Annex III

Assessing Member States' capacity for reliable 'authorisation of PPPs', and its uniformity

Research paper
by Dr Olivia Hamlyn

EPRS | European Parliamentary Research Service

AUTHOR
This research paper has been written by **Dr Olivia HAMLYN** of the University of Leicester at the request of the Ex-Post Evaluation Unit of the Directorate for Impact Assessment and European Added Value, within the Directorate General for Parliamentary Research Services (DG EPRS) of the General Secretariat of the European Parliament.

RESPONSIBLE ADMINISTRATORS

Alina DINU and Ekaterina KARAMFILOVA, Ex-Post Evaluation Unit.
To contact the Unit, please e-mail EPRS-ExPostEvaluation@ep.europa.eu

ABOUT THE PUBLISHER
This paper has been drawn up by the Ex-Post Evaluation Unit of the Directorate for Impact Assessment and European Added Value, within the Directorate–General for Parliamentary Research Services of the Secretariat of the European Parliament.

LINGUISTIC VERSIONS
Original: EN

This document is available on the internet at: http://www.europarl.europa.eu/thinktank

PE 615.668
ISBN: 978-92-846-2734-9
DOI: 10.2861/632821
CAT: QA-02-18-501-EN-N

Contents

Table of tables

Table of figures

Acronyms

BSE	bovine spongiform encephalitis
CA	competent authority
CEFIC	The European Chemical Industry Council
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CfS	candidate for substitution
CJEU	Court of Justice of the European Union
cMS	concerned Member State
CSO	civil society organisation
CZSC	Central zone steering committee
DG SANTE	Directorate-General for Health and Food Safety
dRR	draft registration report
EFSA	European Food Safety Authority
EPPO	European and Mediterranean Plant Protection Organisation
EPRS	European Parliamentary Research Service
EU	European Union
GFL	General Food Law
IPM	integrated pest management
IRA	independent regulatory authority
izSC	inter-zonal steering committee
MS	Member State
NAP	national action plan
NGO	non-governmental organisation
NZSC	Northern zone steering committee
OECD	Organisation for Economic Co-operation and Development
PIG	public interest group
PPP	plant protection product
PPPAMS	Plant Protection Product Application Management System
PPPR	Plant Protection Product Regulation
REACH	Registration, Evaluation, Authorisation of Chemicals
RR	registration report
SUD	Sustainable Use Directive
SZSC	Southern zone steering committee
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom
zRMS	zonal rapporteur Member State
zSC	zonal steering committee

Member State CAs and other organisations

ANSES	Food, Environmental and Occupational Health and Safety (French CA)
BAES	Federal Office for Food Safety (Austrian CA)
BfR	Federal Institute for Risk Assessment (German CA)
BFSA	Bulgarian Food Safety Agency
BVL	Federal Office for Consumer Protection (German CA)
CNOPPP	National Committee for PPP Approval (Romanian CA)
CRAFC	Centre for Risk Assessment on Food Chain (Bulgarian CA)
CRD	Chemicals Regulation Division (UK CA)
Ctgb	Board for the Authorisation of Plant Protection Products and Biocides (Dutch CA)
DAERA	Department of Agriculture, Environment and Rural Affairs (Irish CA)
DAMM	Marketing Authorisation Department
DEPR	Regulated Products Assessment Department (France)
DGAV	General Directorate for Agricultural and Veterinary Affairs (Portuguese CA)
DGFHFSN	Directorate General for Food Hygiene, Food Safety and Nutrition (Italy)
DGSPP	General Directorate of Sustainable Plant Produce (Greece)
DPPP	Directorate of Plant Produce Protection (Greece)
DPPPB	Department of Plant Protection Products and Biocides (Greece)
DPPSC	Directorate of Plant Protection and Soil Conservation (Hungary)
DWP	Department of Work and Pensions (UK)
HSE	Health and Safety Executive (UK)
JKI	Federal Research Centre for Cultivated Plants (German CA)
KEMI	Swedish Chemicals Agency
MCCAA	Malta Competition and Consumer Affairs Authority (Malta)
MRDF	Ministry of Rural Development and Food (Greece)
NFCO	National Food Chain Safety Office (Hungarian CA)
NFSA	Norwegian Food Safety Authority
ORP	Department of Pesticide Registration (Slovakian CA)
PCD	Pesticide Control Division (Ireland)
PRCD	Pesticide Registration and Control Division (Ireland)
PRD	Pesticide Registration Division (Ireland)
SPA	State Phytosanitary Administration (Czech CA)
SPPPF	Service Plant Protection Products and Fertilizers (Belgian CA)
SPPS	State Plant Protection Service (Latvian CA)
SPS	State Plant Service (Lithuanian CA)
Tukes	Finnish Safety and Chemicals Agency

UBA	Federal Environment Agency (Germany)
ÚKSÚP	Central Control and Testing Institute in Agriculture (Slovakia)
UVHVVR	Administration of the Republic of Slovenia for food safety, veterinary and plant protection (Slovenian CA)

Executive summary

This report was prepared at the request of the Ex-Post Evaluation Unit of the European Parliamentary Research Service (EPRS). It examines the implementation by EU Member States of the Plant Protection Product Regulation (the Regulation) which governs the authorisation of plant protection products (PPP) in the EU. It considers first, whether Member States share the same approach towards the authorisation of PPPs containing active substances (and safeners, synergists, etc.) already approved at EU level, pursuant to Articles 4-13 of the Regulation. Second, it examines whether Member State competent authorities (CAs) possess the necessary institutional capacity to deliver independent, transparent and, hence, reliable 'authorization of PPPs' using active substances (and other substances) approved at EU level. Finally, it assesses whether the national authorisation model(s) support or contradict the key principles on which the Regulation is based; specifically precaution, sustainability and substitution.

Despite major changes in EU policy and regulation of PPPs in the last decade (new legislation was introduced in 2009), EU regulation of PPPs, as a whole, is under-researched. The scope of this research was broad. It generated new data in an area which is generally not well understood and about which there is little knowledge. Given this starting point, and the breadth of the research questions, this report should be regarded as a first step towards understanding the various matters covered. As such, the research seeks, first, to generate new knowledge and understanding of the implementation of the Regulation and operation of the zonal system (described below), secondly, to make recommendations for improvement on the basis of these findings and thirdly to identify areas for further research.

The Regulation divides Member States (and Norway) into zones with comparable 'agricultural, plant health and environmental (including climatic) conditions' (Northern, Central and Southern) in order to avoid duplication of work, reduce administrative burden on industry and Member States, increase harmonisation and facilitate mutual recognition of authorisations.[1] Applications for authorisation are submitted to a Member State, acting as zonal rapporteur, who evaluates the application for the relevant zone. National authorisation decisions are made primarily on the basis of the conclusions of this evaluation.

This research employed mixed methods, encompassing both desk-based and empirical strategies. The former involved review of relevant literature, policy and EU case law. The latter involved surveys of Member State CAs and selected stakeholders, both via self-completion questionnaires consisting largely of closed questions. It also involved a questionnaire of open questions distributed to zonal steering committees.

The report is structured as follows. Section I introduces the research. Sections II-IV comprise the theoretical background to the research and include discussions of independence, transparency, the precautionary principle, sustainability and the substitution principle. Section

[1] Recital 29 PPPR.

V sets out the method employed for the empirical element of the research. Section VI discusses the zonal evaluation and authorisation procedures including empirical data on Member State evaluation and decision-making and the operation of the zonal system. Section VII presents and discusses the results of the research with respect to the independence and transparency of the CAs and implementation of the precautionary principle, sustainability and the substitution principle. Findings and recommendations are summarised throughout sections VI and VII. Section VIII concludes and summarises the recommendations.

Overall, the area capable of the greatest and most immediate improvement relates to the transparency of CAs, particularly in terms of access to information. In the medium to longer term, it may be appropriate to review Member State practice and/or the Regulation with a view to establishing opportunities for wider public, stakeholder and/or public interest groups (PIG) participation in decision-making, primarily for the contribution such activities can make to transparency. In addition, consistency in interpretation and application of the precautionary principle and sustainability among Member States, and the ambition with which substitution is implemented, could also be improved, for example through clear guidance from the Commission or through co-operation and agreement between Member States at a zonal or inter-zonal level. Finally, as ever, greater resources – financial, technical, expert, personnel – may improve decision-making, both in terms of its quality and speed, and boost the operation of the zonal system overall. More specific findings include the following:

Zonal evaluation and national decision-making procedures are characterised by diversity. For example, Member States differ in terms of the institutional structure of their CAs, the type and extent of communications with applicants during evaluation and decision-making and the nature of the expert advice (binding or consultative) provided to decision-makers. Overall, very few trends within the zones may be identified. The zonal system is valued by Member States for the benefits it delivers, for example harmonisation, work-sharing and resolution of disagreements between CAs. However, it still faces significant challenges, especially in terms of improving harmonisation, sharing work fairly within the zones and further strengthening trust between the Member States. With respect to harmonised procedures and methods for evaluation, a variety of guidance documents covering certain areas of PPP evaluation is available on the Commission website. However, it appears that some areas are still to be agreed and that some guidance is unable to cover every possible scenario. The zonal system is a new and complex system which warrants further research and continued monitoring in order to understand better its development and operation.

With respect to independence, there are varying levels of formal independence of respondent CAs from government. However, most respondent CAs have sole responsibility for their decisions. Lack of formal independence does not necessarily mean unreliable or unfair regulation.

There are also varying levels of independence from industry. However, few of the respondent Member State report restrictions on recruiting CA heads from industry or on employment in industry after their appointment. This may risk undermining their independence from industry. Difficulties with recruitment and retention of the necessary expert staff may increase

information asymmetry between CAs and industry with attendant risks of regulatory capture. Greater remuneration to attract qualified staff and/or in-house training could reduce information asymmetry and perhaps also the risk of capture.

Respondent CAs lose some formal autonomy due to their being funded wholly or partly by government. In addition, government control over salaries reduces autonomy further and is identified by some CAs as restraining their ability to recruit the required staff. However, most respondent CAs regard themselves as possessing sufficient resources (personnel, technical, financial) to fulfil their obligations under the Regulation, although several did report gaps and deficiencies in resources.

Due to the lack of data concerning stakeholder and public views with respect to the fairness and reasonableness of CA decision-making, the extent to which it is trusted and how far the independence of individual CAs (or lack thereof) is regarded as a problem, it is not possible to determine whether strengthening the formal independence of CAs would improve the quality of their decision-making.

With respect to transparency, levels of transparency among CAs are low, overall. This is so firstly, in terms of the availability of information about evaluation and authorisation procedures and secondly, in terms of access to the information on which decisions are based. Both of these are necessary to enable interested parties to gain an understanding of the procedural and informational basis of PPP authorisations.

Wider public, stakeholder or PIG participation in decision-making is important for improving transparency, may improve the quality of decisions and may also counter the risk of regulatory capture. Currently, the Regulation does not require or provide for such participation during evaluation and authorisation procedures and comparative assessment. Furthermore, the zonal system itself acts as a barrier to participation due to the level at which zonal evaluation procedures are conducted; a level which is far removed from most citizens. Given this legal framework, it is not surprising that consultation activities in Member States are extremely limited, if conducted at all.

CAs are subject to differing levels of accountability to national governments and legislatures. Some Member States operate robust systems of peer review and auditing of decisions which should operate to improve the overall reliability of their decision-making. Increasing transparency could also improve accountability.

With respect to the principles of precaution, sustainability and substitution, there is evidence of inconsistent interpretation and application of the precautionary principle and sustainability amongst Member States. Member States exhibit greater consistency in conducting comparative assessment. This is still a relatively new exercise but eventually ambition could be improved.

While this research has not identified any deficiencies which are likely significantly to undermine the reliability of CA decision-making, as summarised above, there are large parts of the zonal procedure and CA decision-making which could be improved. Of these, the most significant deficiency identified relates to the lack of transparency in evaluation and

authorisation procedures. In addition, the research represents a significant contribution in terms of describing and understanding the zonal system. However, despite the above findings, many questions remain unanswered and, as implementation of the Regulation progresses and the zonal system evolves, new questions will arise. A further significant contribution of this research is to identify areas in which more, and more focused, research is necessary to understand the current situation as well as new developments, perhaps once more experience has been gained with the zonal system, zonal evaluation and comparative assessment.

I – Introduction[2]

The year 2009 saw the introduction of an ambitious new regime regulating plant protection products (PPPs) in the European Union. This regime consists of Directive 2009/128 establishing a framework for Community action to achieve the sustainable use of pesticides (the 'Sustainable Use Directive' or 'SUD')[3] and Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market ('the Regulation' or 'PPPR').[4] The latter repeals the two main directives which previously governed the EU's regulation of PPPs.[5] While the EU has regulated the placing of PPPs on the market since 1979, the introduction of the 2009 regime has been described as a 'radical change in EU pesticide regulation in terms of goals, instruments and scope' (Bozzini, 2017, p.58), driven by an awareness of, and desire to address, the failures of Council Directive 91/414/EEC[6] (Bozzini, 2017, chap.3). The Regulation makes many significant changes to the regulation of PPPs, amongst them the provisions relating to the authorisation of PPPs, including the establishment of a system of co-operation between Member States.[7] Despite these major policy and regulatory changes, the regulation of PPPs in the EU, and particularly the 2009 regulatory regime is generally under-researched.[8]

This report was prepared at the request of the Ex-Post Evaluation Unit of the European Parliamentary Research Service (EPRS). It examines the implementation by EU Member States of the provisions governing the authorisation of PPPs in the EU. It considers first, whether Member States share the same approach towards the authorisation of PPPs containing active substances (and safeners, synergists, etc.) already approved at EU level, pursuant to Articles 4-13 PPPR. Secondly, it examines whether Member State competent authorities (CAs) possess the necessary institutional capacity to deliver independent, transparent and, hence, reliable 'authorisation of PPPs' using active substances (and other substances) approved at EU level. Finally, it assesses whether the national authorisation model(s) support or contradict the key principles on which the Regulation is based; specifically precaution, sustainability and substitution.

---

[2] Thanks are due to the EPRS for their support throughout this project, to Professor Elen Stokes and Dr Steven Vaughan for their valuable comments on this report and aspects of the research and to Kulsum Patel who provided excellent research assistance. Particular thanks are due to Dr Dieter Pesendorfer, who peer reviewed the study at the request of EPRS, for his very helpful comments. Any mistakes are my own.

[3] European Parliament and Council Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L309/71.

[4] European Parliament and Council Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L309/1.

[5] Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances [1979] OJ L33/36; Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1991] OJ L230/1.

[6] Council Directive 91/414/EEC (n 5).

[7] Described further in section VI.

[8] With some exceptions, for example, (Bozzini, 2017; Hamlyn, 2015).

The research engages with two important principles of governance: the independence and transparency of CAs. 'Reliability', as a characteristic of regulators and their decision-making, is perhaps more commonly discussed in academic literature in terms of 'trust', 'credibility' or 'confidence' (for example, Löfstedt, 2005). Trust is a slippery concept and subject to multiple definitions. Giddens offers a helpful definition which specifically links trust to reliability: '[t]rust may be defined as confidence in the reliability of a person or system, regarding a given set of outcomes or events, where the confidence expresses a faith in… the correctness of abstract principles (technical knowledge)' (Giddens, 2013, p.34). Elsewhere, trust is said to be 'the belief that those with whom you interact will take your interests into account' even when in a position of powerlessness. Further, confidence 'exists when the party trusted is able to empathize with (know of) your interests, is competent to act on that knowledge, and will go to considerable lengths to keep its word'. 'Trustworthiness' is said to be a combination of both (La Porte and Metlay, 1996, p.342). Specifically with respect to risk regulation, Löfstedt argues that the public will trust regulators on the basis either of past decisions, i.e. outcomes, or of a belief that the decision-making process is credible (defined as fair, competent and efficient). Fairness and impartiality are important procedural values. If regulators are regarded as lacking these qualities, for example by not demonstrating that they take everyone's interests into account, they are likely to lose trust. In this context, involvement of stakeholders and public participation (discussed in section III.3) may be important for building trust (Löfstedt, 2005, pp.6–7; La Porte and Metlay, 1996, p.344). A regulator's competence (for example proficiency in handling cases, relevant expertise and experience) is also key to building and maintaining trust (Löfstedt, 2005, p.7; La Porte and Metlay, 1996, p.342).

Thus, trust depends on multiple different factors and there may be multiple explanations for its loss (Löfstedt, 2005, p.xviii), including absence of the qualities discussed above or the inequitable distribution of costs and benefits stemming from regulatory decisions (La Porte and Metlay, 1996, p.342). Others look to historical factors, pointing to the number and size of, often food- or health-related, scandals since the 1990s (Löfstedt, 2004, pp.336–337). Research in the field of risk regulation has focused in particular on the role of risk communication (Löfstedt, 2005, 2006), the ability of experts and regulators to understand and accommodate public attitudes towards risks in decision-making (for example, Wynne, 2001, 1989; EGSG, 2007; Slovic, 1997) and the model of any public engagement conducted in building (or diminishing) trust in regulators (Wynne, 2006; Stirling, 2008). Persistent failure to build or maintain trust may ultimately threaten the legitimacy of the regulator (La Porte and Metlay, 1996, p.342).

The legitimacy of EU policy and regulation tends to be discussed in terms of 'output' legitimacy – the quality and effectiveness of its decisions, and 'input' legitimacy – the fairness and democratic quality of its decision-making processes (Barnard and Peers, 2014, pp.4–7; Scharpf, 1999, chap.1). This may be particularly important for independent regulators, due to their lack of the traditional democratic (input) legitimacy derived from being elected and accountable to an electorate (Larsen et al., 2006, p.2860), discussed further in section II. In areas of regulation, such as pesticides, where knowledge of the impacts of pesticide use emerges slowly and therefore where the consequences of decisions may be impossible to evaluate for

many years, the importance of input legitimacy may increase (La Porte and Metlay, 1996, p.455). The research question defines reliability in this context as composed of independence and transparency, both of which relate to inputs. It is the adherence, by CAs, to these two principles which the report attempts to assess. They are used on the basis of an assumption that fulfilment of these criteria will ensure that authorisation decisions are reliable (or trustworthy).

However, it is acknowledged that the link between inputs and outputs is not automatic. For example, formal independence may not necessarily guarantee fair regulation (Stern, 1997, pp.72–74). Furthermore, given the social and ecological uncertainty characterising the contexts of PPP use (Wynne, 1992b; Meir and Williamson, 2005; Pretty, 2005), assessment of the risks they pose is a highly complex task, beset with uncertainties, which present challenges for regulators (Baldwin, 1996, pp.87–88). Thus, the reliability of any authorisation process premised on a risk assessment (as well as institutional independence and transparency) is also contingent on the reliability of the risk assessment, which may be contested, *especially* in situations of uncertainty (for example, controversies over risk assessments of neonicotinoids, glyphosate and endocrine disrupting chemicals, Bozzini, 2017, chap.4). Assessing the reliability of risk assessment in the context of the Regulation, in terms of the quality both of the actual scientific evidence and its evaluation is beyond the scope of this report. However, EU law requires that risk assessment itself should be conducted 'on the basis of scientific advice founded on the principles of excellence, transparency and independence… to ensure the scientific objectivity of the measures adopted'.[9] These principles[10] aim to raise confidence in the EU's risk assessment procedures (Scott and Vos, 2002, p.283). And these are, indeed, the standards required of the zonal rapporteur Member State (zRMS) under the Regulation, as discussed in sections II and III. This is, therefore, a further justification for assessing the institutions conducting risks assessments under the Regulation for these qualities.

The report is structured as follows. Sections II and III introduce a discussion of the principles of independence and transparency, respectively. The sections are based on a narrative (English language) literature review covering the principles of independence and transparency as well as the more general literature on IRAs. Section IV moves to brief discussions of the principles of precaution, sustainability and substitution. This section is a product of a narrative review of (English language) literature (including grey literature) and doctrinal analysis of EU case law on these principles. All three principles are controversial and open to competing interpretations. Given space constraints and the overall focus of the research, it is impossible to do much beyond giving a flavour of the debates. The discussion therefore concentrates on the interpretation of these principles in an EU context.

---

[9] Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, para.183; Case T-13/99 *Pfizer Animal Health SA v Council* [2002] ECR II-3305, para.172.

[10] Elaborated in European Parliament and Council Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1, and Commission, White Paper on Food Safety COM(1999) 719 Final.

Sections II-IV provide an account of the theoretical basis for this research and serve to illustrate how theory has informed the empirical tools employed in the research, in particular the survey of Member State CAs, described in section V.1. Finally, they provide a framework for analysing the results of the empirical work, drawing findings and making recommendations in response to those findings, as presented and discussed in Section VII.

Section V describes the empirical methods employed to conduct this research and sets out precisely which elements of the Regulation are being examined. Section VI performs several functions. Firstly, it summarises the zonal evaluation and authorisation procedure established by the Regulation. Secondly, drawing on desk-based research and responses to the Member State survey, it describes the various evaluation and authorisation procedures operating in the Member States. Thirdly, it reports and discusses perspectives on the zonal system of Member States, stakeholders and the zonal steering committees,[11] gathered during the research.

Section VII presents and discusses the results of the empirical work with respect to the independence and transparency of CAs, evaluation and authorisation procedures and the implementation of the principles of precaution, substitution and sustainability. Recommendations are made on the basis of conclusions drawn throughout sections VI and VII. Section VIII concludes and summarises the recommendations made on the basis of these conclusions.

With respect to the scope of this research, Chapter III of the Regulation relates to PPPs and governs a broad range of Member State activities. The report focuses on Articles 28-39, which deal with authorisation requirements and procedure with respect to zonal evaluation and authorisation, and comparative assessment of PPPs containing active substances classified as candidates for substitution,[12] pursuant to Article 50.[13] Member States are examined in their capacity as 'zonal rapporteur Member States' (zRMS) under Article 35 PPPR,[14] in which capacity they conduct evaluations of applications to authorise PPPs, described in more detail in section VI.1. PPPs may also be authorised in Member States through mutual recognition of an authorisation granted by another Member State pursuant to Articles 40-42 PPPR. Due to the specific focus on the evaluation procedure at zonal level, mutual recognition is not considered further in this report (for more on this procedure, see Articles 40-42 PPPR and Commission, 2014b). Finally, as the state of Luxembourg (whose CA is the Minister of Agriculture, Viticulture and Consumer Protection) only accepts applications for mutual recognition due to a lack of capacity to conduct evaluations (DG SANTE, 2016d, pp.7–8), it is also not considered further.

[11] These are explained in section VI.1.
[12] Article 24, Annex II point 4 PPPR.
[13] Described in more detail in Section III.
[14] This role is discussed in more detail in Section VI.

II – Independence

Article 36(1) PPPR requires the zRMS to 'make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application'. It imposes no more detailed institutional requirements to achieve this other than that Member States must 'designate a competent authority or authorities to carry out the obligations of the Member States laid down in this Regulation'.[15]

Since the mid-1970s, Europe has experienced a wave of regulatory reform characterised by increased delegation (at national and supranational levels) to expert independent regulatory authorities (IRAs) operating outside direct control of the central administration (Majone, 1996, pp.3, 10–11, 47–48). The vast majority of this reform occurred in the field of economic regulation, i.e. regulation of the operation of the market, and focused primarily on competition, financial bodies and 'utilities' – electricity, gas, water, telecommunications etc. – accompanying the privatisation of these previously state-owned industries (Thatcher, 2002a, pp.126–127; Stern and Holder, 1999, p.35). Similar delegation to IRAs in the field of social regulation (i.e. environmental, health, safety, consumer protection etc.), while much less (Gilardi, 2005, p.85), can still be seen as part of this larger trend across Europe (Thatcher, 2002a, p.143; Hellebø Rykkja, 2004, p.141). The CAs examined in this report, being concerned with risk regulation and protection of human health and the environment, fall into the category of social regulation.

The literature on IRAs reflects the different extent of regulatory reform in these two areas and largely focuses on economic regulators. Nonetheless, this literature offers valuable insights for a study of IRAs in the field of social regulation and forms the basis of the brief discussion of independence as a quality of regulators presented in this section. The section firstly considers reasons for delegation to IRAs relevant to pesticide regulators, the limits of regulatory independence and the characteristics of an IRA.

1. Why delegate to IRAs?

Several, largely functionalist and often normative, explanations have been suggested for increased delegation to IRAs (although these are by no means the only explanations (see, for example Thatcher and Stone Sweet, 2002)). The first expresses a desire on behalf of central administrations to achieve policy credibility. The short terms of elected politicians and inability of current legislatures to bind subsequent legislatures may undermine the consistency, permanence and credibility of public policies (Gilardi, 2005, pp.87–88). Governments therefore delegate regulatory powers to separate agencies to demonstrate commitment 'to regulatory strategies that would not be credible without such delegation' (Majone, 1996, pp.41–44; Thatcher, 2002a, pp.130–131). Secondly, and relatedly, IRAs are believed to promote stability by enabling policy to be insulated from the electoral cycle and attendant political uncertainty (Majone, 1996, p.289; Gilardi, 2005, p.88) and the greater ease with which they may engage

[15] Article 75(1) PPPR.

with the public than the executive, for example, due to their freedom from a need to secure votes (Demarigny, 1996; Johannsen, 2003, p.17).

A third reason points to the changing role of the state in the 1980s and 1990s and desires to shift from interventionist policies and to separate administrative tasks from party political influence (Majone, 1996, pp.49, 54, 56). Food and environmental safety scandals, most notably that surrounding bovine spongiform encephalopathy (BSE, also known as 'mad cow disease') in the mid-1990s, also precipitated the creation of IRAs. The separation of policy decisions (remaining with politically accountable actors) and management (executed by neutral institutions) aimed to restore public trust and confidence in decision-making and government authorities and to enhance their credibility and accountability (Thatcher, 2002a, p.132; Hellebø Rykkja, 2004). The BSE scandal also highlighted the dangers of situating responsibility for the conflicting interests of public health and industry within the same (executive) institution (Hellebø Rykkja, 2004, pp.128–129). This provided further incentives for establishing authorities intended to be separate from commercial and economic interests in order to minimise vulnerability to manipulation and 'capture' (Hellebø Rykkja, 2004, pp.135–137; Vos, 2000, p.246), although such outcomes are by no means guaranteed, as discussed further in section II.2.

Fourthly, during the 1980s and 1990s, policy problems increased in complexity and regulation became more technical (Majone, 1996, p.56; Thatcher, 2002a, p.131). Ministers and generalist civil servants were at a disadvantage in decision-making vis-à-vis the expertise and resources concentrated in powerful interests such as industry and NGOs who demonstrated a willingness to challenge government decisions (Thatcher, 2002a, p.132). The expertise of IRAs is often used to invoke their legitimacy (Baldwin, 1996, p.90) and indeed, in the field of risk regulation, their ability to employ outside experts and produce scientific information both to advise citizens and overcome information asymmetries (but see section II.2 for discussion and criticism) with industry is seen as an advantage (Vos, 2000, p.247; Thatcher, 2002a, p.131). Agencies with specialist expertise were deemed better equipped to engage in and implement evidence-based and reasoned decisions (Thatcher, 2002a, p.132) and to do so more efficiently, by lowering the cost of decision-making (Thatcher and Stone Sweet, 2002, p.15).

Fifthly, breaking from previous regulatory styles based on public ownership criticised by some for their secrecy and opaque, ad hoc advice and intervention (Vos, 2000, p.246; Thatcher, 2002a, p.142; Hellebø Rykkja, 2004, p.129), separation from the state, it is argued, endows regulators with identity and clear responsibility (Baldwin, 1996, p.84). The explicit, focused mandates and objectives accompanying delegation (Thatcher and Stone Sweet, 2002, p.19) are said to enable governing institutions and politicians to appear 'responsive and effective in face of crisis' [sic] (Hellebø Rykkja, 2004, p.139) and can enhance openness and transparency (Vos, 2000),[16] although again, this may not necessarily be the case, as discussed in section II.2.

[16] See section III for more on transparency.

Finally, delegation to IRAs allows politicians to shift blame and avoid controversy by disassociating themselves from unpopular or difficult decisions (Thatcher, 2002a, pp.131, 133; Demarigny, 1996, p.175). Where regulatory decisions concerning health and environmental protection are likely to be based on contested or controversial scientific advice, an aim may be to depoliticise questions of risk assessment and risk management by ensuring both a strict division between managerial and scientific tasks and the independence of scientists (Hellebø Rykkja, 2004, p.127; Vos, 2000, pp.238–239). However, given the close relationship between risk assessment and management and the absence of objective and neutral regulatory science (Lee, 2008, p.42), especially in situations of scientific uncertainty and controversy, such an aim may be unachievable (Vos, 2000, p.248).

2. Limits of regulatory independence

Despite the reasons in favour of establishing IRAs, IRAs do not necessarily eliminate all the problems their independent status was designed to address, most notably information asymmetry and immunity from capture by the regulated industry. Carpenter and Moss (2014a, p.13) define 'regulatory capture' as 'the result or process by which regulation, in law or application, is consistently or repeatedly directed away from the public interest and toward the interests of the regulated industry, by the intent and action of the industry itself'. Furthermore, some identify a possible fundamental tension between independence and accountability (Weale, 1996).

With respect to accountability, delegation to IRAs involves the transfer of extensive powers to institutions which are not accountable to the electorate (Majone, 1996, p.4). Thus, while there are good reasons (including accountability) for establishing regulatory authorities that are independent of government, as discussed in section II.1, this separation could in fact weaken IRA accountability to the public via elected officials (Gilardi and Maggetti, 2011, p.201). However, it is rare for political authorities not to retain some control over IRAs and their activities (Demarigny, 1996, p.175) and there are mechanisms for achieving this which fall short of direct interference in decision-making, such as control of appointments, budget allocations, reporting requirements, Parliamentary oversight, procedural requirements, professional standards, public participation and judicial review (Thatcher, 2002a, p.127; Majone, 1996, pp.5, 39–40; Graham, 1998). Ultimately, a balance between the two desirable qualities of accountability and independence is required.

With respect to capture, public interest theories of regulation often assume that regulators pursue collective social objectives which enhance the general welfare of the community (Morgan and Yeung, 2007, p.17). This view has long been criticised (Gönenç, Maher and Nicoletti, 2000, p.42). For example, the economic theory of regulation suggests that regulation is in fact sought by, and operated for the benefit of, industry in order to create and maintain barriers to entry by competitors, rather than prompted by the public interest (Stigler, 1971). It is argued additionally, that where industry does not initially seek regulation, regulation – and regulatory authorities – are generally 'captured' subsequently (Mitnick, 1980, p.38). However, empirical support for this theory, and indeed for the inevitability and widespread existence of

regulatory capture for anti-competitive purposes, is mixed (Carpenter and Moss, 2014a; Christiansen, 2011). More recent literature differentiates between both different types and different degrees of capture and argues for its preventability. It also recognises that some degree of influence by industry may in fact benefit the public interest (Carpenter and Moss, 2014b), for example where it leads to productive co-operation between regulator and industry or promotes care in the regulator for the welfare of regulated firms (Ayres and Braithwaite, 1992, chap.3).

With respect to degree, 'strong capture' describes a situation in which the purposes and rationale for the regulation are vitiated and its benefits are outweighed by the costs of capture. By contrast, 'weak capture' refers to the influence of special interests 'compromis[ing] the capacity of regulation to enhance the public interest' although overall regulation still serves the public interest (Carpenter and Moss, 2014a, pp.11–12). With respect to type, Carpenter and Moss propose 'corrosive capture', which describes the securing, by the regulated industry, of regulation which is less costly or less stringent in terms of its 'formulation, application, or enforcement' than that perhaps required by the public interest (Carpenter and Moss, 2014a, pp.16–18). Kwak (2014) has identified the phenomenon of 'cultural capture' which describes how the psychological nature (rather than the substance) of regulator-industry interactions may produce in the regulator a view of the public interest favourable to the regulated industry. Regulators may come to identify with the regulated industry and adopt industry positions due to the perceived higher status of industry or relationship pressures stemming from frequent social interaction or membership of the same social networks. This may represent a particular risk with respect to the weakening of social regulation. The communication between regulator and applicant promoted by the Regulation, discussed in section VI, raises the potential for cultural capture, in particular, in CA evaluation and authorisation of PPPs. Finally, a materialist perspective argues that industry control over regulators may stem from close and sustained contact between both parties through long-term involvement in the same field and the offering of regulator rewards by industry, such as lucrative subsequent employment. Acting against industry interests in this context could damage personal friendships and future prospects of rewards (Mitnick, 1980, pp.211–212).

Much of the regulator's vulnerability to capture is attributed to information asymmetry between regulator and industry which may persist despite an IRA's endowment of expertise and knowledge (Majone, 1996, p.70). Enhanced independence through delegation to expert regulators is not straightforwardly guaranteed: for example, in some fields, it may be difficult to obtain the necessary training and expertise outside industry (McCarty, 2014, pp.99–103). Industry sources of expertise may enhance industry influence. Industry is able to exercise control over information relevant to regulation due to its complexity, associated uncertainty and the bounded rationality of the parties involved. Such control enables industry to frame or manipulate regulator perceptions of industry problems and solutions through the supply of selective or biased information (Mitnick, 1980, pp.209–211; Ferretti, 2007, p.385). Ultimately, regulators may become agents of the industry (Mitnick, 1980, p.207), although relationships between regulators and industry can also be highly conflictual (Thatcher, 1998).

Ensuring sufficient IRA resources may counter information asymmetry and improving working conditions and salaries may counter industry control of regulator rewards (Mitnick, 1980, p.212). Post-employment restrictions may contribute to the latter, although could also inhibit recruitment of 'a regulator with appropriate managerial expertise' (Gönenç, Maher and Nicoletti, 2000, p.43). In addition, Kwak recommends the development by regulators of 'career paths and educational opportunities… that are more autonomous from the regulated industry' to narrow the expertise gap between regulator and industry, and the implementation of 'personnel and ethics policies' to prevent excessive bias towards industry (Kwak, 2014, pp.119–120). Article 75(3) PPPR requires Member States to 'ensure that competent authorities have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation shall be carried out efficiently and effectively'. The explicit rationale behind these resource requirements is ensuring the efficiency and effectiveness of the authorisation procedure. However, an additional benefit may be a guard against information asymmetry and consequent risk of regulatory capture, provided sufficient attention is paid to potential problems associated with expert regulators, discussed above, for example the source of their expertise or their over-identification with industry.

Some identify increased transparency, for example the publication of information, and involvement of interested parties as means to reduce the risk of capture (Gönenç, Maher and Nicoletti, 2000, p.44; Majone, 1996, p.26; Mitnick, 1980, p.66). Industry influence may decrease with the increase in participation by other interests (Yackee, 2014 and references therein). It has been argued that IRAs may foster public participation (Majone, 1996, p.41) due to the publicity afforded their activities and their potential function as a space for public debate (Demarigny, 1996, p.162). Some, referring largely to independent utilities regulators, identify increased efforts to consult consumer interests (going further than, or in the absence of, a statutory obligation), publish information and operate openly (Graham, 1998, p.508; Thatcher, 1998, pp.131, 139–140). Such transparency and wider involvement, insofar as it enables public scrutiny of regulatory activities and the relationship between the regulator and government, may weaken the risk of capture by enhancing accountability.[17] Furthermore, returning briefly to the potential tension between independence and accountability, in reality, IRAs must co-operate with multiple actors. If the concept of accountability is broadened to encompass more than direct control by Parliament, independence and accountability may be reconciled (Johannsen, 2003, p.25).

However, some have argued that separation from the central administration may undermine both the transmission of public protests directed at elected officials back to the IRA and the responsiveness of IRAs to direct public engagement (Mitnick, 1980, p.70). Furthermore, participatory processes may be vulnerable to 'information capture' – the costly communication of excessive information by (usually well-resourced) stakeholders, often to establish control over regulatory outcomes for strategic advantage. Less well-resourced participants may be excluded, reducing the pluralism of the process, and regulators may be worn down or diverted

[17] The potential for transparency to enhance accountability is discussed further in section III.1.

from their overall regulatory objective by the overload (both in terms of volume and technical density) of information (Wagner, 2010).

More generally, Ayres and Braithwaite (1992, chap.3) have proposed the involvement of one or more public interest groups (PIGs) as third players, alongside industry and regulator, as a means to prevent capture. PIGs may be empowered through, for example, the grant of access to all information held by the regulator, a place in negotiations between regulator and industry and powers equivalent to the regulator's to challenge industry. Their ability to prevent capture manifests in two respects. Firstly, the need to capture two separate groups (regulator and PIGs) increases the costs of capture for industry, acting as a deterrent. Secondly, long-term involvement in the regulatory process, relationship-building and the development of trust between the three parties aims at socialising each into new modes of deliberation and behaviour and to internalising 'a concern for the other player that is in the public interest' (Ayres and Braithwaite, 1992, p.93; Schwarcz, 2014, pp.367–370). Furthermore, PIGs seek to enhance participatory democracy, while avoiding the burden of mass participation in all areas of decision-making. They would engage in dialogue with the regulator/industry and contribute different experience and knowledge to the regulatory process. Incentives to seriously consider such information exist in the potential for PIGs to apply political pressure to regulators through media use and public outreach (Schwarcz, 2014). Environmental, public health, consumer and/or occupational health and safety groups (amongst others) could fulfil this role in the context of PPP authorisation. PIGs may be vulnerable to capture themselves but should be protected by the contestability of their position which allows for the empowerment of alternative PIGs (Ayres and Braithwaite, 1992, chap.3; Schwarcz, 2014, pp.367–370).

3. Features of an independent regulator

It is impossible to offer a definitive description of an IRA. They may vary according to country, organisational culture, legal and political system, field of regulation and their tasks and activities (Thatcher, 2002a, p.127; Stern and Holder, 1999, p.34; Hellebø Rykkja, 2004, pp.132–134). They take various institutional forms, for example, statutorily independent, a unit supervised by a ministry or subject to its instructions, or a non-ministerial government department; some may therefore be 'semi-independent' of government (Thatcher, 2002a, pp.127, 129). Furthermore, context, such as level of economic development, dictates the type of independence (whether from government or industry) emphasised (Stern, 1997, p.69).

That said, two predominant forms of regulatory agency may be identified: the agency and commission. The former is a hierarchical organisation with a single head. It may be a separate organisation or an office or division of a larger government division or department. The latter is usually hierarchical and headed by an appointed expert board or 'commission'. It tends to be a separate organisation. Both contain expert staff and heads able to process 'large numbers of cases rapidly and relatively economically through specialisation of function' (Mitnick, 1980, pp.30–31). While agency heads are often career civil servants, commissioners tend to be experts in relevant fields, for example, law, economics or science, such as academics or former staff of organisations in the relevant industry sector (Larsen et al., 2006, p.2862). Suggestions that

commissions make better decisions are arguable. The need for compromise and consensus in this context (as compared to a single-headed agency) may not necessarily result in better decisions and may risk inconsistency (Graham, 1998, p.507).

Several definitions of independence have been suggested (for example, Thatcher, 2002b, p.956; Mitnick, 1980, p.69: see definitions quoted therein). The definition used in this report[18] draws on that proffered by Smith: an arm's-length relationship with industry; an arm's-length relationship with political authorities; and the attributes of organisational autonomy, for example, 'earmarked funding and exemption from restrictive civil service salary rules – necessary to foster the requisite expertise and to underpin those arm's length relationships' (Smith, 1997). This definition demonstrates a sensitivity towards concerns about capture by industry and too much control by government, discussed above. It also emphasises the operational elements of independence. Autonomy is seen as promoted by the following: secure sources of funding established by law; the absence of potential for senior officers to benefit from political processes; the presence of a primary law governing the IRA which sets out key powers and duties including when and how decisions may be overruled; protection for senior officers from unfair or arbitrary dismissal by politicians, e.g. through fixed terms, and a multiparty appointment process (e.g. involving both the executive and legislature); and the definition of professional standards and adequate remuneration levels (Stern and Holder, 1999, p.43; Gönenç, Maher and Nicoletti, 2000, p.43) – restrictive civil service salary rules can inhibit recruitment and retention of well-qualified professional staff, technical expertise reduces the risk of capture and organisational autonomy helps foster and apply technical expertise (Smith, 1997). Article 74(1) PPPR provides that Member States may levy fees in order to cover costs incurred through work conducted within the scope of the Regulation. Implementation of this provision may enhance the operational autonomy of CAs through reducing reliance on central government funds by providing an external funding stream, if fees charged do genuinely match costs incurred. That said, dependence by a regulator on the regulated industry for funding may constitute another mechanism of capture (Kwak, 2014, p.75).[19] This suggests careful structuring of regulator funding is required to promote both organisational autonomy and independence from the regulated industry.

As discussed further in section V.1, the emphasis in this report is on formal independence. However, formally independent regulation may not automatically lead to effective regulation. Effective regulation is highly dependent on the reputation of the regulatory agency for acting fairly and reasonably and involves 'considerable informal as well as formal accountability to the regulated industry, to large and small consumers, to Parliament, and to public opinion' (Stern, 1997, p.73). Formal independence contributes to generating this accountability but it does not necessarily make the most important contribution (Stern, 1997, pp.72–74). Thus, if the CAs examined in this report do not display all the elements of formal independence, this

[18] For a discussion of its operationalisation, see section V.1.
[19] I am grateful to Dr Dieter Pesendorfer for highlighting this point.

should not be taken to indicate that their authorisation procedures are necessarily ineffective or unreliable.

III – Transparency

As stated in section II, the zRMS is required to make a 'transparent assessment' of the application for authorisation.[20] As with independence, few detailed requirements are imposed or suggested by the Regulation with respect to how this should be achieved. Provisions in the Regulation which are relevant to transparency broadly relate to access to information and are briefly discussed in section III.3.

Transparency is now widely accepted as a principle of good governance and is specifically endorsed by the EU. Some have argued it is a general administrative law principle (Fisher, 2010, p.312) and others that it is a general principle of EU law (Craig and De Búrca, 2015, pp.574–575; Lenaerts, 2004, p.321). Introduced in the Treaty of Amsterdam, it grew in importance through the late 1990s and subsequently (Vos, 2005, pp.129–130). A closely related concept, 'openness', interpreted as communication about EU activity and decisions in 'accessible and understandable' language, was recognised by the Commission (2001b, p.10) as a principle of good governance. Transparency now surfaces in several provisions of the Lisbon Treaty and elsewhere in EU law (Craig and De Búrca, 2015, pp.568–569). Transparency, like independence, was also a significant part of the reform of food safety regulation, post-BSE (Hellebø Rykkja, 2004; Vos, 2000) in an effort to move away from previously non-transparent regulatory processes which had presided over past regulatory scandals (Löfstedt, 2004, p.340). It was central, for example, to the legal framework within which EFSA operates (Fisher, 2010, pp.299–300) and to the operation of the UK FSA (Krebs, 2004).

Transparency is an exquisitely complex concept. Its meaning varies depending on context (Fisher, 2010, p.277) as do the reasons for and against transparency along with its implications (Fisher, 2010, p.283). There are, furthermore, different degrees of transparency, for example in terms of the amount revealed and the size and identity of the permitted audience, and on which its 'capacity to facilitate knowledge' depends (Schauer, 2011, p.1345). As such, this short section cannot encompass a comprehensive discussion of the concept. Instead, it offers a brief tour of the following areas. Firstly, it considers arguments for transparency. Secondly, it highlights some of the challenges and limitations of transparency. Finally, it considers various mechanisms for implementing or enhancing transparency.

1. Why transparency?

According to Fisher, the promotion of transparency is most often associated with making the exercise of power by institutions accessible or visible (Fisher, 2010, p.275). In the context of the Regulation, this would refer to the exercise of power by the zRMS in assessing an application for authorisation and concluding whether or not to recommend authorisation of the PPP in the

[20] Article 36(1) PPPR.

relevant zone, under Articles 28-39 PPPR. Several, closely related and mutually supportive reasons for transparency exist, discussed below.

The most prominent argument for transparency is that it is necessary to ensure accountability; the public cannot hold an authority to account unless its activities are first made visible (Vos, 2005, p.129). This argument sees transparency as a facilitator of democracy, enabling public control to counter corruption or regulatory capture (Schauer, 2011, pp.1348–1349).[21] Accountability is of particular concern here for two reasons. Firstly, as discussed in section II.2, the rise of IRAs prompted doubts over their accountability due to their separation from elected officials and therefore traditional methods of accountability (Thatcher, 2002a, p.141; Everson, 1995). Doubts also concerned difficulties in identifying the responsible institution resulting from the increasingly complex institutional landscape and the blurring of the boundaries between expert advice and policy (Vos, 2005, p.121; Shapiro, 1997) (although it has also been argued that independence promotes visibility, facilitating control (Vos, 2005, p.125)). Secondly, authorisation decisions are based almost exclusively on scientific evidence, in the form of a risk assessment by the zRMS under Article 36(1) PPPR on the basis of the data submitted by the applicant in support of its application.[22] Where scientific knowledge forms the basis of public decisions with significant implications for human health and the environment, as is the case with PPPs, democratic control 'demands some ability on the part of a polity to evaluate the knowledge claims that justify actions taken on its behalf' (Jasanoff, 2006, p.21). With respect to both, transparency appears as a prerequisite for accountability and indeed supports various accountability mechanisms, for example, judicial review and public participation (Majone, 1996, p.300; Craig and De Búrca, 2015, p.548; Stern and Holder, 1999, p.43).

Some have argued that openness, transparency and honesty increase trust or confidence in organisations, while secrecy destroys it (Löfstedt, 2005, p.xv; Peters, Covello and McCallum, 1997). For example, research has discovered increased levels of trust in companies which share more information and which discuss both their risks and benefits (Löfstedt, 2005, p.xv and references therein). The EU has stated that transparency 'strengthens the democratic nature of the institutions and the public's confidence in the administration' (Declaration No 17 on the right of access to information, annexed to the Final Act of the Treaty on European Union [1992] OJ C191/101; Vos, 2005, p.129; Lenaerts, 2004, pp.318–324). The Court of Justice has elaborated, stating that 'openness… contributes to conferring greater legitimacy on the institutions in the eyes of European citizens and increasing their confidence in them by allowing divergences between various points of view to be openly debated'[23] (Craig and De Búrca, 2015, pp.573–574).

As the Court recognised, the improvement of (input (Barnard and Peers, 2014, p.5)) legitimacy is another argument for transparency. As a principle which facilitates citizen participation in decision-making, it is intended to 'guarantee that the administration enjoys greater legitimacy

[21] Discussed in section II.2.
[22] Article 33(3) PPPR.
[23] Cases C-39 and 52/05 P *Sweden and Turco v Council* [2008] ECR I-4723, para.59.

and is more effective and more accountable to the citizen' (Lenaerts, 2004, pp.319–320). For example, where a regulatory decision relies on evidence (as here), public reporting, and therefore the possibility of public scrutiny, of the relevant data, models and assessment methods may prevent regulators adjusting that evidence to suit a policy position (Dudley and Wegrich, 2016, p.1143).[24] Such participation may not necessarily improve decisions but it is regarded as having normative value (Schauer, 2011, p.1349).

Finally, transparency may be employed as a response to involvement by private, particularly economic, actors in regulation (Abbot and Lee, 2015, pp.21–24; Fisher, 2010, pp.312–313). Under the Regulation, private, economic actors (applicants) are required to provide the vast majority of the information on which authorisation decisions are based.[25] This is reasonable given the resources available to applicants and regulators respectively (Lee, 2008, p.78) and may increase the cost effectiveness and efficiency of regulation (Abbot and Lee, 2015, p.10). Relying on information provided by applicants does, however, raise concerns related to information asymmetry, discussed in section II.2. Transparency can ensure the public knows who is involved in, and what they are contributing to, the regulatory process, granting opportunities for scrutiny (Abbot and Lee, 2015, p.21) which again supports accountability.

2. Limitations of transparency

The centrality of openness and transparency to 'better regulation', both for risk regulation and regulation generally elevates these principles almost to the status of 'all-purpose remedy for misgovernment' (Hood, Rothstein and Baldwin, 2001, pp.148–149). However, transparency is not without its limitations, nor is its implementation free of challenges. It involves much more than simply 'turning on the light' (Fisher, 2010, p.306) and may have unintended consequences. There is evidence, for example, that institutional responses to pressures for increased transparency often involve blame shifting, avoidance or prevention, for example through the establishment of expert scientific committees to 'bless' decisions, the institutionalisation of ambiguity through dispersal of regulatory responsibilities or the pooling of information on risks from different sources (Hood, Rothstein and Baldwin, 2001, pp.128–129, 164–169). Furthermore, public communication activities that purport to disseminate factual information in the interests of transparency may instead seek to effect social control through manipulating public opinion and influencing behaviour (Yeung, 2005).

Contrary to the arguments in section III.1, it has been argued that transparency does not promote trust and may, in fact, cause harm (Fisher, 2010, p.282). For example, increased transparency may encourage members of public to make their own decisions about risks, instead of relying on the decisions of expert regulators. It may, furthermore, enable development of policy-vacuums often filled by more efficient communicators than the regulators (Löfstedt, 2005, p.xv, 2004, pp.340–341), who may not act in the public interest.

[24] Although this presupposes that there exist those with the requisite expertise to perform the scrutiny: see section III.2.
[25] Article 33 PPPR.

Lastly, publishing unfiltered scientific findings could cause public alarm with drastic public health consequences (Löfstedt, 2005, p.xv). Furthermore, transparency may precipitate disagreement disruptive of the bases and procedures of decision-making (Fisher, 2010, p.305) especially so, perhaps, with respect to PPPs, where assessments of risk are already contested, as discussed in section I.

These points relate to a more general argument that transparency, in terms of, for example, simply publishing information on a website, is not sufficient (OECD, 2016, p.38). The information itself must be 'intelligible, clear and ultimately accountable' (OECD, 2016, p.45). The corollary to this is the capacity of the recipient of the information to appraise and use that information. Transparency differs little from concealment in a society lacking 'an active interpretive culture willing to criticise and able to make sense' of the disclosed information (Jasanoff, 2006, pp.33–34). In the highly specialised world of plant protection, review by any scientific expert may not be enough; the right expert is required, and even they must be sufficiently detached from the subject matter to ensure unbiased review (Jasanoff, 2006, p.34).

Finally, while transparency is not an unqualified good, so concealment is not an unqualified bad. As such, transparency may have to compete with other important social values which differ, depending on context (Jasanoff, 2006, p.22). Commercial confidentiality, national security and the protection of personal data are all in tension with transparency (Jasanoff, 2006, p.22; Fisher, 2010, p.280; Abbot and Lee, 2015, pp.23–24). Furthermore, non-disclosure may be valuable for promoting honesty and frankness (Fisher, 2010, p.289). Article 63 PPPR protects some of these values, allowing applicants to request information be treated as confidential where it can provide evidence that its disclosure 'might undermine his commercial interests, or the protection of privacy and the integrity of the individual'.[26] Applicants must physically separate that information. The Member State examining the application decides what information is to be kept confidential if access is requested.[27]

The Court of Justice, in *Bayer*,[28] strengthened this protection somewhat, finding that applicants are not required to request confidentiality under Article 63 at the time of application in order

---

[26] The Commission has proposed revisions to this article as part of its recent proposal to revise the General Food Law (n 10) and eight other pieces of relevant legislation, including the Regulation, in order to improve the transparency of risk assessment procedures. Revisions will include greater public access to information and requirements to consult stakeholders and the public, <http://europa.eu/rapid/press-release_MEMO-18-2942_en.htm> accessed 15 April 2018. Beyond the amendments to Article 63, the proposed changes to the Regulation relate to confidentiality and public access to information submitted for the approval of active substances and not the authorisation of PPPs (Commission, Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain COM(2018) 179 final). Article 59 PPPR also grants data protection to test and study reports submitted with an application for authorisation.

[27] Article 33(4) PPPR.

[28] C-442/14 *Bayer CropScience and Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden* (ECLI:EU:C:2016:890).

to benefit from it. Rather, interpreting Article 63 in light of Directive 2003/4/EC on public access to environmental information,[29] it held that CAs may examine an applicant's objection to the request for access and refuse it on the ground that disclosure 'would adversely affect the confidentiality of commercial or industrial information'.[30] On the other hand, however, the Court endorsed a broad interpretation of 'emissions into the environment, affecting or likely to affect' the environment, finding that it covered emissions of PPPs and the substances contained in them.[31] This is significant: under Article 4(2) Directive 2003/4/EC, CAs may not refuse disclosure of 'information on emissions into the environment'. Although the Court limits information disclosable to that relating to actual or foreseeable emissions under 'normal and realistic conditions of use'[32] and despite remaining ambiguity (Buonsante and Friel, 2017) this interpretation provides a significant exception to the protection of confidentiality under Article 63 PPPR. It may mean large amounts of data and studies are disclosable, according to the guidelines laid down by the Court for CAs, including importantly, information on the medium to long-term consequences of emissions on the environment.[33]

3. Implementing transparency

As discussed above, the meaning of transparency may vary depending on context. Narrow definitions would refer to 'minimal openness of process, access to documents and, publication of official measures' (Hofmann, 2014, p.207). Though perhaps minimal, public access to information, in contributing to democratic accountability (Peers, 2014, p.69), is still of course, an important element of transparency and one which has been supported by the Court of Justice and in EU legislation (Craig and De Búrca, 2015, pp.569–574). For example, Regulation (EC) 1049/2001 attributes to 'openness' a guarantee for the administration of greater legitimacy, effectiveness and accountability and a contribution 'to strengthening the principles of democracy and respect for fundamental rights'.[34] In an environmental context, Directive 2003/4/EC recognises the contribution increased public access to environmental information makes to 'a greater awareness of environmental matters, a free exchange of views, more effective participation by the public in environmental decision-making and, eventually, to a better environment'.[35] In reality, however, these ambitious expectations may not be fully realised; 'there is no necessary or automatic link between transparency and other values' (Lee, 2014a, p.197).

---

[29] European Parliament and Council Directive 2003/4/EC on public access to environmental information [2003] OJ L41/26.
[30] *Bayer* (n 28) para. 49.
[31] *Bayer* (n 28) para. 76. See also, Case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe* (EU:C:2016:889), para. 75.
[32] *Bayer* (n 28) paras 76–77, 81. See also, *Stichting Greenpeace Nederland* (n 31) paras 74–75.
[33] *Bayer* (n 28) paras 87–96.
[34] Recital 2 European Parliament and Council Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L145/43.
[35] Recital 1 Directive 2003/4/EC (n 29).

More specifically, the Regulation contains its own requirements on access to information, providing some measure of transparency with respect to the PPP in question and the knowledge base for any decisions made about them. Article 57 imposes an obligation on Member States to keep certain information electronically available to the public on PPPs authorised or withdrawn under the Regulation. In addition, Article 60(2) requires Member States to compile and make available on request, lists of test and study reports concerning individual PPPs and the substances they contain including those for which the applicant claimed data protection under Article 59 PPPR. The lists shall include information on whether the reports were 'certified as compliant with the principles of good laboratory practice or of good experimental practice',[36] enabling some scrutiny of the quality of the information used in decision-making. Commission guidance contains further suggestions for improving the transparency of the authorisation procedure. Most importantly, it recommends publication of the final Registration Report 'if legal provisions in the individual MS allow', with redaction and removal of confidential information (Commission, 2014b, p.14). The availability of such information would certainly enhance transparency but this is a limited move and, as mere guidance, is unable to compel or require disclosure by Member States. That said, the contents of registration reports[37] suggest that at least part of these documents would fall within the scope of 'information on emissions into the environment' under Article 4(2) Directive 2003/4/EC and, to that extent, should therefore be made available upon request, as discussed in section III.2.

A requirement that public authorities give reasons for their decisions is perhaps the most straightforward means by which to enhance transparency (Majone, 1996, p.292). This activates accountability mechanisms, including judicial review, allowing citizens to defend their rights and courts to exercise their supervisory functions (Craig and De Búrca, 2015, p.548). It may also encourage decision-makers to balance the pros and cons of a decision more than a decision-maker whose reasoning will not be revealed and thereby helps control discretion (Shapiro, 1992, pp.180–181). The Regulation, however, imposes no such requirement on Member States, representing a significant omission from the transparency toolkit. The closest the Regulation comes to this requirement is Article 57, discussed above, which contains a minimal requirement to make available 'reasons for withdrawal of an authorisation if they are related to safety concerns'.[38] Uniform Principle A.5 second paragraph requires Member States to 'come to a reasoned decision within 12 months of receiving a technically complete dossier'.[39] However, there is no requirement for its publication.

---

[36] Article 60(3) PPPR.
[37] See the BVL website for examples: <https://www.bvl.bund.de/EN/04_PlantProtectionProducts/01_ppp_tasks/02_ppp_AuthorisationReviewActSub/02_ppp_RegistrationReports/psm_RegReports_node.html> accessed 25 January 2018.
[38] Article 57(1)(g) PPPR.
[39] Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products [2011] OJ L155/127.

Finally, the Regulation establishes a complex authorisation procedure which may operate differently in different Member States (see section VI). Transparency should extend to the 'rules, data and informational requirements… used to make decisions' (OECD, 2013, pp.51–52), essentially, the 'rules of the game'. Such disclosure is not only necessary for the applicants who need to know the requirements for applications but also for interested parties wishing to understand in more detail the authorisation procedure, actors involved and how the information in the application is used and assessed. Such understanding of internal procedures and expectations is argued to build confidence in the regulator amongst general publics and the regulated industry (OECD, 2013, p.52).

Beyond access to information, more ambitious interpretations of transparency would include openness in the form of public participation in decision-making. This interpretation is adopted here for the following reasons. Firstly, the Commission itself emphasised 'effective and transparent consultation' and a 'reinforced culture of consultation and dialogue', recognising the importance of public participation for good governance generally, (albeit, there, in the context of policy formation rather than regulatory decision-making) (Commission, 2001b, pp.15–17). Secondly, the intimate connection between transparency and public participation is frequently acknowledged. For example, consultation has been described as central to transparency (Deighton-Smith, 2004, p.67) and the improved understanding of regulatory decision-making enabled by transparency is argued to ensure more effective participation (Stern and Holder, 1999, p.43). It has been argued, furthermore, that full transparency is only achieved through knowledge of decision-making acquired by direct participation (Shapiro, 1992, pp.204–205), although full transparency in this sense may not maintain or enhance trust in a regulator unless the public's impression of the reliability of its internal operations also increases as a result (La Porte and Metlay, 1996, p.344). Recital 1, Directive 2003/4/EC states that '[i]ncreased public access to environmental information and the dissemination of such information contribute to… more effective participation by the public in environmental decision-making'. Similarly, recital 3, Directive 2003/35/EC[40] states that '[e]ffective public participation in the taking of decisions enables the public to express, and the decision-maker to take account of, opinions and concerns which may be relevant to those decisions, thereby increasing the accountability and transparency of the decision-making process and contributing to public awareness of environmental issues and support for the decisions taken'. The Lisbon Treaty, too, acknowledges the link between openness, transparency and

[40] European Parliament and Council Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment [2003] OJ L156/17. This Directive implements Aarhus Convention provisions on public participation and access to justice. Article 6(1)(b) Aarhus Convention requires Parties to provide for public participation in 'decisions on proposed activities... which may have a significant effect on the environment'. Decisions authorising PPPs could satisfy this requirement. However, it remains for the Parties to the Convention to 'determine whether such a proposed activity is subject to' this obligation. As such, the EU retains discretion over whether to require public participation in PPP authorisation decision-making.

participation[41] and the General Food Law (GFL) conceives transparency as entailing openness and public consultation.[42] While none of the above EU policy or legislative expressions of support for public participation in decision-making places a clear obligation on Member States to ensure participation in their authorisation of PPPs, they do illustrate the EU's overall commitment to such participation. Finally, as discussed in section III.1, participation provides a link between transparency, in terms of access to information, and accountability through the scrutiny that participation enables.

There are, furthermore, other good reasons for allowing public participation in decision-making, relevant to the authorisation of PPPs and the reliability of the process. Involvement may instil a sense of wider ownership over decisions, promoting implementation (Bloomfield et al., 2001, p.510). The availability of more information and perspectives which wider participation grants to decision-makers may result in better decisions (Parkins and Mitchell, 2005, pp.531–533), for example where scrutiny enables the identification of errors (Lee, 2014a, p.197) or where contributions are valued as resources for problem-solving (Steele, 2001). While risk assessment procedures tend to be closed and technocratic affairs, they need not necessarily be so. The reporting of expert deliberations, uncertainties, ambiguities and disagreements for example, may open up decision-making and enhance transparency (Stirling, 2008). A more instrumental rationale argues that participation can foster trust in the decision-makers (Stirling, 2005, pp.221–222), although it also has the potential to decrease trust (Löfstedt, 2004, p.340). Finally, given the often controversial nature of PPP authorisation decisions and the need for, and inevitability of, value judgments in the assessment and management of risk (Wynne, 1992c, p.116; Royal Society, 1992, p.97; Lee, 2008, pp.41–42), especially in situations of uncertainty, public involvement may benefit decision-making by incorporating citizens' values, evaluating risks and benefits and weighing uncertain benefits against uncertain risks (Steele, 2001, pp.421–427).

In light of the above, in the context of the Regulation, transparency would mean some form of public and stakeholder participation or consultation during the zonal authorisation procedure. There is, however, no provision for this in the Regulation and the achievement of transparency in the PPP authorisation procedure is therefore already disadvantaged.

IV – Precaution, substitution and sustainability

As the discussion in this section illustrates, none of these principles is monolithic, especially so with respect to the precautionary principle and sustainability. It is therefore almost a contradiction to refer to *the* precautionary principle or *the* principle of sustainability. However, the rest of the report does so for shorthand, while acknowledging this circumstance.

[41] Articles 1, 10 and 11(2)-(3) TEU and Article 15(1) TFEU.
[42] Arts 9, 10, 38 Regulation (EC) No 178/2002 (n 10).

1. Precaution

The precautionary principle is a key, yet still controversial and contested, part of risk regulation (for a discussion, see Pesendorfer, 2011). Admitting of multiple interpretations, it is impossible to isolate a single, widely agreed-upon definition. It is stated in the Lisbon Treaty to be a basis for EU environmental policy,[43] and recognised as an autonomous principle of EU law, applying to 'ensure a high level of protection of health, consumer safety and the environment in all the Community's spheres of activity'[44] (Lee, 2008, p.75) extending too, to the protection of animal and plant health (Commission, 2000, p.3). The Treaty offers no definition and the closest EU legislation comes to a definition is in Article 7 of the General Food Law,[45] which provides 'where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment'. The Court of Justice has confirmed this, stating that where the existence or extent of risks are uncertain, 'protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent'.[46]

Furthermore, the interpretation and operation of the precautionary principle may vary widely, depending on context[47] and legal culture (Fisher, 2002) and to such an extent that the wisdom of referring to a singular 'precautionary principle' may be open to question. For some, it makes more sense to talk of a 'precautionary approach' (Stirling, 2001). Others argue that 'it is absurd to expect consistent interpretation and application of the principle' (Fisher, 2009, p.31). The context is, of course, the Regulation, which provides that one of its purposes is to 'ensure a high level of protection of both human and animal health and the environment'.[48] It provides, further, that its provisions are 'underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment' and that 'Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory'.[49]

Article 29(1)(e) PPPR provides that a PPP 'shall only be authorised where following the uniform principles… in the light of current scientific and technical knowledge, it complies with

---

[43] Article 191(2) TFEU.
[44] Cases T-74/00, T-76/00 and T-141/00 *Artegodan v Commission* [2002] ECR II-4945, paras 183–184.
[45] Regulation (EC) No 178/2002 (n 10).
[46] Case C-236/01 *Monsanto Agricoltura Italia SpA v Presidenza del Consiglio dei Ministri* [2003] ECR I-8105, para. 111.
[47] For example, the area of law and whether EU or national institutions are applying it.
[48] Article 1(3) PPPR.
[49] Article 1(4) PPPR.

the requirements provided for in Article 4(3)'. Those Article 4(3) requirements include that, 'consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use', it (b) has 'no immediate or delayed harmful effect on human health or animal health' either directly or indirectly (through, for example, water, food or air) 'taking into account known cumulative and synergistic effects'; (c) 'shall not have any unacceptable effect on plants or plant products'; (d) 'shall not cause unnecessary suffering and pain to vertebrates to be controlled'; and (e) 'shall have no unacceptable effects on the environment' having regard to its fate and distribution and its impact on non-target species, including their behaviour. These requirements must be evaluated in light of the Uniform Principles.[50]

The Regulation's predecessor Directive contained wording[51] very similar to Article 4(3)(b) and (e) PPPR which was interpreted in *Sweden v Commission (Paraquat)*,[52] in light of the precautionary principle. In that case, Sweden challenged the Commission's approval of the active substance paraquat on the basis that, *inter alia*, it breached the precautionary principle. The General Court found that those provisions, interpreted in light of the precautionary principle, required 'the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance' justifying refusal.[53] It noted too, that the Directive's safety requirements required compliance with the Uniform Principles.[54] It found furthermore that, 'it must be established beyond a reasonable doubt that the restrictions on the use of the substance involved… make it possible to ensure that use of that substance will be in accordance with the requirements of Article 5(1)'.[55]

This is, therefore, an indication from the Court that the available evidence, taking into account restrictions on use, must show 'beyond a reasonable doubt' that a substance is safe. Although these findings related to action by the Commission rather than national CAs and approval of an active substance rather than a PPP, given the similarity of the wording in the Regulation, it may be that Article 4(3)(b) and (e) would be interpreted similarly and that the interpretation would apply to paragraphs (c) and (d) as well. Indeed, the wording in the Regulation has been strengthened slightly and expanded, so it is perhaps unlikely that the standard of proof for the safety of a PPP, as required for authorisation under Article 29(1) PPPR, would be lowered, if this approach is taken. However, it should be noted that in a case decided subsequently to *Sweden v Commission (Paraquat)* but also in the context of active substance authorisation under Directive 91/414/EEC, the Court followed a different approach,[56] discussed below.

---

[50] Article 4(4) PPPR; Commission Regulation (EU) No 546/2011 (n 39).
[51] Articles 4(1)(b) and 5(1) Council Directive 91/414/EEC (n 5).
[52] Case T-229/04 *Sweden v Commission (Paraquat)* [2007] ECR II-02437.
[53] 52. [52]para. 161.
[54] 52. [52]paras 163-164.
[55] 52. [52]paras 169-170, 227.
[56] Case C-77/09 *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute* [2010] ECR I-13533.

The Court endorsed quite a high standard of protection of health and the environment with this judgment, reflecting the strong wording in the Directive and Regulation (for example 'no unacceptable effect'[57]). It does require 'solid evidence… which may reasonably raise doubts'.[58] However, as the remainder of its analysis shows, this requirement may be satisfied by the existence of a single study conducted in a non-European country in which some conditions of application were not representative of those in Europe.[59] This is not an impossibly high standard.

Although this case is clearly directly relevant to the regulation of PPPs, it should be noted that it creates an inconsistency in EU law generally as regards the interpretation of the precautionary principle and what its implementation requires. The Court, in *Sweden v Commission (Paraquat)*, applying the precautionary principle, apparently interprets the level of protection established in the legislation as a legal burden of proof with which the administration must comply in order to authorise the relevant substance (Anderson, 2014, pp.444–446). This shrinks the administration's discretion to respond to the available evidence in light of the circumstances of the case in question (Anderson, 2014, pp.444–446). This case is apparently the only example of this approach in the context of risk regulation (Anderson, 2014, p.446) and may perhaps be partly explained by the requirement to apply the Uniform Principles which provide finely detailed guidelines for assessing safety. Elsewhere, it has been held that precautionary action must be based on 'the best scientific information available'[60]and 'as thorough a scientific risk assessment as possible'[61] such that the regulator can 'reasonably' conclude that protective or preventative measures are necessary to prevent the potential risk.[62] In this (dominant (Anderson, 2014, p.442)) approach to the precautionary principle in risk regulation, risk assessment is regarded as a procedural requirement (Stokes, 2008, p.492) which 'informs the exercise of political discretion, without dictating outcomes' (Anderson, 2014, p.440) and the administration, not being bound by the scientific evidence[63] (unlike in *Sweden v Commission (Paraquat)*), retains its discretion.[64] It has been forcefully argued that this line of case law does not require the administration to satisfy a burden of proof (Anderson, 2014, pp.437–439).

The difference in judicial reasoning as to what the interpretation and application of the precautionary principle requires creates confusion in the law and places Member States (and

---

[57] Article 4(3)(e) PPPR.
[58] *Sweden v Commission (Paraquat)* (n 52), para. 161.
[59] 52. [52]para. 172-182.
[60] *Alpharma* (n 9), para. 171; *Pfizer* (n 9), para. 158.
[61] *Alpharma* (n 9), para. 175; *Pfizer* (n 9), para. 162. Sometimes the legislative context eliminates the requirement to perform a risk assessment, (Lee, 2014a, p.30); Case C-343/09 *Afton Chemical Limited v Secretary of State for Transport* [2010] ECR I-7027, Opinion of AG Kokott.
[62] *Pfizer* (n 9), paras 160-163; *Alpharma* (n 9), paras 173-176; *Monsanto* (n 46), paras 111-113. See also, in the context of Directive 91/414/EEC, *Gowan* (n 56), paras 72–79.
[63] *Alpharma* (n 9), para. 239.
[64] Whether this discretion is in practice, exercised, is another question, (Lee, 2014b, p.9).

others, primarily applicants) in a difficult position. Do CAs, for example, follow an approach enunciated with respect to wording almost identical to that which binds them? Or do they follow what may be regarded as a different, but dominant, approach to risk regulation? Given this dilemma, we should not be surprised if Member State survey responses indicate differing interpretations of the precautionary principle.

Finally, although the standard of protection established in *Sweden v Commission (Paraquat)* is high, it should not be taken as an endorsement by the Court of the pursuit of 'zero risk'. As a matter of EU law, precautionary action cannot be based a 'hypothetical risk', for science can never provide proof of 'zero risk'.[65] However, Member States are arguably entitled to seek reduction of a known (as opposed to hypothetical) risk to zero, in the absence of complete harmonisation of the field,[66] (Lee, 2008, p.46; de Sadeleer, 2006, p.164) although such measures would still be subject to review under Articles 34 and 36 TFEU.[67]

2. Sustainability

'Sustainability' is not mentioned in the Regulation. It is therefore at least arguable that the Regulation is not, in fact, based on the 'principle of sustainability'. If it is, it is not explicit. *Whether* it is, is likely to be a subjective judgment and depend on the preferred interpretation of sustainability. Sustainability, like sustainable development, is a vague term admitting of multiple interpretations (Ross, 2009, p.33; Bosselmann, 2008, p.23). It may be, then, that *one* interpretation of sustainability can indeed be found in the Regulation. It is my opinion, in light of the interpretation I prefer (Hamlyn, 2015), that the Regulation is not based on sustainability.[68] However, the point is contestable and worth exploring, as follows, especially given that EU pesticides policy expressly seeks to achieve 'the sustainable use of pesticides'.[69]

The sole references to 'sustainable use' in the Regulation are to the Sustainable Use Directive[70] and to the *Thematic Strategy on the Sustainable Use of Pesticides*.[71] There are attempts to achieve coherence between the Regulation and these other two instruments. For example, Recital 29 provides that Member States should be allowed to 'impose appropriate conditions having regard to the objectives laid down in the[ir] National Action Plan' (NAP).[72] In addition, the

---

[65] *Alpharma* (n 9) paras 156–158; *Pfizer* (n 9) paras 143–145.
[66] C-121/00 *Hahn* ECR I-9193, para. 34.
[67] 66. paras 34-37.
[68] A note on terminology: I do not distinguish between 'sustainability' and 'sustainable development' in my discussion. These terms are often used interchangeably. However, for a discussion of their potential differences, see (Paehlke, 2002).
[69] For example, Commission, A Thematic Strategy on the Sustainable Use of Pesticides COM(2006) 372 Final.
[70] Recital 29 PPPR; SUD (n 3).
[71] Recital 36 PPPR; Commission, Towards a Thematic Strategy on the Sustainable Use of Pesticides COM(2002) 349 Final.
[72] Adopted under Article 4 SUD. This is the primary instrument for implementing the SUD.

PPP label should indicate 'where and under what circumstances a plant protection product may be used' in order to achieve coherence.[73] Finally, 'proper use' of PPPs (as required by Article 55, first paragraph PPPR) requires compliance with the SUD.[74] These explicit links between the Regulation and other legal and policy instruments relating to PPPs are sparse and, on face value, fairly weak. The Regulation could, for example, *require* Member States to consider their NAPs or the goal of 'sustainable use' during their authorisation decision-making. This could strengthen mutually supportive operation between the two instruments. However, further research may be necessary to understand fully their relationship.

However, if we look to the rest of EU policy and legislation on sustainability in the context of PPPs, as I have argued elsewhere (Hamlyn, 2015), we will not necessarily be looking to an ambitious understanding of sustainability.[75] Sustainability is a complex concept whose nuances, due to space constraints, cannot be considered fully here. However, it is worth highlighting two elements in particular. Sustainability is often characterised as consisting of three pillars: the environmental, social and economic (Stallworthy, 2008, p.174). It is also closely associated with justice for future generations (World Commission on Environment and Development, 1987). Both these elements are viewed, internationally, as central to sustainable development (United Nations, 2015). More importantly, the EU itself has long acknowledged both these three constitutive pillars and the principle of inter-generational equity as core parts of sustainability/sustainable development (Commission, 2001a; Council of the European Union, 2006; Pallemaerts, 2013, p.362).[76] It is argued that the implications for a regulatory regime based on this interpretation of sustainability are that decision-makers should take environmental, social and economic considerations relevant to the product in question and the interests of future generations into account during authorisation decision-making (Hamlyn, 2015).

However, traditionally, 'sustainable development' as applied to agriculture has often simply meant 'optimising (or reducing) the use of synthetic pesticides and minimising environmental impact' (Carr, 2003, p.170). The interpretation of sustainable use adopted by the SUD and EU policy on PPPs more generally is that of 'risk reduction' (Hamlyn, 2015). For example, Article 1 SUD provides that its aim is to 'achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment'.[77] The Regulation seeks a similar goal. This is evident from various provisions. Firstly, the Regulation aims to 'ensure a

[73] Recital 36 PPPR.
[74] Article 55, second paragraph PPPR.
[75] Although I acknowledge that the 2009 plant protection products regulatory regime, as a whole, constitutes an ambitious and bold reform of pesticides regulation, (Bozzini, 2017, chap.3).
[76] See also Commission, Next Steps for a Sustainable European Future: European Action for Sustainability COM(2016) 739 Final.
[77] See also, Commission, 'Thematic Strategy' (n 69) p.3. NB the SUD does elsewhere also appear to promote reduction of dependence on the use of pesticides. See, for example, Recitals 5 and 18 and Article 4(1) SUD.

high level of protection of both human and animal health and the environment'.[78] This implies the pursuit of safety through reducing risks. Secondly, the Regulation seeks to facilitate and incentivise the placing on the market of 'low-risk' PPPs.[79] Thirdly, as discussed in section IV.3, the Regulation implements the 'substitution principle', requiring the replacement of PPPs containing active substances identified as particularly hazardous with safer PPPs pursuant to comparative assessment,[80] again, in order to reduce risks.[81] It is acknowledged, as discussed in section IV.3, that comparative assessment requires consideration of risks and benefits and specifically the economic disadvantages of replacement.[82] This is, however, a rare acknowledgement of the relevance of the three pillars of sustainability in the Regulation and nowhere can there be found an explicit acknowledgment of inter-generational equity.

In conclusion, the predominant goal of the Regulation is to reduce risks posed by PPPs. As such it reflects the interpretation of sustainability enshrined in the SUD (although it does not explicitly label this approach 'sustainability' or 'sustainable use' as the SUD does) and indeed the interpretation of sustainable development traditionally associated with agriculture. Whether this is the 'true' or best interpretation of sustainability is very much open to debate. Sustainability has been interpreted, including by the EU, more ambitiously to encompass social, economic and environmental dimensions and the interests of future generations. As such, and due to the lack of consensus overall around its meaning (including between different areas of EU policy touching on sustainability), as with the precautionary principle, we should not be surprised if Member States express different understandings of the 'principle of sustainability' in their responses to the survey.

3. Substitution

The 'substitution principle' is a key part of the Regulation. As applied to chemicals generally, this principle seeks to foster the systematic replacement of hazardous substances with safer alternatives. Dating from the mid-20th century in Sweden (or perhaps even earlier (Öberg, 2014, p.565)) it is now a core part of EU chemicals regulation (Löfstedt, 2014, pp.543–546) and a 'key element of precautionary thinking' (Hansen, Carlsen and Tickner, 2007, pp.399–400). Like many environmental principles, defining it is problematic, although The European Chemical Industry Council (CEFIC) offers a simple definition: 'substitution is the replacement of one substance by another with the aim of achieving a lower level of risk' (quoted in Löfstedt, 2014, p.546). Furthermore, it is labelled a 'principle' and should, like the precautionary principle, be treated as a 'guideline' for consideration by decision-makers alongside other risk management strategies rather than a 'policy tool' (Abelkop and Graham, 2014, pp.582–583) or a rule dictating a clear course of action. Some argue the need for application on a case-by-case basis

[78] Article 1(3) PPPR.
[79] Recital 17 PPPR.
[80] Article 50 PPPR.
[81] Recital 19 PPPR.
[82] Article 50(1) PPPR.

(Hansson, Molander and Rudén, 2011, pp.455–456; Löfstedt, 2014, p.555). This is acknowledged in Commission guidance (Commission, 2014a, p.9) and indeed in the Regulation.[83]

However, the simplicity of the principle belies the complexity of its implementation and application (UK Royal Society of Chemistry, 2007). Challenges relate to, *inter alia*, insufficient knowledge about substances, lack of commercial incentives to substitute (although REACH introduced some) (Abelkop and Graham, 2014, pp.583–584), slow processes for identifying candidate substances and continuing controversy over whether substitution should be hazard- or risk-based (Löfstedt, 2014, pp.547–551), although this may be a false dichotomy as the current EU approach to substitution often contains elements of both (Öberg, 2014, p.565).[84] While the former promises to accelerate substitution processes, if trade-offs between candidate and alternative substances are not fully considered, it may have unintended environmental, health, social and economic consequences. However, a risk-based approach will certainly slow the pace of substitution down and is under-researched (as is substitution, generally) (Löfstedt, 2014, pp.546, 551–560; Öberg, 2014, p.567). Some guidance on comparative assessment has been produced (Sunley and van Opstal, 2010; UK Royal Society of Chemistry, 2007; EPPO, 2015), including on economic and practical considerations (Sunley and van Opstal, 2010, p.103) but still, there is little legislative tradition of applying the substitution principle outside the Nordic countries (Faust et al., 2014, p.2). Furthermore, any uncertainty associated with hazard-based approaches is not necessarily dispelled by undertaking risk assessment, a process which also struggles to capture uncertainty (Aven, 2014, p.570). Scientific evidence rarely speaks for itself and demands interpretation (Stilgoe, Irwin and Jones, 2006, pp.50, 72); likewise the uncertainties in the knowledge base produced by (comparative) risk assessment require value judgments and the weighing of competing concerns during decision-making (Aven, 2014, pp.570–571). A more conciliatory view argues that each approach can be appropriate, depending on the circumstances and substances and alternatives involved, provided decisions are based on the best available evidence (Hansson, Molander and Rudén, 2011, p.456).

The Regulation establishes a procedure for implementing substitution. Active substances are approved as 'candidates for substitution' (CfS) according to a number of hazard-based cut-off criteria set out in the Regulation.[85] This classification triggers an obligation to perform a comparative assessment – the mechanism which delivers substitution – on PPPs containing a CfS (mandatory comparative assessment).[86] The comparative assessment should be done at

[83] Annex IV.2 PPPR.
[84] For example in European Parliament and Council Regulation (EC) No 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [2006] OJ L33/1 and the Regulation.
[85] Article 24(1); Annex II.4 PPPR. For more detail on cut-off criteria see the study (Bozzini, 2018) published under Annex II to the European Implementation Assessment.
[86] Derogations are allowed under Article 50(3) PPPR only 'where it is necessary to acquire experience first through using that product in practice'.

national, rather than zonal, level (Commission, 2014a, p.4) and requires a weighing of risks and benefits between the PPP containing the CfS and alternative PPPs or non-chemical control or prevention methods.[87] Member States are required to refuse authorisation or restrict the use of the PPP containing the CfS where the alternative is 'significantly safer for human or animal health or the environment'; substitution 'does not present significant economic of practical disadvantages' and the remaining control and prevention methods 'are adequate to minimise the occurrence of resistance in the target organism'.[88] The impacts of this provision are highly uncertain. However, one study estimates several thousand cases requiring comparative assessments, imposing a significant burden on CAs (Faust et al., 2014).

In addition, Member States may during evaluation, by way of derogation to Article 36(2) PPPR, comparatively assess a PPP not containing a CfS or a low-risk active substance, 'if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State'[89] (optional comparative assessment).

Bozzini argues that the Regulation implements a strong version of the substitution principle (Bozzini, 2017, chap.2). Article 36(2) PPPR illustrates the strength identified by Bozzini in extending substitution to encourage transition to safer control methods even in the absence of a CfS classification. Indeed, the Commission argues that the principles of comparative assessment and substitution appear throughout the PPP regulatory regime beyond the main regulatory tool in Article 50 PPPR (Commission, 2014a, p.3). In addition, Commission guidance suggests that PPPs containing candidates may be compared with alternative PPPs also containing candidates or even the same candidate even though interpretation of the Regulation may appear to prohibit the latter. Though all candidates are classified on the basis of the high hazards they pose to human health and the environment, comparative assessment may reveal they differ significantly in terms of risks posed in practice (Commission, 2014a, p.6). Moreover, evidence from chemicals regulation suggests the EU seeks to encourage or implement the substitution principle ambitiously. In *Toolex*, a Swedish ban on Trichloroethylene was found to be proportionate under Article 36 TFEU (then Article 30 EC) partly on the basis that the ban implemented the substitution principle.[90] The lightness of the ECJ's proportionality review suggested a willingness to encourage application of the substitution principle (Heyvaert, 2001).

Furthermore, much of the literature examined in this section stresses the relevance of socio-economic considerations and trade-offs to comparative risk assessment, and the need for value judgments. The inevitability of value judgments inheres in that fact that the concepts of 'safer'[91]

[87] Article 55(1), Annex IV PPPR.
[88] Article 50(1)(a)-(c) PPPR.
[89] Article 50(2) PPPR.
[90] Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB* [2000] ECR I-05681, paras 46–47.
[91] Article 50(1)(a) PPPR.

and 'alternative'[92] are open to interpretation (UK Royal Society of Chemistry, 2007, p.3) and may be deeply contested. The Regulation provides some guidance for CAs making judgments with respect to 'significant difference in risk'[93] and 'significant practical or economic disadvantages'.[94] However, placing all responsibility for the substitution decision on CAs ignores the likelihood of disagreement among citizens (and probably Member States too) over sets of values and attitudes towards risk (Dudley, 2013). There is, additionally, the problem of incommensurability (not comparing like with like) (Hansen, Carlsen and Tickner, 2007, p.401) – substances may be more or less hazardous in different respects (UK Royal Society of Chemistry, 2007, p.5) – making straightforward ranking or comparison of hazard profiles impossible. With respect to 'alternative', substitution may be chemical or functional (Hansson, Molander and Rudén, 2011). The Regulation implements functional substitution (Bozzini, 2017, p.40) focusing on uses and effect on the target organism produced by the alternative control or prevention method[95] rather than requiring the alternative to be a chemical control method *per se*. However, technical functional equivalence is difficult to demonstrate, often requiring long periods to acquire evidence (Lohse et al., 2003, pp.66–67). The Regulation anticipates this[96] but this is again likely to slow the process down. Finally, though helpful, the guidance is also vague due to the use of other concepts also requiring value judgments, such as 'significant', 'sufficient' and 'adequate' in Article 50 and Annex IV.

Article 12(1) PPPR allows public comments on draft assessment reports[97] assessing active substances against the approval criteria set out in Article 4 and presumably therefore on CfS classifications considered therein. However, there is no provision for consultation during comparative assessment making Article 50 PPPR a very closed process. Given the likelihood of disagreement among citizen and stakeholders generally, the benefits of public engagement in decision-making, discussed in section III.3, and the fact that substitution is often driven by public concern (Lohse et al., 2003, p.73), greater public involvement and consideration of public values in comparative assessment could enhance CA decision-making under Article 50 (Sexton, 1999, pp.214–215) and may, as discussed in section II.2, help counter the risk of regulatory capture. Indeed, various authors recognise the role stakeholders (including the public and NGOs) play in implementing substitution (Lohse et al., 2003, pp.70–71) and support the involvement of consumers and other stakeholders (UK Royal Society of Chemistry, 2007, p.6; Girling, 2014, p.595).

[92] Article 3(8), Annex IV.1 and 3 PPPR.
[93] Annex IV.2 PPPR.
[94] Annex IV.3 PPPR.
[95] Article 50(1)(a) and Annex IV.1 PPPR.
[96] Annex IV.1(c) PPPR.
[97] Article 11 PPPR.

V – Method

This report is the result of mixed methods research. It involved both desk-based and empirical research, the latter employing both quantitative and qualitative research strategies. Research commenced with a doctrinal analysis of the Regulation's provisions on zonal authorisation (Articles 28-39) comparative assessment (Article 50) and textual analysis of relevant grey literature in order to gain an understanding of the procedures and frameworks (both formal (i.e. established by law) and informal (i.e. contained in guidance)) in place and their operation. A review of the information on CA websites concerning national authorisation models was also conducted.

Secondary sources (such as academic research or EU policy documents and case law) do not always contain all the information required to answer research questions (Burton, 2013, p.55). Due to the variation in availability of information online and in English, it was also necessary to undertake substantial empirical research. The empirical research consisted of three strands, described in sub-sections V.1-3. The broad scope of the research and the number of actors involved made it necessary to strike a balance between depth and breadth, hence the choices of instrument described below. This research, as a whole, is descriptive rather than explanatory, although the critical analysis of Member State practice as a basis for making recommendations gives the work a normative streak. Descriptive work, it is acknowledged, has limitations (Fisher et al., 2009, pp.223–224) but also value, for example, in shaping up the study of pesticides regulation and providing an underpinning for further research (Pedersen, 2014, pp.437–438). Overall, the research seeks to describe a picture of the state of implementation of the Regulation across EU Member States and to gather factual information and/or opinions (subjective perceptions) about the zonal authorisation procedure and its implementation from various quarters. It does not seek to explain the levels of implementation revealed or differences between levels of implementation in different MSs, or to develop, prove or generalise a theory. Furthermore, it does not claim to establish any universal truths or to present a full picture of the implementation of the Regulation, the operation of all CAs or the workings of each zone. As discussed in this section, the data do not allow for such conclusions. Instead, the results reported here should be regarded as a first step towards understanding this complex, enormous and largely under-researched field.

The approach to analysis of the data reflects the largely descriptive nature of the research. The data were collated for the purposes of describing and drawing comparisons between different Member State practices and the experiences of Member States, stakeholders and zSC secretariats and for identifying any trends or similarities (for example, during zonal evaluation) within zones or between Member States. The data were also analysed in light of the theoretical discussions and norms identified in sections II-IV, which enabled interpretation and criticism of Member State/CA practices with respect to their independence and transparency and application of the principles of precaution, sustainability and substitution. On this basis, recommendations were made. The data gathered are presented as directly as possible and the conclusions drawn hold true in light of the available samples.

1. Member State survey

A survey of EU Member States and Norway was conducted. The questionnaire[98] contained questions on the zonal system and the zonal authorisation procedure established in the Member State, the application of the principles of precaution, substitution and sustainability and the independence and transparency of the CAs.

1.1 Zonal authorisation procedure

Questions 1-7 concerned the zonal authorisation procedure in the respondent Member State and covered the procedure itself, who evaluates the application, the status of expert advice received, frequency and reason for communication with other Member States in the same zone and the benefits of the zonal system for Member States.

1.2 Precaution, sustainability and substitution

The questions on precaution, substitution and sustainability were developed by reference to the provisions of the Regulation, EU case law, guidance, in particular on substitution and academic literature, as discussed in section IV. Guidance, policy and literature on these three principles is vast and entire discrete surveys could be conducted on the application by CAs of each. However, in order not to overload CAs (and therefore encourage responses) only a few questions were included on each principle, while acknowledging that it is impossible to capture a full understanding of national interpretations and application of such nuanced and complex concepts on this basis. These questions focused, therefore, on assessing the level of CA ambition in their application and the consistency of interpretation and application, by individual CAs and across Member States, of these three principles. Comparative assessment occurs at national level. However, consistency in its application may still be valuable in terms of the predictability of this procedure from an applicant's point of view. The following questions were asked[99]:

8. The PPPR provides that a PPP may only be authorised if, in the light of current scientific and technical knowledge it has no immediate or delayed harmful effect on human health, it does not have any unacceptable effects on plants or plant products, it does not cause unnecessary suffering and pain to vertebrates to be controlled and it has no unacceptable effects on the environment (Articles 29(1)(e) and 4(3)(b)-(e)). Taking into account all the evidence of the safety of the PPP and the restrictions that may be placed on its use (Article 31), please indicate the **standard of proof** the evidence must meet in order for the PPP to be authorised.

9. Does the competent authority produce and follow any internal guidance in its application of the precautionary principle during the authorisation process?

[98] The full questionnaire could be submitted upon request.
[99] For the majority of questions in the Member State survey, respondents were provided with several options for response, discussed in greater detail in sub-section VII.3.

11. Does the competent authority take the principle of sustainability into account in its decision-making regarding the authorisation of PPPs?

12. On what basis does the competent authority decide whether or not to take the principle of sustainability into account in its decision-making regarding the authorisation of PPPs?

13. Sustainability can be interpreted in many different ways. Which interpretation does the competent authority apply in its decision-making?

14. Does the competent authority produce and follow any internal guidance, or follow any external guidance when applying the principle of sustainability in order to apply it consistently?

15. Recital 29 PPPR provides that Member States **may** impose '**appropriate conditions'** on the use of PPPs having regard to the objectives of their National Action Plan adopted in accordance with Directive 2009/128/EC establishing a framework for Community action to achieve a sustainable use of pesticides [2009] OJ L309/71. In practice, **how often does the competent authority do this**?

16. Article 50(4) PPPR requires Member States to perform a comparative assessment of PPPs containing a candidate for substitution 'regularly and at the latest at renewal or amendment' of its authorisation. How often does the competent authority perform such a comparative assessment on PPPs containing a candidate for substitution?

17. On what PPPs does the competent authority conduct comparative assessment?

18. Does the competent authority produce and follow any internal guidance, or follow any external guidance (e.g. from EPPO, Commission etc.), on substitution/comparative assessment in order to deliver consistent results?

1.3 Independence

The questions concerning independence drew heavily on a survey of independent energy regulators in eight European countries conducted by Johannsen (2003) and her operationalisation of the concept of regulatory independence (Johannsen, 2003, pp.31–37). Johannsen's research took, as its starting point, research into, and a previous survey of, IRAs in the pharmaceutical and electricity sectors in the UK and Italy conducted by Gilardi (2001) which, in turn, drew on research by Cukierman, Webb and Neyapti (1992) into the independence of central banks. Following Johannsen, the survey investigates independence in formal, legal/organisational terms, rather than in terms of the operation of these formal rules in practice.

Johannsen's operationalisation of the concept of regulatory independence, relies on Smith's definition of regulatory independence (Smith, 1997): discussed in section II. It measures four key variables: 1. Formal independence from government and the legislature; 2. Independence from stakeholders; 3. Substantive independence (Larsen et al., 2006, p.2860; Johannsen, 2003, p.36) from government and the legislature (concerning competencies and independent decision-making); and 4. Financial and organisational autonomy.

These key variables were largely adhered to. Questions 22-27 concern formal independence from government and the legislature:

22. What is the term of the agency head or commissioners?

23. Is the appointment renewable?

24. Who appoints the agency head or the commissioners?

25. What are the provisions regarding dismissal of the agency head or commissioners?

26. May the agency head or the commissioners hold other offices in government?

27. Is independence a formal requirement for the appointment?

Questions 28-30 concern independence from the regulated industry:

28. According to your national legislation, is it possible for the commissioners/the agency head to have held a position in the plant protection product industry/industrial associations in the years preceding his or her appointment?

29. Are there provisions (in your national legislation) restricting the commissioners'/the agency head's possibilities of accepting a job in the plant protection product industry/industrial associations after their term?

30. Are there any provisions (in your national legislation) forbidding the agency head/commissioners to have any personal or financial interest in the plant protection product industry?

Questions 31, 33, 34 and 36 concern financial and organisational autonomy:

31. What is the source of the competent authority's budget?

33. When the budget has been approved, who controls the budgetary spending?

34. Who decides the competent authority's internal organisation (internal procedures, allocation of responsibility, tasks etc.?)

36. Who is in charge of the competent authority's personnel policy (recruitment, promotion, salaries)?

Question 42 concerns substantive independence:

42. To what extent is the competent authority responsible for the authorisation of new plant protection products under the zonal authorisation procedure?

While many questions were incorporated into this survey with little or no amendment, others were omitted or re-drafted and additional questions were included to reflect the specific features of regulating PPPs and the requirements of this research. Three particular changes may be noted. Firstly, Johannsen's question on the permissibility of 'discussions of pending

cases' between stakeholders and the regulator was omitted as irrelevant to regulator-regulatee relationship in question. Pre-submission meetings between applicants and CAs are encouraged (Commission, 2014b, p.8) and CAs are entitled to contact applicants during the authorisation process for further information.[100] Secondly, due to the EPRS's particular interest in CA resources, Johannsen's questions on financial and organisational autonomy are dealt with under the heading of 'Capacities' and interspersed with questions relating to the sufficiency of these resources. Finally, Johannsen declined to include questions on information asymmetry due to the difficulty of constructing an indicator about which information can be collected (Johannsen, 2003, p.35). Information asymmetry is connected to the matter of (expert) resources so an attempt is made in this survey to tap this concept by introducing three simple questions (Q38-40) regarding the ease (or otherwise) of recruiting and retaining staff and of buying in resources unavailable in-house. It is acknowledged though that these questions can only scratch the surface of this complex concept.

1.4 Transparency and accountability

The questions concerning transparency and accountability were developed on the basis of research into, and guidance on achieving, transparency in regulatory authorities (for example, OECD, 2013, 2016; Jarvis and Sovacool, 2011; Dudley and Wegrich, 2016). These questions aim to get a sense both of the formal, legal obligations of the CA and the CA's practice. Three dimensions of the concept of transparency are assessed. Firstly, clarity with respect to the authorisation rules, procedures and requirements:

43. How much information regarding the zonal authorisation procedure is publicly available (for example on the competent authority website) in the national language(s)? In this question, information includes guidance **addressed to applicants** on how to apply, the required documents, information about the authorisation procedure and how decisions are made.

Secondly, access to, and publication of, information held by CAs:

44. Does the competent authority publish its decisions regarding authorisation of PPPs?

45. To what extent does the competent authority disclose/publish the information sources on which its decisions are based?

46. Is there a clear basis in law or policy for public access to information held by the competent authority, including a clear statement of the limitations to that access (for example, due to commercial confidentiality)?

Thirdly the strength of any consultation processes conducted during zonal authorisation procedures and access to related information:

47. With whom, in addition to the applicant, does the competent authority consult during its authorisation decision-making processes (including comparative assessment)?

[100] Article 37(1) second paragraph PPPR.

48. If the competent authority consults any of the actors listed in question 47, please briefly state how this consultation/engagement is conducted.

49. If the competent authority consults any of the actors listed in question 47 does the competent authority publish or make publicly available their submissions?

50. Is the competent authority required by law to respond formally to these submissions?

51. If **YES**, are these responses published/made publicly available?

52. Is the competent authority required by law to take into account the comments provided during consultation processes in its decision-making?

The final five questions concerned accountability of the CAs and scrutiny of CA decisions:

53. What are the formal obligations of accountability of the competent authority vis-à-vis the government?

54. What are the formal obligations of accountability of the competent authority vis-à-vis the legislature?

55. Where the competent authority is required to produce an annual report, is this report also made public?

56. Are authorisation decisions reviewed or audited?

57. Article 36(3) fourth sub-paragraph PPPR requires that Member States provide the possibility to challenge a decision refusing authorisation of a PPP 'before national courts or other instances of appeal'. Who, **other than a court**, can overturn the competent authority's decision where it has exclusive competence?

Questions were predominantly closed, incorporating space for additional comments, with some open-ended questions. The questionnaire was lengthy and the aim in choice of question format was to strike a balance between enabling respondents to answer questions quickly and encouraging willing respondents to elaborate on their answers, thereby attempting a balance between depth and breadth. As such, respondents provided information of varying degrees of exhaustiveness and clarity.

1.5 Procedure

The survey took the form of a self-completion questionnaire contained within an MS word document. It was distributed to all 28 EU Member State CAs and the Norwegian CA by email at the end of October with the final deadline set in early December 2017. Twelve CAs responded within the deadline. It should be noted that the participating Member States represent all three zones; each zone is covered by the responses of at least two Member States, which, although not enough to ensure full representativeness for the EU as a whole, allows for some comparison.

Respondents were allowed to specify the level of anonymity accorded their answers. The three options were: consent to direct publication of information provided in the survey identifying the respondent CA; consent to direct publication of information provided in the survey without identifying the respondent CA; and consent to the inclusion of the information provided within statistical data but not to direct publication. The availability of different levels of anonymity was intended to encourage responses, while retaining flexibility for willing Member States to agree to the publication and attribution of their responses. Four CAs selected the first option; three CAs selected the second and five CAs selected the third. Selection of the first two options was regarded as most valuable in terms of the clear presentation of results and the development of an understanding of CA activity across the three zones. Therefore, where CAs provided information regarded as particularly helpful to the research, these CAs were approached individually and asked to waive their chosen anonymity level with respect to the relevant information. Some agreed to this request. Results are presented accordingly, with CAs identified and/or quoted where permitted. Information about the authorisation procedures of the 16 CAs which did not respond, gathered from CA websites (where available) is presented alongside these results. In all cases, the position stated is regarded as the official position of the competent authority.

Of the 12 questionnaires which were returned, six were complete.[101] The reasons for the incomplete questionnaires are unclear. Given the length of the questionnaire, it could have been that questions were accidentally missed, or skipped in the interests of time, if questions were regarded as too time-consuming to respond to. Alternatively, it may be that certain questions were not regarded by the individual respondent as relevant to the CA or perhaps that, despite the guarantee of anonymity, CAs were still loath to provide certain information. It should be noted that this tool allowed for factual information as well as opinions (subjective perceptions) to be collected.

1.6. Representativeness of the data collected via the Member State survey

Given the level of detail of the questions contained in the Member State survey and the CA responses, and the fact that all participating Member Sates declared their answers to be the official position of the relevant authority, it is considered that the information gathered is factual data by its nature and not just mere perception/subjective opinion. Therefore, although not all Member States took part in this data collection exercise, the collected data can be viewed as fully representative for the 12 Member States that took part in the survey (subject to the qualifications expressed in section VI.2).

2. Stakeholder survey

A survey of stakeholders in the zonal authorisation procedure was conducted. The survey[102] sought stakeholders' views on the zonal authorisation procedure, seeking in particular their

[101] 'Complete' means all questions relevant to the respondent CA were answered. Most incomplete surveys were missing only one or two answers.
[102] The full list of questions could be submitted upon request.

opinions on the functioning of the zonal system, the consistency in application of the principles of precaution, substitution and sustainability and the level of CA independence and transparency. These questions were developed on the basis of the same desk-based research on which the Member State survey was based. An additional step was taken involving review of the original questions in light of the responses of CAs to the Member State survey. Like the Member State survey, the stakeholder survey contained a mixture of closed and open-ended questions; the former designed to enable swift provision of information and the latter designed to encourage reflection and the expression of opinions. This tool provided primarily for opinions (subjective perceptions) to be collected.

2.1 Selection of stakeholders

Two categories of relevant stakeholders were identified: those with legal obligations under the Regulation and those without such legal obligations but with a legitimate interest in the achievement of the objectives of the Regulation or the implementation of the Regulation and its impacts. Within the first category fell industry, i.e. manufacturers of PPPs.[103] Within the second category fell PPP users and health and environment stakeholders. Stakeholders were selected on the basis of web-based research into their activities.

In the case of industry stakeholders, there exist both European (and international) level industry associations and individual PPP manufacturers. Only the former were approached.[104] This was primarily because these associations were regarded as providing a reliable voice of industry/individual PPP manufacturers on the matters covered in the survey due to their fulfilling the following criteria: operation at a European level, large membership and significant influence and expertise in the area of plant protection and zonal authorisation procedures. Wherever two or more EU level industry associations were found to represent similar sections of the PPP market but only one focused exclusively on PPPs, that one was chosen. At least one industry association representing, at EU level, the manufacturers of synthetic PPPs (including generic PPPs) and biological PPPs was approached; three associations, in total.

With respect to PPP users, there exist European (and international) level associations representing large numbers of smaller member organisations operating at a national level. Only the former were approached for the same reason as above,[105] i.e. that these associations were regarded as providing a reliable voice of their members on the basis of the following criteria: operation at a European level, large membership, significant influence and expertise

[103] CAs also have legal obligations but were approached in the Member State survey.
[104] Except where no European level association existed, in which case the international level organisation was approached. It was specified in the invitation that the individual members of the selected associations would also be welcome to fill in the survey.
[105] It was specified in the invitation that the individual members of the selected associations would also be welcome to fill in the survey.

in the area of plant protection and zonal authorisation procedures. Three, in total, were approached.

With respect to health and environment stakeholders, there exist both pan-European and national NGOs. The latter NGOs tend to be members of one or more of the former NGOs. A selection of both[106] were approached in order to gather a range of views and experience at both European and national level and on the basis that European-level NGOs might not be able to speak directly to zonal authorisation procedures in individual Member States. Stakeholders in this group were selected on the basis of the following criteria: highest interest in the achievement of the objectives of the Regulation, highest level of concern regarding the environmental and health effects of PPPs, expertise in the area of plant protection and a specific focus on PPP or a declared interest in being consulted. In total, six pan-European NGOs, and ten national NGOs were approached.

Finally, one international level organisation with a membership comprising EU Member States, was approached. In total, 23 stakeholders were approached.

2.2 Procedure

The survey also took the form of a self-completion questionnaire but in this case was constructed and distributed using the online EU survey tool from mid-December 2017 to 22 January 2018. It was distributed to four stakeholders with legal obligations under the Regulation, of whom one responded; and 19 stakeholders with an interest in the achievement of the objectives of the Regulation, of whom none responded. As mentioned above, stakeholders were informed that their members were welcome to complete the survey too. Such members were invited to request access if they wished to do so. However, no additional stakeholders completed the survey. In total therefore, one response to this survey was received, from an industry association. This response was complete. It is unclear why only one response was received. Although the survey was open for over four weeks, it is possible that the timing (over Christmas) combined with its length deterred at least some stakeholders from responding. While a single response is clearly nowhere close to representative of the class of stakeholder to which the respondent belongs (or indeed stakeholders, generally), it did contain valuable information and perspectives on the zonal authorisation procedure, as presented below. Respondents were informed that their answers would not be linked directly to them, thus there is no attribution of information or quotes to individual organisations by name. The respondent stakeholder is referred to below as 'the Stakeholder'.

[106] It was specified in the invitation that the individual members of the selected associations would also be welcome to fill in the survey.

3. Zonal steering committee survey

It was originally intended to conduct semi-structured interviews with the zonal steering committee (zSC)[107] secretariats for the years 2017-2018. Prospective interviewees were approached via email to the secretariats of the three zSCs. However, one of the secretariats of the three zSCs suggested that instead written questions could be provided to which the secretariats would respond in writing. This suggestion was considered positively and applied across all three zones. As such, a questionnaire of open questions[108] was distributed by email to the secretariats from late January to the end of February 2018. The questions focused on the operation of the zonal system and the challenges both the zones and individual Member States face during authorisation procedures as well as the independence and transparency of CAs in each zone and the implementation of the three principles discussed in section IV. Questions were developed on the basis of the desk-based literature review, described at the beginning of section V and once all the responses to the Member State survey and Stakeholder survey had been gathered and reviewed. This allowed questions to be refined on the basis of these responses. All three zSCs responded. The information submitted should not be regarded as the official position of the Member States in each zone but rather as the position of the secretariat of the zSC for the given period. Responses are quoted directly and attributed to zSC secretariats generally, rather than to individual Member States in order to preserve confidentiality.

4. Limitations of the research design

This research is, of course, subject to methodological limitations. First, the design emphasises formal independence. Thus, the information gathered is able only to indicate risks of, for example CA vulnerability to excessive governmental influence or regulatory capture rather than identify concrete evidence of either. A fuller understanding of whether CAs are in fact captured or excessively influenced by government would require a more focused and in-depth empirical investigation conducted by a multilingual team of researchers with privileged access to information, as indicated in section VII.1.5. Secondly, the research does not directly review registration reports or authorisation decisions. Given the public unavailability of this information (as identified in section VII.2), the time and resources necessary to gain access (via access to information requests) and language barriers, such an investigation is beyond the scope of this research. This limitation means that it is not possible to track the effect of government or industry influence, or Member State interpretation of the precautionary, sustainability or substitution principle on evaluation and authorisation decision-making. Thirdly, the majority of the research was conducted within a strict timeframe which reduced the time available to gather empirical data. This may have contributed to the low stakeholder response rate, especially where a longer or more flexible timeframe might have enabled less well-resourced stakeholders to participate. Finally, language limitations meant that only

[107] Discussed in section VI.
[108] The full list of questions could be submitted upon request.

English sources (for example, literature and information on CA websites) could be examined, representing a constraint on the completeness of the implementation 'picture' depicted below.

VI – Zonal authorisation

1. Procedure (as laid down by the Regulation concerning the placing of plant protection products on the market)

The Regulation establishes the main framework for authorisation of PPPs, with detail provided in guidance. Article 28 PPPR requires PPPs to be authorised before being placed on the EU internal market. 'Authorisation' of a PPP is defined in Article 3(9) PPPR as 'an administrative act by which the competent authority of a Member State authorises the placing on the market of a plant protection product in its territory' and is permitted where, following the Uniform Principles[109] a PPP complies with the requirements listed in Article 29 PPPR. These requirements largely relate to the safety of the PPP and include that its active substances, safeners and synergists have been approved, that these components and its residues can be determined, that 'its physical and chemical properties have been determined and deemed acceptable' for use and storage and that 'in light of current scientific and technical knowledge, it complies with the requirements' in Article 4(3) PPPR. These requirements were discussed in section IV.1 and also largely relate to the effectiveness and safety, for human and plant health and the environment, of the PPP in question.

The procedure is called 'zonal' because the Regulation divides Member States (and Norway) into zones with comparable 'agricultural, plant health and environmental (including climatic) conditions' (Northern, Central and Southern) in order to avoid duplication of work, reduce administrative burden on industry and Member States, increase harmonisation and facilitate mutual recognition of authorisations.[110] It is acknowledged that 'authorisation', in terms of the final decision as whether or not to allow a PPP on the market in a particular Member State is made by that individual Member State. Evaluation, in terms of assessing the application, is conducted at 'zonal' level by the zRMS whose conclusions are used as the basis for national authorisation decisions. The terminology in available guidance can sometimes be ambiguous. The phrase 'authorisation procedure' is used here to denote the evaluation and decision-making procedure laid down in Articles 28-39 PPPR.

The authorisation procedure and communication and co-ordination between Member States is facilitated by three 'zonal steering committees' (zSC), one for each zone, and an 'inter-zonal steering committee' (izSC), not provided for in the Regulation. The zSCs are chaired by participating Member States on a yearly rotating basis and meet every two months 'to discuss specific applications and issues arising which should be fed into the izSC. The izSC meets every two months and is attended by two representatives from each zSC. It discusses co-ordination between zones, with respect to, for example, which Member State evaluates which parts of

[109] Article 29(6) PPPR; Uniform Principles (n 50).
[110] Recital 29 PPPR.

dossiers that are shared and the evaluation of applications which only require evaluation by one Member State on behalf of all zones, for example applications for the authorisation of PPPs for use in greenhouses etc. under Article 33(2)(b) PPPR. These meetings are chaired and organised by the Commission and participating Member States (Commission, 2014b, pp.5–6, Appendices 1 and 2). Such co-ordination and the efficiencies and harmonisation sought by the zonal authorisation system are facilitated by the EU's online Plant Protection Product Application Management System (PPPAMS). Applicants must submit their applications to Member States using PPPAMS, which works alongside national authorisation procedures rather than serving as a replacement.[111]

Articles 33-39 PPPR establish the evaluation and authorisation procedure. Article 33 sets out what an application for authorisation must contain and provides that an applicant wishing to place a PPP on the market must apply for authorisation (or amendment of an authorisation) to each Member State in which it intends to place the PPP on the market. Applications for authorisation must be made in the form of a 'draft Registration Report' ('dRR') (Commission, 2014b, p.9, 2009).[112]

In addition to the legislative requirements, guidance encourages applicants to notify, at least six months before an application is planned, all zonal contact points in Member States within the relevant zone with a summary of all PPPs for which authorisation will be sought and in which Member States (Commission, 2014b, p.7). Applicants are also advised to request pre-submission meetings with the envisaged 'zonal rapporteur Member State' (zRMS) to enable discussion between zRMS and applicant of the application, its potential problems, quality and strategy (Commission, 2014b, p.8). Again, the aim is efficient and swift operation of the zonal authorisation procedure (Commission, 2014b, p.7).

The applicant should propose which Member State it expects to evaluate the application in the relevant zone,[113] although this should have been proposed during pre-application (Commission, 2014b, p.7). Unless another Member State in the same zone agrees to examine the application, the proposed Member State will act as the zRMS and examine the application.[114] The Regulation does not oblige the zRMS to conduct a 'completeness check' of the application. However, the application requirements set out in Articles 33 and 34 imply its necessity and that where any requirement is missing, the application should not be accepted. Such a completeness check should be administrative, designed to establish the presence of all required elements and conducted within six weeks and within the overall timeframe for

[111] For more detail, see <https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/application_procedure_en>, <https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_auth-ppp_app_procedure_first_authorisation_of_ppp_en.pdf> accessed 2 January 2018.
[112] Currently, as at the date of completion of this manuscript in March 2018, being updated.
[113] Article 33(2)(b) PPPR.
[114] Article 35 first paragraph PPPR.

evaluation. Final review and confirmation of decisions on work allocation pre-submission may be required (Commission, 2014b, p.10).

Under Article 35 second paragraph PPPR, the zRMS may request co-operation with other Member States in the same zone to 'ensure a fair division of the workload'. Under Article 35 third paragraph, other Member States in the same zone are prohibited from proceeding with the file pending assessment by the zRMS to avoid duplication of work (Commission, 2014b, p.4). Where an application has been made in more than one zone, the zRMSs are required to agree on which zRMS will evaluate the data not related to the environment and agricultural conditions (the core dossier) (Commission, 2014b, p.4; Article 35 fourth paragraph PPPR).

The zRMS must make an independent, objective and transparent assessment of the application 'in the light of current scientific and technical knowledge' using available guidance documents and allowing other Member States in the same zone to submit comments for consideration in the assessment.[115] It must apply the Uniform Principles[116] to establish whether the PPP meets the requirements provided for in Article 29 PPPR (above)[117] and must make its assessment available to the other Member States in the same zone (the 'concerned Member States' or 'cMS'). The zRMS has 12 months to decide whether or not the application meets the requirements for authorisation, although this period can be extended for a maximum of six months where the zRMS needs to request additional information from the applicant.[118] The zRMS may do this multiple times and must inform cMSs where it has requested additional information and the impact on the timeline (Commission, 2014b, p.11). The zRMS should also complete its initial assessment within eight months of submission to allow for cMS comments during a suggested period of six weeks (Commission, 2014b, pp.11, 13), leaving ten weeks for the final decision. The zonal dRR should also be sent to the applicant for its comments (Commission, 2014b, p.13). Comments should 'focus on critical issues that affect the risk assessment' (Commission, 2014b, p.13). Following receipt of comments, the zRMS should finalise their assessment and decide whether to grant or refuse authorisation (Commission, 2014b, p.13). The assessment should take the form of a Registration Report (RR) (Commission, 2014b, p.12). Where opinions differ on technical issues and compromise between the zRMS and cMS is not possible, this shall be recorded in the Reporting Table which is to be handled as a supplement to the RR 'for transparency reasons' (Commission, 2014b, p.13).

Where the zRMS is unable to deliver its assessment within the timeframe, it should alert the zSC which will consider whether re-allocation or assistance is possible and appropriate (Commission, 2014b, p.12).

---

[115] Art 36(1) first paragraph PPPR.
[116] Uniform Principles (n 50).
[117] Article 36(1) second paragraph PPPR.
[118] Article 37(1) PPPR.

The cMSs are required to grant or refuse authorisations on the basis of the conclusions of the zRMS, including where the zRMS has concluded that the use of the relevant PPP is acceptable in the zone in principle but not in its own territory, due to its specific conditions (Commission, 2014b, p.14). Concerned Member States may still assess their own national requirements and impose appropriate conditions and 'other risk mitigation measures' in their own national authorisations.[119] Where such measures cannot control their concerns over human or animal health or the environment, a cMS may refuse authorisation 'if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk…'.[120] In such cases, the cMS must immediately inform the applicant and Commission and 'provide a technical or scientific justification' for this decision to refuse authorisation'.[121] The cMSs are required to decide whether or not to authorise within 120 days of receipt of the assessment report and copy of the authorisation from the zRMS.[122] Member States are required to provide the possibility of challenging a refusal to authorise a PPP 'before national courts of other instances of appeal'.[123]

The zRMS is required to compile a file for each application containing, amongst other things, a copy of the application and a report with information on the evaluation of and decision on the PPP.[124] This file must be made available to the other Member States, the Commission and EFSA on request.[125]

Guidance raises the possibility of publishing the final RR 'to increase transparency and openness if legal provisions in the individual MS allow' (Commission, 2014b, p.14).

2. Evaluation and authorisation models in practice

This section sets out the zonal evaluation and authorisation procedures reported by Member States in response to the Member State survey. We were reliant on the indulgence of busy CAs for information. The data are therefore sometimes uneven (different Member States provided different levels of detail), sparse and may be incomplete. Where possible, the data provided were cross-checked or supplemented with information gathered during the review of CA websites and other sources, predominantly a series of reports on audits of seven Member States conducted by DG SANTE in 2016-2017 (DG SANTE, 2017, p.1).[126] Some Member States neither responded to the survey, nor provide online information in English about their zonal authorisation procedures.[127] As such, it was not possible to report fully on these Member States. While some trends may be discerned, the picture presented below, therefore, is

[119] Article 36(2) and (3) PPPR.
[120] Article 36(3) first and second paragraphs PPPR.
[121] Article 36(3) third paragraph PPPR.
[122] Article 37(4) PPPR.
[123] Article 36(4) PPPR.
[124] Article 39(1) PPPR.
[125] Article 39(2) PPPR.
[126] The Member States audited were: France, Germany, Lithuania, Luxembourg, Portugal, Spain and the UK. The report for Spain was unavailable.
[127] Although some websites appear to contain a lot of information in the native language.

inevitably incomplete. The following section begins with an account of the CAs for each Member State before describing the various stages in the authorisation procedure. In some instances, it was not entirely clear which body was the designated CA. These are indicated with square brackets in the tables below. Generally, national zonal authorisation procedures follow the overall shape of the procedure described in section VI.1.

2.1 Competent authorities

Article 75(1) requires Member States to 'designate a competent authority or authorities to carry out the obligations of the Member States laid down in [the] Regulation'. Member States employ a variety of institutional structures as CAs.

Northern zone

In **Lithuania**, the CA is the State Plant Service (SPS) under the Ministry of Agriculture and headed by a Director. It has responsibility for conducting the evaluation, risk assessment and decision-making. Within the SPS, the PPP Authorisation Division has responsibility for evaluation and preparation of decisions regarding PPP authorisation. Decisions are taken by the director of SPS (DG SANTE, 2016c, p.5). In **Denmark**, the CA is the Danish Environmental Protection Agency, which contains a Pesticides and Gene Technology Unit.[128] The **Estonian** CA is the Agricultural Board.[129] In **Finland**, the CA is the Finnish Safety and Chemicals Agency (Tukes).[130] It contains the Chemicals Department, which is responsible for 'risk assessment, approvals and registration of plant protection products'.[131] In **Latvia**, the CA is the State Plant Protection Service (SPPS), a direct administrative institution subordinate to the Ministry of Agriculture,[132] managed by a director.[133] The Plant Protection Department is a unit within SPPS, incorporating four divisions: PPP Registration Division, PPP Evaluation Division, PPP Control Division and the Integrated Plant Protection Division.[134] KEMI, the Swedish Chemicals Agency, is the CA in **Sweden**. It is a supervisory authority under the Government.[135] It is headed by a Director-General and contains the Authorisation and Guidance Department which 'evaluates applications concerning pesticides'.[136] In **Norway**, the CA is The Norwegian Food Safety Authority (NFSA), a governmental body.[137]

---

[128] <http://eng.mst.dk/about-us/organisation/> accessed 23 December 2017.
[129] § 2[1] Plant Protection Act RT I 2004, 32, 226.
[130] <http://www.tukes.fi/en/Branches/Chemicals-biocides-plant-protection-products/Plant-protection-products/> accessed 23 December 2017.
[131] <http://www.tukes.fi/en/Tieto-meista/About-us-something/> accessed 24 January 2018.
[132] s. 4(1) Plant Protection Law 1998.
[133] s. 4(2) Plant Protection Law 1998.
[134] <http://www.vaad.gov.lv/english/about-us/plant-protection/structural-units-of-plant-protection-department.aspx> accessed 23 December 2017.
[135] <https://www.kemi.se/en/about-us/our-work> accessed 23 December 2017.
[136] <https://www.kemi.se/en/about-us/organisation> accessed 24 January 2018.
[137] <https://www.mattilsynet.no/language/english/plants/plant_protection_products/> accessed 23 December 2017.

	CA	Internal Structure	Status	Responsibilities
Denmark	Danish Environmental Protection Agency	Contains Pesticides and Gene Technology Unit		
Estonia	Agricultural Board			
Finland	Finnish Safety and Chemicals Agency (Tukes)	Contains Chemicals Department		Risk assessment, approvals and registration of PPPs
Latvia	State Plant Protection Service (SPPS)	Contains Plant Protection Department, incorporating four divisions: PPP Registration Division, PPP Evaluation Division, PPP Control Division and the Integrated Plant Protection Division. Managed by director.	Subordinate to Ministry of Agriculture	
Lithuania	State Plant Service (SPS)	Contains PPP Authorisation Division	Under Ministry of Agriculture	Evaluation, risk assessment and decision-making. PPP Authorisation Division of SPS responsible for evaluation and preparation of authorisation decisions. Decisions taken by Director of SPS.
Norway	The Norwegian Food Safety		Governmental body	

	Authority (NFSA)			
Sweden	Kemikalie-inspektionen (KEMI)	Headed by Director-General. Contains Authorisation and Guidance Department	Supervisory body under the Government	Agency head/ director responsible for decisions. Authorisation and Guidance Department evaluates applications.

Table 1: Northern zone competent authorities

Central zone

In **Austria**, the CA is the Federal Office for Food Safety (BAES), a subordinate agency of the Federal Ministry of Agriculture and Forestry, Environment and Water Management,[138] managed by a director. In the **Netherlands**, the CA is the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), a semi-autonomous agency whose PPP-related activities are overseen by the Ministry of Economic Affairs. The Ctgb consists of a Board and a Board Secretariat which 'makes preparations – both scientific and administrative – for the decisions'.[139] In **Belgium**, the CA is the Service Plant Protection Products and Fertilizers (SPPPF) of the Directorate General for Animals, Plants and Food which is part of the Federal Public Service Public Health, Food Chain Safety and Environment (FPS-PHFCSE and SPPPF, 2016, p.3). It was difficult to identify the **Hungarian** CA. However, it appears to be the National Food Chain Safety Office (NFCO), within the Ministry of Rural Development and which contains the Directorate of Plant Protection and Soil Conservation (DPPSC).[140] The DPPSC incorporates the Departments of Authorisation and Evaluation. The former grants authorisations for PPPs; the latter 'summarizes, analyzes and evaluates results of efficacy and residue trials carried out with PPPs…, prepares expert's [sic] opinions, and prepares the registration documents for decision-making'.[141] In **Luxembourg**, the CA is the Minister of Agriculture, Viticulture and Consumer Protection (DG SANTE, 2016d, p.4). The CA in **Romania** appears to be the National Committee for PPP Approval (CNOPPP) (Government of Romania, 2013, p.7). In the **Czech Republic**, the CA is the State Phytosanitary Administration (SPA) which is subordinate to the Ministry of Agriculture and appears to be responsible for

[138] <https://www.baes.gv.at/en/about-us/> accessed 23 December 2017.
[139] <https://english.ctgb.nl/about-ctgb/board-and-board-secretariat> accessed 23 December 2017.
[140] <http://www.ceureg.com/17/docs/presentations/IV_6_Milan%20Panczel.pdf> accessed 24 January 2018.
[141] <http://portal.nebih.gov.hu/hu/web/english/hungarian-forest-management/-/asset_publisher/pHBk9pq6UNxK/content/directorate-of-plant-protection-and-soil-conservation/contacts> accessed 27 December 2017.

registration of PPPs, 'their testing and testing methods of plant protection, supervision of pesticide testing in the Czech Republic'.[142] In **Poland**, the CA appears to be the Department of Plant Breeding and Protection.[143]

In **Ireland**, the CA is the Department of Agriculture, Food and the Marine,[144] which contains the Pesticide Controls Division (PCD) and the Pesticide Registration Division (PRD) (together, the Pesticides Registration and Control Division (PRCD)). The PCD is responsible for implementing the Regulation. The PRD contains five expert units whose scientists evaluate pesticides.[145] **Germany** has designated four CAs: Federal Office for Consumer Protection (BVL) Federal Research Centre for Cultivated Plants (JKI), the Federal Institute for Risk Assessment (BfR) and Federal Environment Agency (UBA). BVL is responsible for co-ordinating the evaluation and authorisation of PPPs and along with JKI and DfR sits under the aegis of the Federal Ministry of Food and Agriculture. UBA sits under the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (DG SANTE, 2016a, p.4). In **Slovenia**, the CA is the Administration of the Republic of Slovenia for food safety, veterinary and plant protection (UVHVVR), which is a body within the Ministry of Agriculture, Forestry and Food and contains a PPP Division.[146] In **Slovakia**, the CA is the Department of Pesticide Registration (ORP),[147] within the Central Control and Testing Institute in Agriculture (ÚKSÚP), which is 'a national budget organization directly managed by the Ministry of Agriculture'.[148] In the **UK**, the CAs are the Secretary of State for Environment, Food and Rural Affairs (England and Wales), the Scottish Ministers (Scotland)[149] and the Department of Agriculture, Environment and Rural Affairs (DAERA) (Northern Ireland) (DG SANTE, 2016f, p.5). The English, Welsh and Scottish CAs' functions, in relation to PPPs, are delegated to the Health and Safety Executive (HSE). The HSE is an Executive Non-Departmental Public Body of the Department for Work and Pensions (DWP)[150] and contains the Chemicals Regulation Division (CRD) (DG SANTE, 2016f, p.5). The CRD is responsible for the evaluation and authorisation of PPPs and also acts as the delivery body for DAERA.[151]

---

[142] <http://eagri.cz/public/web/en/srs/portal/about-us/> accessed 23 December 2017.
[143] <http://www.minrol.gov.pl/eng/Ministry/Departments-and-offices/The-Department-of-Plant-Breeding-and-Protection> accessed 23 December 2017.
[144] <http://www.pcs.agriculture.gov.ie/plantprotectionproducts/> accessed 27 December 2017.
[145] <http://www.pcs.agriculture.gov.ie/aboutus/whatareourresponsibilities/> accessed 24 January 2018.
[146] <http://www.uvhvvr.gov.si/en/about_the_authority/organisation/> accessed 23 December 2017.
[147] <http://www.uksup.sk/orp-cinnost/> accessed 23 December 2017.
[148] <http://www.uksup.sk/charakteristika> accessed 23 December 2017.
[149] Reg. 3 Plant Protection Product Regulations 2011.
[150] Framework Document Between The Health and Safety Executive and The Department for Work and Pensions 2016, 2016 para. 1.1.
[151] <https://www.daera-ni.gov.uk/articles/departmental-responsibilities-regarding-pesticides> accessed 27 December 2017.

	CA	Internal Structure	Status	Responsibilities
Austria	Federal Office for Food Safety (BAES)	Managed by Director	Subordinate agency of the Federal Ministry of Agriculture and Forestry, Environment and Water Management	
Belgium	Service Plant Protection Products and Fertilizers (SPPPF)		Part of Directorate General for Animals, Plants and Food which is part of Federal Public Service Public Health, Food Chain Safety and Environment	Federal Minister of Public Health responsible for decisions.
Czech Republic	State Phytosanitary Administration (SPA)		Subordinate to Ministry of Agriculture	Registration of PPPs, 'their testing and testing methods of plant protection, supervision of pesticide testing in the Czech Republic'
Germany	Federal Office for Consumer Protection (BVL), Federal Research Centre for Cultivated Plants (JKI), the Federal Institute for Risk Assessment (BfR) and Federal		BVL, JKI and BfR: under Federal Ministry of Food and Agriculture. UBA: under Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety	BVL: co-ordinating the evaluation and authorisation of PPPs. Agency head/ director responsible for decisions.

	Environment Agency (UBA).			
Hungary	[National Food Chain Safety Office]	Contains the Directorate of Plant Protection and Soil Conservation which contains the Departments of Authorisation and Evaluation		Department of Authorisation grants authorisations. Department of Evaluation evaluates applications and prepares documents for decision-making.
Ireland	Department of Agriculture, Food and the Marine	Contains the Pesticide Controls Division (PCD) and Pesticide Registration Division (PRD) (together PRCD)		PCD responsible for implementing Regulation. PRD responsible for evaluation.
Luxem-bourg	Minister of Agriculture, Viticulture and Consumer Protection			
Nether-lands	Board for the Authorisation of Plant Protection Products and Biocide (Ctgb)	Board and Board Secretariat	Semi-autonomous agency. PPP-related activities overseen by Ministry of Economic Affairs.	Board Secretariat 'makes preparations – both scientific and administrative – for the decisions'. Board of Commissioners is responsible for decisions.

Poland	[Department of Plant Breeding and Protection]			
Romania	National Committee for PPP Approval (CNOPPP)			
Slovakia	Department of Pesticide Registration (ORP)		Within Central Control and Testing Institute in Agriculture (ÚKSÚP), which is 'a national budget organization directly managed by the Ministry of Agriculture'	
Slovenia	Administration of the Republic of Slovenia for food safety, veterinary and plant protection (UVHVVR)	Contains PPP Division	Body within Ministry of Agriculture, Forestry and Food	
UK	Secretary of State for Environment, Food and Rural Affairs (England and Wales), Scottish Ministers (Scotland), Department of Agriculture, Environment and Rural Affairs (DAERA) (N. Ireland).	CA functions delegated to Health and Safety Executive (HSE). Contains Chemicals Regulation Division (CRD). HSE: overseen by Board.	HSE: Executive non-Departmental Public Body of Department for Work and Pensions	CRD: evaluation and authorisation of PPPs

Table 2: Central zone competent authorities

Southern zone

In **Bulgaria**, there are two CAs:[152] the Bulgarian Food Safety Agency (BFSA)[153] which operates under the Minister of Agriculture and Food and the Centre for Risk Assessment on Food Chain (CRAFC). BFSA is headed by an executive director, proposed by the Minister of Agriculture and Food and appointed by the Prime Minister.[154] In **Cyprus**, the CA appears to be the Agrochemicals Control Section of the Department of Agriculture, within the Ministry of Agriculture, Rural Development and Environment.[155] In **Italy**, the CA is Office VII of the Directorate General for Food Hygiene, Food Safety and Nutrition (DGFHFSN) within the Ministry of Health (DG SANTE, 2016b, p.4). In **France**: the CA is French Agency for Food, Environmental and Occupational Health and Safety (ANSES) which is responsible for assessing the efficacy and risks of PPPs and for their authorisation. However, to ensure the independence of ANSES's scientific expertise, the risk assessment and risk management stages are institutionally separate, the former performed by the Regulated Products Assessment Department (DEPR) and the latter by the Marketing Authorisation Department (DAMM) within ANSES (ANSES, 2015, pp.6–8). The Director General is authorised to issue marketing authorisations (ANSES, 2015, p.5). In **Spain**, it was extremely difficult to determine with certainty the CA but there seemed to be a large amount of information, in Spanish, about PPP authorisation on the website of the Ministry of Agriculture and Fisheries, Food and Environment.[156] In **Greece**, searches for the CA were inconclusive. The Ministry of Rural Development and Food (MRDF) appears to contain the Department of Plant Protection Products and Biocides (DPPPB), the Directorate of Plant Produce Protection (DPPP) and the General Directorate of Sustainable Plant Produce (DGSPP).[157] However, it is unclear where the responsibility lies. In **Malta**, the CA is the Technical Regulations Division, within the Malta Competition and Consumer Affairs Authority (MCCAA).[158] A Minister-appointed Pesticides Control Board advises the Director of the MCCAA on *inter alia*, matters relating to the registration of pesticides.[159] In **Croatia**, the CA is the Ministry of Agriculture. In **Portugal**, the CA is the General Directorate for Agricultural and Veterinary Affairs (DGAV), with responsibility for authorisation assumed by the Pesticides Division of the Sanitary and Defence Directorate (DG SANTE, 2016e, p.5).

---

[152] Communication from the Bulgarian Centre for Risk Assessment on Food Chain.
[153] <http://www.babh.government.bg/en/Page/about_us/index/about_us/About%20us> accessed 23 December 2017.
[154] Communication from EPRS.
[155] <http://www.moa.gov.cy/moa/da/da.nsf/page29_en/page29_en?OpenDocument> accessed 23 December 2017.
[156] <http://www.mapama.gob.es/es/agricultura/temas/sanidad-vegetal/productos-fitosanitarios/registro/menu.asp> accessed 23 December 2017.
[157] (DG SANTE, 2015, p.5) See also, < http://wwww.minagric.gr/syspest/syspest_menu_eng.aspx> accessed 24 January 2018. However, a different arrangement is suggested here: < http://www.minagric.gr/images/stories/en_docs/ministry/organogramma_apostolou121217_eng.pdf> accessed 24 January 2018.
[158] s. 4 Plant Protection Products (Implementation) Regulation 2011.
[159] Article 10 Pesticides Control Act 2001.

	CA	Internal Structure	Status	Responsibilities
Bulgaria	Bulgarian Food Safety Agency (BFSA) and Centre for Risk Assessment on Food Chain (CRAFC)	BFSA headed by executive director	Under Minister of Agriculture and Food	
Croatia	Ministry of Agriculture			
Cyprus	[Agrochemicals Control Section]		Part of Department of Agriculture, within Ministry of Agriculture, Rural Development and Environment	
France	French Agency for Food, Environmental and Occupational Health and Safety (ANSES)	Contains Regulated Products Assessment Department (DEPR) and Marketing Authorisation Department (DAMM)		ANSES: assessing efficacy and risks of PPPs. Authorisation decisions. DEPR: risk assessment. DAMM: risk management. Director General issues marketing authorisations
Greece	[Department of Plant Protection Products and Biocides (DPPPB) and the Directorate of Plant Produce		DPPP is within Directorate-General of Sustainable Plant Production (DGSPP) of the Ministry of	

	Protection (DPPP)]		Rural Development and Food (MRDF)
Italy	Office VII of the Directorate General for Food Hygiene, Food Safety and Nutrition (DGFHFSN)		Within the Ministry of Health
Malta	Technical Regulations Division		Within Malta Competition and Consumer Affairs Authority
Portugal	General Directorate for Agricultural and Veterinary Affairs (DGAV)	Contains Pesticides Division of the Sanitary and Defence Directorate	
Spain	[Ministry of Agriculture and Fisheries, Food and Environment]		

Table 3: Southern zone competent authorities

As the above information demonstrates, Member States employ a variety of institutional structures for their CAs. Some opt for an agency structure, favoured by Scandinavian Member States and several Member States in other zones. Others choose divisions, services or offices within the relevant ministries or government departments or provide that ministries or departments themselves are the CA. In still other Member States, the CA may be an individual minister or secretary of state. There seems to be no discernible trend or preference for particular structures according to zone. However, CAs seem largely to operate within, or are overseen by, a ministry, government department or the government generally. This would suggest such CAs are semi-independent.

2.2 Pre-application

Only the **Netherlands** reports conducting pre-submission meetings with applicants, noting that 'this meeting has a positive effect on the quality of the dossier submitted'.[160] However, it appears from the website review and zSC survey that in the **UK**,[161] **Belgium** (FPS-PHFCSE and SPPPF, 2016, p.9). **Czech Republic** (SPA, n.d., pp.4–5) **Germany** (BVL, 2012, p.5) and all Northern and Central zone Member States and **Portugal**[162] at least, such meetings are also available.[163] However, not all applicants request them.[164] Almost half of all Member States require advance notification (usually six months) of intention to apply for authorisation (**Belgium** (FPS-PHFCSE and SPPPF, 2016, p.5), **Netherlands**,[165] **Czech Republic** (SPA, n.d., p.4), **UK**,[166] **Germany**[167] **Slovenia**[168] and all **Northern zone** Member States (Northern zone, 2017, p.8)) in accordance with the guidance (above).[169] One Southern zone Member State reports that different Member States in the Southern zone have different methods for accepting applications, based on the resources available and the need to comply with deadlines in the Regulation: some operate a 'first come, first served' policy up to an annual limit; others accept applications on a trimestral or annual basis. National plant protection priorities may also be a consideration in the acceptance of applications.

2.3 Completeness check and allocation for evaluation

Following submission of the application, based on the website review and Member State survey responses, about a third of Member States appear to conduct a completeness check, or variation thereof.[170] The **UK**, for example, subjects applications to a two-stage sift involving a validation check to determine whether the application is complete and a detailed technical sift

---

160 Member State survey response.

161 <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm> accessed 27 December 2017.

162 Zonal Steering Committee survey responses.

163 Such information was not available in English for the remaining Member States.

164 SZSC survey response.

165 <https://english.ctgb.nl/plant-protection/types-of-application/procedure-zonal-application> accessed 27 December 2017.

166 <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm> accessed 27 December 2017.

167 <https://www.bvl.bund.de/EN/04_PlantProtectionProducts/03_Applicants/04_AuthorisationProcedure/01_FormsTemplates/ppp_FormsTemplates_node.html> accessed 3 January 2018

168 <http://www.uvhvvr.gov.si/en/areas_of_competence/plant_protection_products/authorisation_of_ppps/authorisation_and_permits_for_ppps/authorisation_of_ppps_in_zones/#c18302> accessed 3 January 2018.

169 Such information was not available in English for the remaining Member States.

170 Such information was not available in English with respect to Austria, Belgium, Estonia, Hungary, Luxembourg, Poland, Romania, Slovenia, Slovakia, Sweden and all the Southern zone Member States.

to determine whether the application is of sufficient quality to undergo full evaluation.[171] These decisions are peer reviewed by a senior officer.[172] In the **Netherlands**,[173] risk assessors each check the part of the application which relates to their area of expertise (e.g. ecotoxicology, residues, efficacy, etc.). Some Member States may reject incomplete applications at this stage and require re-submission (for example, **UK**,[174] **Netherlands**); others imply that applicants may still submit the additional information required (**Germany** (BVL, 2012, p.9), **Czech Republic** (SPA, n.d., p.7), **Sweden**,[175] **Belgium** (FPS-PHFCSE and SPPPF, 2016, p.3)**, Portugal**,[176] the **Netherlands** (where the missing information can be easily supplied)[177] and one Northern zone Member State).[178] One Southern zone Member State indicates that different Southern zone Member States may start counting down towards the deadline at different times, for example from receipt of application or confirmation of completeness. One Central zone Member State reports that decisions at this stage are peer reviewed by a senior officer. Some Member States (**UK**,[179] **Sweden**,[180] **Netherlands**,[181] and two Central and one Southern zone Member State**)** appoint a project manager or equivalent to see the application through the authorisation procedure.[182] The **UK** provided more detail about this role, stating that they guide the application through the procedure, communicate with the applicant, co-ordinate the specialist evaluations, collate final documentation and seek comments from other Member States. It is their responsibility to ensure delivery to cost, regulatory quality and adherence to the legal deadline. These project managers appear to perform valuable functions in terms of keeping procedures on track, co-ordination and communication. As such, they form an example of best practice. Overall, with respect to this aspect of the procedure, there seem to be no zone-specific models; there are examples of these procedures in all zones.

2.4 Evaluation

At the evaluation stage, the divergence between procedures is slightly greater, although they do largely consist of one or more phases of evaluation, during which additional information

---

171 <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm> accessed 27 December 2017.
172 Member State survey response.
173 Member State survey response.
174 <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm> accessed 27 December 2017.
175 <https://www.kemi.se/en/directly-to/apply-for-authorisation/this-is-how-we-handle-your-application> accessed 3 January 2018.
176 Member State survey response.
177 <https://english.ctgb.nl/plant-protection/assessment-framework/registration-manual/how-we-handle-application> accessed 27 December 2017.
178 Such information was not available in English for the remaining Member States.
179 <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm> accessed 27 December 2017.
180 Member State survey response.
181 Member State survey response.
182 Such information was not available in English for the remaining Member States.

may be requested from applicants. Some respondents provided fairly generic information about their evaluation processes along the lines that during this stage, applications are allocated to the relevant experts and additional information may be sought from applicants. Online information in English about this aspect of the procedure was either unavailable or very limited in most Member States.[183] Available detail (either online or from the Member State survey) is presented below. However, without full access to the information in native languages on CA websites, it is impossible to establish a full picture of the zonal authorisation procedures in operation and their diversity or similarity both across Europe and within each zone.

Northern zone

In **Sweden**, evaluation is conducted in-house by the Authorisation and Guidance Department of KEMI[184] (chemists, ecotoxicologists, fate experts and toxicologists, with agronomists and legal advisors in support[185]) and involves assessment of the health and environmental risks of the PPP and evaluation of efficacy (with agronomists at the National Board of Agriculture) and residues (with toxicologists at the National Food Agency).[186] '[S]upplementary documentation' may be requested if necessary.[187] KEMI's website states that if, during evaluation, it appears that an application must be rejected or authorised subject to stricter conditions than those applied for, the applicant will be informed before that decision is taken and given an opportunity to express its views.[188] In **Lithuania**, assessment of the application, including risk assessment for human and animal health, is conducted by the Plant Protection Product Authorisation Division of the SPS.[189] In **Latvia**, the PPP Registration and Environment and Ecotoxicology Divisions prepare assessments as to the compliance of PPPs with the requirements of regulation.[190] In **Norway**, NFSA assesses the possible environmental and health risks of PPPs and assesses whether the product is 'agronomically effective'.[191]

---

[183] Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.
[184] <https://www.kemi.se/en/about-us/organisation> accessed 27 December 2017.
[185] Member State survey response.
[186] <https://www.kemi.se/en/directly-to/pesticides-and-biocides/plant-protection-products> accessed 27 December 2017; survey response.
[187] Member State survey response.
[188] <https://www.kemi.se/en/directly-to/apply-for-authorisation/this-is-how-we-handle-your-application> accessed 27 December 2017.
[189] <http://www.vatzum.lt/en/activity/fields-of-activity/plant-protection-products-authorisation/> accessed 27 December 2017.
[190] <http://www.vaad.gov.lv/english/about-us/plant-protection/structural-units-of-plant-protection-department.aspx> accessed 27 December 2017.
[191] <https://www.mattilsynet.no/language/english/plants/plant_protection_products/authorisation_of_plant_protection_products.20905> accessed 27 December 2017.

Central zone

In **Belgium**, the Authorisation Committee for pesticides for agricultural use (which meets at least once a month (FPS-PHFCSE and SPPPF, 2016, p.4)) and other services and experts, including the Belgian Scientific Institute for Public Health and the Agronomic Research Centre of Gembloux, evaluate each section of the application and perform a risk assessment according to 'agreed European models/Guidance documents'.[192] The expert reports are emailed to the applicant as soon as they are available. Any additional information received will be evaluated by the Authorisation Committee during a meeting, after which further information may be requested (FPS-PHFCSE and SPPPF, 2016, p.16). The conclusions drawn are then examined by an Advisory Board (the Registration Committee).[193] In **Germany**, 'assessment authorities' (BVL, BfR, JKI and UBA) (BVL, 2012, pp.5–6) engage in an initial evaluation of the application. This is followed by 'Assessment phase I' during which the assessment authorities may request additional information from the applicant. 'Assessment phase II' follows submission of this additional information and culminates in the assessment authorities providing a decision on 'consent and their assessments' i.e. their contributions to the dRR (BVL, 2012, p.6). Evaluation is performed by in-house scientific advisers'.[194] In the **Netherlands**, risk assessors in the Board Secretariat assess the risk of the PPP in their respective areas ('fate and behaviour, ecotoxicology, human toxicology, residues, efficacy and physical properties and analytical methods'). Each risk assessor group is peer reviewed. Applicants may be requested to submit additional information.[195] In the **Czech Republic**, two institutions are involved in the authorisation of PPPs: the Czech SPA and the Czech Ministry of Health. The former evaluates ecotoxicology, fate and behaviour, physical chemical properties and efficacy and makes the authorisation decision. The latter contracts evaluation of toxicology, operator exposure and residues out to the Czech National Institution of Public Health which supplies both with its report (SPA, n.d., p.5). The SPA may request further information (SPA, n.d., p.7).

In **Slovenia** evaluation begins with a meeting amongst 'external evaluators from designated institutions [and the dossier is] divided among different parts of evaluation and discussed'. Next the individual evaluations are completed in the form of the zonal registration report and uploaded to a national central documentary programme and the co-ordinator informed.[196] In **Slovakia**, the ORP appears responsible for assessment of PPPs and dossier evaluation.[197] In the **UK**, accepted applications are placed into the appropriate stream. During or after an initial evaluation (occurring in weeks 0-30) a maximum of two requests for additional information may be made, the first generally relating to chemistry, toxicology, residues and fate and behaviour and the second generally relating to operator exposure, ecotoxicology and efficacy.

[192] Member State survey response.
[193] Member State survey response.
[194] Member State survey response.
[195] Member State survey response.
[196] Member State survey response.
[197] <http://www.uksup.sk/orp-cinnost/> accessed 27 December 2017.

In weeks 30-43, this additional information is evaluated.[198] In **Austria**, '[a]ssessment reports and opinions of AGES[199] experts in the fields of toxicology, residue behaviour, environmental fate and ecotoxicology, efficacy and phytotoxicity as well as physico-chemical properties and analytical methods form the basis for the decision on authorisation'.[200] In **Ireland**, evaluation appears to be conducted by the Pesticide Registration Division, which contains 'five expert units consisting of the Chemistry Unit, Ecotoxicology Unit, Efficacy Unit, Environmental Fate & Behaviour Unit and the Toxicology Unit. The expert units are made up of Agricultural Scientists, Biologists, Micro-biologists, Chemists, Ecotoxicologists and Toxicologists'.[201]

Southern zone

In **France**, assessment of the application is conducted by DEPR on the basis of studies provided by the applicant in support of their applicant, data from wider literature, ANSES studies and from vigilance and surveillance schemes (ANSES, 2015, p.7). There may be communication with the applicant for further information or clarification. In another Southern zone Member State, the 'detailed evaluation' culminates in a meeting between all experts involved to compare conclusions on different areas of evaluation and define any data gaps, leading to a request for additional information from the applicant and evaluation of the additional data provided. In **Portugal**, following the detailed evaluation, all experts meet to compare the conclusions of their respective evaluations. Any data gaps are defined and requested from the applicant. Once received the additional data are evaluated.

Member States employ a range of services and experts to evaluate applications. Those indicated by respondents are summarised in table 4.

Which of the following evaluates the application?	*Individual civil servants*	*Individual in-house scientific advisers*	*Individual external experts/ consultants*	*An expert advisory committee*	*Other*
	3	9 Including: Belgium, Germany,	6 Including: Belgium, Netherlands	4 Including: Belgium	1

[198] <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm> accessed 27 December 2017.
[199] Austrian Agency for Health and Food Safety.
[200] <https://www.baes.gv.at/en/plant-protection-products/authorisation-of-plant-protection-products/authorisation-procedure/> accessed 23 December 2017.
[201] <http://www.pcs.agriculture.gov.ie/aboutus/whatareourresponsibilities/> accessed 27 December 2017.

	Netherlands, Sweden

Table 4: Services and experts involved in evaluation

2.5 Commenting

The evaluation procedures described above result in the production of a dRR which is sent to the cMSs and applicant for comments. It is on the basis of these comments that the RR is finalised. This process is, indeed, reported by most respondents to the Member State survey and/or described online, although limited or no information about this stage is available in English for many Member States.[202] In **France**, the DEPR 'endorses a document called '"Conclusion of the assessment", which specifies, for each criterion of the uniform principles, whether or not the result complies with the requirements of European regulations' and supports the authorisation decision. This is a summary of the RR, part of which is published on ANSES's website, in the interests of transparency along with the 'Conclusions' (ANSES, 2015, p.7). **Slovenia** reports that all comments from Member States 'are addressed'. **Sweden** reports that 'all comments will be taken under consideration and the evaluation changed if necessary'.[203] The **Netherlands** reports that the 'dRR is amended based on the comments. A final risk assessment is drafted with the same peer review within the risk assessors groups'.[204] One Southern zone Member State reports that any comments are provided to the experts who 'evaluate any emerging data-gaps based on comments received'. Additional information is again requested from the applicant where necessary and evaluated when received. Two other Member States (one Central and one Southern) report similar procedures. In the **Czech Republic**, 'the SPA processes the other Member States' comments and incorporates any amendments to the evaluation report highlighted by those comments. The SPA records in the reporting table which observations were incorporated, and which were not' (SPA, n.d., p.8). In **Portugal**, cMS comments are provided to experts who 'evaluate any emerging data gaps based on comments received'. Further information is then requested from applicants.[205] This additional information is then evaluated. One Southern zone Member State reports disagreement among Southern zone Member States over whether further information provided in response to requests after the commenting stage require a further round of commenting, which may result in deadlines being missed.

2.6 Conclusion of evaluation and authorisation decision-making

Once comments have been received and addressed and the final RR produced, a final decision on authorisation is made. Again, available information indicates that Member States operate

[202] Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Romania, Slovakia and Slovenia, Portugal, and Spain.
[203] Member State survey response.
[204] Member State survey response.
[205] One Southern zone Member State reports that several Southern zone Member States make such requests.

according to slightly different structures and procedures. However, again limited or no information is available in English in many Member States.[206]

Northern zone

In **Sweden**, senior officers meet to discuss the conditions of use which will be included in the authorisation, or reasons for rejection, as applicable. The applicant is then granted an opportunity to comment on 'factual issues' related to the suggested conditions of use or reasons for rejection. Any comments are taken into consideration. Finally, 'the decision is then signed normally by one of the senior officers attending the… meeting and the person responsible for the application'.[207] **Latvian** legislation suggests that the decision is taken by the SPPS.[208] In **Lithuania**, while the PPP Authorisation Division is responsible for the preparation of decisions regarding PPP authorisation, decisions are ultimately taken by the Director of the SPS (DG SANTE, 2016c, p.5).

Central zone

In the **Netherlands**, the final RR is submitted to the Board of the Ctgb with non-binding advice as to authorisation or rejection of the application and, 'when applicable mitigating measures or amendments of the authorisation'.[209] The Ctgb website elaborates: the Secretariat of the Ctgb prepares and submits a draft decision to the Board of the Ctgb which checks the decision to make sure it is correct before deciding whether or not to authorise the PPP and on conditions of use.[210] In **Belgium**, the dossier is again placed on the agenda of the Authorisation Committee which produces a final RR and decision on authorisation (FPS-PHFCSE and SPPPF, 2016, p.16). In the **Czech Republic**, the SPA compiles the decision proposal and sends it to the applicant with a 'summary of how the SPA dealt with the applicant's comments to the evaluation report' including grounds for not accepting any comments. The applicant is allowed ten days to comment. 'The coordinator incorporates any observations into the decision granting or refusing marketing authorisation for the plant protection product (SPA, n.d., p.8). In **Germany**, the BVL compiles the comments of Member States and the applicants and sends them to JKI, UBA and BfR 'for consideration for the final assessment'. On this basis the BVL compiles the final RR. If a refusal seems likely, the applicant is allowed a hearing (BVL, 2012, p.7). BVL is required to make the decision on authorisation in consultation with JKI and BfR and in agreement with UBA. Thus, BVL and UBA share competence in risk management, entailing decision-making by consensus (DG SANTE, 2016a, p.5). In **Slovenia**, '[t]he body competent for plant protection products… within the Ministry competent for agriculture… shall decide on the authorisation…, based on consensus granted by the administrative body responsible for

[206] Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Romania, Poland, Portugal, Slovakia, and Spain.
[207] Member State survey response.
[208] S. II.5, Cabinet Regulation (LV) No. 509 Adopted 24 July 2012 "Regulations Regarding the Placing on the Market of Plant Protection Products According to Regulation No 1107/2009".
[209] Member State survey response.
[210] <https://english.ctgb.nl/plant-protection/application-process> accessed 23 December 2017.

chemicals'.[211] UVHVVR adopts the authorisation decision in agreement with the Chemicals Office within the Ministry of Health.[212] The **UK** notes that where Member States have differing opinions on technical issues, the zRMS and cMS shall try to reach a compromise. Where this is not possible, it will be recorded in a Reporting Table and included as a supplement to the RR, for transparency. Ultimately, the zRMS makes the decision.[213] Authorisations are granted by the CRD of the HSE, on behalf of Ministers.[214] Applicants are given written reasons for a refusal.[215]

Southern zone

In **France**, authorisations are prepared by the Marketing Authorisations Decisions unit in DAMM, supported where necessary by the Marketing Authorisations monitoring committee and ANSES guidelines on the criteria for authorisation (ANSES, 2015, p.8). In **Portugal**, the final RR is provided to the cMSs and applicant along with the national authorisation decision and approved draft label. One Southern zone Member State reports that some Southern zone Member States rely on the authorisation decision of the zRMS (Part A of the final RR) without any change, while others issue national Part As.

The nature of the expert advice provided to decision-makers varies between Member States, with six Member States (including **Sweden**) reporting that it was binding and four (including **Belgium** and the **Netherlands**) reporting that it was 'purely consultative'. **Belgium** elaborated that its Advisory Board 'may overrule a risk assessment conclusion, by means of well-argued solution [sic] in order to reach an acceptable risk for which the evaluation was negative', though health and environmental protection remain the priority. One reports in-house scientific advice was binding but that any advice from its expert advisory committee was consultative. No trend with respect to individual zones emerged.

Despite the sparsity and incompleteness of the data, one or two tentative observations may be made with respect to trends within zones. Firstly, in the Northern zone, evaluation seems largely to be conducted in-house in the CA, whereas in the Central zone, there are more examples of evaluation activities being conducted by one or more bodies and there was one example of this in the Southern zone. Secondly, in the Northern zone, decisions appear largely to be made, or at least signed, by the CA director or senior officer(s). In the Central zone, there

---

[211] Article 5(2) Plant Protection Products Act (ZFfS-1) (UL RS 83/12), available at <http://www.uvhvvr.gov.si/en/legislation_and_documents/plant_protection_products/si_legislation/> accessed 24 January 2018.

[212] < http://www.uvhvvr.gov.si/en/areas_of_competence/plant_protection_products/authorisation_of_pps/authorisation_and_permits_for_ppps/> accessed 23 December 2017.

[213] <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm> accessed 27 December 2017.

[214] <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration.htm> accessed 27 December 2017.

[215] < http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/what-happens-once-my-application-is-completed.htm> accessed 24 January 2018.

were more examples of decision-making shared, or a requirement for consensus, between bodies. Data for the Southern zone are too limited to support a similar observation.

Otherwise, Member State practice during evaluation and authorisation is characterised by difference. Member States employ a diversity of institutional structure for their CAs. Most Member States appear to conduct completeness checks but these checks operate differently; for example, they may consist of one or two stages and some may reject incomplete applications at this stage while others may still accept submission of missing data. During evaluation, Member States may differ in terms of the numbers of authorities examining applications, the type and timing of communication with applicants and the structure of their evaluation, for example requests for more information from applicants may occur before or after the commenting stage. Finally, during completion of the evaluation and final decision-making, Member States may differ in terms of where responsibility lies for the preparation of the final registration report and for the ultimate decision, the availability to the applicant of opportunities to comment on, or attend a hearing with respect to, the final decision and the nature of the advice on which the decision is based.

2.7 Zonal system

DG SANTE's 2016-2017 audit concluded that the zonal system was 'not working effectively' and that most Member States were not using the system as envisaged by the Regulation (DG SANTE, 2017, pp.I, 18). It identified various problems. Member States generally neither take advantage of work done by each other nor implement work-sharing systems (DG SANTE, 2017, p.5). This was attributed mainly to lack of use of harmonised methods and models for evaluation or the existence of additional national data requirements to address specific national conditions which make Member States reluctant to accept each other's evaluations (DG SANTE, 2017, pp.7–8). A variety of guidance documents covering certain areas of PPP evaluation is available on the Commission website.[216] However, it appears that some areas are still to be agreed (see, for example Commission, 2017, p.2) and that some guidance is unable to cover every possible scenario and instead recommend evaluation on a case by case basis (see, for example EFSA Panel on Plant Protection Products and their Residues (PPR), 2012, p.4). The consequences of the lack of use of harmonised methods and models are delays (DG SANTE, 2017, p.18), a huge duplication of evaluation work and failure to free-up resources. These findings were largely echoed by the **CZSC secretariat**[217] and the Stakeholder, which notes 'a serious imbalance between Member States in their resources'. It reports specifically that duplication results from a lack of trust between Member States which would require time to improve, though it did observe that the number of specific national data requirements was declining. Furthermore, imbalances in the numbers of applications submitted between Member States combined with difficulties of co-operation and work-sharing 'undermine the

[216] <
https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en#ddar> accessed 3 April 2018.
[217] CZSC survey response.

aim of the Regulation to ensure a fair division of the workload' (DG SANTE, 2017, p.9), as envisaged by Article 35 second paragraph PPPR.

The results from the Member State and zSC surveys paint a slightly more optimistic picture, indicating that despite problems, Member States seem to be making productive and frequent use of the zonal system. The **CZSC secretariat** notes that its Member States are still transitioning from 'operating individually to operating as a zone' and that while this could not be achieved in the space of 5 years, could be achieved in the longer term. The Stakeholder too considers that the Regulation is encouraging coherence among zonal authorisation procedures 'to a great extent' noting that work-sharing within zones has now exceeded that achieved under Directive 91/414/EEC. It also recognises that 'Member States to a large extent have the desire to improve harmonisation'.

Member States were asked how often they communicate with other Member States during the zonal authorisation procedure. Eight report they communicate 'often' while three selected 'sometimes'. Only one selected 'rarely' and none selected 'never'. Furthermore, 11 out of the 12 respondents find the zonal system/work of the zSC either 'very helpful' (eight) or 'quite helpful' (three). Only one finds it 'neither helpful nor unhelpful'.

Table 5 indicates the range of reasons for communication with the zone. In addition, **Sweden** comments that Member States consult on interpretation of the Regulation. Another Member State reports that the conference calls every two months are used to 'discuss procedural issues and future work planning'. The **Netherlands** reports use of the zonal system to share knowledge and expertise, 'safeguard the quality' and promote co-operation, which it notes has intensified recently. In addition, it reports the establishment of a Directors Conference which backs up voluntary co-operation by ensuring 'Member States commit to the agreements'.

Reason for communi-cation	*Advice*	*Expert support*	*Technical support*	*Exchange research practices*	*Peer review*	*Share information about application*	*Regarding comparative assessment*	*Discuss market-related issues*	*Other*
	6 Inc. Sweden	8 Inc. Germany Sweden	5 Inc. Sweden	1	9	9	3	3	1

Table 5: Reasons for communication within zones

Member State comments generally indicate a positive attitude towards the zonal system. Seven Member States comment on the role the zonal system has played in harmonising evaluation methods and other procedures between Member States.

Sweden/the **NZSC secretariat** comment that the zonal system has enabled the workload to be shared in a way that was not possible before, that it has resulted in better evaluations and swifter authorisation of PPPs and that the zonal system helps highlights areas of disagreement. The **Netherlands** too sees it as a mechanism for facilitating resolution of disagreements and

predicts the system will eventually lead to more efficient use of available capacity amongst CAs. Likewise, the **CZSC secretariat** reports that zonal discussion helps solve problems and disagreements over risk assessment methodologies and specific dossiers, leading to an 'increasingly cooperative assessment and authorisation practice'. The **SZSC secretariat** reports similar benefits. **Sweden** also reports biennial harmonisation workshops in the Northern zone since 2010 leading to development of Northern zone guidance documents (for example, Northern zone, 2017) (which state harmonised and un-harmonised approaches) including guidance on biological efficacy.[218] The **NZSC secretariat**, in addition, reports coming 'very far' in terms of harmonisation and collaboration, 'better cooperation between experts', citing regular teleconferences between experts within the areas of expertise, facilitating harmonisation and resolution of 'difficult evaluation issues'.

The **CZSC secretariat** elaborates, commenting that the zonal system provides an 'effective peer review process, which greatly improves the credibility of the assessment and safeguards its quality' and that it promotes co-operation, improves communication and collaboration between Member States. It identifies various achievements which support these activities, including the 2017 establishment of a secretariat to maintain continuity across rotating chairs, establishment of a Director's Consultation Group to 'exchange information and reach agreements at a higher level' and the regular zonal teleconferences and annual meetings. Furthermore, the system improves mutual understanding of each other's approaches to risk assessment, enabling discovery of harmonised solutions. It feels the Central zone is on course to achieve the aims of the zonal system (avoiding duplication of work, reducing administrative burden on industry and providing more harmonised availability of PPPs)[219] but notes room for improvement.

Belgium also notes the role of the zonal system in simulating work-sharing. Another (**Southern zone**) Member State reports it '[g]ain[s] experience and knowledge on what is happening in the zone'. The **Netherlands** notes the establishment of working agreements since 2014, development of an inventory of best practices and work on harmonising implementation of guidance documents. Another **Central zone** Member State reports quarterly meetings attended by many Member States 'to discuss procedural issues and devise new guidance to promote harmonisation'. It also reports that scientists 'meet frequently but less regularly to discuss shared issues and develop new harmonised guidance', noting that '[h]armonised guidance is essential and has led to major efficiency gains'.

Challenges identified include informing other (Northern zone) Member States about delays,[220] inconsistent implementation of harmonised guidance by Member States which can undermine the processing of zonal applications and the existence of additional, specific national requirements.[221] Indeed, **Germany** notes that the zonal system only works 'if Member States

[218] NZSC survey response.
[219] Recital 29 PPPR.
[220] Swedish Member State survey response.
[221] Anonymous survey response (Central zone).

work together towards harmonisation both in procedure and assessment'. In addition, the **NZSC secretariat** reports difficulties in finding out about the progress of an evaluation and whether delays are occurring, though it feels that overall, timelines are kept 'relatively well' in the Northern zone. The **CZSC secretariat** also reports problems with keeping to legal timeframes. Finally, the **SZSC secretariat** reports problems associated with the timing of publication of different parts of the final RR: the applicant is informed of the completion of the evaluation and grant of authorisation by the zRMS while the cMSs only receive the final RR, required for their national decisions, from the zRMS later. It reports, furthermore, that some zRMSs publish different parts of the final RR at different times, sometimes subject to a delay following grant of the authorisation.

Further challenges identified by the **CZSC secretariat** include heavy workload due to large numbers of applications and, despite a desire among all Member States for extensive harmonisation, difficulties achieving harmonisation. The latter it attributed to national level refinement in environmental risk assessment methodologies in guidance documents, existence of national requirements and the fact that the Central zone spans different EPPO zones. The workload, it notes, depends on applicant choice of zRMS and reports difficulty in assessing the fairness of workload distribution due to national differences in agriculture and sizes of Member States and their CAs.

The **SZSC secretariat** identifies several specific challenges, including the following. Firstly, the existence of nationally-specific risk mitigation measures. This, it states, is being addressed by the development of harmonised risk mitigation measures which may be used across the entire zone but adapted to specific national conditions. Secondly, it reports different approaches among Member States to efficacy assessment. Some do not follow Articles 29(1)(a) and 4(3)(a) PPPR and EPPO guidelines on minimum effective dose and do not base authorisation on the efficacy of the uses applied for and the minimum dose for the acceptable efficacy. There is no scope under Article 36(3) PPPR for cMSs to introduce national requirements in relation to efficacy, meaning that cMS CAs have no choice but to authorise uses of PPPs that they would not authorise as zRMS due to the lack of a demonstration of minimum effective dose. Finally, the **SZSC secretariat** reports difficulties due to changes in guidance documents and endpoints relevant to the assessment of PPPs resulting from confirmatory data, which occur during evaluation. This causes incompatibility between the approval conditions of the active substance and the grounds on which a PPP is evaluated and delays, where a reassessment is triggered. It recommends that such changes not be applied to PPPs already under assessment.

The matter of resources was often raised. The **NZSC secretariat** reports that while many Member States are small, with limited resources, there is an attempt to share work fairly and that Member States are open with each other about their resource problems. Likewise, the **CZSC secretariat** reports that not all CAs have the financial wherewithal to accommodate increased demand, though it too attempts to distribute the workload fairly. The **SZSC secretariat** argues that an unforeseen consequence of the zonal system was an increase in the costs associated with co-ordination within the zone. It reports, further, that smaller Member States receive roughly the same number of applications as larger Member States 'meaning that

even as Concerned MS or for Mutual Recognition, the resources are stretched thin just to grant authorisations'. Thus, the **SZSC secretariat** does not regard the overall administrative burden as having been reduced. However, it praised the practice whereby the applicant contacts prospective zRMS to determine their willingness to receive a new application. This, it argues, benefits applicants as they do not wish to submit applications to reluctant CAs and benefits CAs as only those able and willing will receive applications. It also comments on the quality of RRs. It reports the need, with respect to RRs from some zRMSs, for cMSs to scour the entire document to discover the reasoning behind a particular conclusion/authorisation condition and to ascertain whether any limitations imposed by the zRMS result from national specific requirements (permitted under Article 36(3) PPPR) or from EU requirements to act on such national specific requirements. Both require expert resources which could be better employed elsewhere.

ZSC secretariats were asked whether Member States trusted each other and each other's evaluations. The **NZSC secretariat** reports '[g]enerally, there is trust between NZ MS'. Disagreements over evaluations are solved 'by direct contact with the zRMS or via teleconferences'. Non-harmonised areas and possible areas of mistrust are discussed and resolved during the annual updating of the Northern zone guidance document. The **CZSC secretariat** attributed mistrust to national differences in methodologies and models used for evaluation, leading to work duplication and different decisions. The **SZSC secretariat** reports differing levels of trust (measured according to the extent to which Member States comment on dRRs) among Southern zone Member States, which it attributes largely to available resources.

The Stakeholder feels that the Northern and Southern zones are working 'quite well' but that the Central zone is working 'very badly'. It links the level of functioning of each zone to the level of similarity between the zone's Member States, attributing the poor functioning of the Central zone to 'high variability in agricultural and climatic conditions, as well as the variety in the size and experience level in' CAs and more national data requirements and competing risk assessment methodologies, representing a greater challenge than that faced by either of the other two zones. It notes the Southern zone is 'making progress' in terms of harmonisation. It cites language as a problem in all zones and also notes that the 'drafting and quality' of RRs could be improved, reporting that publication of all RRs in one language – English – would benefit all. It also suggests that European funding to support co-ordination would accelerate the improvement of the zonal system.

Finally, the Stakeholder feels that the inter-zonal system is working 'quite badly'. This, it attributes to a lack of priority from Member States already struggling to meet challenges at the zonal level. It notes significant differences in approach even in those areas where harmonising is possible, for example, uses under 'controlled conditions'.[222] The **NZSC secretariat** also

[222] It is assumed the Stakeholder is referring to those uses specified in Article 33(2)(b) (including use in greenhouses, as post-harvest treatment etc.) where only one Member State need evaluate the application for all zones.

reports co-operation at this level is 'more challenging as there is not much harmonisation and communication between the zones' and that the inter-zonal system in particular can always work better, for example, in terms of harmonisation and efficiency.

The challenges identified are not surprising from a theoretical point of view. The functions of such networks of national regulators may include the spread of regulatory practices across Europe, sharing information and best practices, regulatory convergence (for example common approaches to implementation and development of best practice) and co-operation (Groenleer, 2011). However, the retention of discretion by national regulators (here, for example, over national data requirements) and a lack of mutual trust may limit the harmonisation achievable through co-operation (Groenleer, 2011, p.557), despite attempts to overcome mistrust between Member States, described above. Furthermore, the activities of regulatory science (i.e. science used in regulatory decision-making (Jasanoff, 1990, pp.76–79)) are deeply embedded in national regulatory systems, culture and relations (Rothstein et al., 1999, pp.252–253). Writing in the context of harmonisation of evaluation procedures under Directive 91/414/EEC,[223] Rothstein et al. argue that such harmonisation and standardisation present a challenge for, and even a threat to, the conduct of national regulatory science. Conversely, national regulatory science can act as a barrier to the implementation of harmonised procedures (Rothstein et al., 1999, p.256). The Stakeholder echoes these observations, reporting 'a lot of variation' between Member State zonal authorisation procedures which it attributed to national differences in government structures, financing systems and involvement of external evaluation bodies. It feels complete harmonisation is unrealistic but noted 'much room for improvement'.

3. Summary and recommendations

The picture of the zonal system which emerges is that of both significant progress and significant challenges and even frustration.[224] Both Member States and the Stakeholder appear to value the zonal system for the potential it offers for work-sharing; improved harmonisation, co-operation and collaboration; promotion of mutual understanding; resolution of disagreements etc., and acknowledge the benefits both for Member States and industry that it has so far provided. On the other hand, significant delays persist as a result of the challenges, some of which are regarded as due to unavoidable differences in environmental conditions.[225] Communication between Member States could still be improved and problems relating to the timing of publication and sharing of RRs have been identified. Unsurprisingly, a major challenge is adequate resourcing of CAs. While the zonal system is partly designed to ease the burden of work on CAs, the workload may still be substantial and, despite attempts to share work fairly, may be unevenly distributed. In addition, co-ordination within the zonal system itself and scrutinising RRs (especially poorer quality RRs) require resources. Finally, establishing trust between different CAs has long been difficult (Rothstein et al., 1999, pp.257–258) and remains so, despite evidence of headway. The zonal system is clearly a work in

[223] Council Directive 91/414/EEC (n 5).
[224] Stakeholder survey response.
[225] Stakeholder survey response.

progress and will likely require a significant amount of effort on the part of Member States to improve its functioning. However, early signs are promising.

Due to the stage of development of the zonal system, as well as the quality of the data currently available, it may also be too early to draw any concrete conclusions about its operation. For example, it is not yet possible to identify the convergence of diverse procedures within the zones towards zonal models for evaluation and authorisation. Although some similarities may be discerned between Member States within zones, these are not strong and overall, diversity and difference largely characterise the institutions and procedures examined in this section.

The zonal system is complex and improvements in its operation, for example, harmonisation and work-sharing, will take time, as the **CZSC secretariat** notes (above). Member States are working on these matters and making progress. It will also take time to build the trust necessary to support greater harmonisation and more efficient operation. Given the potential barriers to trust between Member States (for example, differences in national regulatory science, language or (perceived) resource inadequacies) continued trust-building and even the continuation of the status quo are not necessarily guaranteed.

Recommendations

Further, longer-term (external) qualitative and quantitative empirical research is recommended to understand better the operation of the zonal system, the challenges each zone faces, how these may be overcome and the potential for improving evaluation and the overall authorisation process. Such research could identify further examples of best practice with a view to promoting sharing and policy learning among Member States. For example, it was unclear whether all Member States assign project managers to manage applications. Further research could investigate Member State experience with the use of project managers and whether, for example, they reduce the occurrence of delays.

Member States are encouraged to continue communicating and working together in their zones and to step-up activities designed to improve harmonisation of, for example, methods and models for evaluation and to achieve fairer work-sharing with the aim of strengthening trust between each other. **Chairs of zSCs/zSC secretariats** are encouraged to take particular responsibility for co-ordinating and pushing forward these activities. The **Southern zone**, particularly, could consider introducing guidelines or other measures both governing the timing of RR publication and to improve efficacy assessment within the zone.

Information about, and understanding of, the zonal system more generally could be improved in order to provide an evidence base for possible future action and support. The **Commission** is therefore advised to continue monitoring the zonal system, including stakeholder experiences of the zones, in order to keep track of its progress. The **Commission** and **zSCs** are also encouraged to consider whether it would be feasible and valuable for zSCs to report (for example, annually) to the Commission on progress in their

zones. The Commission is encouraged to provide support, for example financial and administrative, for the production of such reports to ensure their quality. In the interests of transparency, any such reports should be made publicly available.

VII – Results and discussion

1. Independence

As described in section V.1, the questions on independence were divided into four categories: formal independence from government; independence from the regulated industry; organisational autonomy and substantive independence. These questions were also prefaced by three general questions concerning the formal independence of the CA, who is responsible for CA decisions regarding PPP authorisations and the professional background of the current agency head/commissioners. Eleven Member States report that the 'independence of the competent authority [was] formally stated either in legislation or in the statute of the competent authority'. The final Member State reports that it was not but commented that '[t]hose working for the competent authority are bound by the Civil Service Code, which requires (*inter alia*) that they are impartial'. Two Member States report that a Board of Commissioners was responsible for decisions and seven report that the agency head/director was responsible. Of the latter, **Sweden** reports that in practice responsibility for most decisions was delegated to officers of the authority. One reports that responsibility lay with the '[e]xpert team evaluating the application incl. their co-ordinator. The Head is only signing the decision prepared [sic]'. It notes further that the decision 'always follows the conclusions of experts'. **Belgium** reports that the Federal Minister of Public Health was responsible. One Southern zone Member State reports that decisions are sub-delegated to the Deputy Director-General responsible for phytosanitary issues.

The structures of the CAs reported correspond to the categories regulators generally fall into (Larsen et al., 2006, p.2862), being led either by commissions or boards, or by an agency head or director. As discussed in section II.3, it is likely that the decision-making of commissions will lean towards more compromise and consensus than the decision-making of an agency head,[226] although this may not necessarily produce better decisions (Graham, 1998, p.506). Commissioners and board members tend to be experts in different relevant areas. Agency heads tend more to have backgrounds as civil servants (Larsen et al., 2006, p.2862). The two Member States (from the Central and Southern zones) with commission-type CAs did indeed report professional backgrounds of the commissioners in relevant specialist areas. Member States with agency-type CAs (from all zones) report professional background predominantly

[226] Although note discussion in sub-section VII.2.6 and below in relation to substantive independence, that some Member States require decisions to be made on the basis of consensus *between* different bodies even if the CA itself is an agency with a single head, for example, **Germany**.

in natural sciences, especially plant-related, agricultural, business and management, civil service or law.

1.1 Formal independence from government

These questions concerned the status of the agency head/commissioners. One respondent simply referred to its national civil service code in response to these questions and **Belgium** indicated that these questions were not relevant for a Minister. Therefore, the responses of the remaining ten Member States are reported here. In seven Member States agency heads/commissioners are appointed for fixed terms (six of 4-6 years, one of 1-3 years). Q25 asked Member States about the provisions regarding dismissal of the agency head/commissioners. In no Member States is dismissal impossible. However, in four Member States agency heads/commissioners are protected to a certain extent from dismissal during their term; dismissal is only possible 'for reasons unrelated to the substance of authorisation decisions [such as] economic interests in the PPP industry, significant neglect of duties etc.'. Six respondents report that there were no specific provisions for dismissal or that 'dismissal was possible at the appointer's discretion'. Of these, **Germany** reports the position is 'subject to general regulations for civil servants'. Thus, while more than half appeared to accept that independence is enhanced by fixed-term appointments, fewer than half report some protection from dismissal. In addition, most Member States allow appointments to be renewed,[227] which could create incentives to act to please the appointers (Johannsen, 2003, p.45), and potentially reduce independence.

In terms of appointment of the agency head/commissioners, there was a fairly even spread across the various range of appointers: a mix of the legislature and executive: two; the legislature: one; the executive collectively: two; one or two ministers: three. There was no discernible pattern within zones. **Germany** reports the appointer of the President of the CA (BVL) is the Federal Ministry of Food and Agriculture which, as a ministry would probably form part of the executive; the President then appoints the head of the PPP department in BVL. One Member State identified 'the Government' as the appointer. Involvement of the legislature helps ensure independence (Smith, 1997). However, only three in total report its involvement.

In nine Member States, independence is a formal requirement for the appointment and in eight, regulators are prohibited from holding other offices in government. In one this is permitted 'with the permission of the executive'. Only in the **Netherlands** is this possible but is apparently subject to strict conditions relating to conflicts of interest and ongoing monitoring.[228]

Member States were also asked one question relating to substantive, as opposed to formal, independence, i.e. the independence of the CA's actual decision-making. They were asked: '[t]o what extent is the competent authority responsible for the authorisation of new PPPs under the zonal authorisation procedure?'. Eight Member States report that the CA is 'solely

[227] Two once, and five more than once. In the other three, positions have no fixed term.
[228] Detail provided in the Netherlands Member State survey response.

responsible'; three (all Central zone) report that the CA 'shares decision-making power with another institution'. Of the three, **Belgium** notes that 'regional authorities are represented in the Authorisation Board' which makes the decision. One comments that a negative conclusion from its Ministry of Health, which evaluates the effects of the PPP on human health would result in a rejection of the application. **Germany** declined to answer the question, referring instead to the three assessment authorities (JKI, BfR and UBA). As stated in section VI.2.6, BVL decides on authorisation in consultation with JKI and BfR and in agreement with UBA. Thus, BVL and UBA share competence in risk management, entailing decision-making by consensus (DG SANTE, 2016a, p.5).

The Stakeholder comments that CAs may be pressured by their governments in response to 'heavy lobbying from anti-pesticide civil society organisations' although it noted this was more common during EU level of evaluations of active substances. It believes, however, that some governments 'issue legislation that ignores or goes beyond the EU PPPR'.

As the discussions in this section and section VI.2.1 show, several CAs are located within government departments or ministries and therefore may be described as 'semi-independent' of government (Thatcher, 2002a, p.129). Although this research has not compared regulator structures in pesticides regulation with other regulatory domains, other comparative research has identified lower levels of delegation to fully independent IRAs in social regulation (including pesticides regulation) than in economic regulation (Gilardi, 2005, p.85), so this result is perhaps not surprising. It also does not necessarily mean that regulation is unreliable as a result. As discussed in sections I and II.3, formal independence does not automatically guarantee fair and reasonable decision-making (Stern, 1997, pp.72–74); for instance, it may be more important that regulators build a reputation for decision-making with these qualities regardless of institutional structure.

1.2 Independence from regulated industry

Independence from the regulated industry may be enhanced by 'maximis[ing] the relational distance from the industry' through prohibiting former employees of industry from being appointed regulators (Johannsen, 2003, p.45). Three (Central zone) Member States employ this measure with respect to the agency head/commissioners while six allow appointments from industry/industrial associations. One (Southern zone) Member State reports it has no specific provisions. No Member States allow the agency head/commissioners to be employed in the regulated industry or industrial associations during their term.

Independence from industry during the appointment may also be enhanced by restricting a regulator's freedom to accept jobs in industry on expiry of their appointment. Only one (Northern zone) Member State reports prohibiting the agency head/commissioners from accepting positions in industry for one or more years following their term, while **Germany** reports that due to the civil service status of the agency head, 'any paid activity after retirement [is] subject to approval by the agency'. Seven Member States report no provisions restricting

employment of the agency head/commissioners in industry following their term.[229] There is some correlation between the power to appoint from industry and the absence of restrictions on employment in industry following the term. Of the Member States exhibiting this correlation, **Sweden** reports that previous employment in industry 'could be regarded as a disqualification' according to Swedish administrative law and that conclusion of an employment agreement prior to the end of the term could also be a violation of Swedish administrative law. The **Netherlands** reports that previous employment in industry (and in NGOs or other organisations in this sector, e.g. farmers organisations) 'in practice… is a reason for rejection in the selection of Board members or head of agency' and that again 'in practice [employment in industry following the term] does not happen as it is a violation of the spirit of our integrity code'. There is a trade-off here. While restrictions on appointing former industry employees and on post-appointment industry employment can reinforce independence from industry, it may hinder appointment of regulators with the necessary expertise (Gönenç, Maher and Nicoletti, 2000, p.43).

In eight Member States, there are provisions forbidding the agency head/commissioners from having any personal or financial interest in the PPP industry (seven in relation both to the appointment and individual cases; one in relation to individual cases). Only two (both Southern zone) report no such provisions. Two Member States referred to their policy on conflicts of interest, including annual monitoring.

The Stakeholder considers that CAs are independent from industry/PPP manufacturers in the sense that it is not aware of any CAs in which industry representatives have a vote in authorisation decisions. This answer appears to interpret the requirements for independence rather more narrowly than the approach adopted in this report. The Stakeholder also confirms that opportunities for communication between evaluators and applicants are many.[230] Stakeholders were asked, additionally, whether they believed CAs were independent of civil society organisations (CSOs) which campaign on pesticides. The Stakeholder believes most CAs are but indicated a belief that '[s]ome Member States respond in a non-scientific manner to pressure from CSOs by demanding more data than scientifically warranted, or by taking measures that serve political purposes rather than rational ones'. All **zSC secretariats** report a belief that the CAs in their zones are independent of government, industry and green CSOs. Such responses are perhaps unsurprising and it is at least open to question whether zSC secretariats would in fact report any concerns about the independence of CAs in their zones.

It is not unheard of for direct interaction between regulators and the regulated industry to be restricted, for example through a ban on discussions of pending cases (Johannsen, 2003, p.47). However, as discussed in section VI.2, such direct interaction is a key feature of the PPP authorisation process and encouraged. On the one hand, this may lead to efficiency gains and, depending on the nature of the interaction, may help overcome some challenges associated with asymmetric information (Johannsen, 2003, p.47). On the other hand, such ongoing

[229] One Member State (in addition to the two already mentioned) did not answer this question.
[230] It noted that this was to discuss the results of risk assessment submitted in response to CA requests.

interaction may reduce the relational distance between regulator and industry. As discussed in section II.2, repeated interaction may increase the risk of 'cultural capture' whereby the regulator adopts a viewpoint favourable to industry through, *inter alia*, increasing identification with industry interests. That said, as discussed in section VII.2.3, in practice the level of communication between applicants and CAs may vary across the EU. However, **France** appears to be taking steps to address the risks of exposure to attempts by interested parties to influence its CA's decision-making process (ANSES, n.d., p.1). ANSES has stated it is drawing up a 'charter on relations with interest groups, to prevent any risk of interference in the Agency's assessment and decision-making processes, while remaining faithful to its willingness to engage in dialogue' (ANSES, 2015, p.4). The charter is designed to achieve equity of access for interested parties, guaranteed expression of a plurality and diversity of points of view, transparency and the traceability of interventions and increased awareness amongst staff about interactions with interested parties (ANSES, n.d.). These steps, if implemented well, offer an example of good practice and are therefore worth attending to. Greater understanding of ANSES's experience with this charter and its success (or otherwise) would be a valuable aim for further research, especially with a view to assessing its potential for adoption by other CAs.

1.3 Organisational autonomy

As discussed in section II.3, for regulators to operate independently from the government and legislature, they require a degree of organisational autonomy and exemption from direct control (e.g. overruling its decisions) or indirect control (e.g. cutting its budget) (Johannsen, 2003, p.48). Regulatory independence may be partially guaranteed by exceptions from state budget regulation and restrictive civil service salary rules (Johannsen, 2003, p.48; Smith, 1997). External funding (e.g. a fee levied on applicants) is regarded as more stable than government funding as it may protect authorities from both general cut-backs and politically motivated budget cuts (Johannsen, 2003, p.48) although, as discussed in section II.3, dependence on industry for funding may compromise CA independence from industry. Based on the Member State survey and website review, overall it appears that at least ten Member States, across all zones, levy fees.[231] Seven Member States report that the source of their budget is the Government. Of these, one reports that the fees levied on applicants only cover costs and are not a source of income. **Germany** reports that fees levied on applicants are directed to the Government. The Stakeholder reports a belief that diversion of fees to central budgets occurs much more widely which it believes prevents the relevant CAs from contributing adequately to work-sharing within zones. This is an interesting insight. However, its accuracy would have to be investigated through further empirical research. Five Member States report their budgets derive from a combination of Government and external funding. Of these, the **Netherlands** reports that external funding makes up 85% of its budget; 70% from application fees and 15% from an annual fee levied on all authorisation holders. In addition. DG SANTE found, in its audit, that four Member States (of the eight audited) have decided not to recover costs. It also revealed delays or the lack of a system to update fees to reflect the actual costs involved in the

[231] As provided for by Article 74(1) PPPR; see section II.3.

authorisation process (DG SANTE, 2017, p.3). These data suggest therefore, fairly low levels of autonomy in this respect due to CA funds deriving largely from government.

Three more questions related to organisational autonomy: who controls budgetary spending, who decides the CA's internal organisation (procedures, allocation of responsibility, tasks etc.) and who is in charge of the CA's personnel policy (recruitment, promotion, salaries). In response to the first two questions, nine Member States selected 'the competent authority' while three selected 'the competent authority and government in co-operation'. In response to the last question, five selected each of the 'competent authority' and 'the competent authority and government in co-operation' while two selected 'the government'. Three Member States referred to some kind of government policy/guidelines governing salaries. **Germany** noted that salary is based on the general civil service pay scale. The **Netherlands** reports that 'salaries… must fulfil the governmental requirements'. This is noteworthy as autonomy over personnel policy is regarded as a defining characteristic of regulatory independence (Johannsen, 2003, p.50; Smith, 1997). Four were fully autonomous according to these three criteria; three from the Central zone, one from the Northern zone.

1.4 Resources

The final category of questions relates to the resources and capacities of CAs. Adequate in-house technical expertise can reduce information asymmetry and counter the risk of regulatory capture and adequate remuneration can facilitate recruitment and retention of such qualified professional staff (Smith, 1997).[232] While most of these questions were designed to gain an insight into the operational challenges CAs face they may also contribute to an understanding of the challenges of information asymmetry (along with targeted questions), which do relate to regulator independence.

Eleven Member States report that their CA's budget is 'adequate to fulfil its duties with respect to the zonal authorisation procedure'. One Member State reports it is not. One Member State did not respond. Nine Member States consider that their CA's 'operational resources support an effective and efficient authorisation procedure'. Three do not. One of these (Southern zone) cites a lack of specialised human resources as the reason.

Q37 concerned available expertise and asked whether the CA possesses sufficient in-house expertise (experts, knowledge, e.g. access to databases, etc.) in all the areas necessary to evaluate the application in house (including comparative assessment) (or access to such expertise from external sources) to make the authorisation decision. Eight Member States report they had sufficient in-house expertise in all or most of the necessary areas. **Sweden** notes it consults 'other agencies in their areas of expertise: Swedish Board of Agriculture for efficacy and National Food Administration for residues'. The **Netherlands** comments that the Ctgb has contracted external scientists, depending on workload. It indicates that it may seek second opinions from other institutions, including universities. Although external experts may bolster regulator independence through the provision of independent advice, academics are still

[232] See section II.3.

vulnerable to capture (Zingales, 2014). With respect to comparative assessment, the Dutch Inspection Service performs the agricultural assessment on the Ctgb's behalf. One (Southern zone) reports it has sufficient in-house expertise in some of the necessary areas, commenting that evaluation of zonal applications is outsourced to experts. Another (Southern zone) reports it has no in-house expertise but has access to external expertise and one (Central zone) reports it has neither in-house expertise nor access to external expertise. One did not select an answer, instead leaving a comment, the meaning of which was, unfortunately, unclear. Two report deficiencies in expertise. Overall, there is much variation in the levels of in-house expertise and access to external expertise among Member States.

Q41 posed a similar question in relation to technical resources and asked whether the CA possesses or has access to sufficient technical equipment/processes necessary for evaluation and the authorisation decision. Five (all Central zone) Member States report they possess/have access to sufficient, or most of the, technical equipment/processes necessary. Of these, **Germany** comments that BVL has a laboratory but notes its inability to analyse certain types of substance and gaps in its ability to determine various properties of substances. One (Southern zone) Member State reports it possesses/has access to some of the technical equipment/processes and comments that it lacks IT platforms and laboratory capacity for formulation analysis. One Southern zone Member State reports it does not possess/have access to the necessary technical equipment/processes. Five report the question was not relevant, of which **Sweden** comments it does not need to do any technical work during evaluation as this is the responsibility of applicants pre-authorisation.

Three further questions attempted to focus more specifically on information asymmetry. With respect to recruitment, four Member States report that it is 'quite easy' to recruit staff with the necessary expertise, technical skills and experience. However, one of these (**Sweden**), comments that it is 'generally difficult to find' staff with experience specifically in risk assessment of PPPs and regulatory issues. Three report it is 'quite difficult' and five report it is 'very difficult'. No zone-specific trends were discernible. Member State comments indicate that this is a complex and evolving matter. For example, the **Netherlands** comments that two years previously, recruitment was 'very difficult' but is currently 'quite easy' and new staff complete a year-long in house training. Another (Central zone) Member State which selected 'quite difficult' provides more detail: '[u]ntil a decade ago recruiting graduates with two or more years' experience in a relevant industry was relatively easy'. It cites several reasons: fewer people/graduates with relevant experience due to changes in higher education and consolidation in the agrochemical industry; constraints on Civil Service remuneration making posts less attractive and high demand in other areas of industry for science specialists with relevant experience (e.g. toxicologists). This CA has responded to these recruitment difficulties by recruiting 'relatively new graduates and commit[ting] major resources to training them in the required areas'. One other (Southern zone) Member State, who reports that recruitment is 'very difficult' also refers to training experts in house 'for several years'. Another (Central zone) Member State which selected 'very difficult' refers generally to limitations on recruiting new staff in the public sector. DG SANTE reports similarly that four Member States identified 'restrictions on public services in hiring new staff' as contributing to failures to comply with

deadlines in the Regulation (DG SANTE, 2017, p.4). Commitments to in-house training may be identified as best practice. CA provision of opportunities to develop expertise outside industry may enhance independence from industry by reducing both reliance on industry training as a source of staff knowledge and the associated risk of over-identification with industry interests, as discussed in section II.2. Such staff development may be particularly valuable where constraints on remuneration reduce CA ability to attract expert staff from industry or consultancies.

With respect to employee retention, two (both Central zone) report it is 'very easy' to retain such staff. Of these, the **Netherlands**, attributes this to the Ctgb offering 'a challenging working environment and [being] socially relevant, meaning that it is seen as an interesting employer'. Five report it is 'quite easy'. Three report it is 'quite difficult'. Of these, one reports a 'continual turnover of staff trained by the Competent Authority leaving within three years to take up a consultancy post'. This it attributes to increased demand for scientific expertise due to the expansion of regulation (biocides and chemicals) leading to 'a major growth in consultancies… paying at least 50% more in starting salaries with potential to rise much higher'. One (Central zone) Member State reports it is 'very difficult'.[233]

Finally, Member States were asked '[i]f resources (experts, knowledge/e.g. access to databases/, etc.) are not available in house, how easy is it to buy those resources from outside? One (Central zone) reports it is 'very easy'. Two report it is 'quite easy' of whom **Sweden** comments that this occurs rarely. Three report it is 'quite difficult'. Of these, one (Southern zone) attributes the difficulties to '[i]nternal bureaucratic procedure' and states that '[a]t EU level expertise is limited due to high workloads in each member state'. The **Netherlands** comments that 'few partners can meet the quality standards of Ctgb… [which] include preventing conflicts of interest' and that some potential partners are not able to deal with fluctuations in demand. The Ctgb quality standards suggest best practice and further research aimed at understanding the effectiveness of these standards, in practice, at promoting independence in the Dutch experience may be worthwhile. Three report it is 'very difficult', with two attributing the difficulties to limited resources.

1.5 Summary and recommendations

In terms of CA relationships with government, most Member States strengthen CA independence through formal requirements of independence both for CAs themselves and appointment as head and by making appointments fixed term. They are weaker with respect to the status of those responsible for making appointments. However, most enjoy substantive independence in terms of having sole responsibility for authorisation decisions.

As discussed in sections I, II.3 and VII.1.1, more important than formal independence from government is that regulators operate fair and reasonable evaluation and decision-making procedures and are seen to do so by all interested parties. Given that only one stakeholder responded to the stakeholder survey, we have limited information on the extent to which

[233] One Member State misunderstood the question; this answer is not reported.

evaluation and authorisation procedures are seen as fair and reasonable. It is therefore very difficult to make general recommendations on the basis of the above findings. Data are lacking and conditions and difficulties are highly specific to individual Member States. Furthermore, change requires resources. These are, for better or worse, austere times and Member States may already face resource-related pressures. Generic advice may be offered, in terms of recommending introduction of fixed term appointments and enhanced protection from dismissal for commissioners/agency heads. However, where regulation is regarded as fair, such changes may not ultimately be necessary and where regulation is regarded as unfair, increasing formal independence may not target the cause of the problem. More detailed research into national conditions and challenges and the reasons behind may therefore be a wise additional step to take before making more concrete recommendations.

Recommendations

It is recommended that further qualitative research is conducted. This research should target two specific enquiries. First, it should seek to understand how the zonal evaluation and national authorisation procedures of the CAs are perceived by all stakeholders, including applicants and the general public, and the extent (if at all) to which these procedures are viewed as fair and reasonable. Secondly, it should move beyond study of formal independence to investigate the existence (if any), in practice, of governmental influence on CA decision-making, for example through review of CA decisions and in-depth examination of interaction between CAs and government during decision-making. Such research may provide a stronger basis on which to make substantive recommendations.

The Regulation places no obligation on Member States to report their progress on the implementation of its provisions.[234] While acknowledging the difficulty of amending legislation, given the lack of information about CAs and the operation of the zonal system, the introduction of such a reporting requirement on Member States could provide valuable information and constitute a step towards filling this knowledge gap. The **EU institutions** are encouraged to consider such an amendment. In the interests of transparency, any such reports should be made publicly available.

With respect to CAs' relationship with industry, the picture is one of relative ease in moving between regulator and industry, although restrictions on personal/financial interests in the industry are stronger. Ultimately, Member State models for governing the relationship between regulator and industry/government differ and not all (potential) measures to

[234] Such reporting requirements exist elsewhere. For example, Member States are required to report on implementation to the Commission every three years, under Article 31(4) European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms [2001] OJ L106/1.

maximise independence from industry/government are taken in all Member States. Such measures may be important for guarding against the risk of regulatory capture by maintaining an arm's-length relationship with industry as much as possible.

In terms of countering governmental influence the zonal system may assume greater importance. Majone has argued that isolated national regulators, though committed to fulfilling statutory objectives, may still be too weak to withstand external political pressure. However, he argues, participation in a transnational network of regulators with similar objectives and problems may incentivise regulators to resist political pressures in order to maintain their reputation amongst other regulators and protect their ability to co-operate (Majone, 1996, p.273).[235] Direct interaction with each other, bypassing ministerial departments, may also grant national regulators power vis-à-vis their national governments, increasing their autonomy (Groenleer, 2011, p.556). If the zonal system can evolve into such a system, this could enhance the independence of CAs and consequently perhaps, the reliability of decisions. This may, therefore, represent another reason for supporting and strengthening the zonal system. It is worth raising the possibility that, for similar reasons, the zonal system may also help counter pressure from the regulated industry and indeed green CSOs. However, where such actors also operate at a zonal or EU level, networks of CAs at these levels may remain vulnerable to, for example, industry influence or capture,[236] albeit likely expensive for industry. Nonetheless, the question of the potential for such networks to strengthen independence from industry would be worth further research.

Recommendations

Regulatory (particularly cultural) capture has been identified as a risk to CAs. However, further empirical research would be required to determine the extent (if at all) to which any CAs are, in practice, influenced or captured by industry. Such research should involve, *inter alia*, qualitative review of registration reports and decisions against information submitted by applicants and modes of interaction between CAs and industry to understand the nature and proximity of the relationship. Recent literature (for example, (Carpenter and Moss, 2014b)) proposes robust methodologies to conduct such research. Greater understanding would provide a stronger evidence base on which to make recommendations. However, pending such research, the following recommendations are made.

Member States are encouraged to review their national provisions regarding potential for commissioners/agency heads to have held positions in industry prior to their appointment to CAs and to accept employment in industry post-appointment. In order to reduce the risk

[235] Although, as discussed in section VI.2.7, challenges different regulatory cultures and levels of trust between Member States still need to be resolved or worked around.
[236] I am grateful to Dr Dieter Pesendorfer for this observation.

of regulatory capture, **Member States** are encouraged, furthermore, to consider strengthening restrictions with respect to both.

Member States are also encouraged share best practice. For example, Member States may benefit from learning about France's experience with its charter on relations with interest groups (section VII.1.2) and the Netherlands' experience with its quality standards (section VII.1.4). If successful, Member States may wish to implement similar measures.

Involvement of public interest groups (PIGs) in regulatory decision-making was discussed in section II.1.2 as a mechanism for reducing the risk of regulatory capture. Again, further research would be required into, for example, their appropriateness, mechanisms for their support (including funding) and to identify potential candidates. PIGs could operate on a national level and, if the PIG itself transcends national boundaries, on a zonal or EU level too.

Research into the potential for the zonal system to act as a counterweight to external pressure was beyond the scope of this study. Further research may therefore be necessary to investigate this question. If this potential is real, **Member States** and the **Commission** should provide support at zonal and inter-zonal level for developing the networks required to ensure individual CAs can take full advantage of the zonal system as a means to maintain and enhance their independence.

With respect to organisational autonomy, most lose some formal autonomy through being largely government-funded. On the other hand, most retain control over budgetary spending and internal organisation while being not entirely autonomous with respect to personnel policy. That government, in some, still has some say over salaries could be regarded as a possible restriction of independence. This is indeed cited by Member States as a problem for recruitment.

With respect to resources, overall, most respondent CAs regard themselves as possessing or having access to sufficient financial, operational, expert and technical resources to carry out their functions with respect to PPP authorisation. This is partly corroborated by the overall findings of DG SANTE's audit,[237] which found that the 'evaluator staff in all MSs were suitably qualified and trained, and are therefore capable of conducting evaluations to a high standard' (DG SANTE, 2017, p.4). This is a positive finding for the smooth functioning of zonal authorisation procedures. However, there are still several Member States which experience resource-related challenges, some of whom report multiple challenges. The trend looks less healthy when it comes to recruitment and retention of staff, and access to/availability of external resources, where there is evidence of more wide-spread difficulties. No Member State directly mentions having to compete with the PPP industry itself for expert staff, although one

[237] Of eight Member States.

does mention competition with industry or private consultancies generally. Some Member States indicate their commitment to training experts in-house, which may reduce the magnitude of the problem. However, these difficulties could place some CAs at a disadvantage, in some areas of expertise, vis-à-vis industry with the associated risks of information asymmetry and regulatory capture.[238]

Recommendations

Member States are encouraged to review the means by which CAs are funded and to consider introducing fees covering the costs of evaluation and authorisation, pursuant to Article 74(1) PPPR. However, while securing CA funding through fees levied on industry may promote independence from government, dependence on such fees may reduce independence from industry. A straightforward recommendation with regard to the benefits to CA independence of retaining such fees is therefore not possible. The further research, recommended above, into CA independence in practice from government and industry should generate greater understanding of the relative prevalence or risk of government influence or industry capture. Appropriate funding structures could be designed or adjusted in response to the identified risks.

While pressures on government budgets are acknowledged, given the need for expertise both to ensure the quality of evaluation and decision-making and to counter information asymmetry, **Member States** may wish to consider the following options. Firstly, review and, if appropriate reduction of, the application of constraints on civil service remuneration in order to promote recruitment and retention of the necessary expert staff. Secondly, the development or enhancement of in-house training programmes in order to cultivate sources of expertise other than from within industry, as a further means to counter asymmetric information and industry influence or capture.

2. Transparency

As stated in section V.I, the questions on transparency sought to assess three dimensions of this concept. Firstly, clarity with respect to the authorisation rules, procedures and requirements, in other words, the 'rules of the game'; secondly, access to, and publication of, information; and thirdly the strength of any consultation processes conducted during evaluation and authorisation procedures.

2.1 Rules of the game

One question sought directly to assess clarity as to the rules of the game and asked Member States '[h]ow much information regarding the zonal authorisation procedure is publicly

[238] See section II.2.

available (for example on the competent authority website) in the national language(s)?' It specified that this information includes 'guidance addressed to applicants on how to apply, the required documents, information about the authorisation procedure and how decisions are made'. Although the question referred to information 'addressed to applicants', it is important that all potential interested parties (e.g. NGOs, farmers, concerned individuals, researchers etc.) should be able to understand how authorisation decision-making works. As discussed in section III.3, this is important for building confidence and understanding amongst both applicant and other interested parties in the regulator (OECD, 2013, p.52). Eight Member States report that 'comprehensive information is available'. Of these, the **Netherlands** notes that 'manuals on risk assessment and registration procedure are made available to applicants and other stakeholders' on the website, indicating a very high level of transparency in this respect. **Sweden** comments that in 'certain cases clarifications might be needed from the authority'. One Southern zone Member State reports that applicants still like confirmation from the CA, 'especially due to ever changing EU guidance'. Three report that 'most information is available but contact with the competent authority is necessary to gain full information'. One (Southern zone) Member State reports no information is publicly available.

The Stakeholder reports finding it 'very difficult' to access information on zonal authorisation procedures from CAs of zRMSs (e.g. application and information requirements, information on how the application is evaluated etc.). It comments that some CA websites contain 'very comprehensive information on application and data requirements' naming the **UK**, **Netherlands**, **Germany** and **Belgium** as examples; all Central zone Member States. It also comments that '[m]ost Member States provide information upon request, but it is not always clear what is expected of an applicant' indicating too that there is a great deal of variation between Member States in this regard. The Central zone does publish information about its meetings and other information, for example regarding evaluation, on publicly accessible pages on CIRCABC.[239]

2.2 Publication and access to information

The next three questions concerned access to, and publication of, information, specifically. As discussed in section III.3, Commission guidance supports publication of RRs (Commission, 2014b, p.14). Q44 asked whether the CA publishes its decisions regarding authorisation of PPPs. Seven Member States report that they publish all decisions. **France** has also committed to making its authorisation decisions publicly available (ANSES, 2015, p.4). Three (all Central zone) report they publish most. Two report they publish some decisions. Of the latter two categories, four Member States comment that they do not publish decisions not to authorise. In light of these answers, it is possible that Member States which report publishing all decisions took the question to refer only to decisions to authorise, rather than reject, applications. The reliability of some of these answers may therefore be open to doubt. Only the **Netherlands**

[239] CZSC survey response. <http://circabc.europa.eu/> accessed 25 February 2018. CIRCABC is an EU online communication and information resource centre, through which Member States share documents relevant to PPP authorisation. An account is required to access it and the location of the publicly available documents relevant to PPP authorisation is not entirely straightforward.

elaborates on the reasoning behind not publishing rejections, indicating that this is considered 'commercially confidential information'. However, it does note that the Ctgb's annual report presents statistics including rejections and amendments. One Southern zone Member State reports that a new IT platform is being developed and it expects to provide 'more detailed information about PPP decisions'.

Q45 asked about the extent to which the CA discloses/publishes the information sources on which its decisions are based. As discussed in section III.1, publication of the knowledge on which decisions are based is important for enabling democratic control of regulatory decision-making (Jasanoff, 2006, p.21), increasing accountability and reducing corruption and the risks of regulatory capture (Schauer, 2011, pp.1348–1349). Two (both Central zone) Member States report they publish all information sources. Of these, **Germany** appears to understand this as meaning the RR, whereas the question was also getting at the data used in the evaluation, for example studies submitted with the application. One (Central zone) reports it publishes most. Three report publishing some of the information sources. Of these, the **Netherlands** comments that it publishes the guidance it uses on the Ctgb website and publishes the assessment report presented to the Ctgb Board in its database. Finally, '[u]pon request, the Ctgb discloses all other information available in the application dossier within the legal limits' of the Regulation. Four report publishing none. Of these, two indicate that sources are still accessible on the basis of national legislation establishing rights of access to information. One did not answer the question.

Reasons for decisions on authorisation are contained in RRs[240] and made available to applicants and other Member States via CIRCABC.[241] However, in terms of access, the **zSC secretariats** report that no Member States publish their RRs, apart from **Germany** and the **Netherlands**, in the Central zone. In addition, as discussed in section VI.2.5, in **France**, ANSES publishes on its website the conclusions of its evaluation and part of the RR for the purposes of transparency. The **NZSC and CZSC secretariats** highlight the potential to access RRs on request and the **CZSC secretariat** comments that PPPAMS could be used to provide information on authorisations to the public. The Stakeholder also notes that RRs are often drafted solely in the national language reducing both their accessibility to 'non-national applicants' and suitability for zonal use. However, the **SZSC secretariat** reports that discussion over publication of final RRs had started amongst all Member States. It should be remembered, that two Member States (**UK** and **Czech Republic**) employ reason-giving or a similar mechanism in order to inform applicants about the grounds for their decisions, and **Germany** provides applicants with a meeting if a refusal looks likely, as set out in section VI.2.7. The **CZSC secretariat** reports that Member States, when acting as cMSs, provide reasons for their decisions to the applicant and inform the other Member States of their decision via CIRCABC. Only two Central zone Member States make these decisions public. The **NZSC secretariat** also

[240] See Article 39(1) PPPR.
[241] zSC survey responses.

reports that all Northern zone Member States, when acting as cMSs, provide reasons to the applicant for their decision.

The Stakeholder notes that publication of RRs would improve the zonal system's functioning, particularly for secondary applicants (manufacturers of generic PPPs) who may not have access to the original RR. It reports significant variations between Member States in terms of providing access to information on PPP authorisations: some RRs are online; some CAs provide information on request and others refuse to do so. The Stakeholder indicates a belief that this hinders the use of previous decisions by applicants to 'facilitate and harmonise their applications' and that significant improvements in the transparency of evaluation and decision-making are possible and could enhance competition.

Q46 asked more generally whether there is a 'clear basis in law or policy for public access to information held by the competent authority, including a clear statement of the limitations to that access (for example, due to commercial confidentiality)'. Only two respond 'no', while ten Member States respond 'yes'. Each of the ten refers to national legislation on public access to information and three to the Regulation. In addition, the **Netherlands** refers to its national tribunal decision following an Article 267 TFEU referral to the CJEU[242] which ruled that public access to part of the information held by the Ctgb 'is regulated by an exclusive system of public access comprised of Article 63 [Regulation (EC) No] 1107/2009 and Directive 2003/4'.[243] It was the only Member State to refer to the CJEU decision.[244]

2.3 Public participation and access to information

The next six questions (47-52) concerned consultation and the accessibility of information deriving from consultation. Q47 asked whom, in addition to the applicant, the CA consults during authorisation decision-making (including comparative assessment). Altogether, five Member States report conducting any consultation of actors outside the CA.[245] Four Member States selected 'other actors involved in plant protection'. One selected 'farmers and other users'. Three selected 'other government departments'. Six consulted no one. Of these, the **Netherlands** notes an exception for '[d]ecisions concern[ing] the first authorisation of a product based on [an] approved active substance not earlier used in the Netherlands'. **Sweden** notes an exception in 'cases of principle nature, for example if a new type of condition for use is introduced'. Neither specifies whom it consults. No Member States consult wider industry, NGOs/CSOs or the general public. It was assumed in this question that all CAs would communicate with applicants. However, the Stakeholder comments that only sometimes is there good communication between applicant and zRMS; other Member States are 'very inaccessible, especially during the evaluation, which makes it unnecessarily difficult to solve upcoming problems'. It also makes the more general comment that zonal evaluation

[242] *Bayer* (n 28).
[243] Directive 2003/4/EC (n 29).
[244] Discussed in section III.2.
[245] One Member State referred to consultation with other CAs in the same zone. This is assumed and so not included here.

procedures 'range from reasonably transparent to not transparent at all, depending on the Zonal RMS responsible for the evaluation'.

One (Central zone) Member State reports that it only consults other actors involved in plant protection, farmers and other users and other government departments when 'sufficient information on the product and alternatives in practice incl. all advantages and disadvantages of both is not available to the agency'. **Sweden** reports that consultation procedures are set up on a case-by-case basis, usually written. The **Netherlands** comments that consultations on decisions last four weeks and submissions during the consultation must be addressed in the final decision. No Member States report publishing any consultation submissions apart from the **Netherlands**, which states '[w]hen applicable, in the final decision a summary of the reaction of each stakeholder is given' and **Sweden**, which reports publication of some decisions, decided on a case-by-case basis. Two refer to the availability of submissions on request. There is information to suggest that the **French** CA, ANSES, generally attempts to improve the openness and transparency of its expert assessments by opening them up to society. It expects, thereby to improve the reliability and quality of decisions and understanding of decisions by all stakeholders.[246] It is not stated, however, whether this is being implemented with respect to PPP evaluations and authorisations.

The Stakeholder reports 'regular contact with CAs' at both national and zonal levels on matters other than with respect to a specific application/comparative assessment. These matters included largely procedural and scientific issues, such as 'dossier formatting, workflow, procedures, and developments in the interpretation and implementation of provisions of the PPPR' or other dossier requirements and interpretation of application requirements. It also reports participation in annual open zSC meetings in the Central and Southern zones in which similar matters are discussed.

Of the five Member States which conducted consultations, only three report they were required by law to formally respond to submissions. Two of these report that responses are incorporated in the final decision/registration report and so are publicly available. Three report the CA is required by law to take submissions into account in its decision-making and two report that, though not legally required, in practice it does. In addition, the **Netherlands** reports that it is also required to do so for any consultation it conducts. The Stakeholder reports a belief that most Member States 'listen to and take into consideration' their comments.

It was clear from the zSC survey that increased participation in zonal evaluation and comparative assessment would not be welcomed by the Member States. Different reasons were provided. Firstly, **zSC secretariats** highlight the scientific nature of the evaluation exercise, the lack of scientific expertise amongst the wider public and risks of non-scientific opinions becoming involved, pressure from NGOs and the triggering of social alarm. Secondly, the **SZSC secretariat** predicts that commercial competitors could pose as members of the public in

[246] <https://www.anses.fr/en/content/expert-assessment-and-openness-society> accessed 28 January 2018.

order to 'foil applications'. Thirdly, the **SZSC secretariat** warns the Uniform Principles could be displaced by public opinion as the basis for authorisation. Fourthly, the **CZSC secretariat** questions the wisdom of making the application publicly available during the application procedure, although it does not provide a reason for this other than data protection. Finally, according to the **SZSC secretariat**, any gains in transparency and the ability to 'say that all concerns raised were addressed' would be outweighed by the drawbacks. With respect, specifically, to comparative assessment, the **SZSC secretariat** feels that wider consultation would only 'trigger discussions on the effectiveness of alternative methods and whether these are enough, without any efficacy trials (following [EPPO] standards) to back those claims'. The **CZSC secretariat** feels wider participation was more appropriate during development of the legislation and guidance documents and indeed, the **NZSC secretariat** reports consulting stakeholders 'on general issue such as [guidance documents] etc.'.

Many of these concerns are legitimate and zSC secretariat scepticism of participation is unsurprising given the additional burden it would impose on CA resources. However, one or two observations may be made. Different types of relevant expertise exist (Wynne, 1992a), and are distributed across society (Steele, 2001). Integration of some of these may benefit the evaluation and decision-making process. Secondly, risk assessment, including comparative assessment, is inherently value-based (Wynne, 1992c, p.116; Royal Society, 1992).[247] Furthermore, given the under-developed nature of comparative assessment, careful input of wider expertise may facilitate its development. Finally, concerns regarding displacement of the Uniform Principles and the onerousness more generally of consultation procedures could be met, to some extent, by the design of the procedure. Wider participation need not mean throwing open every decision to the entire world. Different mechanisms exist which enable participation by more limited groups comprising stakeholders and representatives of wider societal interests, for example, PIGs (discussed in sections II.2 and VII.2.5), consensus conferences (Einsiedel, Jelsøe and Breck, 2001) or citizen juries (Smith and Wales, 2000; see also Fiorino, 1990) and which may be adapted to the procedures established by the Regulation. These may represent a step towards enhancing transparency, especially if publicly reported on. Criteria could be developed to select suitable decisions for wider involvement. It could, further, be provided that inputs thus gathered should be taken into account, rather than regarded as determinative, in order to preserve CA discretion.

The Stakeholder reports opportunities for consultation with most Member States with respect to comparative assessment. However, as no other stakeholders responded to the survey, it is impossible to gauge the level of involvement of other actors. In addition, the Stakeholder notes that experience with comparative assessment is still limited but the indications are that Member States balance the information provided by applicants against that from other sources.

2.4 Accountability

The final five questions concerned the accountability of the CA to the government and legislature and the scrutiny of decisions. As discussed in sections II and III, accountability is

[247] See also section IV.3.

linked to both independence and transparency. Two questions asked what the formal obligations of accountability of the CA vis-à-vis the government and legislature were, respectively, in terms of producing annual reports. Annual reports, due to their high visibility, can be an important mechanism for improving the transparency and accountability of regulators. They can set out the regulator's operations and progress against its objectives allowing oversight institutions to hold them accountable (OECD, 2016, pp.29, 44). Three report no such obligations vis-à-vis the legislature. The **Netherlands** reports an obligation to present 'an annual report for information only' to both government and the legislature but that once every five years the responsible minister audits the CA's business performance and adherence to legal standards. Two report an obligation to present 'an annual report for approval' to the government. **Germany** commented that the BVL, as an independent higher federal authority under the jurisdiction of the Federal Ministry of Health, reports to the Ministry, though it is independent regarding PPP authorisation decisions. However, overall obligations of accountability are strong: ten CAs report being fully accountable to either the government, the legislature or both. **Belgium** adds that the CA is 'accountable to the responsible minister via an administrative contract'. Finally, five Member States report being required to make any annual report produced public.

The last two questions concerned scrutiny of decisions. Review and scrutiny of decisions, internally, externally or both, may aid reliable decision-making. One Member State reports that all authorisation decisions are audited or reviewed. Seven report that a sample is reviewed/audited. Four refer to an internal audit, often according to an annual plan of audits, one noting that this was not regular. One (Central zone) Member State describes an extensive system of internal peer review of all the work of trainee staff, samples of evaluations, contentious decisions, all refused authorisations alongside an equal number of authorisations and all authorisation documentation before release. This same Member State and two others also report external reviews of decisions, one involving peer review of a 'random sample of applications' by an expert committee and, in the **Netherlands**, an audit of authorisation decisions by a commission of experts every five years. The two providing most detail suggest the review/audit emphasises scientific quality. Four Member States report no system of audit/review. The majority, however, report systems for scrutiny of decisions, although these vary in nature and frequency.

Finally, an appeals mechanism may enhance accountability. Article 36(3) fourth paragraph PPPR requires Member States to provide the ability to challenge a decision refusing authorisation 'before national courts or other instances of appeal'. Q57 asked who, other than a court, can overturn the CA's decision where it had exclusive competence. Eight selected 'nobody'. Two (both Central zone) Member States selected the 'government, with qualifications. Of these, the **Netherlands** indicates that this would be possible only where the Ctgb is guilty of 'serious task neglect'. One (Southern zone) Member State selected the 'government, unconditionally'. **Belgium** reports that the responsible minister could do so. One Member State reports an appeal period of 15 days following issuance of the decision on the application but it is unclear as to whom the appeal would be.

2.5 Summary and recommendations

Regarding clarity with respect to the rules of the game – the requirements and operation of the evaluation and decision-making procedures – it appears that while some Member States provide comprehensive and clear information, many do not. The lack of clarity in this regard may cause confusion among applicants and may undermine understanding of the overall authorisation procedure amongst wider interested parties important for transparency generally.

Recommendation

Member States are encouraged to review the amount of information available online about their evaluation and authorisation procedures from the perspective both of applicants and other stakeholders/general publics. It may also be helpful to review other CA websites with high levels of information as examples of good practice. The UK CA website, for example, contains substantial information. In order to enhance transparency with respect to these procedures, **Member States** are encouraged to provide clear and comprehensive information at least in their native language and ideally, eventually, in English.

With respect to access to information, different CAs operate at different levels of transparency. Transparency levels with respect to publication of authorisation decisions are higher overall, but lower with respect to the publication of the information sources on which decisions are based. Very few publish RRs, which should contain reasons for authorisation decisions. On the whole, even if most CAs do not publish comprehensive information of their own accord, in most respondent Member States, there exist avenues by which to access it. That said, as *Bayer* and experience of EU level litigation over access to documents suggest (Lee, 2014a, pp.198–199), even with rights established in legislation, access in practice may not be easy or straightforward. Transparency, of itself, does not guarantee the reliability of decisions. However, the absence of access to information deprives interested parties of the ability to make that judgment. Furthermore, as discussed in section III.2, transparency requires more than publication alone; the information itself must be clear and intelligible (at least). Concerns raised about the quality of some RRs[248] suggest that their publication may foster only limited improvements in transparency.

Recommendations

Member States are encouraged to increase the publication, ideally online, of information on PPPs within the limits of the law, especially the following:

[248] See section VI.2.7.

- Authorisation decisions
- Registration reports
- The information sources on which evaluation and authorisation are based. Ideally, this should include the conclusions of the zRMS's evaluation
- Any submissions (and responses thereto, if relevant) made during any consultation process

To this end, **Member States** are encouraged to step up discussions amongst themselves regarding the publication of registration reports and other information. These discussions may need to happen alongside the development of measures, for example guidelines or training, designed to improve the quality of registration reports in order to support this measure to enhance transparency.

It is acknowledged that CA resources are limited. However, where possible, publication of the above information in English[249] is encouraged for its potential to enhance access to information for a larger audience and to improve the quality of future applications. Increased public availability of such information would facilitate conduct of the research recommended in section VII.1.5.

Stronger measures to improve access to information may be desirable. The **Commission** is therefore encouraged to consider the possibility of amending the Regulation to introduce a requirement that registration reports (at least) are made publicly available.

The limited consultation activities are unsurprising given the absence of an obligation in the Regulation on Member States to consult stakeholders (including general publics) during zonal evaluation.[250] The Stakeholder comments that consultation with third parties/general publics during evaluation would be 'unworkable' due to the complexity of zonal evaluations, for example having to consult across all other countries in the zone and the inevitable language barriers. It also comments that any such consultation 'would completely paralyse the evaluation system'.

Nonetheless, as discussed in section III.3, public participation can enhance the transparency of evaluation and decision-making procedures, for example by improving understanding of their operation. The absence of a space for such participation may therefore reduce levels of transparency in CAs. More generally, from the point of view of transparency to citizens, a general deficiency of the zonal evaluation system is how far removed it is from citizens. There is no provision for wider participation in the evaluation procedure, despite the contribution it

[249] Or another widely used EU language. The impact of the UK's departure from the EU may be a factor in choice of appropriate language.
[250] NB. Article 12(1) PPPR requires EFSA to make draft assessment reports on active substances available to the public for comments.

could make, discussed in section III.3. But even if there were, in practice it would be extremely difficult for citizens of one Member State to contribute to a risk assessment performed in a different Member State, particularly perhaps where different languages are spoken in the relevant Member States. It should also be noted that given the limited information about the zonal system available online, it is likely that very few are even aware of its existence.

In addition, there is no provision for consultation during national authorisation decision-making. But again, even if there were, by the time a cMS comes to take the national authorisation decision, it is too late for citizens or CSOs to scrutinise or influence the evaluation or contribute much to the information on which the decision will be based. More importantly for this report, in terms of transparency, the information (i.e. the zRMS conclusions) on which national authorisation decisions will be based will have been generated through a process which is largely closed to and distant from most citizens. As discussed in section III.3, democratic control of decision-making based on scientific knowledge requires some opportunity for citizens themselves to evaluate the knowledge used as justification for the decision (Jasanoff, 2006, p.21). It was noted further, in section III.1, that potential to enhance the quality of decisions has been attributed to wider participation in both policy formation and regulatory decision-making (Steele, 2001; Ferretti, 2007). This potential is therefore lost in the absence of participatory opportunities. Again, there is a trade-off: consultation takes time and its implementation could therefore undermine the already compromised efficiency of CA decision-making procedures. As it is, however, the absence of an opportunity for consultation may reduce transparency to citizens and other stakeholders. It may therefore be worth re-visiting the balance struck between efficiency and transparency by the Regulation.

PIGs were discussed in sections II.2 and VII.1 for their potential to guard against regulatory capture. However, they may also function as a mechanism for enhancing transparency through involvement and representation of the relevant interest(s) in regulatory processes (Lodge and Stirton, 2001) and may additionally contribute valuable expertise. Such involvement of national PIGs could improve the transparency of cMS decision-making. Furthermore, formalised involvement of transnational PIG(s) in zonal evaluation processes could represent a means by which to open up such processes while avoiding the messiness and difficulty, discussed above, of wider public participation. Space prevents a fuller discussion of these potential benefits and PIG involvement may face obstacles with respect to preserving the confidentiality of applicants' data (discussed in section III.2), but the question is worthy of further investigation.

In terms of transparency to applicants, the position is different. The availability of pre-submission meetings and the communication which occurs between CAs and applicants, described in section VI.2, suggests greater involvement and therefore transparency, although, as the Stakeholder noted, this may not occur with every CA. Greater transparency to wider industry is also suggested by the 'regular contact' with CAs at national and zonal level outside specific applications reported by the Stakeholder (above). All such contact between industry and CAs is clearly valued for improving the operation of the zonal system and contributing to its efficiency. However, such collaboration may reduce the relational distance between

regulator and industry, potentially increasing the risk of cultural capture and thereby compromising CA independence, as discussed in section II.2. There may therefore be a tension between transparency to, and independence from, industry, as well as between efficiency and independence from industry.

Measures for reducing the risk of capture were also discussed in section II.2 and included increased transparency generally through publication of information and greater involvement of interested parties for example through public participation (Gönenç, Maher and Nicoletti, 2000, p.44; Majone, 1996, p.26; Mitnick, 1980, p.66). However, as the above results and analysis suggest, publication of information by CAs is patchy and there are limited opportunities for wider participation in evaluation and decision-making. It seems unlikely then, that CAs are taking advantage of the potential of such measures to counter risks of capture. In light of these findings, it may be hard for zRMSs to achieve a fully 'transparent assessment' of applications for authorisation, pursuant to Article 36(1) PPPR. To the extent that, as discussed in section I, confidence in the reliability of decisions is gained through a belief that regulators take all views into account, the absence of a means by which views may be expressed may undermine trust in the CAs and in the reliability of their decisions, at least amongst those more likely to be excluded. That said, the Stakeholder itself comments that the reliability of the zonal authorisation system is hard to assess, noting disagreement between applicants and zRMSs over evaluations, lack of transparency and opportunities for applicants to comment and comments being 'insufficiently taken into consideration'.

Recommendations

Although there is no legislative requirement, **Member States** are encouraged to consider ways to open up their national authorisation decision-making procedures to wider participation. Member States could experiment, for example, with providing opportunities to comment on dRRs during the commenting phase of zonal evaluation (described in section VI) and/or on draft authorisation decisions. Further upstream, wider participation in the definition of national data requirements could improve the transparency of CA decision-making. If opening up such elements of decision-making to stakeholders and the wider public generally is regarded as time-consuming and unmanageable, participation by a limited number of select PIGs could still improve transparency as well as contributing valuable expertise.

Again, although there is no legislative requirement to ensure participation during zonal evaluation procedures, **zonal steering committees** are encouraged to consider ways to enhance the openness of these procedures. While it may be difficult to reach citizens across the entire zone, a starting point may be to identify PIGs or individuals (for example, users, CSOs, university experts) within the zone who can contribute different knowledge and perspectives to the drafting of, for example, zonal guidance documents. Given that the zonal system is still in its early stages, opening up evaluation and decision-making procedures themselves should be considered in the longer-term and may need to be

implemented gradually and sensitively in order not to over-burden CAs. For example, a willing and capable **zRMS** could pilot a programme whereby a PIG participates in the evaluation of an application, following which the zRMS shares its experience with other Member States.

Stronger measures for improving transparency of the zonal authorisation procedure would come from the EU institutions themselves. **Commission** support for Member States wishing to open up their decision-making procedures could include administrative support and expertise, for example in identifying appropriate PIGs or other actors and designing appropriate participatory procedures and online platforms (such as CIRCABC) to facilitate wider participation and sharing of results and experiences between Member States. Longer-term, the **Commission** is encouraged to draw up guidelines (or similar, non-legislative instruments) for increasing the openness of zonal evaluation and authorisation procedures with particular regard to providing opportunities for wider participation.

The strongest measure for improving transparency through participation would be a legislative requirement. Again, in the longer-term, the **European Parliament**, **Council** and **Commission** are encouraged to review the provisions of the Regulation in light of the findings of this report and overall EU policy commitments to public consultation and participation (discussed in section III.3) and to consider the possibility of introducing a specific provision governing participation during the zonal evaluation and national decision-making procedures, including comparative assessment.[251]

Given the complex structure of the zonal system and limited resources of CAs, further research is recommended to identify and elaborate potential and feasible participatory mechanisms, including PIGs, consensus conferences, citizen juries etc. appropriate to the zonal system and capacity of CAs.

The picture which emerges in most respondents is that of different strengths of accountability existing simultaneously. While most CAs are fully accountable to a political authority, which may compromise independence, in few can authorisation decisions be overturned by government or other body, apart from a court. In this respect, independence is protected. The extensive system of review described by two Member States could be considered examples of good practice. Due to the nature of the data available, it is not possible to determine how widespread such systems are throughout the non-respondent Member States, but the adoption of such practices could enhance the quality and perhaps reliability of decisions. To the extent that accountability is supported by transparency, it suffers here due to the low levels of transparency, discussed in the rest of this section.

[251] The benefits of wider participation in comparative assessment were discussed in section IV.3.

Recommendation

Member States who do not already do so are encouraged to produce annual reports as a step towards enhancing the transparency of their operations and thereby also their accountability. Such reports would need to contain information about the CA's operations and progress against its objectives of a sufficient quality and intelligibility to enable proper scrutiny by the relevant oversight institutions and the public.

Member States are also encouraged to establish internal and/or external procedures for scrutinising their decisions, for example annual audits of a sample of decisions, where these are not already in operation. There are already examples of good practice and Member States are encouraged to use already established zonal networks to share such practices.

3. Precaution

3.1 Discussion

Member States were asked two questions on the precautionary principle. Firstly, they were asked to 'indicate the standard of proof the evidence must meet in order for the PPP to be authorised' 'taking into account all the evidence of the safety of the PPP and the restrictions that may be placed on its use'. The question and available answers were designed in light of the Court's decision in *Sweden v Commission (Paraquat)*,[252] discussed in section IV.1. The following answers were available:

> 'a) The evidence must provide certainty that the PPP will meet the requirements in Articles 29(1)(e) and 4(3)(b)-(e);
>
> b) The evidence must show beyond a reasonable doubt that the PPP will meet the requirements in Articles 29(1)(e) and 4(3)(b)-(e);
>
> c) The evidence must show, on the balance of probabilities, that the PPP will meet the requirements in Articles 29(1)(e) and 4(3)(b)-(e); and
>
> d) Other.'

Six selected a) and five selected b), each representing a mix of Member States from all three zones, with **Germany** declining to select an answer.

It is interesting that so many indicated that they require certainty as to the safety of a PPP in order to authorise it. Scientific certainty is impossible to achieve, no less so here, given persistent conditions of ignorance surrounding the potential harm arising from interactions between pesticides and the environment (Pretty, 2005). As such, as discussed in section IV.1, regulation may not seek zero risk, again on the basis that this is impossible to prove. However,

[252] *Sweden v Commission (Paraquat)* (n 52).

the responses perhaps indicate six Member States pursuing a very high level of safety, beyond that endorsed by EU law in this area, through the application of a strong interpretation of the precautionary principle which pursues certainty of safety. As discussed in section IV.1, Member States are arguably entitled to seek certainty of safety in terms of reducing *known* (as opposed to hypothetical) risks to zero[253] (Lee, 2008, p.46) but may not pursue certainty of safety overall, as this is impossible to achieve, as indeed, one Member State noted in a comment. The meaning of 'certainty' may be open to different interpretations, including among the respondent Member States. It is also not possible to detect, on the basis of the available data, how the reported requirement for 'certainty' might be reflected in national authorisation decisions. A more in-depth and detailed study of the divergences between Member State application of the precautionary principle in practice was beyond the scope of the present research.

Sweden, in particular, demonstrates a nuanced understanding of the question of scientific uncertainty noting the need for political judgment. It comments that:

> *'In practice, the risk assessment methodology is based on statistical probabilities. The inherent uncertainties are not propagated in the step-wise procedure and therefore not expressed numerically in the final calculated risk ratio used for decision-making. Moreover, there are further uncertainties in [sic] that are not accounted for in the calculations. The interpretation of standard of proof is therefore ultimately a policy level issue, rather than a scientific.'*

In comments, three Member States note that they rely on the Uniform Principles here, one of whom selected answer a) and one (**Sweden**) answer b).[254] One (Central zone) Member State indicates that it uses the standard, established in *Sweden v Commission (Paraquat)*, for 'compliance with the requirements for approval of an active substance [which] must be shown beyond a reasonable doubt',[255] as it considers this 'an appropriate reference point for PPP authorisation'. The fact, though, that six Member States indicate their standard of proof is 'beyond a reasonable doubt' perhaps indicates wider adherence to this decision, which, as discussed in section VI.1, may be in doubt. Again, however, the data do not allow conclusions to be drawn about how the requirement for 'beyond a reasonable doubt' may actually be reflected in national authorisation decisions.

The second question asked whether Member States produce and follow any internal guidance in applying the precautionary principle. Three Member States indicate that they apply the precautionary principle on a case-by-case basis. The other nine indicate they employ external guidance, with two specifying the Uniform Principles, three EFSA guidance, five Commission guidance and two Northern zone guidance. In the Central zone, the **CZSC secretariat** provides support to Member States by acting as a contact point for questions or forum for discussion

[253] *Hahn* (n 66).
[254] The third, **Germany**, did not select an answer.
[255] See discussion in section IV.1.

and by distributing agreements and conclusions. The **NZSC secretariat** reports that it provides no specific guidance on the precautionary principle.

Although the Stakeholder does not believe that the precautionary principle is applied consistently across Member States, it reports that 'most competent authorities' apply it correctly in the sense that 'most apply the Uniform Principles, and therefore comply with the requirements of the PPPR'. It does believe, however, referring to politically contentious decisions, that some Member States reject applications in cases of 'clear and unequivocal' compliance with the Uniform Principles, inappropriately using the precautionary principle as a justification.

3.2 Summary and recommendations

There may be some inconsistent interpretation and application of the precautionary principle. Member States appear to interpret and apply the precautionary principle with differing levels of ambition, perhaps suggesting at least two different standards of proof in operation in the EU for the grant of a PPP authorisation. This is perhaps not surprising given that the law relating to the interpretation and application of the precautionary principle is not entirely clear.[256] While the Uniform Principles exist to ensure that evaluation and authorisation decisions implement the requirements of the Regulation, by 'all the Member States at a high level of protection of human and animal health and the environment',[257] the fact that two different Member States appear to derive different standards of proof from them may indicate still the potential for inconsistent interpretation and application here. Six Member States report they apply the standard of proof indicated by the Court in *Sweden v Commission (Paraquat)* in the context of active substance approval. However, given the uncertainty of the law in this area, it may not be entirely clear what the correct approach should be in the context of PPP authorisations. Finally, Member States appear to refer to multiple different sources of guidance which may further indicate a diversity of approaches.

Recommendations

The above analysis suggests inconsistent application of the precautionary principle within the EU in the context of PPP evaluation and authorisation. However, to understand truly the divergences between Member State application of the precautionary principle in practice, a systematic, qualitative and comparative review of authorisation decisions would be required. Such research would provide a stronger evidence base on which to pursue efforts to harmonise interpretation and application of the precautionary principle, including the following two recommendations.

Member States are encouraged to collaborate at zonal and inter-zonal level to decide upon a harmonised interpretation and method of application of the precautionary principle in

[256] See discussion in section IV.1.
[257] Paragraph A.1 Uniform Principles (n 50).

the context of PPP evaluation and authorisation. In the interests of enhancing co-ordination and efficiency within the zones, as well as transparency, **Member States** should set these out in guidance and publish that guidance.

Perhaps more importantly, given that EU law relating to the precautionary principle may be unclear and therefore causing inconsistent application, the **Commission** is encouraged to develop (and publish) guidance to clarify, perhaps on the basis of such research as suggested above, how the precautionary principle should be interpreted and applied in the context of PPP evaluations and authorisations.

Both **Member States** and the **Commission** are encouraged, in drawing up such guidance, to consult with wider stakeholders and/or relevant PIGs with the aim of enhancing both the transparency and quality of the guidance.

4. Sustainability

4.1 Discussion

Member States were asked five questions on sustainability. One Member State appears to have misinterpreted these questions as relating to the substitution principle. These answers are therefore excluded as unreliable and the responses of the remaining 11 are presented.

Firstly, Member States were asked whether they take the principle of sustainability into account in their decision-making regarding the authorisation of PPPs (Q11). Seven Member States indicate that they do so 'with every application' and one indicates that it does so 'with most applications'. **Sweden** selected 'never'. It comments, in response to Q12 which asks about the basis on which Member States decide whether or not to take this principle into account, that '[t]he concept "Principle of sustainability" cannot be found in the Regulation'. I agree, as discussed in section IV.2.[258] One Member State comments that it is taken into account on the basis of internal expert discussions. The **Netherlands** comments that the ability to take sustainability into account is limited, noting that the Regulation 'does not provide the possibility to take into account socio-economic effects and to weight [sic] the environmental risks and benefits of the measures and plant protection products used in a crop system'. It notes further that it is running pilots to develop integrated pest management (IPM) systems, including '[a]uthorisation of applications fitting in an IPM system and the development of the needed risk assessment methodology'. The aim is to create a 'framework to stimulate a sustainable agricultural practice'. Results will be shared with the Commission, EFSA and other

[258] It was argued, in this section, that 'sustainability' is not mentioned explicitly in the Regulation. It argued further that 'sustainability' should be interpreted to incorporate social, economic and environmental dimensions and the interests of future generations. This interpretation is not to be found in EU policy or legislation on PPPs. Instead, the SUD and policy interprets 'sustainability' to mean 'risk reduction' and pursues this goal. For more, see (Hamlyn, 2015) The Regulation also pursues this goal.

Member States. Two Member States did not answer Q11, including **Germany** which notes, in comments, that it applies the Uniform Principles and Commission guidance.

ZSC secretariats were also asked whether Member States in their zones take sustainability into account during evaluation. The **NZSC secretariat** reports that it is not aware of any Member States who do. All three referred to the SUD as the regime relevant to sustainability and pesticides. Two **zSC secretariats** comment that sustainable use of pesticides was outside the scope of the zonal system or beyond its remit to provide any guidance on sustainability. The **CZSC secretariat** feels that sustainability is taken into account in the assessment of efficacy 'when reflecting the resistance situation in a certain [good agricultural practice]', following the Uniform Principles. The **SZSC secretariat** feels that 'sustainable use' imposes no limits on authorisations. The responses reflect the nebulous nature of sustainability[259] and therefore the difficulty of assessing the extent to which Member State have regard to it during evaluation. Indeed, the **SZSC secretariat** queries what is meant by 'sustainability' and states that it is a national issue.

Neither Q11 nor Q12 were designed to gather an understanding, specifically, of the interaction of the Sustainable Use Directive with national zonal authorisation procedures. However, either in comments to Q11 or in response to Q12, three Member States refer to their National Action Plans (NAP)[260] and/or the EU's SUD itself. The **Netherlands** expresses its opinion regarding the difficulties of implementing sustainability within the framework of the Regulation, noting that '[o]nly the resilience of the agricultural system is guaranteed by the assessment of non-target arthropods and plant and risk mitigation measures as is laid down in the uniform principles and the guidance documents', '[t]he methodology to account for sustainability in the assessment is largely missing…'. In the context of an interpretation of sustainability as risk reduction, **Belgium** highlights the potential to review authorisations[261] and its monitoring programme of active substances in water and its power to modify or withdraw applications on the basis of the results. The comments of **zSC secretariats** discussed above imply that the SUD and PPPR are regarded as operating separately.

Despite the lack of provision for considering NAPs during authorisation decision-making, Recital 29 PPPR provides that Member States may impose 'appropriate conditions' on the use of PPPs having regard to the objectives of their NAPs. Q15 asks Member States how often they do this in order to gain an impression of the potential influence of the primary national instrument for achieving the sustainable use of pesticides in authorisation decision-making. While one Member State selected 'never', two selected 'in some authorisations' and five selected 'in every authorisation'. There were no zone-specific trends. **Sweden** notes, in practice, this occurs in few cases. The **Netherlands** refers to the influence of, *inter alia*, its NAP on agricultural practice, which is taken into account in risk assessments of PPPs, demonstrating a means by which efforts to achieve sustainable use of pesticides surface during PPP

[259] See section IV.2.
[260] Article 4 SUD (n 3).
[261] Article 44(1) PPPR.

authorisation decision-making. **Germany** comments that in all authorisations it 'imposes labelling requirements and use restrictions according to the specific circumstances in Germany', although it does not refer directly to the objectives of its NAP. One Southern zone Member State reports that it does not impose such conditions as they are seen as causing a 'lack of harmonisation between authorisation procedures in the different MSs'.

Q13 asked Member States to indicate their interpretation of sustainability. The available answers were as follows, with answers a), b) and c) constituting interpretations of sustainability which could be found in the 2009 regulatory regime as a whole: a) reducing the risks of using PPPs; b) optimising the use of PPPs, i.e. increasing efficiency of use to maintain or improve the benefits of using PPPs while reducing their risks; c) reducing dependence on PPPs; and d) considering the social, economic and environmental implications, including for future generations, of authorising or not authorising the PPP. Two Member States decline to answer this question. **Sweden** specifies e) 'a combination of the above' and in a comment differentiates between the approach taken with individual applications and the overall policy behind risk assessment. The former requires maintaining a high level of protection and reducing the risk, pursuant to the Regulation. The latter requires a 'balance between the benefits of using PPPs and the level of protection… [as] expressed in the protection goals for the risk assessment'. Most selected a) and/or b), as shown in figure 1. Two Member States (both Central zone) select both a) and b), two select a) and d) and one selects a), b) and c).

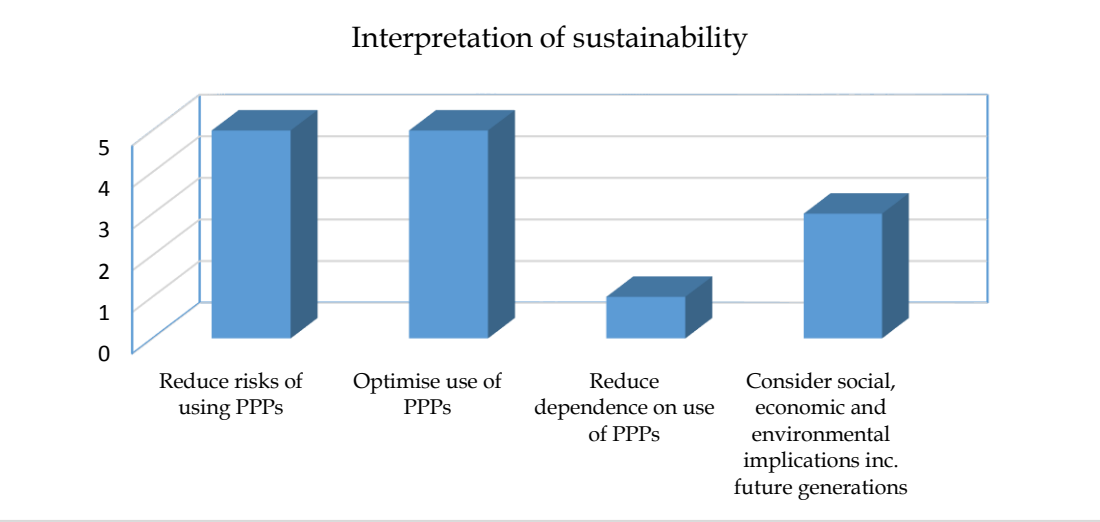

Figure 1: Interpretations of sustainability

It is significant that two Member States take social, economic and environmental implications, including for future generations, into account. As discussed in section IV.2, this interpretation of sustainability is not expressed in the SUD, nor in the Regulation. As the **Netherlands** forcefully argues:

> *At the moment only the reduction of risk is possible within the framework of the Regulation. To realise a viable sustainable agricultural practice…the*

> *interpretation of sustainability applied in…decision-making should also include social, economic and environmental implications, including implications for future generations.*

Q14 asked whether Member States follow any internal or external guidance when applying the principle of sustainability in order to apply it consistently. Two respondents report that they follow external guidance, three report they follow both internal and external guidance and four report they follow no guidance.[262]

The Stakeholder is of the opinion that all Member States take the principle of sustainability into account and apply it consistently. It understands the principle to be incorporated into the Uniform Principles and therefore CAs take the principle into account when they apply the Uniform Principles.

4.2 Summary and recommendations

Although, again, the data are patchy, two tentative observations may be put forward. The first, as with the precautionary principle, has to do with consistency in interpretation and application of the 'principle of sustainability' both between and within Member States. Not every Member State takes sustainability into account in its authorisation decision-making and those that do, do not necessarily do so with every application and may not necessarily rely on guidance to ensure consistency in application. Moreover, responses from zSC secretariats suggest a belief that Member States are not *required* by the Regulation to take sustainability into account. In addition, Member States employ different interpretations of sustainability, potentially indicating varying levels of ambition in terms of the objectives they seek to achieve in implementing sustainability. These variations in practice may ultimately indicate an inconsistent basis for, and potential unpredictability in, decision-making across Member States, at least with respect to sustainability. In this respect, the **Netherlands'** comments that no methodology for taking sustainability into account during assessment exists, is pertinent. Without a methodology or clear guidance, potential for inconsistency is perhaps not surprising. However, the available data do not allow conclusions to be drawn regarding the extent to which these differing interpretations of sustainability or Member State decisions not to consider sustainability are reflected in national decision-making. As with the precautionary principle, a more in-depth study of national authorisation decisions would be required to understand their effect, if any.

Secondly, although the Regulation neither requires nor empowers Member States to consider their NAPs, the SUD or sustainability generally, when deciding whether or not to authorise a PPP, it appears that some Member States do so in practice. Furthermore, while Member States are entitled to have regard to the objectives of their NAPs when imposing 'appropriate conditions' on the use of PPPs, not all do so or do so all the time. This may suggest further inconsistencies in Member State decision-making practices in terms of the level of regard to sustainability during authorisation procedures.

[262] This includes Sweden who indicated it does not apply the principle of sustainability.

Recommendations

As with the precautionary principle, further empirical research is recommended to developed a greater understanding of the role sustainability (including its various interpretations) plays in PPP evaluation and authorisation. Such research should again involve a systematic, qualitative and comparative review of national authorisation decisions and would inform efforts to clarify the interpretation of sustainability and its role (if any) in decision-making, including the following recommendations.

The **Commission** is encouraged to develop and publish guidance clarifying whether Member States are required to take sustainability into account during evaluation and authorisation procedures. If Member States are so required, the **Commission** is further encouraged to clarify how sustainability is to be interpreted and applied in order to ensure consistent and predictable decision-making.

The Netherlands reported that it was working towards a framework for sustainable agriculture and that results of its experiments would be shared. The **Commission**, **EFSA** and other **Member States** are encouraged to review and consider seriously any findings or recommendations the Netherlands makes.

Member States are also encouraged to collaborate at zonal and inter-zonal level to decide upon a harmonised interpretation and method of application of sustainability in the context of PPP authorisation. In the interests of enhancing co-ordination and efficiency within the zones, as well as transparency, **Member States** should set these out in guidance and publish that guidance.

Both **Member States** and the **Commission** are encouraged, in drawing up such guidance, to consult with wider stakeholders including relevant public interest groups with the aim of enhancing both the transparency and quality of the guidance.

5. Substitution

5.1 Discussion

Member States were asked three questions on substitution and comparative assessment. Article 50(4) PPPR requires Member States to perform a comparative assessment of PPPs containing a candidate for substitution 'regularly and at the latest at renewal or amendment' of its authorisation (in addition to the requirement for comparative assessment during initial evaluation of an application[263]). Q16 asked how often CAs perform such a comparative assessment. One Member State's answer was unclear and is therefore not reported here. Of the remaining responses, ten Member States indicate comparative assessment is conducted at

[263] Article 50(1) PPPR.

renewal and amendment, two of which also comment that it is also conducted for new authorisations. One Member State indicates comparative assessment is conducted at first authorisation and renewal. Member States may review an application at any time, in accordance with the provisions of Article 44 PPPR. This may lead to the withdrawal or amendment of an authorisation. The timing of amendments can therefore be unpredictable. However, without prejudice to Article 44, authorisations are granted for a maximum of one year 'from the date of expiry of the approval of the active substance' in the PPP 'and thereafter for as long as the active substances… are approved'.[264] Active substances are approved as candidates for substitution for a maximum of seven years.[265] This means that unless an authorisation is amended pursuant to Article 44, comparative assessments in the respondent Member States may be performed every seven or eight years, at most.

Q17 asked Member States to indicate the PPPs on which they conduct comparative assessments. All respondents selected 'PPPs containing active substances classified as candidates for substitution pursuant to Article 24(1) PPPR', as required by Article 50(1) PPPR. Only two Member States indicate a more ambitious substitution programme. **Sweden** indicates that it performs optional comparative assessments under Article 50(2) PPPR. **Belgium** referred to Article 29(1)(d) PPPR which provides that to be authorised the technical formulation of a PPP must be 'such that user exposure or other risks are limited as much as possible without compromising the functioning of the product'. It notes that it performs a kind of comparative assessment 'between formulation types containing the same active substance but for which efficacy/selectivity or effects on health or environment may differ due to co-formulants'. Commission guidance also recognises the presence of the concept of comparative assessment in this provision (Commission, 2014a, p.3).

Finally, Q18 asked whether Member States follow any internal or external guidance in order to deliver consistent results. All respondents indicate that they follow either external or both internal and external guidance with three referring to EU and EPPO guidance. The **Netherlands** reports use of its own manuals for comparative assessment which contain *inter alia* 'European guidance on comparative assessment and national guidance on assessment of practical and economic disadvantages'. One (Southern zone) Member State reports that it followed internal guidance which 'specifies national options on issues left as optional in the EU Guidance'. **Sweden** reports no guidance for comparative assessment under Article 50(2), which is therefore conducted on a case-by-case basis. The **CZSC secretariat** notes that Member States still have only limited experience with comparative assessment and the **NZSC secretariat** reports that it is beyond its remit to provide guidance on it.

The Stakeholder feels that some CAs are correctly implementing comparative assessment but does not know whether it is implemented consistently across CAs. It is, however, sceptical about the usefulness of comparative assessment for achieving the sustainable use of pesticides and risk reduction particularly, partly due to the high levels of safety PPPs must meet for

[264] Article 32(1), second paragraph PPPR.
[265] Article 24(1) PPPR.

authorisation anyway. It indicates that industry, generally, holds this view. It doubts comparative assessment could be better implemented and regards it as 'mainly a political gesture to demonstrate the desire to reduce the use of pesticides' by which 'already under-resourced Competent Authorities are unnecessarily burdened'. The **CZSC secretariat** echoes these concerns, doubting its ability to enhance safety, reporting that comparative assessment had not yet led to the withdrawal of products and attributing to it a risk of increased resistance to the remaining active substances.

5.2 Summary and recommendations

The respondent Member States appear to exhibit greater consistency, with all or most conducting comparative assessment on the same occasions, on the same PPPs and following guidance to ensure consistency. The greater consistency here is perhaps not surprising given the greater clarity of the relevant provisions in the Regulation, despite the unsettled nature of the substitution principle in the literature, as discussed in section IV.3. At the same time, few respondent Member States implement a more ambitious interpretation of the substitution principle by, for example, exercising the power in Article 50(2) PPPR. However, it is perhaps wise to remember that this principle is still a relatively new addition to the regulatory toolbox and to view substitution therefore as a process of continuous development, rather than a single decision (Hansson, Molander and Rudén, 2011, p.456), evolving as guidance, assessment models etc. develop (Commission, 2014a, p.8).

Recommendations

In order to encourage a more ambitious application of the substitution principle, the **Commission** is advised to develop or commission and publish guidance for conducting optional comparative assessment under Article 50(2) PPPR.

Substitution and comparative assessment are still novel and may have unintended consequences. Further research is therefore recommended to investigate the effects of these new provisions and whether substitution is in fact reducing risks from PPPs. Furthermore, given the novelty of these provisions, it may be wise to allow for a few more years of experience before embarking on such research.

Hanssen et al. have made recommendations for promoting substitution. These include increasing the availability of data about toxicity, chemical composition and technical functionality; developing green chemistry and providing helpdesk functions, for example technical help from experts (Hansson, Molander and Rudén, 2011, pp.457–458). The **Commission** and/or **Member States** may wish to consider investigating and developing one or more of these initiatives.

VIII – Conclusion and recommendations

1. Conclusion

The scope of this research was broad. It generated new data in an area which is generally not well understood and about which there is little knowledge. Given this starting point, the need to break new ground and the breadth of the research questions, this report should be regarded as a first step towards understanding the various matters covered. However, many questions remain unanswered and, as implementation of the Regulation progresses and the zonal system evolves, new questions will arise. More, and more focused, research will be necessary to understand the current situation as well as new developments, perhaps once more experience has been gained with the zonal system, zonal evaluation and comparative assessment. The conclusions of this research are summarised here. Section VIII.2 summarises the recommendations.

While this research has not identified any deficiencies which are likely significantly to undermine the reliability of CA decisions-making, there are large parts of the zonal procedure and CA decision-making which could be improved. Overall, the dimension currently capable of the greatest and most immediate improvement relates to the transparency of CAs, particularly in terms of access to information. In the medium to longer term, it may be appropriate to review the Regulation and relevant guidance and policy with a view to establishing opportunities for wider participation in decision-making primarily for the contribution such activities can make to transparency and to countering the risk of regulatory capture. In addition, given the discussions above[266] regarding the diversity of interpretations and their context-dependency, consistency in interpretation and application of the precautionary principle and sustainability among Member States, and the ambition with which substitution is implemented, could also be improved, for example through clear guidance. Finally, as ever, greater resources – financial, technical, expert, personnel and greater remuneration in order to attract qualified staff may reduce information asymmetry, improve decision-making, both in terms of its quality and speed and boost the operation of the zonal system overall.

However, it should be remembered that there are tensions between the various values which the regulation and decision-making should support. Restricting the movement of regulator heads between industry and CAs may improve independence but could simultaneously hinder recruitment of those with the necessary expertise. Consultation may improve transparency but at the same time reduce the efficiency of evaluation and authorisation procedures and further burden CAs. Increased accountability to government for example, depending on how it is implemented, may reduce independence. As such, steps to improve one area need to be carefully researched and designed in order to avoid undermining progress in another area.

[266] See sections IV.1, IV.2, VII.3 and VII.4.

1.1 Authorisation procedure and zonal system

Zonal evaluation and national decision-making procedures are characterised by diversity. For example, Member States differ in terms of the institutional structure of their CAs, the type and extent of communications with applicants during evaluation and decision-making and the nature of the expert advice (binding or consultative) provided to decision-makers. Overall, very few trends within the zones may be identified. The zonal system is valued by Member States for the benefits it delivers, for example harmonisation, work-sharing and resolution of disagreements between CAs. However, it still faces significant challenges, especially in terms of improving harmonisation, sharing work fairly within the zones and further strengthening trust between the Member States. It is a new and complex system which warrants further research and continued monitoring in order to understand better its development and operation.

1.2 Independence

There are varying levels of formal independence of respondent CAs from government. However, most respondent CAs have sole responsibility for their decisions. Lack of formal independence does not necessarily mean unreliable or unfair regulation.

There are also varying levels of independence from industry. However, few of the respondent Member States report restrictions on recruiting CA heads from industry or on employment in industry after their appointment. This may risk undermining their independence from industry. Increased transparency and/or PIGs may provide mechanisms by which to counter regulatory capture.

Most respondent CAs lose some formal autonomy due to their being funded by government. In addition, government control over salaries reduces autonomy further and restricts CA ability to recruit the required staff. However, most respondent CAs regard themselves as possessing sufficient resources (personnel, technical, financial) to fulfil their obligations under the Regulation.

Due to the lack of data concerning stakeholder and public views with respect to the fairness and reasonableness of CA decision-making, the extent to which it is trusted and how far the independence of individual CAs (or lack thereof) is regarded as a problem, it not possible to determine whether strengthening the formal independence of CAs would improve the quality of its decision-making.

1.3 Transparency

Levels of transparency among CAs are low, overall. This is so firstly, in terms of the availability of information about evaluation and authorisation procedures and secondly, in terms of access to the information on which decisions are based. Both of these are necessary to enable interested parties to gain an understanding of the procedural and informational basis of PPP authorisations.

Public participation in decision-making is important for improving transparency. Currently, the Regulation does not require or provide for such participation during evaluation and

authorisation procedures and comparative assessment. Furthermore, the zonal system itself acts as a barrier to participation due to the level at which zonal evaluation procedures are conducted; a level which is far removed from most citizens. Given this legal framework, it is not surprising that consultation activities in Member States are extremely limited, if conducted at all.

CAs are subject to differing levels of accountability to national governments and legislatures. Some Member States operate robust systems of peer review or auditing of decisions which should operate to improve the overall reliability of their decision-making. Increasing transparency could also improve accountability.

1.4 Precaution, sustainability and substitution

There is evidence of inconsistent interpretation and application of the precautionary principle and sustainability amongst Member States. Member States exhibit greater consistency in conducting comparative assessment but overall, levels of ambition are low. Comparative assessment is still a relatively new exercise but eventually ambition could be improved.

2. Recommendations

2.1 Authorisation procedure and zonal system

Further, longer-term (external) qualitative and quantitative empirical research is recommended to understand better the operation of the zonal system, the challenges each zone faces, how these may be overcome and the potential for improving evaluation and the overall authorisation process. Such research could identify further examples of best practice with a view to promoting sharing and policy learning among Member States. For example, it was unclear whether all Member States assign project managers to manage applications. Further research could investigate Member State experience with the use of project managers and whether, for example, they reduce the occurrence of delays.

Member States are encouraged to continue communicating and working together in their zones and to step-up activities designed to improve harmonisation of, for example, methods and models for evaluation and to achieve fairer work-sharing with the aim of strengthening trust between each other. **Chairs of zSCs/zSC secretariats** are encouraged to take particular responsibility for co-ordinating and pushing forward these activities. The **Southern zone**, particularly, could consider introducing guidelines or other measures both governing the timing of RR publication and to improve efficacy assessment within the zone.

Information about, and understanding of, the zonal system more generally could be improved in order to provide an evidence base for possible future action and support. The **Commission** is therefore advised to continue monitoring the zonal system, including stakeholder experiences of the zones, in order to keep track of its progress. The **Commission** and **zSCs** are also encouraged to consider whether it would be feasible and valuable for zSCs to report (for example, annually) to the Commission on progress in their zones. The Commission is encouraged to provide support, for example financial and administrative, for the production

of such reports to ensure their quality. In the interests of transparency, any such reports should be made publicly available.

2.2 Independence

It is recommended that further qualitative research is conducted. This research should target two specific enquiries. First, it should seek to understand how the zonal evaluation and national authorisation procedures of the CAs are perceived by all stakeholders, including applicants and the general public, and the extent (if at all) to which these procedures are viewed as fair and reasonable. Secondly, it should move beyond study of formal independence to investigate the existence (if any), in practice, of governmental influence on CA decision-making, for example through review of CA decisions and in-depth examination of interaction between CAs and government during decision-making. Such research may provide a stronger basis on which to make substantive recommendations.

The Regulation places no obligation on Member States to report their progress on the implementation of its provisions.[267] While acknowledging the difficulty of amending legislation, given the lack of information about CAs and the operation of the zonal system, the introduction of such a reporting requirement on Member States could provide valuable information and constitute a step towards filling this knowledge gap. The **EU institutions** are encouraged to consider such an amendment. In the interests of transparency, any such reports should be made publicly available.

Regulatory (particularly cultural) capture has been identified as a risk to CAs. However, further empirical research would be required to determine the extent (if at all) to which any CAs are, in practice, influenced or captured by industry. Such research should involve, *inter alia*, qualitative review of registration reports and decisions against information submitted by applicants and modes of interaction between CAs and industry to understand the nature and proximity of the relationship. Recent literature (for example, (Carpenter and Moss, 2014b)) proposes robust methodologies to conduct such research. Greater understanding would provide a stronger evidence base on which to make recommendations. However, pending such research, the following recommendations are made.

Member States are encouraged to review their national provisions regarding potential for commissioners/agency heads to have held positions in industry prior to their appointment to CAs and to accept employment in industry post-appointment. In order to reduce the risk of regulatory capture, **Member States** are encouraged, furthermore, to consider strengthening restrictions with respect to both.

Member States are also encouraged share best practice. For example, Member States may benefit from learning about France's experience with its charter on relations with interest

[267] Such reporting requirements exist elsewhere. For example, Member States are required to report on implementation to the Commission every three years, under Article 31(4) European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms [2001] OJ L106/1.

groups (section VII.1.2) and the Netherlands' experience with its quality standards (section VII.1.4). If successful, Member States may wish to implement similar measures.

Involvement of public interest groups (PIGs) in regulatory decision-making was discussed in section II.1.2 as a mechanism for reducing the risk of regulatory capture. Again, further research would be required into, for example, their appropriateness, mechanisms for their support (including funding) and to identify potential candidates. PIGs could operate on a national level and, if the PIG itself transcends national boundaries, on a zonal or EU level too.

Research into the potential for the zonal system to act as a counterweight to external pressure was beyond the scope of this study. Further research may therefore be necessary to investigate this question. If this potential is real, **Member States** and the **Commission** should provide support at zonal and inter-zonal level for developing the networks required to ensure individual CAs can take full advantage of the zonal system as a means to maintain and enhance their independence.

Member States are encouraged to review the means by which CAs are funded and to consider introducing fees covering the costs of evaluation and authorisation, pursuant to Article 74(1) PPPR. However, while securing CA funding through fees levied on industry may promote independence from government, dependence on such fees may reduce independence from industry. A straightforward recommendation with regard to the benefits to CA independence of retaining such fees is therefore not possible. The further research, recommended above, into CA independence in practice from government and industry should generate greater understanding of the relative prevalence or risk of government influence or industry capture. Appropriate funding structures could be designed or adjusted in response to the identified risks.

While pressures on government budgets are acknowledged, given the need for expertise both to ensure the quality of evaluation and decision-making and to counter information asymmetry, **Member States** may wish to consider the following options. Firstly, review and, if appropriate reduction of, the application of constraints on civil service remuneration in order to promote recruitment and retention of the necessary expert staff. Secondly, the development or enhancement of in-house training programmes in order to cultivate sources of expertise other than from within industry, as a further means to counter asymmetric information and industry influence or capture.

2.3 Transparency

Member States are encouraged to review the amount of information available online about their evaluation and authorisation procedures from the perspective both of applicants and other stakeholders/general publics. It may also be helpful to review other CA websites with high levels of information as examples of good practice. The UK CA website, for example, contains substantial information. In order to enhance transparency with respect to these procedures, **Member States** are encouraged to provide clear and comprehensive information at least in their native language and ideally, eventually, in English.

Member States are encouraged to increase the publication, ideally online, of information on PPPs within the limits of the law, especially the following:

- Authorisation decisions
- Registration reports
- The information sources on which evaluation and authorisation are based. Ideally, this should include the conclusions of the zRMS's evaluation
- Any submissions (and responses thereto, if relevant) made during any consultation process

To this end, **Member States** are encouraged to step up discussions amongst themselves regarding the publication of registration reports and other information. These discussions may need to happen alongside the development of measures, for example guidelines or training, designed to improve the quality of registration reports in order to support this measure to enhance transparency.

It is acknowledged that CA resources are limited. However, where possible, publication of the above information in English[268] is encouraged for its potential to enhance access to information for a larger audience and to improve the quality of future applications. Increased public availability of such information would facilitate conduct of the research recommended in sections VII.1.5/VIII.2.2.

Stronger measures to improve access to information may be desirable. The **Commission** is therefore encouraged to consider the possibility of amending the Regulation to introduce a requirement that registration reports (at least) are made publicly available.

Although there is no legislative requirement, **Member States** are encouraged to consider ways to open up their national authorisation decision-making procedures to wider participation. Member States could experiment, for example, with providing opportunities to comment on dRRs during the commenting phase of zonal evaluation (described in section VI) and/or on draft authorisation decisions. Further upstream, wider participation in the definition of national data requirements could improve the transparency of CA decision-making. If opening up such elements of decision-making to stakeholders and the wider public generally is regarded as time-consuming and unmanageable, participation by a limited number of select PIGs could still improve transparency as well as contributing valuable expertise.

Again, although there is no legislative requirement to ensure participation during zonal evaluation procedures, **zonal steering committees** are encouraged to consider ways to enhance the openness of these procedures. While it may be difficult to reach citizens across the entire zone, a starting point may be to identify PIGs or individuals (for example, users, CSOs, university experts) within the zone who can contribute different knowledge and perspectives to the drafting of, for example, zonal guidance documents. Given that the zonal system is still in its early stages, opening up evaluation and decision-making procedures themselves should

[268] Or another widely used EU language. The impact of the UK's departure from the EU may be a factor in choice of appropriate language.

be considered in the longer-term and may need to be implemented gradually and sensitively in order not to over-burden CAs. For example, a willing and capable **zRMS** could pilot a programme whereby a PIG participates in the evaluation of an application, following which the zRMS shares its experience with other Member States.

Stronger measures for improving transparency of the zonal authorisation procedure would come from the EU institutions themselves. **Commission** support for Member States wishing to open up their decision-making procedures could include administrative support and expertise, for example in identifying appropriate PIGs or other actors and designing appropriate participatory procedures and online platforms (such as CIRCABC) to facilitate wider participation and sharing of results and experiences between Member States. Longer-term, the **Commission** is encouraged to draw up guidelines (or similar, non-legislative instruments) for increasing the openness of zonal evaluation and authorisation procedures with particular regard to providing opportunities for wider participation.

The strongest measure for improving transparency through participation would be a legislative requirement. Again, in the longer-term, the **European Parliament**, **Council** and **Commission** are encouraged to review the provisions of the Regulation in light of the findings of this report and overall EU policy commitments to public consultation and participation (discussed in section III.3) and to consider the possibility of introducing a specific provision governing participation during the zonal evaluation and national decision-making procedures, including comparative assessment.[269]

Given the complex structure of the zonal system and limited resources of CAs, further research is recommended to identify and elaborate potential and feasible participatory mechanisms, including PIGs, consensus conferences, citizen juries etc. appropriate to the zonal system and capacity of CAs.

Member States who do not already do so are encouraged to produce annual reports as a step towards enhancing the transparency of their operations and thereby also their accountability. Such reports would need to contain information about the CA's operations and progress against its objectives of a sufficient quality and intelligibility to enable proper scrutiny by the relevant oversight institutions and the public.

Member States are also encouraged to establish internal and/or external procedures for scrutinising their decisions, for example annual audits of a sample of decisions, where these are not already in operation. There are already examples of good practice and Member States are encouraged to use already established zonal networks to share such practices.

2.4 Precaution, sustainability and substitution

The above analysis suggests inconsistent application of the precautionary principle within the EU in the context of PPP evaluation and authorisation. However, to understand truly the divergences between Member State application of the precautionary principle in practice, a

[269] The benefits of wider participation in comparative assessment were discussed in section IV.3.

systematic, qualitative and comparative review of authorisation decisions would be required. Such research would provide a stronger evidence base on which to pursue efforts to harmonise interpretation and application of the precautionary principle, including the following two recommendations.

Member States are encouraged to collaborate at zonal and inter-zonal level to decide upon a harmonised interpretation and method of application of the precautionary principle in the context of PPP evaluation and authorisation. In the interests of enhancing co-ordination and efficiency within the zones, as well as transparency, **Member States** should set these out in guidance and publish that guidance.

Perhaps more importantly, given that EU law relating to the precautionary principle may be unclear and therefore causing inconsistent application, the **Commission** is encouraged to develop (and publish) guidance to clarify, perhaps on the basis of such research as suggested above, how the precautionary principle should be interpreted and applied in the context of PPP evaluations and authorisations.

Both **Member States** and the **Commission** are encouraged, in drawing up such guidance, to consult with wider stakeholders and/or relevant PIGs with the aim of enhancing both the transparency and quality of the guidance.

As with the precautionary principle, further empirical research is recommended to developed a greater understanding of the role sustainability (including its various interpretations) plays in PPP evaluation and authorisation. Such research should again involve a systematic, qualitative and comparative review of national authorisation decisions and would inform efforts to clarify the interpretation of sustainability and its role (if any) in decision-making, including the following recommendations.

The **Commission** is encouraged to develop and publish guidance clarifying whether Member States are required to take sustainability into account during evaluation and authorisation procedures. If Member States are so required, the **Commission** is further encouraged to clarify how sustainability is to be interpreted and applied in order to ensure consistent and predictable decision-making.

The Netherlands reported that it was working towards a framework for sustainable agriculture and that results of its experiments would be shared. The **Commission**, **EFSA** and other **Member States** are encouraged to review and consider seriously any findings or recommendations the Netherlands makes.

Member States are also encouraged to collaborate at zonal and inter-zonal level to decide upon a harmonised interpretation and method of application of sustainability in the context of PPP authorisation. In the interests of enhancing co-ordination and efficiency within the zones, as well as transparency, **Member States** should set these out in guidance and publish that guidance.

Both **Member States** and the **Commission** are encouraged, in drawing up such guidance, to consult with wider stakeholders including relevant public interest groups with the aim of enhancing both the transparency and quality of the guidance.

In order to encourage a more ambitious application of the substitution principle, the **Commission** is advised to develop or commission and publish guidance for conducting optional comparative assessment under Article 50(2) PPPR.

Substitution and comparative assessment are still novel and may have unintended consequences. Further research is therefore recommended to investigate the effects of these new provisions and whether substitution is in fact reducing risks from PPPs. Furthermore, given the novelty of these provisions, it may be wise to allow for a few more years of experience before embarking on such research.

Hanssen et al. have made recommendations for promoting substitution. These include increasing the availability of data about toxicity, chemical composition and technical functionality; developing green chemistry and providing helpdesk functions, for example technical help from experts (Hansson, Molander and Rudén, 2011, pp.457–458). The **Commission** and/or **Member States** may wish to consider investigating and developing one or more of these initiatives.

Bibliography

Abbot, C. and Lee, M., 2015. Economic Actors in EU Environmental Law. Yearbook of European Law, p.1.

Abelkop, A.D.K. and Graham, J.D., 2014. Principles and tools of chemical regulation: a comment on 'the substitution principle in chemical regulation: a constructive critique'. Journal of Risk Research, 17(5), pp.581–586.

Anderson, C., 2014. Contrasting models of EU administration in judicial review of risk regulation. Common Market Law Review, 51(2), pp.425–454.

ANSES, 2015. Press Kit: New missions for ANSES in the area of plant protection products, fertilisers and growing media.

ANSES, n.d. Charte relative aux relations avec les porteurs d'intérêt dans le cadre de l'instruction des dossiers d'intrants du végétal.

Aven, T., 2014. The substitution principle in chemical regulation: a constructive critique, by Ragnar Löfstedt. Journal of Risk Research, 17(5), pp.569–571.

Ayres, I. and Braithwaite, J., 1992. *Responsive regulation: transcending the deregulation debate*. Oxford socio-legal studies. New York ; Oxford: Oxford University Press.

Baldwin, R., 1996. Regulatory legitimacy in the European context: the British Health and Safety Executive. In: G. Majone, ed., *Regulating Europe.* London ; New York: Routledge.

Barnard, C. and Peers, S., 2014. Introduction. In: C. Barnard and S. Peers, eds., *European Union Law*. Oxford, United Kingdom: OUP.

Bloomfield, D., Collins, K., Fry, C. and Munton, R., 2001. Deliberation and Inclusion: Vehicles for Increasing Trust in UK Public Governance? Environment and Planning C: Government and Policy, 19(4), pp.501–513.

Bosselmann, K., 2008. *The principle of sustainability: transforming law and governance*. Aldershot, England ; Burlington, VT: Ashgate.

Bozzini, E., 2017. *Pesticide policy and politics in the European Union*. S.l.: Springer International Publishing.

Buonsante, V.A. and Friel, A., 2017. What is Information Relating to Emissions into the Environment? European Journal of Risk Regulation, 8(2), pp.453–460.

Burton, M., 2013. Doing empirical research: Exploring the decision-making of magistrates and juries. In: D. Watkins and M. Burton, eds., *Research methods in law*. Oxfordshire, England ; New York, London: Routledge.

BVL, 2012. Authorisation procedure for plant protection products.

Carpenter, D.P. and Moss, D.A., 2014a. Introduction. In: D.P. Carpenter and D.A. Moss, eds., *Preventing regulatory capture: special interest influence and how to limit it*. New York: Cambridge University Press.

Carpenter, D.P. and Moss, D.A. eds., 2014b. *Preventing regulatory capture: special interest influence and how to limit it*. New York: Cambridge University Press.

Carr, S., 2003. New Biotechnology, Crop Protection and Sustainable Development. In: F. den Hond, P. Groenewegen and N. van Straalen, eds., *Pesticides: Problems, Improvements, Alternatives*. Blackwell.

Christiansen, J.G., 2011. Competing theories of regulatory governance: reconsidering public interest theory of regulation. In: D. Levi-Faur, ed., *Handbook on the politics of regulation*. Cheltenham, UK ; Northampton, MA, USA: Edward Elgar.

Commission, 2000. Communication on the precautionary principle COM(2000) 1 final.

Commission, 2001a. A Sustainable Europe for a Better World: A European Union Strategy for Sustainable Development COM/2001/0264 final.

Commission, 2001b. European Governance: A White Paper COM(2001) 428 final.

Commission, 2009. Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report SANCO/6895/2009 rev 1.

Commission, 2014a. Draft Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009 SANCO/11507/2013 rev. 12.

Commission, 2014b. Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 SANCO/13169/2010 rev. 9.

Commission, A Thematic Strategy on the Sustainable Use of Pesticides COM(2006) 372 Final.

Commission, Next Steps for a Sustainable European Future: European Action for Sustainability COM(2016) 739 Final.

Commission, 2017. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products SANTE-10832-2015 rev. 1.7.

Commission, Towards a Thematic Strategy on the Sustainable Use of Pesticides COM(2002) 349 Final.

Commission, White Paper on Food Safety COM(1999) 719 Final.

Council of the European Union, 2006. *Renewed EU Sustainable Development Strategy*.

Craig, P. and De Búrca, G., 2015. *EU law: text, cases and materials*. 6th edn ed. OUP.

Cukierman, A., Webb, S.B. and Neyapti, B., 1992. Measuring the Independence of Central Banks and Its Effect on Policy Outcomes. The World Bank Economic Review, 6(3), pp.353–398.

Deighton-Smith, R., 2004. Regulatory Transparency in OECD Countries: Overview, Trends and Challenges. Australian Journal of Public Administration, 63(1), pp.66–73.

Demarigny, F., 1996. Independent administrative authorities in France and the case of the French Council for Competition. In: G. Majone, ed., *Regulating Europe*. London ; New York: Routledge.

DG SANTE, 2015. Final Report of an Audit Carried out in Greece to Evaluate Controls on the Marketing and Use of Plant Protection Products. European Commission.

DG SANTE, 2016a. Final Report of an Audit Carried out in Germany to Evaluate the System for Authorisation of Plant Protection Products. European Commission.

DG SANTE, 2016b. Final Report of an Audit Carried out in Italy to Evaluate Controls on the Marketing and Use of Plant Protection Products. European Commission.

DG SANTE, 2016c. Final Report of an Audit Carried out in Lithuania to Evaluate the System for Authorisation of Plant Protection Products. European Commission.

DG SANTE, 2016d. Final Report of an Audit Carried out in Luxembourg to Evaluate the System for Authorisation of Plant Protection Products. European Commission.

DG SANTE, 2016e. Final Report of an Audit Carried out in Portugal to Evaluate the System for Authorisation of Plant Protection Products. European Commission.

DG SANTE, 2016f. Final Report of an Audit Carried out in the United Kingdom to Evaluate the System for Authorisation of Plant Protection Products. European Commission.

DG SANTE, 2017. *Overview Report: Authorisation of Plant Protection Products*. EUR-OP.

Dudley, S.E., 2013. Comment on Löfstedt's 'The substitution principle in chemical regulation: a constructive critique'. Journal of Risk Research, pp.1–5.

Dudley, S.E. and Wegrich, K., 2016. The role of transparency in regulatory governance: comparing US and EU regulatory systems. Journal of Risk Research, 19(9), pp.1141–1157.

EFSA Panel on Plant Protection Products and their Residues (PPR), 2012. Guidance on Dermal Absorption: Guidance on Dermal Absorption. EFSA Journal, 10(4), p.2665.

EGSG, 2007. *Taking European Knowledge Society Seriously*. Luxembourg: EUR-OP.

Einsiedel, E.F., Jelsøe, E. and Breck, T., 2001. Publics at the technology table: The consensus conference in Denmark, Canada, and Australia. Public Understanding of Science, 10(1), pp.83–98.

EPPO, 2015. PP 1/271 (2) Guidance on comparative assessment. EPPO Bulletin, 45(3), pp.388–391.

Everson, M., 1995. Independent Agencies: Hierarchy Beaters? European Law Journal, 1(2), p.180.

Faust, M., Vogs, C., Rotter, S., Wöltjen, J., Höllrigl-Rosta, A., Backhaus, T. and Altenburger, R., 2014. Comparative assessment of plant protection products: how many cases will regulatory authorities have to answer? Environmental Sciences Europe, 26, p.11.

Ferretti, M.P., 2007. Why Public Participation in Risk Regulation? The Case of Authorizing GMO Products in the European Union. Science as Culture, 16(4), pp.377–395.

Fiorino, D.J., 1990. Citizen Participation and Environmental Risk: A Survey of Institutional Mechanisms. Science, Technology, & Human Values, 15(2), pp.226–243.

Fisher, E., 2002. Precaution, precaution everywhere: Developing a Common Understanding of the Precautionary principle in the European Community. Maastricht Journal of European and Comparative Law, 9, p.7.

Fisher, E., 2009. Opening Pandora's box: contextualising the precautionary principle in the European Union. In: M. Everson and E. Vos, eds., *Uncertain Risks Regulated*. Abingdon: Routledge-Cavendish.

Fisher, E., 2010. Transparency and Administrative Law: A Critical Evaluation. Current Legal Problems, 63(1), pp.272–314.

Fisher, E., Lange, B., Scotford, E. and Carlarne, C., 2009. Maturity and Methodology: Starting a Debate about Environmental Law Scholarship. Journal of Environmental Law, 21(2), pp.213–250.

FPS-PHFCSE and SPPPF, 2016. Guidance for the Applicant of an Authorisation of a Plant Protection Product.

Giddens, A., 2013. *The Consequences of Modernity*. Oxford: Wiley.

Gilardi, F., 2001. Policy Credibility and Delegation of Regulatory Competencies to Independent Agencies: A Comparative Empirical Consideration. [online] Available at: <https://www.researchgate.net/publication/228773015_Policy_credibility_and_delegation_of_regulatory_competencies_to_independent_agencies_a_comparative_empirical_consideration> [Accessed 2 Jan. 2018].

Gilardi, F., 2005. The Institutional Foundations of Regulatory Capitalism: The Diffusion of Independent Regulatory Agencies in Western Europe. The ANNALS of the American Academy of Political and Social Science, 598(1), pp.84–101.

Gilardi, F. and Maggetti, M., 2011. The Independence of Regulatory Authorities. In: D. Levi-Faur, ed., *Handbook on the politics of regulation*. Cheltenham, UK ; Northampton, MA, USA: Edward Elgar.

Girling, J., 2014. Commentary on the Löfstedt substitution paper. Journal of Risk Research, 17(5), pp.593–595.

Gönenç, R., Maher, M. and Nicoletti, G., 2000. The Implementation and the Effects of Regulatory Reform. OECD Economics Department Working Papers 251.

Government of Romania, 2013. Decision approving the National Action Plan for mitigating the risks related to the use of plant protection products. (2013) Official Gazette of Romania PART I, No 585

Graham, C., 1998. Is There A Crisis In Regulatory Accountability? In: R. Baldwin, C. Scott and C. Hood, eds., *A Reader on Regulation*. Oxford University Press, pp.482–516.

Groenleer, M., 2011. Regulatory governance in the European Union: the political struggle over committees, agencies and networks. In: D. Levi-Faur, ed., *Handbook on the politics of regulation*. Cheltenham, UK ; Northampton, MA, USA: Edward Elgar.

Hamlyn, O., 2015. Sustainability and the Failure of Ambition in European Pesticides Regulation. Journal of Environmental Law, 27(3), p.405.

Hansen, S.F., Carlsen, L. and Tickner, J.A., 2007. Chemicals regulation and precaution: does REACH really incorporate the precautionary principle. Environmental Science & Policy, 10(5), pp.395–404.

Hansson, S.O., Molander, L. and Rudén, C., 2011. The substitution principle. Regulatory Toxicology and Pharmacology, 59(3), pp.454–460.

Hellebø Rykkja, L., 2004. Independent Food Agencies – Restoring Confidence. Policy and Society, 23(4), pp.125–148.

Heyvaert, V., 2001. Balancing Trade and Environment in the European Union: Proportionality Substituted? Journal of Environmental Law, 13(3), pp.392–407.

Hofmann, H.C.H., 2014. General Principles of EU Law and EU Administrative Law. In: C. Barnard and S. Peers, eds., *European Union law*. Oxford, United Kingdom: Oxford University Press.

Hood, C., Rothstein, H. and Baldwin, R., 2001. *The government of risk: understanding risk regulation regimes*. Oxford: Oxford University Press.

Jarvis, D.S.L. and Sovacool, B.K., 2011. Conceptualizing and evaluating best practices in electricity and water regulatory governance. Energy, 36(7), pp.4340–4352.

Jasanoff, S., 1990. *The fifth branch: science advisers as policymakers*. Cambridge, Mass. ; London: Harvard UP.

Jasanoff, S., 2006. Transparency in Public Science: Purposes, Reasons, Limits. Law and Contemporary Problems, 69(3), pp.21–45.

Johannsen, K.S., 2003. Regulatory Independence in Theory and Practice – a Survey of Independent Energy Regulators in Eight European Countries. AKF Forlaget.

Krebs, J., 2004. Establishing a Single, Independent Food Standards Agency: The United Kingdom's Experience. Food and Drug Law Journal, 59, pp.387–398.

Kwak, J., 2014. Cultural capture and the financial crisis. In: D.P. Carpenter and D.A. Moss, eds., *Preventing regulatory capture: special interest influence and how to limit it*. New York: Cambridge University Press.

La Porte, T.R. and Metlay, D.S., 1996. Hazards and Institutional Trustworthiness: Facing a Deficit of Trust. Public Administration Review, 56(4), pp.341–347.

Larsen, A., Pedersen, L.H., Sørensen, E.M. and Olsen, O.J., 2006. Independent regulatory authorities in European electricity markets. Energy Policy, 34(17), pp.2858–2870.

Lee, M., 2008. *EU Regulation of GMOs: Law and Decision Making for a New Technology*. Edward Elgar.

Lee, M., 2014a. *EU Environmental Law, Governance and Decision-Making*. 2nd ed ed. Hart.

Lee, M., 2014b. The Legal Institutionalisation of Public Participation in the EU Governance of Technology. [online] Rochester, NY: SSRN. Available at: <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2461145> [Accessed 25 Jan. 2018].

Lenaerts, K., 2004. 'In the Union we trust': Trust-enhancing principles of Community law. Common Market Law Review, 41(2), pp.317–343.

Lodge, M. and Stirton, L., 2001. Regulating in the Interest of the Citizen: Towards a Single Model of Regulatory Transparency? Social and Economic Studies, 50(2), pp.103–137.

Löfstedt, R., 2004. Risk Communication and Management in the Twenty-First Century. International Public Management Journal, 7(3), p.335.

Löfstedt, R., 2005. *Risk Management in Post-trust Societies*. Houndmills, Basingstoke, Hampshire ; New York: Palgrave Macmillan.

Löfstedt, R., 2006. The Post-Trust World. Pharmaceutical Executive, 26(12), pp.114–114.

Löfstedt, R., 2014. The substitution principle in chemical regulation: a constructive critique. Journal of Risk Research, 17(5), pp.543–564.

Lohse, J., Lundie, S., Ahrens, A., Wirts, M. and Liner, L., 2003. Never Change a Running Process? Substitution of Hazardous Chemicals in Products and Processes: Definition, Key Drivers and Barriers. Greener Management International, 2003(41), pp.56–76.

Majone, G. ed., 1996. *Regulating Europe*. London ; New York: Routledge.

McCarty, N., 2014. Complexity, capacity, and capture. In: D.P. Carpenter and D.A. Moss, eds., *Preventing regulatory capture: special interest influence and how to limit it*. New York: Cambridge University Press.

Meir, C. and Williamson, S., 2005. Farmer Decision-making for Ecological Pest Management. In: J. Pretty, ed., *The Pesticide Detox: Towards a More Sustainable Agriculture*. London ; Sterling, VA: Earthscan.

Mitnick, B.M., 1980. *The Political Economy of Regulation: Creating, Designing, and Removing Regulatory Forms*. New York: Columbia University Press.

Morgan, B. and Yeung, K., 2007. *An introduction to law and regulation: text and materials*. Cambridge, UK ; New York: Cambridge University Press.

Northern zone, 2017. Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Version 6.0.

Öberg, T., 2014. Substitution of chemicals based on assessment of hazard, risk and impact. Journal of Risk Research, 17(5), pp.565–568.

OECD, 2013. Principles for the Governance of Regulators: Public Consultation Draft. OECD.

OECD, 2016. *The Governance of Regulators' Practices: Accountability, Transparency and Co-ordination*. Paris, FRANCE: OECD Publishing.

Paehlke, R., 2002. Sustainability, Sustainable Development, and Values. In: J.M. Gillroy and J. Bowersox, eds., *The Moral Austerity of Environmental Decision Making: Sustainability, Democracy, and Normative Argument in Policy and Law*. Durham ; London: Duke UP.

Pallemaerts, M., 2013. Developing More Sustainably? In: A. Jordan and C. Adelle, eds., *Environmental Policy in the EU: Actors, Institutions and Processes*, 3rd ed. London ; New York: Routledge.

Parkins, J. and Mitchell, R., 2005. Public Participation as Public Debate: A Deliberative Turn in Natural Resource Management. Society & Natural Resources, 18(6), pp.529–540.

Pedersen, O.W., 2014. The Limits of Interdisciplinarity and the Practice of Environmental Law Scholarship. Journal of Environmental Law, 26(3), pp.423–441.

Peers, S., 2014. The EU's Political Institutions. In: C. Barnard and S. Peers, eds., *European Union law*. Oxford, United Kingdom: Oxford University Press.

Pesendorfer, D., 2011. Risk regulation and precaution. In: D. Levi-Faur, ed., *Handbook on the politics of regulation*. Cheltenham, UK ; Northampton, MA, USA: Edward Elgar.

Peters, R.G., Covello, V.T. and McCallum, D.B., 1997. The Determinants of Trust and Credibility in Environmental Risk Communication: An Empirical Study. Risk Analysis, 17(1), p.43.

Pretty, J., 2005. Preface. In: J. Pretty, ed., The Pesticide Detox: Towards a More Sustainable Agriculture. London ; Sterling, VA: Earthscan.

Ross, A., 2009. Modern Interpretations of Sustainable Development. Journal of Law and Society, 36(1), p.32.

Rothstein, H., Irwin, A., Yearley, S. and McCarthy, E., 1999. Regulatory Science, Europeanization, and the Control of Agrochemicals. Science, Technology & Human Values, 24(2), pp.241–264.

Royal Society, 1992. *Risk: analysis, perception and management*. London: Royal Society.

de Sadeleer, N., 2006. The Precautionary Principle in EC Health and Environmental Law. European Law Journal, 12(2), pp.139–172.

Scharpf, F.W., 1999. *Governing in Europe: effective and democratic?* Oxford: Oxford University Press.

Schauer, F., 2011. Transparency in three dimensions. University of Illinois Law Review, 2011(4), pp.1339–1358.

Schwarcz, D., 2014. Preventing capture through consumer empowerment programs: some evidence from insurance regulation. In: D.P. Carpenter and D.A. Moss, eds., *Preventing regulatory capture: special interest influence and how to limit it*. New York: Cambridge University Press.

Scott, J. and Vos, E., 2002. The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO. In: C. Joerges and R. Dehousse, eds., *Good Governance in Europe's Integrated Market*. Oxford University Press, pp.253–286.

Sexton, K., 1999. Setting Environmental Priorities: Is Comparative Risk Assessment the Answer? In: K. Sexton, A.A. Marcus, K.W. Easter and T.D. Burkhardt, eds., *Better Environmental Decisions: Strategies for Governments, Businesses, and Communities*. Island Press.

Shapiro, M., 1992. The Giving Reasons Requirement. University of Chicago Legal Forum, 1992, pp.179–220.

Shapiro, M., 1997. The problems of independent agencies in the United States and the European Union. Journal of European Public Policy, 4(2), pp.276–277.

Slovic, P., 1997. Trust, Emotion, Sex, Politics, and Science: Surveying the Risk Assessment Battlefield. University of Chicago Legal Forum, 1997, pp.59–100.

Smith, G. and Wales, C., 2000. Citizens' Juries and Deliberative Democracy. Political Studies, 48(1), pp.51–65.

Smith, W., 1997. Utility Regulators – The Independence Debate. Public Policy for the Private Sector, Note No. 127.

SPA, n.d. Application for Authorisation of a New Plant Protection Product in Compliance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council - with the Czech Republic as the Zonal Rapporteur Member State. Available at: <http://eagri.cz/public/web/file/130398/APPLICATION_FOR_AUTHORISATION_OF_A_NEW_PLANT_PROTECTION_PRODUCT___CZ_ACTING_AS_ZRMS.pdf> [Accessed 27 Dec. 2017].

Stallworthy, M., 2008. *Understanding Environmental Law*. London: Sweet & Maxwell.

Steele, J., 2001. Participation and Deliberation in Environmental Law: Exploring a Problem-solving Approach. Oxford Journal of Legal Studies, 21(3), pp.415–442.

Stern, J., 1997. What makes an independent regulator independent? Business Strategy Review, 8(2), p.67.

Stern, J. and Holder, S., 1999. Regulatory governance: criteria for assessing the performance of regulatory systems: An application to infrastructure industries in the developing countries of Asia. Utilities Policy, 8(1), pp.33–50.

Stigler, G.J., 1971. The Theory of Economic Regulation. The Bell Journal of Economics and Management Science, 2(1), pp.3–21.

Stilgoe, J., Irwin, A. and Jones, K., 2006. *The received wisdom: opening up expert advice*. London: Demos.

Stirling, A., 2001. The precautionary principle in science and technology. In: T. O'Riordan, J. Cameron and A. Jordan, eds., *Reinterpreting the Precautionary Principle*. London: Cameron May.

Stirling, A., 2005. Opening Up or Closing Down? Analysis, Participation and Power in the Social Appraisal of Technology. In: M. Leach, I. Scoones and B. Wynne, eds., *Science and Citizens: Globalization and the Challenge of Engagement, Claiming citizenship : rights, participation, and accountability*. London ; New York: Zed Books.

Stirling, A., 2008. 'Opening Up' and 'Closing Down': Power, Participation, and Pluralism in the Social Appraisal of Technology. Science, Technology & Human Values, 33(2), pp.262–294.

Stokes, E., 2008. The EC courts' contribution to refining the parameters of precaution. Journal of Risk Research, 11(4), pp.491–507.

Sunley, R. and van Opstal, N., 2010. EPPO Workshop on Comparative Assessment in the framework of substitution: a summary of the conclusions and recommendations. EPPO Bulletin, 40, pp.101–104.

Thatcher, M., 1998. Institutions, regulation, and change: New regulatory agencies in the British privatised utilities. West European Politics, 21(1), pp.120–147.

Thatcher, M., 2002a. Delegation to Independent Regulatory Agencies: Pressures, Functions and Contextual Mediation. West European Politics, 25(1), pp.125–147.

Thatcher, M., 2002b. Regulation after delegation: independent regulatory agencies in Europe. Journal of European Public Policy, 9(6), pp.954–972.

Thatcher, M. and Stone Sweet, A., 2002. Theory and Practice of Delegation to Non-Majoritarian Institutions. West European Politics, 25(1), pp.1–22.

UK Royal Society of Chemistry, 2007. Exploring the Practical Aspects of Chemical Substitution. Royal Society of Chemistry.

United Nations, 2015. Transforming our World: The 2030 Agenda for Sustainable Development A/RES/70/1.

Vos, E., 2000. EU Food Safety Regulation in the Aftermath of the BSE Crisis. Journal of Consumer Policy, 23(3), pp.227–255.

Vos, E., 2005. Independence, Accountability and Transparency of European Regulatory Agencies. In: D. Geradin, R. Muñoz and N. Petit, eds., *Regulation through Agencies in the EU: A New Paradigm of European Governance*. Edward Elgar Publishing, pp.120–137.

Wagner, W.E., 2010. Administrative law, filter failure, and information capture. Duke Law Journal, 59(7), pp.1321–1432.

Weale, A., 1996. Environmental Regulation and Administrative Reform in Britain. In: G. Majone, ed., *Regulating Europe*. London ; New York: Routledge.

World Commission on Environment and Development, 1987. *Our common future*. Oxford paperbacks. Oxford ; New York: OUP.

Wynne, B., 1989. Understanding public risk perception. In: A. Saltelli, D. Stanners and M. D'Alessandro, eds., *Risk Analysis in Nuclear Waste Management*. Kluwer Academic Publishers.

Wynne, B., 1992a. Misunderstood misunderstanding: social identities and public uptake of science. Public Understanding of Science, 1(3), pp.281–304.

Wynne, B., 1992b. Risk and Social Learning: Reification to Engagement. In: S. Krimsky and D. Golding, eds., *Social Theories of Risk*. Praeger, pp.275–297.

Wynne, B., 1992c. Uncertainty and environmental learning: Reconceiving science and policy in the preventive paradigm. Global Environmental Change, 2(2), pp.111–127.

Wynne, B., 2001. Creating Public Alienation: Expert Cultures of Risk and Ethics on GMOs. Science as Culture, 10(4), pp.445–481.

Wynne, B., 2006. Public Engagement as a Means of Restoring Public Trust in Science - Hitting the Notes, but Missing the Music? Community Genetics, 9(3), pp.211–220.

Yackee, S.W., 2014. Reconsidering agency capture during regulatory policymaking. In: D.P. Carpenter and D.A. Moss, eds., *Preventing regulatory capture: special interest influence and how to limit it*. New York: Cambridge University Press.

Yeung, K., 2005. Government by publicity management: sunlight or spin? Public Law, pp.360–383.

Zingales, L., 2014. Preventing economists' capture. In: D.P. Carpenter and D.A. Moss, eds., *Preventing regulatory capture: special interest influence and how to limit it*. New York: Cambridge University Press.

EU case law

Case C-473/98 *Kemikalieinspektionen v Toolex Alpha* AB [2000] ECR I-05681

Case T-13/99 *Pfizer Animal Health SA v Council* [2002] ECR II-3305

Case T-70/99 *Alpharma v Council* [2002] ECR II-3495

Cases T-74/00, T-76/00 and T-141/00 *Artegodan v Commission* [2002] ECR II-4945

C-121/00 *Hahn* ECR I-9193

Case C-236/01 *Monsanto Agricoltura Italia SpA v Presidenza del Consiglio dei Ministri* [2003] ECR I-8105

Case T-229/04 *Sweden v Commission (Paraquat)* [2007] ECR II-02437

Cases C-39 and 52/05 P *Sweden and Turco v Council* [2008] ECR I-4723

Case C-77/09 *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute* [2010] ECR I-13533

Case C-343/09 *Afton Chemical Limited v Secretary of State for Transport* [2010] ECR I-7027, Opinion of AG Kokott

Case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe* EU:C:2016:889

C-442/14 *Bayer CropScience and Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden* (ECLI:EU:C:2016:890)

EU legislation

Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances [1979] OJ L33/36

Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1991] OJ L230/1

Declaration No 17 on the right of access to information, annexed to the Final Act of the Treaty on European Union [1992] OJ C191/101

European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms [2001] OJ L106/1

European Parliament and Council Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L145/43

European Parliament and Council Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1

European Parliament and Council Directive 2003/4/EC on public access to environmental information [2003] OJ L41/26

European Parliament and Council Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment [2003] OJ L156/17

European Parliament and Council Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [2006] OJ L33/1

European Parliament and Council Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L309/71

European Parliament and Council Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market [2009] OJ L309/1

Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products [2011] OJ L155/127