EFSA in the international arena:
caught in a legal straightjacket – or performing an autonomous role?

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1. Introduction

Most agencies of the European Union (hereinafter also ‘EU agencies’) are established in environments that are replete with other organizations, not only other European bodies and member state agencies, but also international organizations and third country agencies. In order for EU agencies to execute their tasks and to realize their objectives, they usually engage in exchanges with such organizations. In fact, they often do not have much choice, as isolation from their environments is not a real option.³

The European Food Safety Authority (EFSA) is not an exception to this practice, as it operates in a field – that of the assessment of risks related to food and feed – that has for an important part been developed by international organizations, such as the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO), and third

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country agencies, such as the US Environmental Protection Agency (US EPA) and the US Food and Drug Administration (US FDA). Delivering high-level scientific advice requires EFSA to interact with members of global epistemic communities, in order to take stock of the achievements of their fellow bodies worldwide, as well as of the findings made by research centres and institutes in countries outside Europe. Indeed, the very concept of independent scientific advice, on which EFSA has been built, draws its legitimacy from the level of excellence of the outputs delivered by the international organizations and third country bodies that are active in its environment.

Through their interaction with EU agencies, international organizations and third country agencies may thus affect policies, policymaking processes, institutions and behaviour in the EU and its member states. But EU agencies do not necessarily serve as passive channels for the influence of these organizations. They often seem to play an active role as policy entrepreneurs, making use of the opportunities offered by the policies and policymaking processes of these organizations to influence institutions and behaviour in the EU and its member states. Through their interaction with international organizations and third country agencies, EU agencies may even increase their autonomy vis-à-vis their political overseers, namely the EU institutions and member states.

Here, EFSA seems to be an exception. Whereas it, for instance, cooperates with the FAO and the WHO – its experts participating in the meetings of these bodies – it usually does so

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at the request and in support of the European Commission, in line with the relatively limited scope of action allowed by its legal framework. This is slightly different for some of its sister EU agencies, such as the European Medicines Agency (EMA). Even though international relations are the prerogative of the Commission, in practice EMA has often represented the EU in international meetings, such as those of the International Conference on Harmonization, which includes authorities and industries of the three most important regulatory regions of the world with regard to the development of innovative medicines (the USA, the EU and Japan). At first glance, EFSA’s international role thus seems to be limited, or at least more limited than that of other EU agencies.\(^7\)

The above raises the question of what international role EFSA actually has performed – has it indeed been constrained by the formal-legal controls put in place by the legislator and the concerned EU institutions or has it even so been able to act relatively autonomously at the international level? In order to address this question, this chapter examines EFSA’s international relations, notably those with international organizations and third country agencies in its field of action. It adopts a dynamic perspective, describing these relations throughout the agency’s development. The chapter demonstrates that EFSA has developed a considerable international role, despite the relatively limited scope of action allowed by its legal framework.

This chapter first presents an overview of the relevance of agencies’ international relations from the perspective of agency autonomy. It discusses the reasons why agencies engage in interactions at the international level, and the consequences of the establishment and

\(^7\) This contribution focuses on EFSA’s international role; it does not compare EFSA’s role to that of other EU (regulatory) agencies, such as EMA or the European Chemicals Agency.
maintenance of international relations by EU agencies. Based on this, it then analyses the case of EFSA and its relations with international organizations and third country agencies. The chapter ends with a short conclusion on how to understand EFSA’s international role, and identifies the practical implications of our findings as well as avenues for further research on the international relations of EU agencies.

2. EU agencies’ international relations

2.1 International relations as a key dimension of agency autonomy

The extent to which an agency establishes and maintains its own relations with external actors, such as Commission Directorates-General (DGs) other than their ‘parent’ or ‘partner’ DG, other EU agencies, non-EU member states and, of particular interest here, international organizations, is a key dimension of its autonomy.

Agencies clearly cannot act as they please in the international arena. The EU institutions may involve them in the EU’s relations with international institutions working in their particular fields of action, but they often do not have to do so, at least not formally. In accordance with the Meroni doctrine, agencies can only engage in exchanges with institutions in the international scene if an international legal personality, or rather international role, is explicitly foreseen in their statutes. In any case, it is usually not EU

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9 European Court of Justice, Joined cases C-9/56 and 10/56 Meroni & Co. vs. High Authority, [1958] ECR 133, pp. 152-4. In a narrow reading, also extended to the food safety domain, this doctrine implies that EU agencies may only perform tasks that have been explicitly attributed to them and do so within the legal boundaries prescribed in the delegating provisions. See e.g. Joined cases C-154/04 and 155/04, Alliance for Natural Health, [2005] ECR I-6451, §90. The doctrine has been constitutionalized by Article 290 TFUE.
agencies but the Commission and the Council of the EU, and increasingly the European Parliament (EP), that decide on formal agreements between third countries and European or international bodies. The opportunities for agencies to engage in international relations are thus constrained by formal mandates and legal powers.

There are various reasons why the EU institutions do not allow agencies to develop a fully autonomous international role. The key argument, particularly used by the Commission to substantiate its central position, is the need to ensure the unity of the EU’s actions in its relations with its partners. The Commission claims that if it has to answer to the Parliament on the achievement of policy objectives for which EU agencies in practice are the responsible actors, it also needs to exert some kind of ultimate control over the operations of agencies. This holds especially for establishing and maintaining international relations, where there is said to be a clear need for the EU to speak with one voice. Along the same line of reasoning, it is fundamental for EU institutions that EU agencies do not appear to be committing the EU to international obligations.

Yet, agencies often enjoy some room for manoeuvre with regard to the exchanges in which they engage on a daily basis. As found by an evaluation of EU agencies published in December 2010: ‘Many [EU agencies] have signed multiple MoUs with key international organisations, and contacts are maintained through meetings, and sometimes concrete co-
operation at the operational level.\textsuperscript{13} In addition, while agencies generally cannot themselves enter into formal international agreements with other institutions, they can, for instance, make use of more practical working arrangements.\textsuperscript{14} The growth of these – often informal – exchanges in the international arena, according to the Common Approach subscribed by the Commission, the EP and the Council and published in July 2012, has made it necessary to ‘streamline’ the international relations of agencies, in order to ‘ensure that agencies operate within their mandate and the existing institutional framework’.\textsuperscript{15}

2.2 Objectives and tasks requiring international relations

Whereas in many areas international cooperation preceded cooperation at the EU level, the interaction between EU agencies and international institutions can to a large extent be explained by the progressive externalization (or internationalization) of many EU policies and programmes. Such policies and programmes are no longer restricted to the EU. They are increasingly triggered by the effects of such transboundary problems as international terrorism, irregular immigration, climate change, global pandemics and food scares. The resolution of such problems in an ever more interlinked world necessitates interaction in an international framework, and requires information and knowledge that is not always readily available, or complete, at the EU level. From a functional perspective, this may represent an


additional argument to explain the Commission’s and the Council’s recourse to EU specialized agencies and their subsequent role in international relations.

Hence, establishing and maintaining relations with other institutions, including international and third country counterparts, is usually part of the tasks that agencies carry out in pursuit of their objectives. Four broad categories of tasks can be identified for which agencies engage in international relations: the implementation of rules and standards, the development thereof, the collection of information and data, and the coordination of cross-border activities.¹⁶

A first category consists of interactions between international and third country counterparts and the EU agencies that play a role in the implementation of EU legislation in technical areas or on scientific issues. These ‘regulatory’ agencies take decisions on individual cases or prepare advice substantiating such decisions taken by the Commission and the member states, often building on international agreements to which the EU and its member states are signatories. They may also be invested with inspection tasks or be responsible for training experts.¹⁷ A second, closely related category comprises interaction as a result of the support given by agencies to substantiate the position of the EU vis-à-vis its international partners in the context of the negotiation of international standards and rules.

¹⁶ Most agencies are assigned with one or more tasks at the same time; some agencies are involved in activities covering all four tasks.
A third category includes interaction between international organizations and third country agencies and the EU agencies that have advisory functions. The activities of these agencies include collecting, analysing and disseminating information in their respective policy fields. To that end they often create and coordinate information networks, connecting public and private research institutes and centres in the member states, or establish links with such networks at the international level.

A fourth and final category covers interactions between other organizations and the EU agencies that have coordination tasks. These agencies coordinate operational activities across national borders, often in close cooperation with international and non-EU member state organizations, facilitating the exchange of information and supporting the member states and their national authorities, also in their international relations.

2.3 Beyond functional needs for international relations: political and strategic motives

Apart from their formal involvement in global affairs on behalf of the Commission and the Council, agencies also engage in international relations on their own initiative, without such interaction being explicitly prescribed by formal rules and procedures. The development of these relations does not merely seem to reflect the need that the Commission or the Council sees for such relations, but rather derives from the needs of the agency in question.

The need for material and immaterial resources, including information and knowledge beyond what is formally required, constitutes the most obvious reason for EU agencies to

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establish connections with other organizations. Interaction also takes place in order to reduce environmental uncertainty.\footnote{Thompson, J. D. 1967. Organizations in action: Social science bases of administrative theory. New York: McGraw-Hill; Aldrich, H. E. 1976. ‘Resource Dependence and Interorganizational Relations.’ Administration \& Society 7:419-53; Pfeffer, J., and Salancik G. 1978. The External Control of Organizations. New York: Harper and Row.} Being highly specialized actors in an often pre-defined sector, EU agencies are confronted on a daily basis with their global epistemic communities of reference, and seem to realize that they cannot be effective in the execution of their policies and programmes without taking into account the positions of other organizations, including international ones.

Furthermore, maintaining cooperative relations with international organizations and third country agencies may add to agencies’ autonomy. The transfer of rules and standards from international and third country counterparts through agencies may, for instance, increase the information asymmetry between agencies and their political overseers. The need to generate legitimacy is another important reason for agencies to establish ties with other international actors.\footnote{Meyer, J., and Rowan B. 1977. ‘Institutionalizing Organizations: Formal Structure as Myth and Ceremony.’ American Journal of Sociology 83 (2):340-63; DiMaggio, P. J., and Powell W. W. 1983. ‘The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields.’ American Sociological Review 48 (2):147-60.} To increase their acceptance and credibility, or their reputation, agencies link up with institutions that are in conformity with the prevailing rules, norms and beliefs of the environments in which they are embedded. Maintaining close ties with other, pre-existing organizations confers trust on EU agencies and thereby may further boost their autonomous position vis-à-vis the EU institutions and the member states.\footnote{Groenleer, M. 2009. The Autonomy of European Union Agencies, supra, footnote n. 18; Barnett, M. N., and Finnemore M. 2004. Rules for the World: International Organizations in Global Politics. Ithaca: Cornell University Press; Carpenter, D. P. 2010. Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA. Princeton: Princeton University Press.}
It could, of course, be that EU agencies gain autonomy vis-à-vis their political overseers while losing autonomy vis-à-vis international institutions. Yet, interaction with international institutions does not necessarily result in a loss of autonomy for agencies vis-à-vis international institutions, as illustrated by the network type of relations in which many EU agencies engage. Nor does the EU as such become automatically more dependent on international counterparts. On the contrary, with the creation of specialized agencies that can interact at an operational level with their international counterparts, the EU may very well advance political and strategic goals in the international arena in a more efficient and effective way than by assigning all international interactions to the Commission.

Networking with international organizations and third country agencies is therefore a key strategy for EU agencies, also benefitting the EU at large.²²

2.4 Implications for agencies and the EU at large

As a result of the interaction between EU agencies and international organizations and third country agencies, EU policy processes seem to have changed: more actors at various levels are either directly or indirectly involved, and these actors have assumed distinct roles in the policy process. So, on a general level, EU agencies further fragment the EU’s politico-administrative system, as a greater multiplicity of actors at a variety of levels are able to influence policies and programmes.²³ This should not be overstated, however, and assumed

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to have negative effects. In practice, the relations between EU agencies and international organizations and third country agencies often leave EU policy processes more or less intact and are generally instrumental to the support and credibility of EU policies. Whereas the 2010 evaluation of EU agencies noted that it was not possible to determine the effects of the many exchanges between agencies and other institutions, including international ones, and certainly not whether these interactions led to coherence and complementarity, it nonetheless concluded that ‘at least formally, there is a basis for assuming that some alignment takes places through these exchanges’.  

Moreover, in many cases the member states or their national authorities still control EU agencies and their relations with international organizations and third country agencies. They certainly do not completely cede sovereignty to such organizations through EU agencies at the supranational level, especially not when it concerns salient issues such as food safety. Even when member states delegate significant powers to agencies, they usually do so only after they or their national authorities have been assured that they will retain influence over the agencies’ activities, at least formally, through representation in their decision-making bodies, or through designating experts to perform the actual work.  

Although the relations between EU agencies and international institutions do not lead to fundamental power shifts, they do have a subtle effect on other actors in their environments. The interaction between EU agencies and international institutions as well as

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third country agencies may further spur a process of vertical (or sectoral) integration in Europe (and even globally) among civil servants, international officials, scientists, and representatives of business and interest groups in the same way that it occurs at the EU level with the agencies acting as networking hubs. Notably, national bureaucrats residing in subunits of ministries or agencies may gain influence vis-à-vis other, formally more powerful European and national officials or politicians. They often directly interact with EU agencies and their international counterparts, thus bypassing the political level in the EU and the member states when it comes to their day-to-day technical, scientific or managerial work.\(^\text{26}\) Precisely because they are part of transnational networks of knowledge-based professionals with a shared interest, EU agencies, international institutions and national agencies may increase their autonomy from their political masters.\(^\text{27}\)

Thus, whereas EU agencies appear to further the fragmentation of the EU politico-administrative system, they also seem to link up different levels of governance, thereby allowing not only a greater influence of agencies at the national level (member state as well as non-member state) but also a greater influence of international institutions.\(^\text{28}\) EU agencies ‘may play a distinctive role in improving the coordination of the organisational networks through which European policies are managed’, both upwards through their

\[\text{References}\]
relations with other supranational and global actors in their policy field, and downwards in relation to national authorities.\textsuperscript{29}

3. EFSA’s international relations

3.1 Legal framework

In order to analyse EFSA’s international relations it is necessary to first briefly examine the legal framework in which the Authority operates vis-à-vis the outside world. In general, the point of reference is Regulation (EC) No 178/2002, hereinafter the General Food Law (GFL). The GFL recognizes the legal personality of EFSA for all dealings with the EU and its member states, with specific reference to the need to buy its premises and interact with the host member state.\textsuperscript{30} But the GFL also makes clear that the Parma-based agency is working for the risk managers of the EU, and that only the Commission, the EP and the member states may request an EFSA opinion.\textsuperscript{31} Indeed, in a very limited number of circumstances is a power to engage in relations with international or third country agencies explicitly attributed.

The GFL assigns the Authority a number of tasks that are relevant to its international relations. First of all, it requires EFSA to provide scientific and technical assistance, underlining that this may be done only when requested by the Commission, with a view to

\textsuperscript{30} Article 46(1) of Regulation (EC) No 178/2002.
\textsuperscript{31} See Article 29 of Regulation (EC) No 178/2002. Exceptionally, EFSA also has the possibility of undertaking a self-task.
improving cooperation between the EU and applicant countries, international organizations and third countries.\(^\text{32}\) It is considered fundamental that the Commission’s positions are underpinned by strong scientific and technical arguments developed on the basis of internationally available and recognized information, evidence, data and risk assessment practices. Hence, EFSA supports the Commission with regard to scientific and technical issues in its work at the World Organisation for Animal Health (OIE), the International Plant Protection Convention (IPPC), the European and Mediterranean Plant Protection Organisation (EPPO), the Codex Alimentarius Commission (CAC), the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the World Health Organisation (WHO), and the Food and Agriculture Organisation (FAO).

Furthermore, the GFL requires EFSA to work with applicant countries, third countries or international bodies to search for, collect, collate, analyse and summarize relevant scientific and technical data in the fields within its mission.\(^\text{33}\) In that respect, it could be concluded that reference to data collection with international organizations and third countries should be interpreted as also implying data exchange with these bodies. In fact, it is extremely unlikely that data collection is only one-way and that that international and third country risk assessment bodies submit their data to EFSA without agreements on the mutual exchange of data. The GFL also specifically requires the Authority to work with countries that have concluded agreements with the EU by virtue of which they adopt and apply EU legislation, such as the rules and procedures laid down in the GFL.\(^\text{34}\)

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\(^{33}\) Article 33(2) of Regulation (EC) No 178/2002. In the period until 2007 the Authority also contributed to strengthening the food safety systems in accession or candidate countries, through involving these future EU member states in its work. This contribution, however, concentrates on EFSA’s relations with international organizations and non-EU countries not being accession or candidate countries.

\(^{34}\) Article 49 of Regulation (EC) No 178/2002.
Finally, the GFL foresees an obligation for the Authority to identify emerging risks that are of relevance to the EU.\footnote{Article 34 of Regulation (EC) No 178/2002.} Although this provision does not explicitly mention an attribution of powers allowing EFSA to engage in international activities, one could argue that such powers, in line with the doctrine of implied powers, are ‘implied’ by the powers expressly stated in the GFL.\footnote{On the doctrine of implied powers in case of the European Community and European Union, see Eeckhout P. 2004. \textit{External relations of the European Union: Legal and constitutional foundations}. Oxford: Oxford University Press.} In a world characterized by such phenomena as global trade, mass migration and climate change, EFSA has an obligation to attend to scientific signals from international bodies and third countries’ agencies, and thus enable the EU risk managers to be avant-garde. In order to be aware, and possibly ahead of emerging trends in the development of new risks or of risks that are expected to become of relevance to the EU, it seems that the Authority must be allowed to interact at the international level.

In addition to the GFL, other EU legal acts may establish a framework for EFSA’s cooperation with third countries or international bodies – for example the EU Pre-accession Programme or certain international agreements between the EU and third countries or international organizations in which EFSA is attributed an operational role.\footnote{For more details on EU agencies’ contributions to the EU Pre-accession Programme, see Coman-Kund F. 2012. ‘Assessing the role of EU agencies in the enlargement process: the case of the European Aviation Safety Agency.’ \textit{Croatian Yearbook of Eur. Law}, 8, 335-368.} Yet, it is apparent from the brief analysis above that the only areas of action where EFSA enjoys some margin of manoeuvre and the possibility to undertake a more proactive approach are those of data collection and emerging risks.
3.2 Development over time

2003–05: forging international links in an ad hoc manner

Having outlined the legal framework and the formal restrictions it imposes on EFSA’s role at the international level, it is time to look at how the agency has implemented this structure in its daily activities. Between 2003, when EFSA started operating, and 2006, EFSA’s institutional interactions with international or third country bodies developed in an ad hoc manner. The Authority engaged in relations with international organizations, including visits to identify future areas of cooperation, exchanges of information about significant reports or opinions prior to publication, and the organization of conferences on topics of common interest, such as harmonized approaches.

At the request of the Commission, EFSA experts also participated in meetings of international bodies such as the Codex Alimentarius – a joint FAO/WHO body that develops international food standards on, for instance, principles of risk analysis and biotechnology. Furthermore, links were forged, for instance through visits, with food safety authorities in non-EU countries both in Europe (e.g. Norway and Switzerland) and outside Europe (e.g. the USA, Japan, China, Canada and Australia/New Zealand), and initiatives were undertaken to cooperate in particular areas of risk assessment, such as pesticides.38

2006–08: investing in closer contacts with key international partners

While EFSA established and maintained a variety of international contacts in the period preceding 2006, this seemed not a result of a deliberate strategy or systematic approach. In 2006, EFSA’s Management Board identified the further development of EFSA’s international activities as one of the key recommendations arising from the report of the External Evaluation.\(^{39}\) As a result, from 2007 onwards, the Authority invested in closer contacts with key international partners. It collaborated more closely with international organizations on projects such as with regard to data collection and the assessment of global scientific issues within its remit, the organization of seminars on issues of common concern, and played a more important role in the meetings of the Codex Alimentarius.

Moreover, EFSA and the US FDA signed a statement on confidentiality arrangements to facilitate the sharing of non-public information, and held a technical meeting during which they discussed scientific subjects common to both agencies, such as approaches to the risk assessment of nanoscience and nanotechnologies, animal cloning and aspartame.\(^{40}\) In 2008, EFSA hosted several delegations of international partners in order to initiate and foster technical cooperation. These delegations included New Zealand’s minister of Food Safety, the director general of the Beijing Food Safety Administration, representatives of the Mercosur Countries (Brazil, Argentina, Uruguay and Paraguay) and representatives of the Japanese Food Safety Commission. The Authority also hosted a Technical Assistance and


Information Exchange study and was part of the Commission delegation to the CODEX Task Force on Biotechnology in Japan.\footnote{European Food Safety Authority. 2008. Annual Activity Report, at 24, available online at http://www.efsa.europa.eu/en/corporate/doc/aar08.pdf (last accessed on 15 September 2012).}

\textit{2009–present: towards a more strategic international relations approach}

However, it was felt that a more well-thought-out approach to international activities was necessary. In 2009, EFSA published a policy paper titled ‘International Activities – A Strategic Approach’\footnote{European Food Safety Authority. 2009. International Activities – A Strategic Approach. Document Describing EFSA’s strategic approach to its international activities, mb 29 01 09 item 8 doc 5 – International Activities – adopted, available online at http://www.efsa.europa.eu/en/corporate/pub/intstrategic.htm (last accessed on 27 August 2012).}, which outlined the framework in which it operates and put forward four strategic objectives to be pursued in its international activities, namely: to support the EU in its international commitments; to ensure access to international scientific data and information in order to provide a strong basis for risk assessment and the identification of emerging risks; to participate in risk assessment at the international level; and to promote coherence in risk communications and build awareness of EFSA’s activities at the international level.

As a start, the Authority mapped the variety of existing relations, both informal and formal, and at various levels in the organization. On that basis, it prioritized organizations and countries with whom closer collaboration and an alignment of positions were considered of relevance to EFSA, and with whom longer term relations would thus have to be developed.\footnote{European Food Safety Authority. 2009. Annual Activity Report, available online at http://www.efsa.europa.eu/en/corporate/doc/aar09.pdf (last accessed on 15 September 2012).} In 2009, the strategic approach was implemented through operational follow-
up actions. Priority was given to actions in support of EU policy, indicating the Authority’s
dependence on the Commission to back up its choice in international relations.44

In terms of practical achievements, the strategic approach has been translated into a
Memorandum of Cooperation (MoC) with the Japanese Food Safety Commission (FSC) on
the collection and sharing of the data required for the assessment of current and emerging
risks. As such, the memorandum goes beyond the agreement between EFSA and the FDA,
negotiated in 2007, which is limited to confidentiality arrangements that are applicable only
to data exchanges.45 In addition, visits and meetings have been held with US counterparts,
the OIE, the WHO and the FAO.46 EFSA has provided a higher volume of scientific and
technical support for the Commission delegation to the Codex Alimentarius, which appears
to reflect the Commission’s enhanced trust in the scientific competences of the Parma-
based agency.

International collaboration, consultation and joint opinions, all “implemented in line with
the framework agreed with the European Commission”, characterize EFSA’s activities in
2010. The Scientific Panel on food additives and nutrient sources added to food (ANS)
adopted an opinion on lycopene which was linked to a JECFA (Joint FAO/WHO Expert
Committee on Food Additives) opinion, while the opinions on lead (CONTAM) and
bisphenol A (CEF) received inputs from the WHO.47 EFSA also exchanged letters of
cooperation with several counterparts including Health Canada and the WHO, received

44 See European Food Safety Authority, International Activities – above, Annex II, Key Initiatives, Actions
and Indicators of Success relating to ‘EFSA’s International Activities – A Strategic Approach.
45 The agreements are available online on EFSA’s corporate website at
47 European Food Safety Authority. 2010. Annual Activity Report, available online at
international delegations from South Korea, Norway, China, Algeria and Japan, and, among others, co-organised with the WHO a seminar on seafood safety.\textsuperscript{48} In 2011, EFSA’s international activities grew exponentially. In addition to receiving a great number of international delegations, EFSA regularly invited FAO and OIE experts to participate in plenary meetings in the field of animal health, and strengthened relationships with the European and Mediterranean Plant Protection Organization (EPPO). Notably, the Authority provided a significant amount of scientific support to the Commission in the framework of the Codex Alimentarius.\textsuperscript{49}

Here, two cases are examined that are illustrative of EFSA’s increased contribution in the international arena, in particular its scientific support work: for the meetings of the Codex Committees on Pesticides Residues (CCPR), and for the EU position on ractopamine, a growth promoter used in animal feed.

\textit{EFSA and the Codex Committees on pesticides residues}

Pursuant to the Regulation on Maximum Residue Levels (MRLs) of Pesticides, EFSA is required to assess the safety of the MRLs put forward by the concerned business operators.\textsuperscript{50} Since EFSA is the competent body in the EU for delivering scientific advice on this particular matter, the Commission systematically asks the Authority for comments on the recommendations of the relevant Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and pesticide MRLs at steps 3 and 6 of the Codex procedure.

In 2011, for example, the JMPR evaluated twelve active substances regarding the setting of toxicological reference values to be used in consumer risk assessment. EFSA compared the acceptable daily intake (ADI) and acute reference dose (ARfD) values derived by the JMPR with the values derived at EU level, and, where differences were identified, provided further explanations for the reasons for those differences. EFSA expressed a reservation about the proposed toxicological reference values for five of the twelve substances, a reservation that was duly reflected in the Commission’s position at the JMPR.

**EFSA and ractopamine**

Another, high profile example of EFSA’s contribution to the EU stance in the international standard setting or regulatory arena is the case of ractopamine hydrochloride. The use of ractopamine as a feed additive is authorized in various countries, including the USA, Canada, Japan and Mexico, for growth promotion in pigs, cattle and, to a limited extent, turkeys. However, the use of this substance is banned in several other regulatory countries and regions, such as China and, notably, the EU. As a result, measures preventing the import of meat from animals that were fed ractopamine have been put in place in these legal systems. The adoption of a standard foreseeing the possibility of establishing an acceptable daily intake and maximum residue levels is therefore of great importance for the USA, Canada, Japan and Mexico, as it would demonstrate the possibility of the safe use of ractopamine under certain conditions and allow trade between these countries and the EU.

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52 Pharmacologically classified as a phenethanolamine β-adrenoceptor agonist.

According to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the establishment of such a standard was scientifically justified and possible.⁵⁴

EFSA was asked by the Commission to provide an opinion on the evaluation of ractopamine hydrochloride performed by the JECFA, in consultation and cooperation with other organizations such as the European Medicines Agency (EMA) and the German Federal Office of Consumer Protection and Food Safety (BVL), acting as EU Reference Laboratory for substances such as ractopamine. EFSA’s Scientific Panel on Feed Additives (FEEDAP) concluded that the human study used by the JECFA could not be taken as a basis to derive an ADI and, consequently, no proposal for MRLs could be made. EMA’s Committee on Veterinary Medicinal Products (CVMP) and countries such as China and India supported EFSA’s conclusions with regard to the safety evaluation of ractopamine.⁵⁵

On the basis of the science expressed by its agencies, the Commission not only claimed that ractopamine poses risks to human health, but also that it has negative effects on animal health and welfare. Nevertheless, the EU was not successful in convincing other countries such as the USA, Canada and Mexico. On 5 July 2012, after years of political deadlock, the Codex Alimentarius Commission (CAC) narrowly adopted (69 votes in favour, 67 against) the first MRLs for ractopamine hydrochloride, irrespective of the scientific position put forward by the EU on the basis of EFSA’s and EMA’s advice.⁵⁶ It remains to be seen whether the World Trade Organisation (WTO) will accept the scientific arguments

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⁵⁴ Ractopamine has been evaluated at the 40th, 62nd, 66th, JECFA meetings, and by a special review in 2010.
⁵⁶ As duly highlighted by the Commission in a press release available online at http://europa.eu/rapid/middayExpressAction.do?date=06/07/2012&guiLanguage=en (last accessed on 3 September 2012).
furnished by EFSA and EMA as justifying the restrictive measures adopted by the EU if it is confronted with a challenge related to their compatibility with the recently adopted standard.

In spite of the mixed outcomes so far, the above examples show the increased strength and profile of the Authority’s international relations, and the efforts EFSA put into streamlining its interactions at the international level, especially when it comes to supporting the EU’s position in the international arena. The Authority now engages in operational cooperation with international organizations that undertake similar work, and maintains close contacts with other food safety authorities that have collected data or carried out studies that are of relevance to food and feed safety in the EU.

3.3 From functional necessity to strategic asset

It seems that until 2007, engaging in interactions with international organizations and third country bodies was primarily seen as a functional necessity ensuing from the agency’s objectives and tasks. Establishing relations with food safety agencies in countries outside the EU and with international organizations was regarded as essential for sharing data and information, as well as for developing common methodologies and underlying principles. By building collaborative partnerships, EFSA sought to secure a larger pool of scientific data and information; it also allowed the Authority to take part in international harmonization efforts on data collection and risk assessment. Finally, international relations were seen as necessary to promote coherent communication, based on shared perceptions of the risks in the food and feed chain.
It also appears that international cooperation has been considered of importance in view of the changes in EFSA’s institutional environment and the risks that may emerge from such changes. In 2008, the EFSA Strategic Plan for 2009–13 identified the most important drivers for change, including globalization, increased innovation, matters linked to sustainability and climate change, and the societal and policy changes that have a potential impact on EFSA’s future work.\(^{57}\) In order to identify emerging food and feed risks as early as possible, it was proposed to strengthen the Authority’s international relations. As stated in EFSA’s 2009 Annual Report: ‘Crops, animals, and food and feed products are transported around the world in an increasingly global world – as are the associated risks. Therefore, being involved internationally – in support of EU policy – is paramount for EFSA’s ability to keep Europe’s food supply safe and to protect consumers.’

Yet, it seems that, over time, the Authority realized that establishing and maintaining international relations can also serve other purposes, notably the ‘ultimate aim’ of becoming a scientific point of reference not only for the EU but also outside the EU. Through international relations, EFSA can assert itself vis-à-vis agencies in the member states and the EU institutions. In its 2007 Annual Report, EFSA mentions two reasons for stepping up its activities in the area of international relations.\(^{58}\) The first reason is primarily functional: to ensure ‘that EFSA has access to the best information and science worldwide for conducting its risk assessments’. The second reason is more of a strategic nature: to ensure ‘that recognition of EFSA’s support to European food and feed laws, through its risk assessments, is increasingly global’.

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\(^{58}\) European Food Safety Authority. 2007. Annual Activity Report, supra, footnote n. 41, at 40.
The 2009 Annual Report is even clearer on this point, as it acknowledges that ‘the Authority is also building awareness of its activities internationally to build its reputation as an organization that is globally recognised and trusted as the European reference body for risk assessment.’\textsuperscript{59} In this respect, it should not be forgotten that one of the reasons why the EU created a European food agency was the need to regain the confidence of the EU’s international partners\textsuperscript{60} by establishing food safety and animal and plant health measures in line with basic rules set in the international arena, notably those in the framework of the WTO (also referred to as sanitary and phytosanitary, or SPS, measures).

Another, related development is the ‘mainstreaming’ of international relations in the Authority’s day-to-day activities: international relations are now an integral part of other activities, not a separate activity (under a separate heading in the annual report). Of course, the agency still receives international delegations and meets to discuss cooperation with its counterparts, but such visits and discussions have become part of EFSA’s scientific and technical work, which thus encompasses authorities in the member states and the EU institutions, as well as international organizations and agencies in non-EU countries. International cooperation is also no longer an activity undertaken only at the managerial level, by the director or by a separate unit in the authority; contacts have become more operational and are increasingly established and maintained by EFSA experts.

In other words, EFSA’s international relations have developed both quantitatively – in terms of its volume – and qualitatively, in terms of the way they are established and

\textsuperscript{59} European Food Safety Authority. 2009. Annual Activity Report, supra, footnote n. 44, at 25.

\textsuperscript{60} See e.g. recital n. 22 of Regulation (EC) No 178/2002.
maintained, the reasons underlying such relations and the variety of actors that are involved in them.

3.4 Limited autonomous power

The quantitative and qualitative change in EFSA’s international relations may have implications for the place of the Authority in the EU food and feed regulation landscape and, more broadly, for the EU’s institutional system. We begin, however, with an assessment of the effects on the Authority’s performance – of great importance for its international reputation.

To what extent has international cooperation led to improved scientific advice, in the sense that scientific outputs are of higher quality? Whether EFSA’s international relations contribute to the delivery of outputs that are of a higher quality than in the past, is of course difficult to prove. From the discussion about the way EFSA’s strategic approach to international relations is implemented, it appears that cooperation enhances the agency’s risk assessment work. The interactions currently taking place between EFSA and its international counterparts, notably data sharing and collection, enable the Authority to be increasingly complete and accurate in carrying out its support tasks. However, this does not mean that EFSA’s assessment work, through its international role, is necessarily more accepted (in the EU and globally), or that disagreements over science have disappeared, as the ractopamine case clearly shows.
Yet, EFSA – through its international relations – contributes to the creation of a single European regulatory space, building epistemic communities of supranational and national specialized civil servants and scientific or technical experts. Although we have not dealt with this aspect here in depth, EFSA has for instance supported accession and candidate countries in their efforts to adapt to EU rules and guidelines and to learn from established practice. As the network’s hub, the Authority has linked up international organizations and agencies in third countries with the EU institutions and agencies in the member states in an often informal way, through mutual visits, coordination meetings, joint conferences, etc.  

Indeed, one of EFSA’s strengths is its enhanced role in network governance: it remains independent, but cooperates with member states’ risk assessment bodies and includes their experts on EFSA’s panels more than it did previously.

Apart from more accurate and complete scientific advice in support of the EU’s position and a level of sectoral integration through functional cooperation in its area of competence, EFSA’s increased international role may lead to a de facto power shift from EFSA’s political overseers, particularly the Commission’s Directorate-General SANCO, to the Authority itself (or at least a power struggle between these actors). When a new regulatory body is created, and especially when independence is such a hallmark as in the case of EFSA, it can be expected that the new body will endeavour to fight with established actors for at least some ‘breathing space’, as indeed also happened in the case of the Authority.  

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Whereas EFSA’s early years were characterized by an antagonistic relation with the Commission, for instance over its role in risk communication, this does not seem to be the case for EFSA’s international activities, however.

The absence of a power struggle over international relations could at least partly be explained by the fact that EFSA’s international activities have gained strength only in recent years and cooperative institutional relations had developed in the meantime. It also appears that in conducting its international activities, the Authority has respected the pre-existing institutional balance and operated within the legal framework set out in the GFL and in line with EU objectives and priorities. Although EFSA’s creation as such may have contributed to the fragmentation of the EU’s institutional system in terms of the multiplication of actors involved in food and feed regulation, it appears that its technical contributions to the scientific discussions at the international level have not caused incoherence or inconsistency with the position of the EU, as represented by the Commission and the member states.

The likelihood of EFSA speaking with a different voice than the Commission or the member states is reduced not only as a result of the legal framework applicable to EFSA’s international activities, but also through the explicit and prior approval of key documents in which EFSA’s international approach is outlined. Until now, this explicit and prior approval has, on the one hand, proven an adequate control mechanism preventing any

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63 E.g. EFSA’s Annual Management Plans and Annual Activity Reports, *supra*. 

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action or reaction not considered in line with or supportive of the policies pursued by the Commission and the member states; it has, on the other hand, also limited the agency’s autonomy in international operations.

Furthermore, if we benchmark EFSA’s international activities against the Common Approach on EU agencies recently agreed upon by the Commission, the Parliament and the Council, we find that these appear to be complying with the requirements laid down in this document. In line with the Common Approach, agencies should have a clear strategy for international activities; the strategy should be approved by agencies’ management boards; an early exchange of information should be ensured between agencies, the partner DGs and if appropriate EU delegations; and agencies should not represent the EU or commit it to an outside audience.64 These are all features that can be found in EFSA’s strategic approach to international activities. Indeed, EFSA’s international strategy has been adopted by the Management Board, on which the Commission is represented, and entails full and prior coordination with the partner DGs for endorsement of international initiatives that go beyond the tasks explicitly mandated by the GFL.65

One aspect that deserves closer scrutiny and a deeper analysis is the role of national agencies vis-à-vis their ministries as a result of their relations with EFSA, and in turn, the positions of national agencies and ministries together vis-à-vis the international scientific committees and bodies with which EFSA is also liaising. EFSA’s networking capabilities may have contradictory effects. On the one hand, they may empower national agencies vis-

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64 Point n. 25 of the Common Approach annexed to the Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies of 19 July 2012.
à-vis their ministries because national agencies are the ones directly liaising with the Authority in transnational networks. This bypassing is a more frequently described phenomenon in multilevel settings. On the other hand, EFSA’s networking capabilities might also lead to a gradual attenuation of the residual role played by national agencies in international scientific committees and bodies, because their role is slowly but surely being taken over by the Authority in view of reinforcing the EU’s position in multilateral negotiations and international organizations.

4. Conclusions

This chapter discussed the importance of international relations for assessing the input an EU agency can offer to the broader EU legal and political system, by examining the international role of the European Food Safety Authority (EFSA). The analysis showed that the agency’s international relations, despite being embedded in a rather stringent legal framework, have gained strength throughout its ten-year existence and in recent years have been streamlined. The agency now contributes on a regular basis to the EU’s position in the international arena. In view of the budgetary constraints that many risk assessment bodies in the EU member states face, it is not unlikely that EFSA’s role as a networking hub for data collection and sharing in the international arena, will only further increase.

Furthermore, whereas the establishment and maintenance of international relations was initially mainly seen as a functional necessity, EFSA came to realize that such relations

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could also serve to further develop its international reputation. International relations have now been mainstreamed into the agency’s day-to-day activities. Establishing and maintaining such relations is no longer only a managerial task: it is now also an operational one. In future research, these (preliminary) findings should be compared with the development over time of other regulatory agencies’ international relations, in order to shed light on differences and similarities, both legal and political.

EFSA’s international relations and the quantitative and qualitative growth thereof seem to have contributed, in a functional way, to improved (or at least more complete and accurate) scientific advice. More broadly, they have also added to increased administrative (or regulatory) integration in the EU, among individual member states, especially those that have recently become EU members, particularly in the field of food and feed risk assessment. The increased role of the agency in the international arena does raise questions about the division of labour between the risk managers and the risk assessor, and a possible power shift from the former to the latter. The analysis demonstrated that EFSA’s operations until now have been consistent with the legal framework in which it operates and with the recently adopted Common Approach on EU agencies.

Thus, although EFSA is another European actor at the international level and therefore furthers the fragmentation of the EU politico-administrative system, it at the same time contributes to linking up different levels of governance, both ‘upwards’ to international bodies and ‘sideways’ to third country agencies. Further research needs to be conducted on what this means for ‘downward’ relations with agencies at the national level, and their role and influence in the field of food and feed risk assessment.