The Food and Veterinary Office: Risk, Responsivity and Reflexivity Combined?

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Abstract

Reflexivity has been identified at different stages of EU food and veterinary regulation: principally at the level of scientific advice (EFSA) and regulatory management (comitology committees). However no attention has been paid to the operation of reflexivity, and the related concept of responsive regulation, at the separate stage of monitoring implementation of EU food and veterinary law at the domestic level. In addition the monitoring of EU food safety and veterinary public health law by regulators in third countries has been given little systematic attention. This monitoring task has become a highly specialised function of the European Commission, through its subunit the Food and Veterinary Office (FVO), which enjoys an unusual status as a quasi-independent regulatory actor, albeit maintained within the formal Commission structures. This paper will investigate the degree to which the regulatory work of the FVO is marked by responsive processes. The investigation will examine two particular aspects of the FVO in order to make a preliminary assessment about the scope of responsivity: i) the historical and contextual evolution of the FVO as a regulatory actor and ii) the current legislation governing its operation as an auditor and monitor of national implementation and enforcement. Given the FVO’s role as a public auditor of public regulators ‘on-the-ground’, reference will also be made to the dynamics of ‘regulation inside government’, the ‘audit society’ and ‘risk-based regulation’ in order to add to understandings of the factors affecting FVO’s potential for responsiveness and reflexivity.

Introduction

Reflexivity and responsiveness have emerged as two novel and linked concepts in regulation theory¹. Responsive regulation has developed as a notion of viable regulation which is neither ‘command-and-control’ nor pure ‘self-regulation’ but which takes account of the conduct of the individual regulatees, which in turn “should channel the regulatory strategy to greater or lesser degrees of government intervention...an attitude that enables the blossoming of a wide variety of regulatory approaches”². Reflexive law and regulation³ shares a number of similarities with research into

² Ayres, I. and Braithwaite, J. (1992) Responsive Regulation: Transcending the Deregulation Debate (New York, OUP)
responsiveness and has examined processes whereby meaningful deliberation and learning between regulators and the regulated forms the central basis of effective regulatory outcomes in certain circumstances. Reflexivity has been underlined as a requisite approach to regulation in a number of contexts, particularly in areas characterized by multi-level governance, dominated by complexity and uncertainty, affected by information asymmetries and tainted by crises. Yeung conceptualises the common ground between these two concepts well by claiming that they “may be viewed in the context of increasing calls to develop regulatory processes and institutional structures that will enhance deliberation and enable participation, which Black identifies as proceeding under the banners of reflexive law, responsive regulation, or most broadly, ‘proceduralisation’, all of which ascribe a critical role to deliberative, participatory procedures as a means for securing regulatory objectives”.

The regulatory environment for EU food safety and veterinary public health displays many of the features of a ‘site’ requiring reflexive and responsive processes given the complexity, scientific uncertainty, historical crisis and information asymmetries which have marked its evolution over many decades. Existing research has already identified the existence of different forms of reflexivity within EU foodstuffs comitology committees, as well as within the work of the European Food Safety Authority (EFSA) and its mechanisms for scientific advice on food risks. No research has explored the operation of reflexivity and responsiveness at the implementation and enforcement stages of EU food and veterinary law, particularly at the stage of monitoring of compliance.

Central to the effectiveness of EU food safety and veterinary public health law is the oversight of its uniform implementation, application and enforcement by Member States. Chief responsibility for this task rests with the European Commission, as guardian of the treaties, under Article 17(1) TEU (ex Article 211 EC Treaty) and Article 247 TFEU (ex 216 of the EC Treaty). Poor implementation and enforcement of EU food and veterinary law have been the cause of a number of high-profile food scares, most significantly the BSE crisis in the 1990s. In 1999, a relatively minor contamination of pig and poultry meat with dioxins erupted into a major dispute between the European Commission and Belgian authorities, due primarily to conflicts over the latter’s implementation of EU risk management decisions.

In response to the failings of regulation during the BSE crisis, the EU

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established the Food and Veterinary Office (FVO) in order to ensure a permanent force to oversee Member States in their role as food safety regulators. The FVO is also responsible for monitoring food safety and veterinary services in non-EU countries which export live animals and food to the EU. Given its highly specialised responsibility, an examination of the FVO is vital to understanding the degree of reflexivity and responsiveness at this stage of EU food regulation. This paper will proceed by giving an overview of the historical context which lead to the creation of the FVO. This will be followed by an exploration of some of the features of the FVO’s regulatory approach which can aid in the formation of preliminary assessments about the institution’s ability to function in a responsive manner.

The European Commission’s Food and Veterinary Office

It is clear from the historical circumstances from which the FVO emerged as a specialised directorate of the European Commission that its creation was linked to a number of specific failures in regulation. The BSE crisis of the mid-1990s exposed these failings and created the momentum for considerable regulatory adjustment which included as one of the earliest steps the creation of the FVO. These weaknesses included: poor independence of EU monitors from other political and policy actors within the Commission and the Member States, poor operational capacity, weak approaches to overall auditing of national control services, inaccessibility of inspection reports and the poor orientation of regulation around risks and emergencies.

At a very fundamental level the BSE crisis severely affected the image of agriculture and agricultural policy within the EU, a policy which had been at the core of European integration and regulation since the initial establishment of the EEC. The model of agricultural policy as laid out in the founding provisions of the Treaty of Rome – increased agricultural productivity based on technical progress – was now severely criticised for having failed consumer welfare and public health protection. In reaction to this a strong new orientation around the regulation of food safety emerged, which would involve a much tighter scrutiny of how individual Member States implemented and enforced existing harmonized EU legislation at the domestic level. As part of this renewed focus on the uniformity of regulation throughout the EU, the European Commission established the Food and Veterinary Office (FVO), tasked with the development of “formal auditory procedures such that the effectiveness of Member State competent authorities could be properly assessed”.

To ensure that...control systems are effective, the Commission, through the Food and Veterinary Office (FVO), carries out a programme of audits and inspections. These...

controls evaluate the performance of national authorities against their ability to deliver
and operate effective control systems, and are supported by visits to individual
premises to verify that acceptable standards are actually being met.\(^{14}\)

However the FVO is not an independent agency and certainly does not enjoy the powers to take
formal action against Member States or third countries for breach of EU food or veterinary law, a
task which rests with the regulatory comitology committee, the Standing Committee on the Food
Chain and Animal Health (SCFCAH). The FVO audit reports however form the basis for important
decisions of the SCFCAH. The FVO occupies a headquarters in Grange, Co. Meath, Ireland, quite
apart from the principle Commission DGs (Health & Consumer Affairs and Agriculture) in Brussels
and this separation has been deemed necessary for the maintenance of ‘Chinese walls’ as between
the FVO and the Commissions DG for Health and Consumer Affairs (DG SANCO) (discussion with FVO
official). It has its own staff cohort, most important of which are its contingency of qualified
veterinarians and food safety experts who undertake the formal auditing missions. However Scott, in
his treatment of different European agencies, classified the FVO as a ‘Commission agency’ which can
be regarded as an “independent unit within the Commission...charged with monitoring the
compliance by member state and third nations governments with food safety and animal health
legislation”\(^{15}\) and likens it to similar units such as Eurostat and the EU Fraud Office (OLAF). Eurostat
is governed by its own legislation, while OL AFF was established under Decision 1999/352/EC amidst
serious allegations of corruption and nepotism directed at members of the Santer Commission\(^{16}\).
Decision 1999/352/EC and Regulation 1073/1999 governing the organisation and tasks of OLAF
stress the importance of the autonomous role and independence of OLAF, designed to “guarantee
the Office’s proper conduct of investigation without interfering with its other tasks, such as those
which are the prerogative of the Commission, in particular in matters of legislation”\(^{17}\). While no
such legal instrument covers the role and position of the FVO within the broader institutional
framework of the Commission, the historical context for its establishment, not unlike that for OLAF,
is a clear response to concerns over the Commission failures to ensure proper implementation of EU
rules.

The FVO’s predecessor was the Office of Veterinary and Phytosanitary Inspection and Control
(OVPIC) which was established in 1991 and functioned under the auspices of the Directorate-General
(DG) for Agriculture in order to “conduct on-site inspections and audit national-inspection
systems”\(^{18}\). As far back as 1993 it had been decided to re-locate the OVPIC to Grange, Co. Meath
Ireland. Plans to substantially overhaul the OVPIC were brought forward in 1996 as the BSE crisis


\(^{15}\) Scott, C. (2005) “Agencies for European Regulatory Governance: A Regimes Approach”, in Geradin, D.,
Muñoz, R. and Petit, N.(eds) Regulation through Agencies in the EU: A New Paradigm of European Governance
(Cheltenham, Edward Elgar); van der Meulen, B.M.J. and Freriks, A.A. (2006) “Millfeuille: The emergence of a

\(^{16}\) Pujas, V. (2003) “The European Anti-Fraud Office (OLAF): a European policy to fight against economic and
financial fraud?”, Journal of European Public Policy, 10(5), p.782

\(^{17}\) Decision 1999/352/EC, Recital (5); In Commission v. ECB (C-11/00) the ECJ reaffirmed the importance of
OLAF’s independence, in particular its independence from the European Commission (para.139) and the
prerogatives which it enjoyed to investigate all EU bodies, offices and agencies including the European Central
Bank.

European Politics, 25(4), p.106; prior to 1991 the Commission had operated a veterinary inspection service
since 1983 which had been expanded to include products of animal origin plants and plant products.
unfolded. According to Daniel Kelemen, competition with the Commission for staff lines and resources lead to a proposal to transform OVPIC into an independent agency, thereby guaranteeing long-term capacity, despite initial Commission reluctance about alienating the office’s substantial powers.

The proposed independent agency, the European Agency for Veterinary and Phytosanitary Inspection (EAVPI), to be created under the Article 43 legal basis of EC Treaty (the CAP legal basis), was designed to: i) develop inspectors’ autonomy thereby enhancing the credibility of their work, ii) differentiate inspection services from other Commission departments, iii) ensure a highly specialized cohort of personnel with their own identity, iv) ensure a staff cohort capable of rapid deployment, iv) administrative and financial autonomy, v) avoid duplication of work with other Commission experts, and vi) preserve legislative and decision-making prerogatives of the Commission. The EAVPI was to receive its own independent revenue stream through a 1% allocation of the fees charged by Member State competent authorities for veterinary services provided to the agri-food industry. The EAVPI was to be headed by a management board composed of one representative of each Member State, two representatives of the Commission and two veterinary scientists, charged with drawing up a three-year work programme, an annual work programme to be adjusted mid-year and an annual general report. While the original EAVPI proposal set its task as the inspection of Member States to ensure uniform application of food and veterinary law, verify food and veterinary controls in third countries, it also provided for the EAVPI to “carrying out any other task which the Commission may confer on it”. No further specifications were given concerning the precise division of roles as between the EAVPI and the European Commission, particularly in terms of how both organisations should deal with non-compliance.

As the BSE crisis reached a crescendo in 1997, the European Parliament’s Temporary Committee of Inquiry into BSE (hereafter the Medina Ortega Report) was published in February, making a number of references to the breakdowns in the EU’s regime for checking on national implementation and enforcement of veterinary public health. Particular emphasis was placed on the fact that pressure from UK veterinary services had resulted in the Commission refraining from checking issues pertaining to BSE during inspections; a situation characterized as “an attitude of ‘benign neglect’ of the issue (a willingness to let a British problem be dealt with by the British)”. While the scientific committee were harshly criticised for their inertia in addressing the emerging risk of nvCJD and its link to BSE, this was itself attributed to the failure to adequately disseminate the findings of European veterinary inspections upwards through the Commission to the relevant advisors and policy-makers (a so-called ‘disinformation policy’). The Medina Ortega report also identified the poor levels of ‘follow-up’ from veterinary inspection reports and the “lack of coordination between the veterinary legislation unit and the inspection unit” as well as an overall lack of vigilance (culpa in vigilando). A weak legal framework, inadequate financial resources and poor staff numbers were

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19 Ibid
20 Although the acronym was not used in the proposal it is employed here for the sake of brevity
21 This provision as re-number as Article 37 EC Treaty by the Treaty of Amsterdam and, since the adoption of the Lisbon Treaty, has been returned as Article 43 of the TFEU
23 Ibid, p.7
24 Medina Ortega Report, p.4
25 Ibid, p.14
also identified as structural problems which hindered the effectiveness of the Commission’s monitoring and inspection roles. While not giving an official imprimatur to the creation of an EAVPI, the Medina Ortega report recommended that any new regimes for inspection, both of Member States competent authorities ‘on-the-ground’ and oversight by the EU, be conducted on the basis of European standard EN45004\(^{26}\), an internationally accredited standard for inspectors. Significantly the Medina Ortega report also recommended the need to ensure a strong iterative process between inspection and law-making:

“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”\(^{27}\)

In April the Commission moved to react to allegations form the European Parliament over poor scientific advice and control and inspection failings with a *Green Paper on Food Law*\(^{28}\) and a *Communication on Consumer Health and Food Safety*\(^{29}\) published on the same day. The *Communication on Consumer Health and Food Safety* advocated an overhauled regulatory structure whereby the “responsibility for legislation should be separate from that for scientific consultation...responsibility for legislation should be separate from that for inspection...[and]...there should be greater transparency and more widely-available information throughout the decision-making process and inspection measures”\(^{30}\). While the idea of an independent agency in the form of the EAVIP was not ruled out, the immediate proposal was for the creation of the Food and Veterinary Office under the auspices of the DG for consumer policy and consumer health protection. This unit would undertake its work on the basis of control priorities, to be identified through risk assessment\(^{31}\), covering the entire food chain and undertaken through the use of formal audit procedures to assess the control systems of the competent national authorities. The new FVO would also 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”\(^{32}\). In addition the FVO would be required to respect the other prerogatives of actors in the governance constellation in place for food in the EU: “they will discharge their responsibilities in a manner that respects the different roles attributed to

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\(^{26}\) European Standard EN45005 General criteria for the operation of various types of bodies performing inspection

\(^{27}\) Medina Ortega Report, p.21


\(^{29}\) European Commission (1997) *Communication from the Commission on Consumer Health and Food Safety*, COM(97) 183 final

\(^{30}\) Ibid p.3

\(^{31}\) Ibid, p.23:

> “the establishment of inspection priorities, taking into account the need to meet legislative commitments, through an informal risk assessment procedure. This will include an assessment of risk both on a country or regional basis, e.g. geography, climate, health situation, competence of official services, previous trade problems etc, and for individual production sectors, e.g. husbandry practices, presence of zoonoses, types of treatment and use of hazard analysis critical control points (HACCP) techniques in processing establishments, previous inspection reports etc.”

\(^{32}\) Ibid,p.22
the Commission and national authorities in the implementation of the relevant Community legislation” while also ensuring the maintenance of “close links...with the scientific committees to ensure that in inspection and control activities are kept informed of the most recent developments in the relevant fields”.

The Green Paper on Food Law covered a very wide range of issues and has been regarded as seminal in initiating an overall discussion about the values and principles which should underlie food policy in the EU. While the Green Paper on Food Law is littered with references in the involvement of stakeholders to a much greater extent, this requirement for engagement is specifically ruled out for issues of implementation of EU law:

> “in the interests of transparency, all parties concerned should be encouraged to discuss the implementation and application of Community legislation openly in a forum where Member States can be consulted and where different socio-economic interests can express an opinion. To this end the Commission would invite comments on the desirability of convening periodic meetings with representatives from Member States, producers, industry, commerce and consumers to discuss general issues relating to the implementation of Community legislation. However, matters relating to the non-compliance of national legislation with Community law would be excluded from the scope of such meetings, and would continue to be dealt with in accordance with established Commission procedures”.

By 1998, the original proposal for an independent agency was finally withdrawn, partly on foot of reservations expressed by the European Parliament, which feared that “transferring food inspection from the Commission to an agency controlled by a member state-dominated board might lead to a renationalisation of Community policy”. While numerous reports on the BSE crisis all pointed toward the need for an inspection and audit system that would be independent, impartial and objective, it was felt that this would be “best 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 techniques etc” but maintained within the European Commission. Part of the new guarantees on transparency of inspections would involve the publication of an annual FVO report, the online availability of individual mission reports as well as “discussions with consumer and producer associations...organised regularly to discuss the outcome of the inspection programmes”.

33 Ibid p.25-27
34 O’Rourke, R. (2005) European Food Law (Sweet & Maxwell, London), p.4
37 In addition to the Medina Ortega report and the Commission Communications a report was also produced by the European Economic and Social Committee as well as the Commission’s own Inspection General Services (IGS).
39 Ibid p.4
The 2000 White Paper on Food Safety also re-affirmed the Commission’s view that the transfer of the tasks entrusted to the FVO to a proposed European Food Agency (subsequently EFSA) would have been inappropriate. This was based on the belief that such a transfer would constitute an “unwarranted dilution of democratic accountability” and would be at odds with the constitutional role contained in Article 211 and 216 of the EC Treaty for the Commission to undertake oversight of the implementation at the national level. This ultimate rejection of the idea of an independent EU watchdog for food and veterinary law “marked a significant shift” from the original advocacy for such an agency by the Commission during the height of the BSE crisis\textsuperscript{40}.

While no specific piece of legislation was originally adopted to govern the FVO or its operation, Regulation 882/2004 has laid down a number of important elements for the FVO’s work within the broader multi-level governance arrangement for food safety and veterinary public health regulation. Regulation 884/2004 was born out of the general reform of food law initiated by the White Paper on Food Safety and enacted by Regulation 178/2002 which set out the general principles of food regulation. No mention is specifically made of the FVO throughout the text of Regulation 882/2004, but rather to the functioning of ‘Community controls’\textsuperscript{41}. The provisions on Community controls to be undertaken by the FVO are all constructed around the concept of audits\textsuperscript{42}. Regular audits are to be maintained in order to ensure the Member States undertake their responsibilities in line with multi-annual national control plans\textsuperscript{43}. In addition Community controls must focus on the ‘functioning and organisation of competent authorities themselves, the investigation of ‘important or recurring problems’ as well as ‘emergency situations, emerging problems or new developments’ in the EU Member States\textsuperscript{44}. In line with some of the references to dialogue put forward in the numerous Commission communications on the reform of food regulation, Article 46(3) provides a legal basis for exchanges between the FVO and Member States over the content of audit reports:

“In the case of reports on controls carried out in a Member State, the Commission shall provide the relevant competent authority with a draft report for comments, take those commend into consideration in preparing the final report and publish the competent authority’s comments together with the final report”\textsuperscript{45}.

The general audits of Member States take place once every three years\textsuperscript{46}. Article 46 of Regulation 882/2004 details the operation of audits in third countries which must investigate whether there is “compliance or equivalence of third-country legislation and systems with Community feed and food

\textsuperscript{40} Buonanno, L. (????) ‘Politics versus Science: Apportioning Competency in the European Food Safety Authority and the European Commission’, ??????, p.20

\textsuperscript{41} Regulation 882/2004, Title VI

\textsuperscript{42} “‘audit’ means a systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.”, Regulation 882/2004, Article 2(6)

\textsuperscript{43} Regulation 882/2004, Article 45(1)

\textsuperscript{44} Ibid, Article 45(2)

\textsuperscript{45} Ibid, Article 45(4)

law and Community animal health legislation". These official audits must cover the following principle aspects of food safety and veterinary public health regulation in third countries:

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<th>Regulation 882/2004, Article 46(1)</th>
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<td>- (a) the legislation of the third country;</td>
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<td>- (b) the organisation of the third country’s competent authorities, their powers and independence, the supervision to which they are subject and the authority they have to enforce the applicable legislation effectively;</td>
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<td>- (c) the training of staff in the performance of official controls;</td>
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<td>- (d) the existence and operation of documented control procedures and control systems based on priorities;</td>
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<td>- (f) where applicable, the situation regarding animal health, zoonoses and plant health, and procedures for notifying the Commission and relevant international bodies of outbreaks of animal and plant diseases;</td>
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<tr>
<td>- (g) the extent and operation of official controls on imports of animals, plants and their products;</td>
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<tr>
<td>- (h) the assurances which the third country can give regarding compliance with, or equivalence to, Community requirements</td>
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In addition separate criteria are established within Regulation 882/2004 for the frequency of EU controls in third countries which are to include: i) risk assessment on the basis of exports to the EU, ii) provisions established in specific EU legislation, iii) the volume and nature of imports from particular countries, iv) the results of audits previously undertaken, v) the results of controls undertaken at border inspection posts or other controls undertaken by Member States, vi) information received by EFSA, vii) information received by international organisations such as the WHO, OIE and the Codex Alimentarius Commission, and vii) evidence of emerging disease situations.

As previously mentioned, the legislative history of Regulation 882/2004 points toward specific deficiencies in the system of EU controls of national authorities (both in the EU Member States and in third countries) which the reforming legislation sought to address. These problems included the “lack of a harmonised Community approach to the design and development of national control systems...[and the] need to define the role of the Commission’s own control services so as to ensure the most efficient use of available resources”. The regulation was also seen as necessary to promote “enhanced administrative co-operation in the development and operation of control systems...[through] the exchange of best practice between national authorities”. Detailed legislation on the Commission’s role in auditing and verifying national implementation and enforcement of food and veterinary law was fragmented and lacking in places. Where legislation did call on the EU to verify national control measures it was in the form of “an authorisation to inspect

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47 Regulation 882/2004, Article 46
48 Ibid., Article 46(2)
without imposing an obligation to do so”. What comes across very strongly in the Commission’s proposal for what subsequently became Regulation 882/2004, is the need to move from individual inspection systems as detailed in sectoral legislation to a proper system of audits. This was deemed necessary because of the need to make best use of the constrained resources which Commission inspectors operated under. For example, in relation to third countries the Commission notes that:

“Commission Decision 86/474/EEC requires the Commission carry out controls in a large number of countries and establishments annually. Due to resource constraints, only a small fraction of these countries and establishments are in fact visited each year in relation to the products concerned. It is clear that the rules as existing at present must be adapted so as to take account of these constraints and apply an audit approach to third countries as soon as practicable”.

In its annual reports the FVO characterises its own work as follows:

“The mission of the FVO is, through its audits, inspections and related activities, to:

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

- contribute to the development of European Community policy in the food safety, animal health and welfare and plant health sectors;

- contribute to the development and implementation of effective control systems in the food safety, animal health and welfare and plant health sectors; and

- inform stakeholders of the outcome of its audits and inspections.”

An important element of FVO auditing is the drawing up of recommendations which should be followed by action plans from auditees containing planned measures to address shortcomings. The FVO then carries out follow-up activities to ensure improvements actually take place which can include further inspections, written reports and high-level meetings, sometimes with higher Commission officials.

Therefore, to conclude this historical and legal overview of the FVO, it is clear that the establishment of this ‘Commission agency’ was driven by the need to establish an institutional structure which counteracted the negative images of inefficiency and poor credibility which had marred the Commission throughout the unfolding of the BSE scandal. The shifting of powers to units possessed of the necessary expertise and technocratic competence was a vital part of this requisite overhaul of EU regulation. However the maintenance of the FVO within formal Commission structures, and indeed

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its creation without its specific grounding institutional legislation, is indicative of the importance (and political sensitivity) of many of its regulatory functions. In addition it is clear that there was a desire to ‘insulate’ inspection and monitoring functions (reporting) from actual regulatory action for non-compliance. On the one hand the FVO was not intended as the wholesale regulator in all food safety and veterinary public health matters i.e. ‘not a European FDA’. However, on the other hand the FVO can be as a ‘stillborne’ EU regulatory agency, with important functions of regulation through information, but also a significant if ‘unclear’ role as a unit with enforcement and compliance powers.

The FVO as Auditor and Regulator ‘Inside Government’

As previously mentioned, the FVO’s role is that of an auditor tasked with ‘verifying the effectiveness’ of national control measures for food safety and veterinary public health. The role differs from the conventional definition of an auditor which is charged with the verification of validity and reliability of an undertaking’s financial accounts, though there are some similarities. The type of control exercised by the FVO can also be characterized as a form of ‘regulation inside government’, albeit within the “complex multi-layered controls system” of the EU’s internal market structures. When regulating competent authorities in third countries the FVO is not strictly a ‘regulator inside government’, but is still acting as one public regulator auditing another public regulator within the broader context of international trade law and the SPS Agreement. This public-to-public type regulation is an important consideration in studying the FVO using insights from regulation theory, as most of this literature is grounded in empirical research on regulator-firm interaction. In addition, the FVO must operate as a risk-based regulator, a common strategy increasingly adopted by a wide variety of regulators in the regulatory state. This section aims to elaborate on theoretical understandings of these three phenomenon of regulation in order to identify elements relevant to the exploration of the FVO’s responsive and reflexive dynamics.

A common theme in the literature on audit institutions has been the framing of a dichotomy between audit institutions as ‘watchdogs’ or ‘guidedogs’, or whether auditors seek to assert roles as ‘policemen’ or as ‘consultants’. Michael Power added considerably to theoretical understandings of auditing as a particular form of regulation in the The Audit Society: Rituals of Verification (1997). In particular, Power’s study of auditing in many areas of regulation spotlights the phenomenon “not [as] that of the isolated practitioner judgement, but that of collectively negotiated settlements”. This differs from the conventional understanding of financial auditing as a neutral, objective assessment of a state of affairs. Power also delves into the causes of the so-called ‘audit explosion’

and identified, in addition to the demands created by new public management, accountability and transparency, a transformation in regulatory style “which is moving away from a command and control mode of operation...to regulate target organizations indirectly ‘from below’”\textsuperscript{61}. This involves a regulatory approach which attempts to cultivate a commitment and capacity for dynamic but effective compliance on the part of the regulatee. However Power is wary in regarding the shift toward auditing as a panacea to regulatory failure. Among the consequences of the audit explosion has been the adoption of specific behavioural practices by auditees that ‘make them auditable’ which in certain circumstances can be a form of creative compliance.

The differences between auditing, monitoring, inspection, verification, surveillance and evaluation, are at best fuzzy and Power submits that this “vagueness is an essential part of the phenomenon”\textsuperscript{62}. This lack of clarity in the understanding of auditing speaks to the degree of distance and ‘separateness’ which the regulator should adopt vis-a-vis the regulatee. This is one of the most interesting issues raised by \textit{Audit Society} and it is worth quoting Power in full on this question:

“a...puzzle or paradox of the audit society concerns the nature and periodicity of audit and inspection reports and the extent to which such reports support deliberative processes. Where audit reports are not designed to continue stakeholder dialogue then it is necessary to trust the auditors and their independence becomes an important benchmark of trust. Quality kitemarks and financial audits reports are like this. In contrast National Audit Office Value for Money (VFM) audit reports are in narrative form. And social audits, which seem messy and diverse, may worry much less about independent audit reporting and more about stakeholder involvement (Cotton et al. 2000). Here the hypothesis is intriguing: greater stakeholder involvement in auditing, of whatever kind, may alleviate anxieties about auditor independence and may support less standardised reporting”\textsuperscript{63}

The FVO clearly fits in to the latter category as it is clearly not aiming to give a momentary snapshot of a country’s progress in terms of implementations, but is more focused on aiding the overall regulatory objective of enhanced food safety and veterinary public health protection. Therefore, on the basis of Power’s hypothesis, we would expect the auditing activities of the FVO to entail a large amount of deliberation, stakeholder involvement and a commitment to the development of a strong culture of food safety within institutions which constitute auditees.

Scott conceives of public audit (where one public body audits the activities of another) as a form of meta-regulation whereby auditors “speak softly and carry no big sticks”\textsuperscript{64}. Central to the success of public audit interactions is the existence of a structural coupling where the normative structures of the auditor (regulator) and the auditee (regulated) are aligned\textsuperscript{65}. More broadly Scott believes that auditing is effective in advancing successful regulation because it draws not just on coupled normative structures (community) but also utilises the more pragmatic benefits of competition (naming and shaming) and design (randomness of on-the-spot checks). This dynamic speaks further

\textsuperscript{61} Ibid, p.113
\textsuperscript{62} Ibid, p.116
\textsuperscript{63} Ibid, p.117
\textsuperscript{65} Ibid, p.214
to the likelihood of strong responsive elements of the FVOs work as a public auditor of other public authorities at the domestic level.

Broader research work has been undertaken into the nature of public-to-public regulation and has been termed ‘regulation inside government’. The rise of regulation inside government as a spin-off of new public management has been tracked by Hood et al. and examines “oversight of bureaucracies by other public agencies operating at arm’s length from the direct line of command, the overseers being endowed with some sort of official authority over their charges”\(^{66}\). The overall conclusion of research into regulation inside government in the UK points to the increased usage of reflexive regulation and enforced self-regulation as characteristics of intra-public sector regulation. James regards as a central feature of regulation inside government the monitoring of performance and the use of “persuasion or direction of regulated bodies to change their behaviour”\(^{67}\). Of course regulation inside government, just like the regulation of private interests by public actors, is liable to failures caused by problems such as capture by regulated bodies, regulation in the interests of the regulators and high transaction costs\(^{68}\). Crucially also, as stipulated by the regulation inside government experts, a public auditor auditing a given bureaucratic institutions should be at “arm’s-length from the direct lines of command and control”. The FVO fits perfectly with this conception in its dealings with Member States because, while formally part of the European Commission, it is a separate actor from the Standing Committee for the Food Chain and Animal Health (comitology committee), which is formally charged with acting on reported infringements and failings\(^ {69}\) and controls the direct hierarchical and legal authority to address non-compliance.

**The FVO as a Risk-Based Regulator**

Another defining feature of the background to the establishment of the FVO, and the very nature of its regulatory task, is its functional role as a risk regulator. Risk must central to any considerations of food safety and veterinary public health regulation given its scale and the complexity of the modern global food chain. Zero-risk in unattainable and therefore any system of regulation will represent a second best option\(^ {70}\). Risk regulation has become a field of considerable academic endeavour as “‘risk’ is fast becoming the central organising principle in regulation and public service delivery”\(^ {71}\). However one can also distinguish between these primary day-to-day risks (salmonella, foot-and-mouth disease etc) and ‘institutional risks’, which focus on the failings of actors to achieve the objectives of primary risk prevention and control: “the risk that the organisation will not achieve its objective, rather than the societal risks per se (i.e. risks to health and safety, etc)”\(^ {72}\). Assessment of institutional risk very neatly encapsulates the function of the FVO, concentrated as it is on auditing

\(^{66}\) Hood, C., James, O. and Scott, C. (2000) “Regulation of Government: Has it increased, is it increasing, should it be diminished?”, *Public Administration*, 78(2), p.284


\(^{68}\) Ibid, p.333

\(^{69}\) Regulation 882/2004, Article 62


the ‘fitness for purpose’ of food safety and veterinary public health services in the EU Member States and third countries.

In many respects the FVO is exceptional in terms of the regulatory structures which have been created in the EU to address different risks. In his now well-established critique of risk regulation in the EU, Majone has consistently called for the establishment of “far-reaching delegation powers to European agencies”\(^73\) in order to demonstrate a credible overall commitment to the principles of risk regulation which, above all require insulation from politicization. In particular he has pointed to the weaknesses in procedural harmonization for risk regulation in the EU rooted in:

> “the lack of a European administrative infrastructure [which] means that between the supranational level of rule-making and the national, or sub-national, levels of enforcement an institutional vacuum exists which is supposed to be filled by the loyal cooperation of all the competent authorities”\(^74\)

In contrast the FVO was established with a very clear mandate, as well as targeted organizational capacity, to oversee this very important stage of ‘regulation in action’ at the national level. Majone emphasises procedural harmonization and consistency as part of good European risk regulation, which is also open to policy-learning and institutional reform. Given its specialised function FVO adds positively to the riches of procedural harmonization for food safety and veterinary public health risk regulation. Boerzel has noted that inspection and auditing of the application of EU law ‘on the ground’ is rare because they “are labour intensive, tend to be time-consuming, and politically fraught”\(^75\). Much more often the Commission uses a network of complaints and ‘external actors’ to aid in the detection of non-compliance through the maintenance of “numerous contacts with national implementation authorities, non-governmental organizations, consultancies, researchers, and corporations in member states”\(^76\). Yet the fraught and difficult task of direct auditing mission in Member States and third countries is precisely the challenging job which the FVO undertakes. This can be said to be a more systematic and consistent form of regulation than the potential arbitrary usage of information received via an informal network. Thus the FVO satisfied many of Majone’s criteria for a risk regulator. The legislative basis of the FVO’s tasks found in Regulation 882/2004 also clearly points toward a focus on risk-based regulation, particularly in relation to the organisation of audits in third countries.

In a recent publication Black and Baldwin have highlighted a number of ways that a risk-based approach to regulation can at times clash with the needs of a responsive regulatory approach and identify “a need to apply risk-based regulation in a newly reflective manner and to conceive of it in a more nuanced way”\(^77\). Black and Baldwin identify five key areas central to the examination of responsive regulatory phenomenon: i) the behaviour, attitudes and cultures of regulatory actors, ii)

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\(^76\) Ibid

the institutional setting of the regulatory regime, iii) the different logics of regulatory tools and strategies (and how these clash/interact), iv) the regime’s own performance over time and v) changes in each of these elements. The achievement of responsiveness in each of these areas of regulation when risk-based regulation is deployed is the central focus of Baldwin and Black’s analysis. It is worth providing a brief summary of how risk-based regulation accounts (or fails to account) for each of these five issues of responsiveness.

Responsive regulation places great emphasis on accounting for i) individual firms’ behaviour, attitudes and cultures and adopting an appropriate regulatory approach to deal with these different characteristics. Baldwin and Black identify a number of ways in which risk-based regulation can be poor in accounting for cultural matters. While many risk-based models effectively incorporate historical behaviour as part of risk assessment, a crucial dynamic which risk-based models often fail to integrate into their internal logic is the difference between “two firms with similarly high risk scores...[which may]...be respectively well-intentioned and ill-informed or ill-intentioned and ill-informed”78. This difference has key implications for the appropriateness of the regulators response, i.e. hard sanctioning or soft capacity building. In order to target resources in an appropriate and efficient way taking account of the amenability of firms is crucial, though the creation of an accurate picture of amenability is not an easy task. This in turns raises further questions as to whether ‘amenability analysis’ should itself be calibrated into the overall risk assessment calculations or whether it should be kept separate as a political or policy consideration. It would appear that Regulation 882/2004 rules do not make any reference to the attitude of audited competent authorities, nor is such an evaluation included in the FVO mission reports. Any political decision over the amenability of a given country, and the consequent taking of risk management decisions, would be the preserve of the SCFCAH.

In terms of the ii) institutional setting of a regulatory regime, a regulatory approach which is truly responsive must take account of “the challenges and limitations imposed”79 by environmental realities issues such as fragmented and shared powers across levels of governance, the faith placed in overseas regulators by regulatees, the constraints imposed by the demands of regulatory competition and expert imbalances as between regulators and regulatees. Here the FVO is well equipped to integrate institutional environmental concerns, with the examination of issues such as the arrangements as among domestic competent authorities specifically mandated by Regulation 882/200480. Another feature of the institutional environment which should be considered is the political backing which regulators enjoy and the affects of transparency on this ‘political license’:

“We suggest that regulators need a political license. They need political support if they are to act aggressively against firms...moreover risk-based systems themselves carry significant political risks for regulators. Risk-based regulation requires a regulator to prioritise and thus to decide to commit fewer resources to fulfilling its legal mandate

78 Ibid, p.190
79 Ibid, p.194
80 For example Article 4(3) of Regulation 882/2004 requires EU Member States to ensure that where “authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination, shall be ensured between all the competent authorities involved” and Article 46(1)(b) similarly makes provision of FVO examination of “the organisation of the third country’s competent authorities”
with respect to some firms, or risks, than others. The regulatory reality of selection clashes with the political, and civil, expectation of universal protection and the transparency of the selection process can render the regulator politically vulnerable.81

The effects of transparency on political licence is a particularly interesting issue in relation to FVO’s role. All audit mission reports are publicly accessible and clearly detail the outcomes of audit missions. Recently the detail of these FVO reports have formed the basis for a strong and ultimately successful campaign by the Irish Farmers Association (IFA) in restricting the importation of Brazilian beef in the EU. Deficiencies in the traceability of Brazilian bovine animals was one of the central criticisms of the IFA, which insisted that such failings would not be tolerated of an EU Member State. Doubt was also cast on the FVO’s own abilities of detection when the IFA undertook their own overseas inspection of the beef industry in Brazil and successful published its findings, garnering support from members of the European Parliament and secured an ultimate restriction of Brazilian beef in the spring of 2008. Using the evidence of Brazilian failings already identified by the FVO, as well as their own regulatory investigations, as their ammunition the IFA successful raised doubts over the FVO’s role as an effective monitor.

In terms of iii) issues connected with the logic of control instruments, which speaks to the effect of a given regulatory action on the overall management of a problem, responsive regulators should be conscious of interactions between different ‘logics’ of control and steering and how they will interact in ways that could potentially lead to “distortions and failures of contact”.82 Inversely, there also exist many interesting examples involve logics of control which are ‘anti-risk’ based regulation, such as legislatively mandated controls at specified intervals. However, again, risk-based regulation can often fail to meet the needs of a responsive approach to understanding the effects of interactions as between different control instrument logics.

“risk-based regulation has its own logic – that of risks and outcomes. Risk-based regulation starts with identifying risks to be managed, not rules to be complied with. The logic of risk and outcomes can cut across the logic of compliance. In a risk-based system of monitoring, officials are likely to find that noncompliance with certain rules does not in fact have an impact on the risk or outcome they are concerned with, suggesting, of course, that the role is otiose”.83

Therefore risk-based regulation often does not aid the fostering of enhanced regulation in certain areas classified as low risk, but where certain legal requirements nonetheless exist. This may mean that in certain areas, notionally within the remit of the regulator, the failure to attach priority attention will mean that the area in question will not be exposed to any regulatory processes, responsive or otherwise.

In terms of iv) issues of performance, responsive regulation ensures that indicators of performance form an important element to overall regulatory strategy and its adjustment where necessary. This consideration also speaks to the heart of the credibility and legitimacy of any given system of regulation which must justify its work to the public and to interested parties. Awareness of how well

82 Ibid, p.198
83 Ibid, p.199
a regulatory system is working must focus not just on identified issues, such as those perceived as major risks, and how they are being managed, but also the scale of ‘off the screen’ problems which are not being detected/monitored. This is no easy task and much of the problem here involves devising a reporting system which links the actual work of the regulator with particular outcomes that may have been caused by a complex mix of different counterfactuals and correlations. Where performance is reliant upon informational inputs from firms themselves, and their successes/failures over a given period through a meta-regulation arrangement, further problems can emerge as to whether firms’ understandings of success match with regulators’ objectives. Performance justification pursued by risk-based regulators is a similarly thorny issue. Regulators who hold out a risk-based regulatory strategy itself as sufficient justification however fall foul of making ‘lavish’ claims about the capacities of risk-based approaches, much of which is rooted in “considerable dissonance between the regulator’s understanding of risk priorities and those of the firms, or indeed the wider public”84. Again, examples can be drawn with the restrictions on Brazilian beef in 2008. Much of the strength of the IFA’s argument was grounded in the regulatory failures which the FVO failed to include in their reports on Brazilian beef industry. The FVO may have had justifications for not attaching significance to these issues, but no clear justifications were communicated publicly and the detailed investigations of the IFA exposed these areas where enforcement of EU law was lacking.

In terms of the last issue highlighted as being pertinent to building responsiveness, v) the openness to change, Black and Baldwin highlight the danger that any risk-based regulatory regime may fall victim to ‘model myopia’ over time as “regulatory officials become committed to an historically captured set of risk indicators and assessment criteria”85. Risk-based regulation tends to place considerable emphasis on statistical indicators of risk over a number of years but this poses the danger of locking-in a focus on certain risks and not on others: “as a result, analyses of relative risk scores will not indicate whether the regulatory regime is addressing a major portion of the challenges faced or only a small percentage of these”86. Here the stated role of the FVO as a contributor to legislative and policy change through interaction with other Commission actors, as set out in the various official communication produced at the time of its formation, would appear to satisfy this requirement of responsiveness.

Conclusion

The FVO is concentrated on the problem of ‘institutional risk’; the risk that EU food and veterinary law will not be properly implemented and enforced in EU and non-EU countries and undertakes this task through interaction with national competent authorities in the form of audit missions. In this way, certainly in connection with its dealing with EU Member States, the FVO acts as a regulator ‘inside government’. FVO’s task is officially characterized as (and supposedly limited to) a form of ‘audit’, with decisions over legal enforcement lying exclusively with the relevant comitology committee, the Standing Committee on Food Chain and Animal Health. The maintenance of ‘Chinese walls’ between monitoring and enforcement was a crucial driver of the FVO’s establishment. However, as with many modern audit institutions, the FVO goes beyond mere

84 Ibid, p.203
85 Ibid, p.206
86 Ibid, p.208
neutral reporting and engages with auditees in a cooperative effort to advance change and in this way exercises a very significant role in the advancement of EU food and veterinary policy.

The legal provisions governing how the FVO should organise its own work indicate a broadly risk-based regulatory approach. An examination of these features, using in particular the work of Black and Baldwin, aids an initial assessment of some of the issues of responsiveness and reflexivity observable within the FVO. Positive indicators of responsivity can be observed from the FVO’s focus on the historic behaviour of auditees, in particular that of third countries, though criteria seem not to exist to take account of the amenability of competent authorities in different jurisdictions. Similarly considerations about institutional environments also from part of the FVO’s audit reports, though the FVO’s own institutional environment, whereby its mission reports are all publicly accessible has lead to difficulties in its own public licence, as evidenced by the 2008 restrictions on Brazilian beef. This is potentially linked to the absence of any concerted public effort to explain why certain risks are prioritised over others.

Further research is necessary to uncover some of the internal rationale of the FVO in the organisation of its work. This paper has sought to direct my initial research in the area by showing the appropriateness of taking the FVO as a viable case study of responsiveness and, furthermore, of reflexivity.