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## No. 35

The Role of the EU in  
Transnational Regulation of  
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Governance?\*

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## Abstract

This paper explores how far experimentalist features of the EU's internal food safety governance regime are being extended to the Union's external governance of food safety. Hence, it analyses whether and how far the Union's engagement with both third countries and global institutions displays features of experimentalism. Our analysis shows that while the EU constitutes a powerful global standard setter in the field of food safety, its unilateral role is to some extent mitigated by both its cooperative engagement with third countries at the bilateral level and by its embeddedness within multilateral global governance institutions, such as the WTO and the *Codex Alimentarius Commission*. Furthermore, our analysis of two crucial institutional mechanisms of EU's external food safety governance, namely the EU Food and Veterinary Office (FVO) and the EU Rapid Alert System for Food and Feed (RASFF) shows that both are designed, and often function well as reflexive institutions with strong features of de-centralised implementation, reporting and peer review, as well as learning and recursive revision of rules. Both FVO and RASFF provide important opportunities for third countries to participate in the Union's internal governance and rule-making processes. However, reviewing the performance of both institutions in previous food crisis situations, the analysis also reveals some important shortcomings in their practical functioning as experimentalist tools, which calls for the further improvement of these mechanisms.

## 1. Introduction

Analysis of the EU's internal governance of food safety through the lenses of experimentalist governance revealed that this domain incorporates several characteristics of experimentalism (Vos 2010). In this highly harmonised domain that has been subject to EU intervention since the 1960s we observed a new phenomenon whereby substantial responsibilities are devolved to a variety of actors, foremost the European Food Safety Authority (EFSA), national authorities and stakeholders, at both a scientific and political level. Thereby recursive learning processes of provisional goal-setting and revision through feedback from practical experiences play an important role. In this way, we observed that the broad framework set by the General Food Law is implemented in a decentralised way by a variety of lower-level actors through deliberative mechanisms, such as networking activities, exchange of information and knowledge, reporting on activities carried out, monitoring and installation of peer review mechanisms. These mechanisms in turn provide opportunities for learning through the recursive revision of EU legislation in the light of implementation experience at national and local level. Important examples of such deliberative and recursive learning mechanisms are the EU Rapid Alert System for Food and Feed (RASFF) as well as the EU Food and Veterinary Office (FVO) by means of its annual reports that contribute to the EU's policy-making on food safety (Vos 2010).

This paper seeks to assess whether and how far the EU also adopts an experimental approach in its external governance of food safety. To this end, we will examine whether and how far EU governance of food safety displays experimentalist features in relation to both third countries (TCs) and global institutions (Sabel & Zeitlin 2008; 2010; 2011). In our analysis we will focus on the balance between unilateral, bilateral, and multilateral channels for the external projection of EU food safety governance, examining how far the EU's role as a unilateral global food safety standard-setter is mitigated by its participation in both bilateral and multilateral governance initiatives. Subsequently, we will analyse two specific institutional mechanisms, which play a crucial role in EU's external food safety governance by overseeing and enforcing the EU system of import safety vis-à-vis TCs, namely the FVO (section 3) and the RASFF (section 4). Here we will mainly examine the experimentalist nature of these mechanisms, i.e. the opportunities that they provide for TCs to participate in EU's internal governance and rule-making processes thereby inducing learning and revision of rules within the EU. It is however first necessary to analyze the role of the EU as an external actor in transnational food regulation (section 2). The main question that we will address, therefore, is how and through what institutional channels and mechanisms does the EU seek to extend both its rules and its governance processes in the area of food safety beyond its borders. And most importantly, can we identify experimentalist features in these external governance processes?

## **2. The European system of import safety in the context of global governance**

As in many European policy areas, the shaping of EU external food safety policy follows the dual rationale of promoting the safety of foods traded on the internal market on the one hand and defending the interests of EU economic actors on the other. With regard to the first objective, the EU is under a constitutional obligation<sup>1</sup> to protect the health and safety of EU citizens vis-à-vis TC imports of food in view of the fact that the EU internal and world markets are increasingly permeable. At the same time, there seems to also be a genuine concern of the EU for food safety worldwide where it prohibits exporting foods and feeds that are unsafe.<sup>2</sup> The externalisation of food safety requirements is surely also beneficial for EU economic actors entering non-EU markets. The tightening of regulatory standards in TCs helps to avoid a

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<sup>1</sup> See Articles 3 and 5 TEU and 12 and 168 (1) TFEU.

<sup>2</sup> See Articles 12 of Regulation 178/2002.

comparative disadvantage arising for EU companies bound by strict health and environmental standards when they compete with foreign companies (Laïdi 2008). Analysis of EU's transnational food safety activities reveals that while the Union constitutes a powerful global standard setter in this field (section 2.1.), its unilateral role is to some extent mitigated by the cooperative engagement with TCs on the one hand (section 2.2.), and the EU's embeddedness within multilateral global governance institutions on the other hand (section 2.3.).

## **2.1. The EU as an exporter of food safety standards...**

First the EU actively promotes the export of its food safety standards to TCs. This supports its characterisation as a *unilateral agenda setter* (Sabel & Zeitlin 2011) in this policy field. In other words the EU seeks to extend its internal standards (both procedural and substantive) beyond its borders as a condition for market access for TCs.<sup>3</sup> Hence, the EU has been characterised as a “normative empire” that is able to extend its regulatory requirements to TCs based on the combination of two decisive factors: 1) the strength and attractiveness of the EU internal market for foreign companies and 2) the stringency of the EU health and safety standards, which makes importing countries adjust their regulations in order to reach the Union's level of protection (Laïdi 2008).

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The extraterritorial effect of EU food safety standards is embedded in the legislative framework governing the European system of import controls on food products, which we will refer to as the European system of food import safety. The most important elements of this framework are the General Food Law Regulation (GFL)<sup>4</sup> and the Official Food and Feed Controls Regulation (OFFC).<sup>5</sup> The GFL provides that food and feed imported into the EU must comply with EU requirements, conditions that are recognised by the EU to be at least equivalent thereto or requirements laid down in specific agreements concluded by the EU and the exporting country.<sup>6</sup> The OFFC establishes a general framework for official controls carried out by both Member States' authorities and the Commission aiming to ensure compliance with EU food law.<sup>7</sup> This Regulation also sets the general principles underlying the establishment of import conditions, the recognition of equivalence, the approval of

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<sup>3</sup> See Article 11 of Regulation 178/2002.

<sup>4</sup> Regulation 178/2002.

<sup>5</sup> Regulation 882/2004.

<sup>6</sup> Article 11.

<sup>7</sup> Including EU feed law, animal health and welfare rules, and plant health provisions.

pre-export checks carried out by TC competent authorities, and the recognition that certain commodities may require specific controls prior to their introduction into EU territory. Moreover, it lays down specific Commission duties concerning the collection of relevant information from trading partners as well as the performance of inspections in TCs.<sup>8</sup>

In implementing these legal provisions, the EU adopts a so-called risk-based approach to import controls of food products. Import controls are not uniform across sectors, but are based on an assessment of the risks that specific imports pose to human, animal, and plant health – the higher the risk, the stricter the conditions for their entry into the EU, and the greater the level of controls.<sup>9</sup> Although this approach ensures that EU regulators can be flexible in adjusting the stringency of import requirements to both the actual risk level of every product category and the safety conditions of different importing countries, it also creates challenges for the effectiveness of EU surveillance and law enforcement capacities. Not only do market surveillance and law enforcement authorities both at EU and national level need to be able to detect new food safety risks in a timely manner, but a constant and timely flow of information also needs to be ensured between border control points, European and TC competent authorities and inspectors, health and food safety experts, private business operators, and other actors involved. Noteworthy is that the vast majority of TC imported goods in the EU are not subject to systematic border controls, which would be practically unfeasible given the volume of incoming goods. Most imported goods therefore circulate freely on the EU internal market once they have fulfilled formal customs requirements (Alemanno 2009). It is therefore clear that the implementation of this multi-level and multi-actor regulatory framework, which is regularly reviewed and revised in the light of new risk assessments and safety incidents, depends on an effective cooperation with TC authorities to ensure food safety within the EU.

## **2.2. ...in a collaborative setting**

The export of EU rules to TCs is therefore not only a matter of unilateral adjustment by the importing countries, but is actively promoted by the EU institutions. The EU has developed several mechanisms to ensure cooperation with TCs while

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<sup>8</sup> See Report from the Commission to the European Parliament and the Council on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed, animals, and plants, COM (2010) 785 final, p. 6.

<sup>9</sup> See *ibid*, p. 4 and p. 6-7.

strengthening their technical and institutional capacities to comply with its food safety standards, or to ensure an equivalent level of food safety.

Firstly, before a TC is permitted to export food commodities to the EU, its competent authorities need to engage in an intensive exchange of information with the EU authorities, notably the Commission. Among other things, the TC provides and the Commission evaluates information concerning its food safety regulations, control and inspection procedures, and risk assessment procedures. The Commission provides guidelines specifying how this information should be drawn up and presented.<sup>10</sup> This cooperation can intensify in the case of developing countries. For these countries the high costs of compliance with EU safety requirements, and the often lacking technical and financial capacities in the developing world present an enormous challenge (Broberg 2009).<sup>11</sup> The OFFC explicitly obliges the Commission to build the institutional capacity of developing countries necessary to meet the requirements of EU regulation.<sup>12</sup> Here, the Union can adopt special measures of support, such as a phased introduction of the requirements, exemptions, assistance from EU experts, joint projects, and training.<sup>13</sup> In the literature these capacity building activities have been assessed both negatively, focusing on the self-interest of the EU (Lecomte van Hove 2001; Prévost, 2009) and positively, focussing on the learning potential for the developing countries (Rakpong 2011; Jaffee & Henson 2004).

Secondly, EU officials visit the TC, and carry out official controls on its territory in order to verify the compliance or equivalence of that country's legislation and systems with EU food safety requirements.<sup>14</sup> The FVO is an important actor in this regard. Studies reveal that when carrying out its control missions in TCs, the FVO tends to actively engage in a dialogue with the national and local authorities and exporting businesses (Lawless 2010, Rakpong 2011). In these cases FVO inspections and audits as well as the ensuing recommendations have been able to

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<sup>10</sup> See Articles 47 and 48 of Regulation 882/2004.

<sup>11</sup> It should be noted that European decision-makers seem well aware of their role (and responsibility) as a dominant global standard-setter. See Report from the Commission to the European Parliament and the Council on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed, animals, and plants, COM (2010) 785 final, p. 5: "The EU is also aware that its requirements often serve as benchmarks for international trade and carry a huge impact on developing countries, many of which are highly dependent on access to European markets."

<sup>12</sup> See Article 50 (2) of Regulation 882/2004.

<sup>13</sup> DG SANCO of the European Commission launched in 2006 the programme *Better Training for Safer Foods* (BTSF) that aims to improve and update (and keep up-do-date) knowledge on food and feed law, animal health and welfare and plant health rules and to ensure more harmonised and efficient controls, see Article 51 of Regulation 882/2004. Recently this task was transferred to the Executive Agency for Health and Consumers (EAHC), set up by Commission Decision 2008/544.

<sup>14</sup> See Article 46 of Regulation 882/2004.

exert considerable pressure on TC food safety policy and administrative arrangements. On the other hand, it is shown that FVO missions also give TCs the opportunity to communicate back to the EU, and to draw attention to issues of concern (*ibid.*)<sup>15</sup>

Thirdly, in some cases the EU can approve pre-export checks on exported products directly by TC authorities. The purpose of such checks is to verify that products satisfy EU safety requirements immediately prior to their export to the EU. An approval of pre-export checks triggers a reduction of the frequency of import controls at the EU border.<sup>16</sup> This approval needs to be granted through a decision of the Commission based on comitology procedures, which amongst others designates the TC authority responsible for pre-export checks. This TC authority will subsequently be considered as the *competent authority* in the sense of Article 2 (4) of the Official Food and Feed Controls Regulation. This approval process can be indicated as the transfer of the so-called internal *competent authority model* applicable to the national enforcement authorities within the EU,<sup>17</sup> to external regulatory cooperation with TCs, whereby the TC competent authority acts as a “*de facto*” agent of the EU in ensuring compliance with the latter’s food safety regulation even before exported products reach the Union border (Rakpong 2011).<sup>18</sup>

In parallel to these import safety mechanisms, the EU often engages in bilateral trade agreements, which include so-called sanitary and phytosanitary (SPS) provisions covering trade in agricultural products.<sup>19</sup> Some agreements deal exclusively with veterinary issues, while others form part of general trade or association agreements. These can also take the form of an equivalence agreement,

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<sup>15</sup> See also below at 3.2.

<sup>16</sup> See Article 23 of Regulation 882/2004.

<sup>17</sup> See Article 2 (4) of Regulation 882/2004.

<sup>18</sup> In a case study on EU-Thai trade relations in the area of food safety J. Rakpong shows that the Competent Authority Model has created a transnational “*quid pro quo*” relationship between EU and Thailand. Under this model Thai food exports enjoy “presumed equivalency status” which accelerates access to the EU market due to the reduced level of border controls. Moreover, through the resulting stronger institutional capacity of the Thai system, Thai authorities become stronger partners able to be heard when EU decisions concerning Thai products are being taken. See several illustrations of that on pp. 149-155.

<sup>19</sup> See Articles 11 and 12 of Regulation 178/2002, which explicitly foresee the conclusion of bilateral agreements in the area of food trade with TCs. See a list of existent SPS agreements on the European Commission website [http://ec.europa.eu/food/international/trade/agreements\\_en.htm](http://ec.europa.eu/food/international/trade/agreements_en.htm) (last accessed 7.02.2013).

in which the EU recognises regulatory standards of the third country as equivalent to those of the Union, thus permitting the imports from that country.<sup>20</sup>

We thus observe that the EU pursues a sophisticated transnational regulatory approach to ensuring the safety of imported food commodities.<sup>21</sup> It is risk-based, and thus flexible, and differentiated according to the respective risk category of both specific products and importing countries. Finally, this approach is dynamic and reflexive in the sense that it relies on cooperation and constant updating of risk information between a variety of actors from both the EU and TCs. Whether the implementation of this dynamic approach in practice is always successful is open to further research.<sup>22</sup>

### **2.3. The EU as an actor within the multilateral context of the WTO and the Codex Alimentarius Commission**

Another important dimension of EU's governance of food import safety is that it operates within the larger multilateral context of global governance institutions dealing with food safety issues. Of paramount importance in this regard is the EU membership in the World Trade Organisation (WTO) as well as in its "satellite" organisations, such as in the standardization body the *Codex Alimentarius Commission (Codex)* (see Masson-Matthee 2007). The EU's participation in the multilateral framework of both WTO trade rules and international food standard-setting could potentially mitigate its role as a unilateral "exporter" of EU food safety rules to TCs, to the extent that the setting of EU rules is in turn influenced by, or even based on, norms and standards developed jointly with other international actors within these multilateral *fora*.

In the academic literature on global governance, the WTO has been characterised as an effective mechanism of external accountability of powerful states and regional entities, such as the EU (Keohane 2003). By imposing upon its members the duty to justify import restrictions including regulatory standards by reference to the principles of non-discrimination among trade nations, proportionality of the restrictive measures,

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<sup>20</sup> See Article 49 of Regulation 882/2004 which states: 'Following the implementation of an equivalence agreement, or a satisfactory audit, a decision may be taken, in accordance with the procedure referred to in Article 62(3), recognising that measures that third countries or their regions apply in specific areas offer guarantees equivalent to those applied in the Community, if the third countries supply objective proof in this respect'.

<sup>21</sup> On the institutional aspects of this approach see in more detail the following sections 3. and 4..

<sup>22</sup> See for some shortcomings in practice below at 3.2. and 4.4..

adherence to existing international standards, and the duty to consult with trading partners, the WTO forces its 158 members to consider the external effects of internal policy making on foreign jurisdictions. (see Helmedach & Zangl 2006).<sup>23</sup> In a similar vein, scholars of global administrative law (GAL) see the WTO as a potentially important promoter of GAL principles, such as transparency, participation, reason giving and review in domestic regulation. According to Stewart and Badin these requirements help “ensuring the fair and even handed treatment of political outsiders and promoting the rule of law more generally” (Stewart & Badin 2009: 18). From an experimentalist perspective, Sabel and Zeitlin have characterised WTO law as a potential diffusion mechanism of experimentalist governance. By subjecting powerful actors such as the EU to multilateral deliberative constraints with regard to the justification of import restrictions the WTO has the potential to transform unilateral regulatory initiatives by developed countries into a joint governance system with stakeholders from the developing world, if not a fully multilateral experimentalist regime (Sabel & Zeitlin 2011).<sup>24</sup>

It is indeed widely recognised that WTO law is able to induce considerable change in domestic legislation and regulatory approaches, in particular in the areas of food or environmental safety and consumer protection (see De Búrca & Scott 2001).<sup>25</sup> A notable example is the overhaul of the legislative and institutional framework for EU food safety and risk regulation in the late 1990s and early 2000. It has been observed that the new principle of risk analysis involving a strict separation between the functions of risk assessment and risk management introduced in the General Food Law Regulation was not only a consequence of the problems of undue political interference in scientific risk assessment during the BSE crisis (see Vos 2000). In conjunction with that, the EU reform also goes back to the implementation of the WTO Agreement on Sanitary and Phytosanitary Measures, which entered into force in 1995, and was further reinforced by the findings of the dispute settlement bodies in

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<sup>23</sup> See Understanding on Rules and Procedures Governing the Settlement of Disputes, Marrakesh Agreement Establishing the World Trade Organization, Annex 2.

<sup>24</sup> For a critical perspective on the participation of developing countries in the WTO see Prevost 2009.

<sup>25</sup> It should be mentioned that this aspect of WTO law also often leads to critical comments with regard to the legitimacy of the WTO in restraining domestic autonomy especially in core areas of national policy-making such as public health and environmental protection, see G. Shaffer (2001), *The WTO under Challenge: Democracy and the Law and Politics of the WTO's Treatment of Trade and Environmental Matters*, 25 *Harvard Environmental Law Review* 1-93.

the beef hormones dispute between the EU and the US (Demortain 2012; Fisher 2007).<sup>26</sup>

Finally, EU's participation in international standard setting bodies, especially in the *Codex*, as well as the use of the resulting food safety standards as a basis for European regulation, indicates that many of the rules, which the EU imposes on TCs as a condition for market access, have not been developed in a unilateral fashion. In other words, to the extent that EU food safety rules exported to TCs are based on *Codex* and other international standards, they can be seen as the result of joint decision-making in global multilateral *fora*. TCs subject to those rules as importers into the EU have, at least in principle, participated in their setting at global level.<sup>27</sup> The increasing importance of international standards in EU food safety regulation results from WTO law. According to the SPS and TBT Agreements, the EU is obliged to base its food safety regulations on existing international standards (Scott 2009, Howse 2011).<sup>28</sup> In this way, WTO law would provide a presumptive "safe harbour" for Member States against challenges to domestic regulations adopted on the basis of international standards. Any deviation resulting in a higher level of protection than that achieved under the relevant international standard needs to be scientifically justified. As a result, many instances of European food safety regulation including import safety are based on international standards in general, and on *Codex* standards in particular (see Van der Meulen 2010; Mendes 2011).<sup>29</sup>

It is noteworthy that EFSA plays an important role in providing support on scientific matters to the EU and the Member States in the development and establishment of international food safety standards.<sup>30</sup> EFSA's experts assist the Commission in several *Codex* committees, and participate in two *Codex Ad Hoc* Intergovernmental

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<sup>26</sup> Beyond formal procedures of dispute settlement, the WTO creates other more informal deliberative fora, in which the EU and its trading partners can engage in information exchange, learning and, sometimes, mutual adjustment. WTO administrative committees, such as the SPS Committee, have been described as a hidden world of WTO governance, which operates in a dynamic, cooperative, and reflexive fashion (Lang & Scott 2009).

<sup>27</sup> Besides the EU 185 countries are currently members of the *Codex*, see *Codex* website at <http://www.codexalimentarius.org/members-observers/en/> (last accessed 14.02.2013).

<sup>28</sup> Article 3 (1) of the SPS Agreement and Article 2 (4) of the TBT Agreement.

<sup>29</sup> E.g. the definition of "food" in Article 2 of the General Food Law is based on the *Codex*, see Van der Meulen 2010: 237-238 with further examples. The obligation to consider international standards such as *Codex* standards in the development and adaptation of EU food law, where appropriate, is also laid down in the General Food Law Regulation (Art. 5(3)) together with the obligation for the EU to contribute to the development of international standards (Article 13 (a) and (b) of the General Food Law Regulation).

<sup>30</sup> Regulation 178/2002, preamble para. 39; see also Articles 23 (i) and 33 (2).

Task Forces.<sup>31</sup> While a key objective of this scientific support can be seen in advancing the EU preferred risk assessment approach within the *Codex*, EFSA also defines its task as “to be able to contribute to and to learn from international risk assessments activities and be fully embedded in the international scientific community.”<sup>32</sup> Therefore, EFSA as a networked agency seems to play an important role not only within EU’s internal governance of food safety (Vos 2010), but also in the external dimension connecting EU scientific experts and authorities with actors at global level.

#### 2.4. Experimentalist features

Our analysis showed that the Union’s role in transnational regulation of food safety vis-à-vis TCs can only be properly understood when viewed within the larger context of global governance. On the one hand, due to the economic attractiveness of its internal market and the strictness of its food safety rules the EU appears to be a powerful global standard-setter triggering processes of regulatory adjustment in TCs. This presents a challenge especially for developing countries seeing the high costs of compliance with EU safety requirements, and the often lacking technical and financial capacities in the developing world. On the other hand, it has also been shown that simply viewing the EU as a unilateral setter of import safety rules does not do justice to its involvement in multilateral governance institutions at the global level. Above all, WTO law and international standards, such as *Codex* standards, can, in principle, be seen as mechanisms of holding EU decision-makers to account for the external effects of the Union’s standards on other, especially developing, countries.

In experimentalist terms, these global governance institutions have the potential to destabilise EU’s internal decision processes by subjecting them to certain deliberative constraints. Moreover, with the increasing use of international standards as the basis for EU food safety regulation, global governance is transforming the nature of the EU as a unilateral standard-setter in this area. Bearing in mind the first characteristic of experimentalist governance, namely framework rulemaking, it follows that EU import safety rules exported to TCs as a condition for market access can be considered as, to some extent, the result of joint governance within global multilateral *fora*. With regard to the other three conditions of experimentalist

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<sup>31</sup> See EFSA, *International Activities – A Strategic Approach*, para. 11, document available at <http://www.efsa.europa.eu/en/corporate/doc/intstrategicen.pdf> (last accessed on 13.02.2013).

<sup>32</sup> *Ibid*, para. 6.

governance, namely discretion in the local implementation of rules, peer review, and recursive revision, it has been shown that rather than simply imposing EU standards on importing countries, the EU has developed several mechanisms of both co-operation with and capacity-building support for TCs in meeting its import safety requirements. In some cases, such as with the competent authority model, TC authorities are even acting as *de facto* agents of EU food safety regulation, which in turn allows them to communicate their needs and concerns back into the EU regulatory process.

### **3. The role of the EU Food and Veterinary Office in external governance of food safety**

#### **3.1. Role and tasks**

The EU Food and Veterinary Office (FVO) plays a crucial role in ensuring the functioning of the EU risk-based food import safety system, as set forth above. The FVO is a service within the Commission's Directorate General Health and Consumer Protection (DG SANCO). Its task is to ensure that Union legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced. It also undertakes market surveillance in these areas. The latter task is founded in the OFFC that lays down a number of rules for the performance of amongst other EU controls in the Member States and in TCs.<sup>33</sup> With regard to TCs, Article 46 states that Commission experts may carry out official controls in TCs in order to verify the compliance or equivalence of third country legislation and systems with EU food safety law. In fact, one out of three FVO missions take place outside of the EU.<sup>34</sup>

Through its audits, inspections and related activities the FVO aims to:

- 1) check compliance with the requirements of EU food safety and quality, animal health and welfare and plant health legislation within the European Union and compliance with EU import requirements in third countries exporting to the EU;

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<sup>33</sup> Articles 45-46. With regard to TCs Article 46 states that Commission experts may carry out official controls in TCs in order to verify the compliance or equivalence of third country legislation and systems with EU food safety law. In fact, one out of three FVO missions take place outside of the EU, see FVO Programme of Audits for 2013, p. 6.

<sup>34</sup> According to the FVO Programme of Audits for 2013, p. 6, 31 % of all missions are planned for TCs.

- 2) contribute to the development of European Community policy in the food safety, animal health and welfare and plant health sectors;
- 3) contribute to the development and implementation of effective control systems in the food safety, animal health and welfare and plant health sectors; and
- 4) inform stakeholders of the outcome of its audits and inspections.<sup>35</sup>

Rather uniquely, the FVO acts as an auditor of national law enforcement capacity. According to the Commission, by carrying out a programme of audits and inspections the FVO ensures that control systems at national level are effective. It evaluates the performance of national authorities against their ability to deliver and operate effective control systems, and undertakes visits to individual premises to verify that acceptable standards are actually being met.<sup>36</sup> The FVO, therefore, can be considered as the “eyes and ears” of the Commission.

The establishment and structure of the FVO goes back to the political and legal restructuring of the EU food safety system following the BSE crisis and the recommendations made by the *Medina Ortega* report. One of the aspects criticised by the latter was the quality and coordination of national and EU veterinary inspections during the BSE crisis. Amongst other things, the report stressed the need to ensure a better coordination between inspection and law-making in the EU:

“Any future structure should ensure the closest possible coordination between the legislative authorities and the bodies responsible for monitoring and verifying the practical application or otherwise of the rules. The inspectorate should act to follow up all legislation, and, conversely, the results of the inspections should be subject to constant scrutiny by the legislative and executive bodies.”<sup>37</sup>

In response, the Commission proposed to create the FVO.<sup>38</sup> This body would be “fully consulted on the development of veterinary, phytosanitary, and food legislation as, in many cases, their expertise will be needed to ensure that legislative proposals are properly informed by the situation in Member States and third countries.”<sup>39</sup> Thus, recursive rule-making in the sense of on-going revision of legislative objectives in the light of the results of FVO’s work has been an important feature of its governance design from the outset.

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<sup>35</sup> FVO Annual Report 2008, p. 2.

<sup>36</sup> European Commission (2000), *White Paper on Food Safety* COM(1999) 719 final.

<sup>37</sup> Medina Ortega Report, February 1997, p. 21.

<sup>38</sup> COM (97) 183 final.

<sup>39</sup> *Ibid.* p. 22.

In the aftermath of the BSE crisis independence of the EU audit system was regarded to be crucial. However, it was considered that independence could be achieved “through the establishment of a clearly defined legal and official status of the control services, covering their mission, the functions, and responsibilities of personnel, the procedures, the working practices etc”<sup>40</sup> while maintaining the services under the organisational structure of the Commission (Lawless 2010). The location of the FVO is in Grange, Ireland, which emphasises its exceptional status as an independent body within the Commission. While the FVO does not enjoy powers to take formal action against Member States or TCs for breach of EU food safety law, its mission reports form an important evidentiary basis for any actions taken by the Commission in situations in which the application of EU food safety law both at national level and within TCs is found to be unsatisfactory.

### **3.2. The experimentalist features of FVO’s missions in Third Countries**

When carrying out missions in TCs the FVO operates within the type of complex, diverse and strategically uncertain regulatory environment, which is seen as favourable to the emergence of experimentalist governance (Sabel & Zeitlin 2011). Firstly, regulatory and production conditions vary considerably among importing countries, often requiring different means to achieving the objective of EU food import safety. Secondly, monitoring and compliance with EU rules is more difficult to achieve by traditional command-and-control approaches based on the direct control by the FVO of individual food production establishments in TCs approved for export to the EU (Lawless 2010). These insights have led to the introduction of a new “systems approach” under the Official Food and Feed Controls Regulation, which is strongly related to the concept of an “audit” as defined under this regulation. According to this approach the focus of FVO missions is no longer on the inspection of individual exporting establishments – although this remains part of FVO’s work – but rather on the effectiveness of TC regulatory systems as a whole. Thus, when *auditing* control systems at national level the FVO undertakes a systematic examination “whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.”<sup>41</sup> In contrast to the previous situation, TCs that have

<sup>40</sup> European Commission (1998), *Communication from the Commission to the European Parliament, the Council, and the Economic and Social Committee on Food, Veterinary, and Plant Health Control and Inspection*, COM (1998) 32 final, p. 3.

<sup>41</sup> See Article 2 (6) of Regulation 882/2004.

been approved as having effective control systems in place, currently supply themselves the names of the establishments to be included in the EU lists of establishments approved for export. This leads Lawless to conclude that:

“As a consequence the current approach does necessarily require much more attention to the individual effectiveness of the regulatory system of a Third Country and, as a consequence, openness to learning about all the relevant circumstances in a given jurisdiction which are relevant to its operation.” (Lawless 2010)

The way the FVO operates when auditing TCs, in fact, displays several features of cooperative and reflexive governance, which aims at enhancing the control capacity on both sides of the EU-TC relationship. The process starts with the annual development of the FVO programme for audits, which identifies priority areas and countries to be visited (both within and outside the EU). This programme is published on the FVO website, and reviewed mid-year in order to keep it up to date to recent developments, such as food safety incidents. When identifying audit priorities, the FVO considers factors such as risk, legal requirements, trade and policy considerations, with risk being the main factor.<sup>42</sup>

In preparation of each mission, the FVO agrees in a consensual way on the itinerary of the mission with the national authorities of the audited country.<sup>43</sup> The priorities of each mission are being set considering the so-called country profiles developed and updated by an internal FVO unit. Country profiles ensure that an overall profile of each country visited is being maintained and updated, collating the findings of different general and specific missions over time. In addition,, when planning the mission the FVO also distributes so-called pre-mission questionnaires in order to obtain more information on regulation and the agri-food structure of the TCs.

Upon arrival in the TC the FVO team continues to closely cooperate with the national officials through personal meetings and the discussion of outstanding issues. Together, FVO and TC officials visit exporting establishments, such as production sites and farms. Lawless reports that problematic issues are noted and raised with TC officials during the course of the mission; and they are again raised at a close-out meeting with the TC authorities at the end of the FVO visit (Lawless 2010).

After the mission is completed the FVO prepares an audit report with recommendations to the country's competent authorities to deal with any

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<sup>42</sup> See FVO Programme of Audits 2013, p. 4.

<sup>43</sup> This account draws on the empirical study by James Lawless, “The EU's Food and Veterinary Office: Reflexive Risk Regulation in Action?” Paper presented at the Centre for Regulation and Governance of the University College Dublin in July 2010, on file with author.

shortcomings revealed during the FVO mission, giving the TC authorities the opportunity to comment on the report at draft stage. Where the TC authorities dispute a finding or recommendation of an FVO report, this is recorded alongside the final report. The TC authorities are requested to present an action plan to the FVO describing how they intend to address any shortcomings. This indicates that a certain degree of discretion as to how to implement FVO recommendations is granted to the local authorities. Subsequently the FVO, together with other Commission services evaluates this action plan and monitors its implementation through a number of follow-up activities. General review missions, follow-up inspections, requests for written reports and high-level meetings can be used by the FVO to ensure that improvements in the control systems are achieved.<sup>44</sup> Two examples show that the FVO's actions leads to reflection and adaptation of EU action and legislation, and that the functioning of the FVO with regard to TCs displays several features of experimentalist governance.

The first example relates to the crucial role played by the FVO in the so-called EU competent authority model as implemented in Thailand. In relation to two products, namely fresh baby corn and poultry meat, the relevant Thai government department has been granted the status of a competent authority in the sense of Article 2 of the OFFC. This status confers upon the Thai competent authorities the responsibility for guaranteeing that where these products are exported to the EU, they comply with the relevant EU food safety regulations, for which they issue the relevant export certificates that give presumed equivalency status under EU law, and reduce the frequency of full EU border checks thus accelerating access to the EU market (Rakpong 2011: 92, 127, 149).

Both prior to and after conferring the competent authority status, the FVO was responsible for checking the competency of the Thai authorities in question. The FVO reports have served as guidance for them in addressing areas of food safety concern indicating what has to be done in order to maintain the competent authority status. As a result, FVO recommendations have led to major reforms in the Thai food safety regulatory system and institutional structures. At the same time, Thai competent authorities have used FVO missions to communicate back to the EU, to attest their willingness to comply with the recommendations and issues raised, and to raise any concerns regarding the impracticality of the recommendations or the time frame for compliance (Rakpong 2011: 129-130).

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<sup>44</sup> FVO Annual Report 2008, p. 2.

The study also shows positive spill over effects following the introduction of the competent authority model for Thailand's regulatory and law enforcement capacity to respond to food safety incidents. This model has served as a "due-diligence defence" assisting Thai authorities in sustaining claims to limit the scope of EU import bans in case of certain incidents, such as for example during the 2007 "Shigella" outbreaks in Thai baby corn. By taking quick and effective crisis management measures Thai authorities were able to convince the EU Commission and FVO that the crisis situation was controlled, which in turn led the EU to take a more lenient approach and to refrain from imposing an outright ban on all baby corn from Thailand (Rakpong 2011: 149-155).

The second example relates to a series of FVO inspections concerning pesticide controls in food of plant origin intended for export to the EU that were carried out in 13 TCs<sup>45</sup> between 2004 and 2010. These missions were carried out subsequent to RASFF notifications of infringements of EU legal limits for pesticide residues in products from these countries. These missions evaluated the adequacy of systems in place for the control of pesticides in foodstuffs of plant origin intended for export to the EU. The FVO team in each country reviewed "the controls in place on the production and export, including a review of national legislation, competent authority organisation, their controls and enforcement capability, facilities (laboratory capability) and measures in place for the determination of pesticide residues in foodstuffs of plant origin."<sup>46</sup>

In its recommendations addressed to national competent authorities in the audited countries the FVO suggested an improvement in the national official controls systems with regard to EU MRLs, including better provision of information to farmers, better inspections, sampling of products for export, better evaluation of laboratories, and the broadening of scope of analyses in the pesticide residues laboratories.<sup>47</sup> It is noteworthy that the FVO also recommended following the sampling procedure for pesticide residues in line with the respective Codex Guidelines CAC/GL 33-

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<sup>45</sup> Argentina, Brazil, Chile, Costa Rica, Dominican Republic, Egypt, India, Israel, Kenya, Morocco, South Africa, Thailand, and Turkey; See Overview report of a series of missions carried out in third countries between 2004 and 2010 to evaluate controls of pesticides in food of plant origin intended for export to the European Union, No. 2010-6140-OR.

<sup>46</sup> The legal standards relevant for the FVO evaluation were Article 11 of the GFL, further specific EU provisions concerning maximum residue levels (MRL) of pesticides, and also MRLs established by the *Codex Alimentarius* Commission as international standards considered in EU legislation, *ibid.* P. 6.

<sup>47</sup> Noteworthy here is that one recommendation contained a reference to *Codex* standards, namely to follow the sampling procedure for pesticide residues in line with the respective *Codex* Guidelines CAC/GL 33-1999. This indicates that alongside EU standards the FVO also promotes international food safety standards. *Ibid.*, p. 15.

1999,<sup>48</sup> clearly indicating the FVO's readiness to promote international food safety standards.

The FVO's process of audits, evaluations, and recommendations led to further EU action. Firstly the EU Commission organised a series of training sessions (regional workshops, training courses etc) on pesticide controls; and secondly, on request of the TCs, the EU established 'import tolerances' under Regulation 396/2005, namely MRLs set for imported products to meet the needs of international trade under certain circumstances.<sup>49</sup> This shows that to some extent, the MRLs for pesticides standards were adjusted to the needs of the TCs in this case. Finally, the results of these missions provided the basis for increasing the levels of import controls on pesticide residues for certain specified produce from the Dominican Republic, Thailand, Turkey and Egypt under Commission Regulation 669/2009 implementing the Official Food and Feed Regulation.<sup>50</sup>

With regard to the first experimentalist feature of joint definition of framework goals by central and local units – in this case by EU authorities and TC authorities and other stakeholders – it should be noted that the FVO ensures compliance of TC regulation with EU standards. In contrast to the EU internal dimension,<sup>51</sup> in the external dimension we therefore observe an asymmetry in the functioning of the FVO to the extent that TCs do not directly participate in the formulation of EU food safety standards applied to them as a condition for market access. Additionally, FVO reports can serve as the basis for restrictive measures towards the country visited, such as increasing the frequency of import controls, import bans, or other import restrictions, which brings in an element of hierarchy and sanction in cases of non-compliance. In line with the multilateral context of EU standard setting we also observe that when auditing TCs, the FVO explicitly refers to *Codex* standards. Moreover, a joint definition of applicable import safety standards can be assumed in cases, in which the FVO acts within the framework of an existing bilateral SPS or equivalence agreement between the EU and the audited TC.

Our findings furthermore indicate several reflexive features in FVO's external governance of food safety, which could be seen as approximating further features of

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<sup>48</sup> *Ibid.*, p. 15.

<sup>49</sup> *Ibid.* p. 16: "where the use of the active substance in a PPP is not authorised in the EU for reasons other than public health reasons for the specific product and specific use; or a different level is appropriate because the existing EU MRL was set for reasons other than public health reasons for the specific product and specific use."

<sup>50</sup> *Ibid.*

<sup>51</sup> See Introduction.

experimentalism, namely broad discretion in the implementation of framework goals by local actors, reporting and peer review, and the subsequent recursive revision of the framework rules at the central level. Especially when operating within the competent authority model in TCs, the FVO forms part of networked transnational governance, in which EU and TC authorities cooperate. The two examples that we examined show that this system not only relies on the capability of both sides to learn from each other, but also triggers processes of adaptation and revision of rules on both sides. Surely, the onus of adaptation is more on the importing TC, especially in the case of economically weaker export dependent countries. What is interesting, however, is that the FVO's engagement with these countries is likely to trigger a process of EU support and capacity building, which in turn increases the chances of the TC to make its voice heard in the EU decision-making process on import conditions relevant to it.

More generally, FVO reports may highlight areas where the Commission needs to clarify or amend legislation or areas where new legislation may be required.<sup>52</sup> It is noteworthy that all FVO reports, inspections programmes, country profiles, annual reports etc are published on its website, which arguably allows for public overview and monitoring of the FVO's work.<sup>53</sup> In addition, the FVO as part of the Commission is also subject to audits carried out by the European Court of Auditors (CoA), which adds an element of reflexivity within the EU.<sup>54</sup> This institution has thus revealed some important shortcomings of FVO's work from an experimentalist perspective. These revelations show that at least in the area of meat import controls following the reforms of the EU hygiene package legislation the coordination between the central EU level and the national level was insufficient obstructing to some extent processes of peer review and mutual learning. Moreover, FVO's internal risk analysis model was found to be not transparent and did not take sufficient account of information transmitted through RASFF. Lastly, FVO was not always effective in inducing change and regulatory improvement within the EU Member States. Although these findings mostly concern the internal functioning of the EU official controls system, they do

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<sup>52</sup> FVO Annual Report 2008, p. 3.

<sup>53</sup> Article 7 of Regulation 882/2004 obliges the competent authorities to carry out their activities with a high level of transparency. The public shall, *eg.*, have access to all relevant information concerning their control activities and their effectiveness. Although this provision is addressed at national competent authorities this also implies the transparency of FVO's work reporting on the effectiveness of national control activities. It is noted though that some of these documents are published with enormous delay. For instance, the latest FVO annual report published on the internet is the one of 2008.

<sup>54</sup> European Court of Auditors, *The Commission's management of the system of veterinary checks for meat imports following the 2004 hygiene legislation reforms*, Special Report No 14/2010.

affect the overall functioning of its system of import safety, which is based on an effective cooperation and exchange of information between the EU and the Member States. Moreover, this raises the question to what extent similar problems could also occur in FVO's cooperation with TCs.

#### **4. The role of the Rapid Alert System on Food and Feed in external governance of food safety**

##### **4.1. RASFF as a transnational network**

Article 50 of the GFL establishes RASFF as an information exchange network involving the Member States, the Commission as a member and manager of the system, and the European Food Safety Authority (EFSA). Moreover, the membership of the network is not confined to EU Member States, but includes the European Free Trade Association (EFTA) countries Norway, Liechtenstein, Iceland, Switzerland and the EFTA Authority as full members of the network.<sup>55</sup> However, the RASFF is more than a regional (EU + EFTA) network. Other TCs importing into the EU and international organisations also participate in the RASFF. According to Article 50 (6) GFL applicant countries, TCs or international organisations may participate in the RASFF on the basis of agreements between the EU and those countries or organisations.

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To enhance the information exchange with TCs the Commission is obliged to establish contact with designated RASFF contact points in TCs. Moreover, it is obliged to inform a TC without undue delay if a RASFF notification concerns a product originating from or distributed to a TC.<sup>56</sup> The information exchange is facilitated through the electronic database *RASFF Window*, which gives non-RASFF member countries direct access to a database of notifications directly relevant to them. The Commission sees the development of data exchange tools such as *RASFF Window* as indispensable in making RASFF a source of global inspiration.<sup>57</sup>

The main objective of RASFF is to allow for a rapid exchange of information about measures taken in response to serious risks detected in food and feed products on the European, and sometimes global market. The mechanism requires that the Commission be immediately notified of all measures taken to prevent or restrict the

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<sup>55</sup> RASFF annual report 2011, p. 7.

<sup>56</sup> Article 50 (4) of Regulation 178/2002 and Article 10 of RASFF implementing Regulation 16/2011 OJ L 6 (2011), p. 7.

<sup>57</sup> See Commission Communication on RASFF COM (2009) 25 final, "30 Years of Keeping Consumers Safe", p. 35.

marketing of a food adopted by national authorities or by food business operators.<sup>58</sup> In 2011 3812 original notifications were exchanged through RASFF complemented by 5345 follow-up notifications.<sup>59</sup> Most notifications were triggered by border controls of imported food products, while the second largest category of notifications concerns official controls on the EU internal market.<sup>60</sup> Some notifications are also triggered by official controls through TC authorities in a non-member country.<sup>61</sup> Moreover, in many cases<sup>62</sup> TCs are notified about a problem with a food product exported to them. This shows that RASFF also fulfils the function of ensuring food safety outside of the EU, and thus for consumers worldwide.

Within the RASFF system, every notification needs first to be sent to the Commission, which, as the RASFF manager, verifies and compiles the information and documentation submitted, and immediately forwards it to all other members of the network.<sup>63</sup> Surely, the two roles of the Commission within RASFF, that of a manager and that of a member equal to other members, can conflict. However, case law of the Court of Justice clarified that the Commission's role as an equal member of the network takes precedence over its responsibility as a manager who could reject a notification based on insufficient or erroneous information, or when disagreeing with measures of a RASFF member who triggered the notification. In the *Bowland Dairy* case, which concerned a complaint over the Commission's attempt to block a RASFF notification by the UK's Food Standards Agency, the European Court of Justice, thus rejected the right of the Commission to reject another member's notification.<sup>64</sup> Following this judgment, the Commission now states in its RASFF annual reports that it can reject notifications only in agreement with the notifying member, and after having consulted it.<sup>65</sup> This stresses the non-hierarchical nature of the RASFF network.

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<sup>58</sup> There are four types of notifications under RASFF: Alert notifications, Border rejections, Information notifications and RASFF news see Articles 3-6 of of Regulation 16/2011.

<sup>59</sup> An increase of 6,7 % as compared to the previous year. See RASFF annual report 2011.

<sup>60</sup> 30 % of all alert notifications and over 80 % of all border rejections concerned products originating from a third country, see RASFF annual report 2011 p. 43.

<sup>61</sup> *Ibid.*, p. 11; see also Commission Communication on RASFF, *ibid.* fn. 59, p. 31 describing the *aflatoxin* contamination of dog food from the US, in which the US Food and Drug Administration has alerted RASFF of that problem.

<sup>62</sup> 586 notifications in 2008, see RASFF annual report 2011, p. 29.

<sup>63</sup> Article 50 (2) Regulation 178/2002.

<sup>64</sup> Case T-212/06 *Bowland Dairy Products Ltd. Vs Commission*, ECR 2009 II-04073

<sup>65</sup> *Ibid.*, See also Article 9 of Regulation 16/2011.



Member States<sup>67</sup> and the likely extension of the EU RASFF system to China.<sup>68</sup> According to Alemanno (2010: 214), the EU is currently focusing its efforts on extending its reactive ‘safety-net’ regulatory model including the RASFF beyond its borders, “thus inevitably giving rise to an interesting legal export of its own approach to import safety”.

Another interesting example of the global extension of RASFF is the cooperation with the International Food Safety Authorities Network (INFOSAN), the alert system of the World Health Organisation (WHO). INFOSAN is an information network that exchanges information about food safety issues with international implications with national focal points in over 160 member-countries.<sup>69</sup> RASFF and INFOSAN cooperate on a case-by-case basis. A first crucial case of such cooperation took place during the 2008 global melamine contamination crisis (see Alemanno 2010). Here high levels of melamine were found in infant milk and other dairy products in China in the summer of 2008, as a result of which six children had died and over 300,000 people had become ill. The global scope of the contamination problem (contaminated milk ingredients were shipped around the world) triggered, in the words of the Commission, an unprecedented degree of international cooperation. INFOSAN took the global lead in the crisis gathering information from amongst other China, the US Food and Drugs Administration, and RASFF, and was sending updated information to all INFOSAN members across the globe.<sup>70</sup>

Based on the positive experience of international cooperation during this crisis, the EU is currently seeking to extend its cooperation with INFOSAN. It has approached the WHO about working together with INFOSAN, “to create a strong global system to ensure food safety and thus to protect people across the globe.”<sup>71</sup> It is suggested that INFOSAN, which was established only in 2004, could profit from the 30 years of EU experience with RASFF in creating a global rapid alert network. However, making such a global system work would require capacity-building in TCs. For that purpose the EU RASFF team within the Commission organises training sessions under the *Framework of Better Training for Safer Food* programme for different regional groups, including ASEAN and the Mercado Común del Sur (Mercosur) as well as in

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<sup>67</sup> See Commission Communication on RASFF, *ibid.* fn. 59, p. 37.

<sup>68</sup> This follows the positive experience both countries have had with the establishment of the China Rapid Alert System for Non-Food Consumer Products (RAPEX), see Alemanno 2010.

<sup>69</sup> Commission Communication on RASFF, *ibid.* fn. 59, p. 33; World Health Organisation, International Food Safety Authorities Network (INFOSAN), October 2007, available at [http://www.who.int/foodsafety/fs\\_management/infosan/en/](http://www.who.int/foodsafety/fs_management/infosan/en/) (last accessed on 4 May 2012).

<sup>70</sup> Commission Communication on RASFF, *ibid.* fn. 59, p. 33.

<sup>71</sup> *Ibid.*, p. 34.

Africa and non-EU European countries in order to better liaise with both INFOSAN and RASFF.<sup>72</sup>

### 4.3. The experimentalist features of RASFF's external governance

Both the active participation of TCs in RASFF and its cooperation with global institutions such as INFOSAN show that RASFF can today be considered a transnational network. Moreover, the type of cooperation triggered by TC involvement in the rapid alert network seems to display several features of experimentalism.

With regard to the first feature, namely joint rule-setting,<sup>73</sup> the observations made with regard to the experimentalist nature of the FVO<sup>74</sup> also apply here. As long as RASFF serves to enforce extraterritorially food safety rules set by the EU in a unilateral fashion, it appears to support the export of EU standards to TCs rather than being truly experimentalist. However, as shown above,<sup>75</sup> the setting of EU food safety standards is subject to the reflexive discipline of WTO law on the one hand, and is often based on standards set within multilateral regimes at global level (eg *Codex*) on the other. This multilateral, rather than unilateral nature of EU standards is reflected in RASFF's work, namely where the network is used to monitor compliance of imported products with international standards as incorporated in EU legislation.<sup>76</sup>

Other experimentalist features, such as the active input of TCs as local units, reporting, peer review and recursive rule-making are clearly present in RASFF. To begin with, hierarchy is absent within the latter, and all RASFF contact points, including those in TCs, participate in the information exchange as equal partners. TCs are both recipients and transmitters of relevant information within RASFF. As will be shown below, a RASFF notification concerning a problem with an imported product or a product exported to a TC triggers processes of cooperation, mutual consultation, reporting, and monitoring of progress between EU and TC authorities and other relevant actors, such as business operators. The data collected through

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<sup>72</sup> *Ibid.* p. 37.

<sup>73</sup> See Introduction.

<sup>74</sup> At 3.2..

<sup>75</sup> At 2.3..

<sup>76</sup> E.g. the RASFF annual report 2011 indicates a decrease in *aflatoxins* notifications for the product category nuts for the third year in a row, which is related to the change of EU legislation in 2010 whereby the maximum levels for *aflatoxins* in almonds, hazelnuts, pistachios, and Brazil nuts have been aligned with *Codex* maximum levels. The decrease in notifications has, in turn, resulted in reduction of the required control frequency at import. See p. 18.

RASFF is publicly accessible through the portal database published on the Commission website together with weekly overview reports. This element of transparency in the functioning of RASFF could be seen as allowing, in principle, for public monitoring (especially through media) of the activities triggering RASFF notifications as well as their follow-ups.

Examples of these experimentalist features relate to the role of RASFF in relation to a notified problem with an imported product that may lead to a mission of the FVO to the relevant TC. In this respect, both FVO and RASFF play important complementary roles in the process of engagement with TCs. All measures following an incident notified through RASFF are being monitored by both the FVO – where it gets involved – and all RASFF members. The latter in turn evaluate, if and in what way they are concerned by the food problems reported by the original notification. Thus, national food safety authorities and control bodies within and outside the EU are continuously learning from each other's actions, and updating information. The actions taken by the TC concerning each food incident reported within RASFF are being reviewed and their success assessed not only by the Commission, but also by all members of the network, and TCs concerned.

Another example of RASFF's effective functioning in a reflexive and learning inducing way relates to the Fukushima nuclear accident in March 2011. The release of radioactivity at the Daiichi nuclear power plant in Fukushima following a severe earthquake seriously affected also the feed and food chain. EU action began four days after the accident with DG SANCO sending a RASFF notification, which recommended carrying out analyses on the level of radioactivity in feed and food imported from Japan. Subsequently the Commission adopted a precautionary emergency measure based on Article 53 of the General Food Law, which imposed special conditions on the import of feed and food originating from Japan. This included a requirement for pre-export checks by Japanese authorities on all exported food and feed from the affected zone complemented by random controls at EU borders. Additionally, Member States had to report the results of their controls through RASFF and the European Community Urgent Radiological Information Exchange system (ECURIE).<sup>77</sup>

Interestingly, at first the EU applied maximum levels for the pre-export checks of radioactivity, which were established by EU legislation.<sup>78</sup> However, for reasons of

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<sup>77</sup> RASFF annual report 2011, p. 34.

<sup>78</sup> Council Regulation (EURATOM) No 3954/8724.

providing consistency between pre-export controls performed by the Japanese authorities and the controls on feed and food from Japan at import, the Commission decided in April 2011 to apply the stricter maximum levels already applied in Japan. This is a clear example of adaptation of EU standards in view of regulatory practices in a TC.

The original emergency measure was subsequently reviewed and updated on a regular basis to take account of the development of the situation. According to the Commission in the overall management of the crisis situation RASFF has proven to be indispensable to ensure an effective and rapid communication with the Member States and Japan concerning the development of the situation, the measures to be taken, and the sharing of control results.<sup>79</sup>

Importantly, RASFF notifications feed back into EU legislation in general and recursive reformulation of food import rules in particular. EU rules are constantly revised in the light of the performance of TCs following a RASFF notification. The most direct consequence of RASFF notifications is the ongoing updating of EU rules concerning the intensity of border checks for certain product categories and countries of origins. Moreover, when immediate measures are required because of an eminent safety risk, RASFF notifications can also lead to more restrictive measures such as the import bans, or stricter import requirements. The monitoring of regulatory progress in TCs triggered through RASFF at the same time gives the TC the chance to show that restrictive measures are no longer necessary, and should be lifted.

#### **4.4. Shortcomings in the functioning of RASFF: the case of the *E-Coli* outbreak**

There are, however, other examples presenting a more differentiated picture of RASFF as an experimentalist mechanism. On the one hand, especially in bigger food crisis situations, RASFF often in combination with FVO missions to TCs clearly manages to uncover weaknesses of the existing EU food safety system allowing both EU and TC regulators to draw lessons, and to adjust their systems in view of new knowledge and experience. On the other hand, however, both RASFF's functioning and the learning processes induced are not always successful in practice.

The dramatic food contamination following the *E-coli* (Shiga toxin-producing *Escherichia coli* (STEC) 0104:H4) outbreak in Germany is a case in point of the latter. In May 2011 a major outbreak occurred due to a contamination of sprouted

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<sup>79</sup> RASFF annual report 2011, p. 35.

seeds with STEC, most likely linked to a consignment of fenugreek seeds imported from Egypt.<sup>80</sup>

As soon as the outbreak was notified, the German and *Länder* health services were mobilised, launching alert systems at all levels (local, national, EU and international).<sup>81</sup> The EU crisis response mainly focused on coordination and provision of relevant information through EFSA risk assessments, RASFF notifications, and the involvement of further EU actors, such as the FVO and the European Centre for Disease Prevention and Control.<sup>82</sup> For the purposes of our analysis the role that RASFF played in the dissemination of erroneous information concerning the source of the *E-coli* outbreak is of high interest.

Following tests carried out at the Hamburg Institute for Hygiene and Environment, which showed four cucumbers from Spain carrying traces of the *e-coli* bacterium, the Hamburg sub-federal authorities accused cucumbers of Spanish origin to be the contamination source and issued a RASFF alert<sup>83</sup> concerning Spanish cucumbers.<sup>84</sup> Only few days later, however, the Federal Institute for Risk Assessment (BfR), a federal expert authority, had to correct the test results from Hamburg, because the *E-coli* bacterium identified on the Spanish cucumbers was in fact not identical with the dangerous *E-coli* strain (O104:H4), which caused the outbreak.<sup>85</sup> The RASFF notification from Hamburg was subsequently declared “closed” by the Commission. Yet by that time considerable economic and political damage had already occurred<sup>86</sup>

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<sup>80</sup> Technical Report of EFSA from 5.07.2011, *Tracing seeds, in particular fenugreek (Trigonella foenum-graecum) seeds, in relation to the Shiga-toxin producing E. coli (STEC) O104:H4 outbreaks in Germany and France.*

<sup>81</sup> *Ibid.*

<sup>82</sup> For a more detailed account of all actions see *ibid.*

<sup>83</sup> The RASFF portal contains an alert notification from 27.05.2011 with the reference number 2011.0703 and title: “shigatoxin-producing Escherichia coli (O8:H19 stx2+) in organic cucumbers from Spain”.

<sup>84</sup> See Financial Times Deutschland, *EHEC entlarvt Ämter als Gurkentruppen*, 04.06.2011, <http://www.ftd.de/wissen/leben/:gefaehrlicher-darmkeim-ehc-entlarvt-aemter-als-gurkentruppen/60061033.html> (last access 24.02.2013).

<sup>85</sup> See website of the German Institute for Risk Assessment at [http://www.bfr.bund.de/de/presseinformation/2011/13/ehc\\_keime\\_auf\\_spanischen\\_gurken\\_stimmen\\_nicht\\_mit\\_dem\\_erreger\\_typ\\_der\\_betroffenen\\_patienten\\_ueberein-70721.html](http://www.bfr.bund.de/de/presseinformation/2011/13/ehc_keime_auf_spanischen_gurken_stimmen_nicht_mit_dem_erreger_typ_der_betroffenen_patienten_ueberein-70721.html) (last accessed 16.01.2013).

<sup>86</sup> According to the Commission the losses for farmers in the fruit & vegetable sector were estimated at least 812 Million (Mio) € in the first 2 weeks. In addition a temporary export ban of vegetables to Russia occurred, constituting an annual value of 600 Mio €. See SANCO/13004/2011, *Commission Staff Working Document on the lessons learned from the 2011 outbreak of Shiga toxin-producing Escherichia coli (STEC) O104:H4 in sprouted seeds.*

especially among Spanish agricultural producers .<sup>87</sup> which led to strong political tensions between both German and Spanish authorities and media. This led to calls for reform of the RASFF in particular by the Spanish food safety authority with regard to establishing clearer criteria for the use of this mechanism.<sup>88</sup> It appeared that the RASFF system suffered from various problems relating to the coordination of internal risk communication between the German authorities due to the lack of coordination between the sub-federal and federal level.<sup>89</sup>

However, the final reports on the *E-coli* outbreak issued by the German federal authorities involved in its crisis management, such as the Federal Institute for Risk Assessment, the Robert Koch Institute, and the Federal Authority for Consumer Protection and Food Safety, do not mention any of these coordination and communication problems. On the contrary, the final official report of the Federal Institute for Risk Assessment even heralds the management of this crisis by the German authorities as a success and concludes that

‘... the newly developed outbreak investigation strategy of the Task Force EHEC with close collaboration between German federal and federal state authorities and between food safety authorities, health authorities and scientists was a recipe of success and can be a model for future food-borne outbreak investigations.’

The EU institutions, however, seem to be more critical about the problems that occurred during this outbreak. As ‘lessons learned’ from this crisis, the Commission thus suggests extensive measures<sup>90</sup> aiming at improving crisis management and food safety in the EU, in particular in relation to coordination and communication between different levels and actors.<sup>91</sup> This indicates that a learning process has taken place at EU level in view of the implementation experience during the outbreak, although interestingly, this learning process is not backed up by any explicit analysis of what exactly the Commission deems had gone wrong. The Commission thus does

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<sup>87</sup> A total of 350 Million Euro, see *ibid.*, Annex 2.

<sup>88</sup> See Financial Times Deutschland, *ibid.* fn. 85.

<sup>89</sup> The RASFF notification from Hamburg was first based on erroneous scientific evidence. Moreover, the sub-federal authorities did not coordinate its risk communication strategy with the responsible federal authorities, such as the BfR. While the German *Länder* are responsible for law enforcement and crisis management at sub-federal level, the BfR is the German RASFF contact point for the EU. Such problems of coordination between the sub-federal and federal level have led to calls by the German opposition party for the government to ensure a more effective communication between the *Länder*, the federal authorities, and the EU. *Ibid.*

<sup>90</sup> See overview in Commission staff working document on E-coli, *ibid.* fn. 88, Annex 1.

<sup>91</sup> *Ibid.*

not mention the problems of German risk communication described above. Yet the Commission seems to hint at these problems where it argues that in order to 'ensure efficient and coordinated risk communication and communication towards the public at all levels – local, national, EU and international',

“... information must be timely, **sound and robust**, and that all involved partners should coordinate their communication activities in a faithful and transparent fashion so as to avoid the transmission of contrasting messages to the public.” (*Original emphasis*)<sup>92</sup>

It seems therefore that a major problem of risk communication during the E-coli outbreak was that wrong or unverified information was communicated by the Hamburg authorities through RASFF too quickly, without prior validation by the formal German federal RASFF contact point (BfR). This is related to a more general problem with regard to RASFF's operation, namely the question whether or not unverified information can be communicated through it.<sup>93</sup> The RASFF implementing regulation reflects indeed the need to exchange risk information as early as possible in order to allow learning processes and effective crisis management by all members concerned by a notification. At the same time, this requirement might be seen as in tension with the principle of transparency, also inherent in RASFF's operation, as mentioned above. It has been observed that the demand for increased transparency of the RASFF system combined with the demand for the transmission of incomplete information increases institutional risk. Casey and Lawless in their study of the 2008 Irish pork dioxin contamination have noted that given the transparent nature of RASFF notifications, any exchange of information is a potential “political” minefield as it carries the possibility of reputational damage (Casey & Lawless 2011: 345). In contrast to the *E-coli* outbreak, in the Irish pork contamination case, the tension between transparency and early risk communication materialised by preventing RASFF members from sharing important yet incomplete risk information at an early stage of the crisis (ibid: 337). German risk communication during the E-coli outbreak demonstrates the other extreme of the same problem while raising doubts as to whether the “right” lessons have been learned from previous food incidents such as the 2008 Irish pork dioxin scandal. This highlights the need for clarification in the future of how and when risk information should be communicated by whom through RASFF. The Commission Staff Working Document on *E-Coli* does not address this question.

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<sup>92</sup> See *ibid.*, p. 8.

<sup>93</sup> According to the RASFF implementing regulation 16/2011 “the fact that not all relevant information has been collected shall not unduly delay transmission of alert notifications.”

## 5. Conclusions

This chapter has examined whether and how far EU external governance of food safety in relation to TCs and global institutions displays an experimentalist architecture comparable to that previously identified in the Union's internal food safety governance system (Vos 2010). Overall, significant potential for experimentalism has been identified in the functioning of EU's food import safety system in general and in the operation of its institutional mechanisms, such as the FVO and RASFF, in particular.

Thus the role of the EU as an external actor of transnational food regulation needs to be differentiated. On the one hand, it cannot be denied that the EU constitutes a "normative empire," i.e. a powerful unilateral global standard-setter in the area of food safety, because it is able to extend its regulatory requirements to TCs as a condition for their market access. This is especially problematic in the case of developing countries, for which EU food safety standards can become *de facto* trade barriers. On the other hand, European decision-makers seem to be aware of their role (and responsibility) in this regard. Not only is there a legal obligation in the EU to consider the impact of its food regulation on developing countries, but the Union has also developed several governance mechanisms to build the technical and financial capacity of developing countries exporting to it.

Moreover, our analysis has shown that the EU system of food import safety needs to be seen in the context of global food safety governance institutions, such as the WTO, and international standards setting bodies, such as the *Codex Alimentarius* Commission. These global institutions can be seen as mechanisms for holding EU decision-makers to account for the external effects of EU standards on other, especially developing, countries. In experimentalist terms, these institutions have the potential to destabilize EU's internal decision processes by subjecting them to certain deliberative constraints. Moreover, with the increasing use of international standards as the basis for EU food safety regulation, global governance is transforming the nature of the EU as a unilateral standard-setter in this area.

It follows that EU food safety rules exported to TCs as a condition for market access can be considered to some extent as the result of joint rule-setting within global multilateral *fora*. Furthermore, rather than simply imposing EU standards on importing countries, the EU has developed several mechanisms of both co-operation with and capacity-building support for TCs in meeting the EU import safety

requirements. In some cases, such as with the competent authority model, TC authorities may even act as *de facto* agents of EU food safety regulation, which in turn allows them to communicate their needs and concerns back into the Union's regulatory process.

However, it should be stressed that the extent to which experimentalism actually takes place in EU external governance of food safety may vary depending on the specific context and relationship with the TC. While the present study demonstrated *the potential* of this complex system to foster experimentalism, we also see a need for more detailed empirical research to examine specific cases of EU-TCs interactions in this area, as well as the functioning of WTO governance and international standard-setting from an experimentalist perspective. Notably, the extent to which global governance institutions are able to foster the development of experimentalism in the EU is likely to depend on the realization of further conditions.

Firstly, multilateral global regimes, such as the WTO and *Codex*, could be seen as fostering experimentalism at the lower EU level of governance even if they themselves do not display an experimentalist architecture, because they still can destabilize EU internal decision-making, e.g. by imposing legal justification requirements for trade restrictive regulation. It seems however that the potential of global governance to act as a diffusion mechanism of experimentalism (Sabel & Zeitlin 2010) increases where global institutions like WTO and *Codex* themselves function as experimentalist systems. Taking the example of EU import conditions, the question arises whether TCs can in fact be regarded as effectively influencing the setting of these conditions within WTO or the *Codex*, if the latter are *de facto* dominated by few powerful international actors, such as the EU? Moreover, can we regard the *Codex* as an effective diffusion mechanism for experimentalism in the EU, if TC implementation experience does not feed back into its standard setting? Some studies concerning WTO committees and *Codex* standardisation do in fact indicate features of experimentalism also at global level (Lang & Scott 2009; Demortain 2012), but further research is necessary. Secondly and related to the first point, joint goal-setting at global level can only be assumed to the extent that developing countries are in fact able to make their voice heard in both the WTO and international standard setting bodies. It is, therefore, important to study the conditions under which the participating capacity of poor countries in global governance initiatives could be improved.

Furthermore, our analysis of the FVO and RASFF as institutional mechanisms of EU's external food safety governance has shown that both are designed, and often

function as reflexive institutions with strong features of decentralised implementation, reporting and peer review, as well as learning and recursive revision of rules. Both FVO and RASFF provide important opportunities for TCs to participate in EU's internal governance and rule-making processes.

Closer analysis of FVO missions in TCs has shown that the latter formulates its recommendations under the active participation of the national authorities of the audited country, which in turn autonomously develops a plan of how to implement these recommendations. This process is being constantly monitored. Follow-up action includes subsequent reviews, recommendations, and monitoring of implementation. Especially when operating within the competent authority model in TCs, the FVO makes part of networked transnational governance, in which EU and TC authorities cooperate. The reported examples show that this system not only relies on the capability of both sides to learn from each other, but also triggers processes of adaptation and revision of rules on both sides. Surely, the onus of adaptation is more on the importing TC, especially in the case of economically weaker export dependent countries. What is interesting, however, is that the FVO's engagement with these countries is likely to trigger a process of EU support and capacity building, which in turn increases the chances of the TC to make its voice heard in the EU decision-making process on import conditions relevant to it.

However, in practice some problems exist with regard to the effective coordination between the FVO and the Member States in the area of meat import controls; a lack of coordination between RASFF notifications and FVO's annual audit planning; and difficulties of the FVO to effectively induce change and regulatory improvement within the EU Member States. While these findings mostly concern the internal functioning of the EU official controls system, they do affect the overall functioning of the EU system of import safety, which is based on an effective cooperation and exchange of information between the EU and the Member States. Moreover, this raises the question to what extent similar problems could also occur in FVO's cooperation with TCs.

Our analysis of RASFF has demonstrated that today it can be considered a transnational network due to both the active participation of TCs and RASFF cooperation with global institutions such as INFOSAN. Moreover, the active input of TCs as local units, reporting, peer review and recursive rule-making are clearly strong features of RASFF. Hierarchy is absent within the latter, and all RASFF contact points, including those in TCs, participate in the information exchange as equal partners. TCs are both recipients and transmitters of relevant information within

RASFF. A RASFF notification concerning a problem with an imported product or a product exported to a TC triggers processes of cooperation, mutual consultation, reporting, and monitoring of progress between EU and TC authorities and other relevant actors, such as business operators. The data collected through RASFF is publicly accessible through the portal database published on the Commission website together with weekly overview reports. Finally, EU rules are constantly being revised in the light of the performance of TCs following a RASFF notification. The most direct consequence of RASFF notifications is the ongoing updating of EU rules concerning the intensity of EU border checks for certain product categories and countries of origins.

At the same time our analysis of RASFF's functioning during the *E-Coli* outbreak has indicated problems of reflexivity and institutional learning. It seems that a major problem of risk communication during the *E-coli* outbreak was that wrong or unverified information was communicated through RASFF too quickly and without prior validation by the German federal RASFF contact point (BfR). This is related to a more general problem with regard to RASFF's operation, namely the question whether or not unverified or uncertain information can be communicated through the network. Although this question was already raised in previous EU food safety crises, for example during the 2008 Irish pork dioxin contamination, it is not directly addressed in the current reflection on the regulatory problems during the *E-coli* outbreak at EU level, nor at national level. This is surely something that needs to be done in the future.

In sum we conclude that there is a strong potential for the extension of the experimentalist features of EU food safety governance both transnationally and to the global governance of food safety. Whether this potential is fully realised in practice seems to depend on the precise relationship of the Union with individual TCs, and its willingness to address the shortcomings we revealed in the FVO and RASFF systems, as well as on the successful functioning of WTO governance and international standard-setting as diffusion mechanisms of experimentalism. This requires further, in-depth research.

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