no longer any need to adjudicate on the action in so far as it was directed against the Commission.

<sup>102</sup> In Case T-133/03, *Schering-Plough*, above n.100, for example, the relevant provision was Article 5(4) of Regulation 542/95: '[w]here the Agency is of the opinion that the application cannot be accepted, it shall send a notification to that effect to the holder of the marketing authorisation within the period referred to in paragraph 1, stating the objective grounds on which its opinion is based:

- (a) within 30 days of receipt of the said notification, the marketing authorisation holder may amend the application in a way which takes due account of the grounds set out in the notification. In that case the provisions of paragraphs 1, 2 and 3 shall apply to the amended application;
- (b) if the marketing authorisation holder does not amend the application as provided for in (a) above, this application shall be deemed to have been rejected.'



said, members of the agency's scientific committees do represent the competent authorities of the Member States and are also appointed by the Member States, even if they are mandated to act in a non-partisan manner. EFSA, meanwhile, does not have Member State representatives on its management board – a fact that is unique among the European agencies<sup>103</sup> – and has independent scientific experts on its scientific committees who do not represent the competent authorities of the Member States. Nevertheless, a lack of resources and capacity (especially when compared with the United States FDA), as well as the above-mentioned decisional deadlock in GM cases, might lead EFSA to seek to strengthen its cooperation with national authorities, perhaps even to include them in its organizational structure.

The role of the European Parliament in respect of the agencies, although primarily institutional, is important. The Parliament sets the budget and the annual discharge, which affords it considerable influence. In the case of the EMEA, the Parliament also has two representatives (national experts appointed as impartial individuals) on the management board. The Commission has criticized this representation,<sup>104</sup> but the Parliament has insisted on having representatives as long as the Member States are also represented, pointing to the fact that it is not MEPs who are on the board but merely representatives of the Parliament.

The Parliament's power of budgetary oversight raises questions regarding the agencies' financial independence more generally. In the case of EMEA, of a total budget of €173 307 000 for the year 2008, the agency received 72.9% from applicant fees and 21.9% from the Commission. The remaining 5.2% came from other sources. Since the agency's establishment, the ratio of fees to direct Commission funding has continued to rise. This financial dependence on its clients has been criticized on several grounds, most important of which is perhaps that speed rather than quality of assessment will become the EMEA's focus.<sup>105</sup> Although the dangers of this type of fee-for-service arrangement are clear, it should not be forgotten that many national

<sup>103</sup> An advisory forum comprising Member State representatives responsible for risk assessment was created within EFSA as compensation.

<sup>104</sup> European Commission, 'Draft interinstitutional agreement', above n.50.

<sup>105</sup> See, for instance, J. Abraham and G. Lewis, *Regulating medicines in Europe: competition, expertise and public health* (London: Routledge, 2000); Garattini and Bertele, 'Adjusting Europe's drug regulation', above n.99.

medicines agencies in Europe are also heavily dependent on applicant fees (the United States FDA is also funded by user fees, amounting to almost one-fifth of its budget, which also reflects a rising amount). EFSA, on the other hand, derived its entire €66.4 million budget for 2008 from the EU budget, and the August 2007 findings of a DG SANCO consultation on the possibility of introducing applicant fees found support for the idea in only a limited set of cases.<sup>106</sup> This arrangement poses its own potential failings, for not only is EFSA institutionally to some extent linked to DG SANCO, but so too is it financially dependent on the Commission as well.<sup>107</sup>

We perhaps see this reflected in elements of EFSA's science-making, where it would appear that the agency's commitment to hard science is to be balanced with its principal's interests. Randall uses the example of the agency's position on genetically-modified organisms (GMOs):

Accepting a wide-ranging precautionary approach, leaving virtually all GM issues in a state of regulatory suspension, was anathema not only to the United States Government and American agribusiness, but also to EFSA, its exchequer (the Commission) ... EFSA chose to do what its most important customer, the Commission, expected it to.<sup>108</sup>

With the exception of the maize crops referred to earlier, the Commission has adopted all EFSA opinions in the GM arena.

As the aim of both agencies is to provide quality and objective information, this begins with the scientists. So what of the independence of the individual experts involved in the EMEA committees and EFSA panels? The 'older' medicines agency committees (e.g., the CHMP) are comprised of experts nominated by the Member States. The 'newer' ones (e.g., the HMPC) have members from the Commission, patient organizations and some agency nominations. All are required to sign declaration of interest forms, with EMEA members demonstrating that they have no ties to industry. The need for this was highlighted by the 'Poggiolini affair' of the early 1990s,

<sup>106</sup> DG SANCO, 'Summary of the comments received on the consultation paper on the advisability and feasibility of establishing fees for EFSA', August 2007, [http://ec.europa.eu/food/consultations/sum\\_cons\\_Efsa\\_fees\\_En.pdf](http://ec.europa.eu/food/consultations/sum_cons_Efsa_fees_En.pdf).

<sup>107</sup> The fact that both agencies are mentioned under the Commission's budget line also implies a certain dependence on the Commission.

<sup>108</sup> Randall, 'Not that soft', above n.59.

where Dulio Poggiolini, then head of both the former Committee for Proprietary Medicinal Products (CPMP, now CHMP) and the Italian drug agency, was accused of taking bribes and gifts from the industry.<sup>109</sup> In contrast, members of the scientific committee and panels of EFSA are selected on the basis of their scientific excellence after an open competition and nominated by the management board. Nevertheless, EFSA has experienced some controversies over conflicting interests as well. For instance, several members of its GMO panel had evaluated some products on behalf of their national agencies as well as for EFSA. Abstention over a conflict of interest is possible, although for the GMO panel it was decided that only where the representative was involved in the risk management element at home – not the scientific assessment – was there a conflict.<sup>110</sup> The committee and panel members' declarations are available on the respective web sites (for EFSA, they are renewed annually) and a register of names is publicly available – this was not initially the case when the EMEA first commenced operations. Meanwhile, EFSA has further sharpened its rules on declarations of interests.<sup>111</sup>

### Accountability

Accountability is, in general, a contentious subject in the supranational context. The unelected nature of the Commission and the ECJ in particular has led to a wide-spread notion of a 'democratic deficit' in the EU. Nevertheless, it is generally accepted that being accountable at the EU level means being accountable to the European Parliament, which comprises directly-elected representatives and exercises budgetary control. The Parliament's representation on the EMEA management board may help serve this accountability function, but, as these representatives have little direct contact with the Parliament, it appears more cosmetic than substantial.<sup>112</sup>

<sup>109</sup> See G. Permanand, *EU pharmaceutical regulation*, above n.60, p. 129.

<sup>110</sup> L. Levidow and S. Carr, 'Europeanising advisory expertise: the role of "independent, objective and transparent" scientific advice in agri-biotech regulation', *Environment and Planning C: Government and Politics* 25 (2007), 880–95.

<sup>111</sup> EFSA, 32nd Meeting of the Management Board, Bucharest, 11 September 2007.

<sup>112</sup> E. Vos, 'Independence, accountability and transparency', in Geradin, Muñoz and Petit (eds.), *Regulation through agencies*, above n.9.

What of public accountability more widely? Since the 2005 legislation was introduced, the EMEA management board has included two consumers' and one doctors' representatives. These representatives are appointed by the Council in consultation with the Parliament from a list chosen by the Commission. Patient representation may be seen as a key step towards improving accountability, and it followed concerted lobbying by consumer-oriented groups. But the Commission's nominations will need to be carefully scrutinized to ensure that no conflicts of interest arise (such as industry sponsorship). EFSA's management board comprises, in addition to the one Commission representative, fourteen independent experts (appointed by the Council in consultation with the Parliament, but on the basis of a Commission nomination), four of whom have experience with organizations promoting consumer or patient interests within the food chain. There is, however, no requirement that these experts be completely free of industry links, even if they are not permitted to receive payments. That said, failures to declare conflicts of interest have been noted in the case of the GMO panel.<sup>113</sup> It is not clear, therefore, that the current management board constellation of either agency really serves the interests of accountability. In fact, the argument could be made that the Commission, the European Parliament and the Member States (in the case of the EMEA), can all exert some control over the agency via their representatives.<sup>114</sup>

### Transparency

Related to independence and accountability is transparency. If a regulator is going to be successful in securing public trust, it needs to be as open and forthcoming as possible in respect of its activities generally, and of (scientific) decision-making specifically. Among other things, this means 'reason giving' – making decisions and dissenting views available, delivering timely responses, granting access to documentation and involving stakeholders. In the EU context, transparency most often means accessibility of documents, and, in this regard, both EFSA and the EMEA are subject to the EU's legislation

<sup>113</sup> Friends of the Earth, 'Throwing caution to the wind – a review of the European Food Safety Authority and its work on genetically modified foods and crops', November 2007, [www.foeeurope.org/GMOs/publications/EFSAreport.pdf](http://www.foeeurope.org/GMOs/publications/EFSAreport.pdf).

<sup>114</sup> *Ibid.*

on public access to European institutions' documents.<sup>115</sup> Their web sites therefore post a considerable amount of information, covering both the science and the administration and operations of the agencies. At the same time, they fall short in certain areas.

For instance, although it is potentially able to publish minority opinions, EFSA has, to date, not done so. The agency is obliged to look out for potential scientific divergences between various bodies and, in such cases, actively try to ensure agreement among the scientists. In instances where EFSA and another EU or Member State scientific authority may disagree, Article 30 of the 'General Food Law'<sup>116</sup> requires the two to try to resolve the disagreement between them. It is only where this is not possible that a (joint) document explaining the discrepancies is made public. More specifically, EFSA's GMO panel has been accused of 'selectively "front-stag[ing]" the most internally consensual and scientifically defensible arguments, thus selectively enacting transparency'.<sup>117</sup> So, while EFSA's advice is held up to be transparent on the basis of consent, the process of reaching the consensus is not necessarily made available. Moreover, it is not clear that the agency adequately states the scientific uncertainties in its opinions, and perhaps takes too black and white a view.<sup>118</sup> Addressing uncertainties might help risk management (by the Commission and Member States) in the public interest, but, on the other hand, it may also give the impression of poor science.

EMEA has a similar role as watchdog, looking out for potential scientific conflicts with a similar 'conflict clause',<sup>119</sup> and the transparency issue is one it has fought since its inception. The agency may want to be as open as possible, but commercial secrecy is a major concern in the pharmaceutical sector and the industry represents a strong actor. It is, therefore, understandable that sensitive information and data needs to be suppressed. However, if companies are able to anonymously withdraw products where a negative assessment is suspected, and the minutes of meetings to discuss marketing applications, the names of rejected

<sup>115</sup> European Parliament and Council Regulation 1049/2001/EC regarding public access to European Parliament, Council and Commission documents, OJ 2001 No. L145/43.

<sup>116</sup> Regulation 178/2002/EC, above n.78.

<sup>117</sup> Levidow and Carr, 'Europeanising advisory expertise', above n.110.

<sup>118</sup> M. Van Asselt, E. Vos and B. Rooijackers, 'Science, knowledge and uncertainty in EU risk regulation', in M. Everson and E. Vos (eds.), *Uncertain risks regulated* (London: Routledge-Cavendish, 2009).

<sup>119</sup> Article 59, Regulation 726/2004/EC, above n.69.

products and the reasons for rejection, not to mention the names of withdrawn products and the withdrawing companies, are not made available in the public domain, it is perhaps then unsurprising that the EMEA has in the past been heavily criticized for paying only lip-service to the idea of transparency. Most of this has changed under the 2005 legislation,<sup>120</sup> and reflects just how important (risk) communication is in terms of ensuring confidence in the regulator and in the sector more widely. It remains the case, however, that research information on clinical and preclinical trials, or information on evaluations, are not released (the FDA makes both available), while much of the material that is made public remains quite technical and inaccessible to the lay user.

### Participation

Related to transparency is the issue of wider participation and how public health concerns are taken on board in the agencies' assessments. In this regard, a 2003 Court of First Instance ruling vis-à-vis an EMEA opinion is instructive. In Case T-326/99,<sup>121</sup> Nancy Olivieri, a former clinical investigator of the active ingredient deferiprone, which had been given a favourable first opinion by the EMEA, presented new information in respect of the drug's potential toxicity and inefficacy in the treatment of thalassemia. After an initial suspension, the CPMP revisited the application at the Commission's request – though did not involve Dr Olivieri in the deliberations – and issued a revised, still favourable, opinion upon which the Commission issued an authorization of the drug Ferriprox. Dr Olivieri sought to have the Commission decision and the underlying EMEA revised opinion overturned. However, her demand was rejected, as the Court of First Instance held that she did not have an interest in bringing the proceedings in order to protect public health or in order to defend her professional reputation, and the complaint was declared inadmissible. An important element in this case was the Court's decision that, while third parties can be consulted with respect to scientific input, and can have special access when doing so on public health grounds, they do

<sup>120</sup> See, for example, G. Permanand, E. Mossialos and M. McKee, 'Regulating medicines in Europe: the European Medicines Agency, marketing authorisation, transparency and pharmacovigilance', *Clinical Medicine* 6 (2006), 87–90.

<sup>121</sup> Case T-326/99, *Olivieri v. Commission and European Agency for the Evaluation of Medicinal Products* [2003] ECR II-06053.

not have an automatic right to participate or be heard. Only when the Commission deems it 'indispensable in order to safeguard public health' can persons other than the marketing authorization holder be invited to share their observations.

The EU does nonetheless seek broader involvement of stakeholders, in particular civil society groups, as part of its good governance policy. Participation is a key tenet of the Commission's good governance criteria, and both agencies could do more in this respect. The EMEA has a Patients' and Consumers' Working Party, which provides recommendations to the EMEA and its human scientific committees on all matters of direct or indirect interest to patients in relation to medicinal products, but does not grant patients nearly the same degree of access to the evaluators as it does the industry. Meanwhile, EFSA, through its recently-established Stakeholders Platform, seeks to ensure a higher degree of stakeholder involvement in agenda-setting.

### **The role of industry**

Although not the focus of this chapter, a final element worthy of consideration – given that it impacts on their adherence to principles of good governance – is the agencies' relationship to industry. The EMEA's role includes providing applicants with scientific advice up to six years in advance of their filing an application. This is in order to work with companies towards their products fulfilling the approval criteria, and is clearly a function of the agency's single market duties. The extent of this cooperation is not always clear – what, in practice, is the line between helping applicants understand what is needed to meet the requirements of a successful application for their product, and actually instructing them on what they need to do to 'get a pass'? It also goes considerably further than that undertaken at national level or by the FDA.

If not so explicit, EFSA would seem to have a similar mandate and design in respect of the single market, where 'the agency's institutional architecture has therefore been framed by the imperative to construct an authority capable of restoring market confidence without threatening the habit of those multinational companies which occupy this arena'.<sup>122</sup> More specifically, a 2004 report by Friends of

<sup>122</sup> G. Taylor and M. Millar, "The appliance of science": the politics of European food regulation and reform', *Public Policy and Administration* 17 (2002), 125–46.

the Earth highlighted a pro-biotechnology industry bias in the work of the GMOs panel, not just in terms of favourable opinions, but also in the selective use of evidence in reaching those opinions.<sup>123</sup> These relations tie into the question of agency independence more widely, and echo broader views that the agencies may be too close to the industry.

### *C. EMEA, EFSA and Member State health systems*

With respect to their impact on national health systems, the agencies were not designed to affect Member State priorities and policy competences. In this regard, the constitutional asymmetry noted in Chapter 1 of this volume, between the EU's comparatively well-developed economic policy (single market) versus poorer social policy (including health) functions, is reflected in the agencies' mandates. It is clear, for instance, that the EMEA's centralized authorization system for pharmaceuticals does not affect the powers of the Member States to set prices or to include medicines in the scope of national health systems or social security schemes. In EFSA's case, the agency's inability to put specific issues on the political agenda, as well as its susceptibility to Member State politicking, suggests that its immediate impact on national health care systems is limited. On the other hand, EFSA can decide to issue an opinion on its own initiative, thereby indirectly influencing the political agenda. At the same time, the EMEA's authorizations do establish what medicines can and cannot (and by extension could or should) be available within national markets and health systems. Meanwhile, EFSA's expert advice on safe food and foodstuffs has the potential to affect countries' health care strategies to improve nutrition and combat diet-related diseases and obesity. These types of indirect or potential impacts, especially in view of a policy environment that promotes comparative best (or good) practice learning, are important and should be stressed. And given both agencies' commitment to strong communication activities to apprise and update stakeholders (especially consumers), they may be able to implicitly influence agendas more than is generally thought.

Despite an explicit impact not being envisaged, it is also clear that both agencies will increasingly serve as contact points for Member States

<sup>123</sup> Friends of the Earth, 'Throwing caution to the wind', above n.113.



and stakeholders, such as health care professionals, industry, patient and consumer organizations, and other nongovernmental organizations. The EMEA is, for example, obliged to assist Member States in the communication of health risks and to help them in the provision of information to health care professionals and the general public about those medicinal products evaluated by the agency.<sup>124</sup> Furthermore, the agency closely cooperates with the Member States' competent authorities in pharmacovigilance and post-marketing authorization tracking. It is also required to develop contacts with the relevant stakeholders.<sup>125</sup> EFSA too needs to closely collaborate with the competent authorities of the Member States. Moreover, it has developed contacts with the stakeholders through its Consultative Stakeholder Platform. In view of its increasing profile and importance – both because of its expanding role as assigned to it by EU legislation and its proactive attitude – EFSA increasingly seems to be growing into the above-mentioned *primus inter pares* of interdependent and deliberative networks of national authorities. We see this through its Advisory Forum and the networks of organizations that are active in the relevant technical areas. Further, due to their design and embedding of national authorities and experts within their structures and operations, and in having only a modest number of staff (the EMEA has approximately 500 core staff, and EFSA has 350),<sup>126</sup> both agencies are heavily dependent on decentralized networks of national authorities.

In this manner, both agencies can be viewed as constituent elements within a new, emerging architecture of experimentalist governance in the EU,<sup>127</sup> and would appear to be impacting decision-making within national health care systems, even if not as markedly as hard law.

## 5. Conclusion

This chapter has served to outline the role of European agencies in general, and the EMEA and EFSA in particular. It has sought to

<sup>124</sup> Article 57, Regulation 726/2004/EC, above n.69.

<sup>125</sup> Article 78, Regulation 726/2004/EC, above n.69.

<sup>126</sup> By comparison, and covering a much smaller population, the FDA has altogether some 9000 individuals employed in the two areas.

<sup>127</sup> C. Sabel and J. Zeitlin, 'Learning from difference: the new architecture of experimentalist governance in the EU', *European Law Journal* 14 (2008), 271–327.

examine their respective roles in relation to health protection and their (real and potential) impacts on national health systems, in terms of scientific evaluation, recommendation/opinion-giving, and the involvement of national counterparts and authorities. The discussion has outlined the emergence of both agencies and examined their mandates in health protection, along with factors that impact on how they execute their functions. By way of conclusion, we briefly revisit some of the main points in respect of the agencies' roles as protectors of health.

Understanding the reasons for the delegation of authority to EU-level agencies in the fields of medicines and foodstuffs means understanding national and EU-level policy-makers' aims in respect of: securing political commitments for long-term goals; increasing credibility at the same time as disassociating policy-making from science; increasing efficiency in highly technical areas; serving the aims of the single market; and harmonizing/standardizing national measures to the greatest extent possible. Additionally, the uncertainties surrounding risk analysis – such as where experts disagree on a given issue (e.g., the unknown long-term effects of a given medicine or the applicability of the precautionary principle to GMOs) – mean that policy-makers are often keen to derogate the science in order not to suffer the political costs of bad decisions or mistakes. The potential for such blame-shifting is likely to have contributed to the creation of both agencies, and EFSA in particular (not to mention the number of national food safety authorities that sprang up throughout Europe following the BSE crisis).

In the wakes of the thalidomide and BSE crises, we have seen that the need to ensure patient safety and (re-)establish consumer confidence has resulted in (further) centralization in both the pharmaceutical and foodstuffs sectors. Indeed, the fact that Community involvement in health and safety regulation may be considered to be spillover from the market integration objective may in turn explain why the Community has not been well-equipped to face these and other difficulties. The EU's response, in the main, has been to 'Europeanize' the science, with expert committees being established or consolidated at the EU level. In turn, these committees have evolved into regulatory agencies, each with considerable authority.

Considering the EMEA as a 'protector of health', it serves this function primarily through its evaluations. By allowing only those medicines that have passed the 'public health test' and demonstrated

their quality, safety and efficacy onto the European market, Member States and consumers can have a high degree of trust in the medicines they use. As with any regulatory regime, it is not perfect. The recent withdrawals and issuance of ‘black-box’ warnings on several high profile drugs highlight the need to be vigilant and to have good pharmacovigilance, as well as risk analysis structures and procedures, in place. Additionally, the changes introduced by the 2005 legislation have shored up and strengthened the EMEA’s role in key areas. Yet it remains the case that the agency’s mandate is heavily oriented towards serving the interests of the single market and the industry, and that there are numerous measures that could be made available to the agency towards better serving public health interests, or at least serving them more directly. In many respects, the same can be said of EFSA. The agency clearly has serving the public interest through communicating the findings from good science as its primary aim, while also striving to arrive at better science in order to ensure human health. Yet we have seen that both the risk assessment and risk communication exercises can still be highly political. Moreover, the division between risk assessment and risk management is not so easy in practice.

It is clear that more than thirty years after the thalidomide tragedy and more than ten years after the BSE crisis, many improvements have been made in order to ensure consumers’ health and trust. These reform initiatives were led primarily by the desire of the European institutions to regain trust in their science-based decision-making, while also ensuring health protection and the free movement of medicines and foods. Both the EMEA and EFSA have played an important part in this. While neither agency has the executive power to regulate in the manner of an independent regulatory agency such as the FDA, they both play a decisive role in the context of the internal market policy in the re-regulation of health issues at the EU level. As such, they have an influence on national health systems. We observed that their design and structure, which rely heavily upon (and to some extent absorb) national competent authorities, mean that they are likely to become true reference points for health-related questions. In this manner, both agencies – indeed, the proliferation of European agencies in general – can be seen as elements of the emergent architecture of experimentalist governance in the EU.<sup>128</sup>

<sup>128</sup> *Ibid.*

Although both agencies still have gaps as regards accountability and transparency, they may serve as examples for the ‘new EU health care governance patchwork’,<sup>129</sup> highlighting the resort to more ‘soft’ mechanisms for deliberation and networking with the various actors involved.

<sup>129</sup> See Chapter 2 in this volume.