

# Confidentiality in EU Pesticide Risk Assessment: A Violation of the Aarhus Convention?

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*Master thesis in environmental law*

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## 1. Introduction

The widespread use of pesticides<sup>1</sup> entails risks for humans and the environment. Research has shown that pesticides have a major effect on biodiversity in Europe.<sup>2</sup> To prevent unwanted and unforeseen environmental effects, risk assessment (hereafter: RA) is a vital step in protecting human health and the environment. RA is therefore a key component of EU law on chemicals.<sup>3</sup> The RA process for plant protection products and their active substances are specified in EU law. The recently adopted Regulation 1107/2009 on the registration of plant protection products<sup>4</sup> (hereafter: RPPP) is explicitly underpinned by the precautionary principle. Industry has to demonstrate that pesticides “do not have any harmful effects on human or animal health or any unacceptable effects on the environment”.<sup>5</sup> Thus, the burden of proof regarding the safety of a pesticide lies with the producers.<sup>6</sup>

However, there has been fierce criticism by environmental NGO's on the functioning and independence of the RA procedure under the RPPP. It is said that the RA procedure lacks independence and may be easily influenced by the pesticide producer who is responsible for carrying out the RA tests.<sup>7</sup> Consequently, the RA data submitted in the approval procedure may be biased. In the European Parliament similar concerns have been voiced.<sup>8</sup> In addition, some argue that the European Food and Safety Authority (hereafter: EFSA), insufficiently reviews the RA studies, potentially due to conflicts of interests and links with the industry.<sup>9</sup> Recently, the European Ombudsman decided that EFSA had failed to reply effectively to complaints on various conflicts of interests amongst members of an EFSA working group.<sup>10</sup>

Transparency is an important prerequisite for the public's trust in RA. Disclosure of RA information allows for public review, thereby potentially contributing to sound and objective RA. However, access to pesticide RA data is often limited by the protection and confidentiality of business information and property rights.<sup>11</sup> Hence, environmental NGO's criticise the EU pesticide registration process as being insufficiently transparent and open to review by independent researchers and other interested parties.<sup>12</sup>

EFSA recently addressed the complex dilemma of transparency on the one hand, and the protection of confidential information on the other. EFSA is aware of the demand for more

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<sup>1</sup> Under EU law, rather than speaking of pesticides in general one should distinct between "active substances" (the active component) and "plant protection products" (the final product placed on the national market). However, in this paper the term "pesticide" refers to both active substances as well as plant protection products, unless indicated otherwise.

<sup>2</sup> Geiger et al. 2010, p. 97-105.

<sup>3</sup> Environment, Health and Safety Committee 2008, p. 3.

<sup>4</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EECL (*OJ* 2009, L 309/1).

<sup>5</sup> Art. 1(4) RPPP and preamble par. 8.

<sup>6</sup> For example see: Commission answer on Parliamentary Question E-007546/2011.

<sup>7</sup> Robinson 2011; PAN Europe 2012a; PAN Europe 2012b.

<sup>8</sup> For example see: Parliamentary Question E-007546/2011.

<sup>9</sup> Corporate Europe Observatory 2011; Corporate Europe Observatory 2012; Robinson 2011; PAN Europe 2012b; European Court of Auditors 2012, p. 11; Horel & Corporate Observatory 2013. Similar criticism has been voiced in the European Parliament (Peter, *BBC News* 10 May 2012), which postponed its approval of EFSA's accounts for 2010 due to an unsatisfactory management of conflict of interest (European Parliament 2012). In response see: EFSA 2012a. More generally, authorities are often regarded by the public to have close links with the chemical industry (Gouldson 2004, p. 141).

<sup>10</sup> European Ombudsman 27 March 2014 in case nr. 2522/2011/(VIK)CK against EFSA.

<sup>11</sup> Art. 63 RPPP.

<sup>12</sup> Robinson 2011, p. 9; PAN Europe 2012a, p. 9; Corporate Europe Observatory 2013.

transparency in the scientific decision-making process.<sup>13</sup> Bernhard Url, Deputising Executive Director at EFSA, stresses that transparency is intimately linked to trust in the RA process.<sup>14</sup> Therefore, EFSA plans to adopt a new policy on openness and transparency by December 2014, addressing the controversial topic of access to pesticide RA data.<sup>15</sup>

Anticipating these developments, this paper will discuss the right to access to pesticide RA data from a legal perspective, with a particular focus on the Aarhus Convention of which the EU and the Member States are signing parties.<sup>16</sup> The discussion on the functioning of the pesticide RA often takes place in the field of natural sciences. This paper, on the other hand, will focus on a procedural requirement of sound RA: the right to environmental information. The following two research questions will be addressed:

- 1. Does the right to access to RA pesticide data under EU law comply with the passive right to environmental information in the Aarhus Convention?<sup>17</sup>*
- 2. If not, what changes to EU pesticide law could improve access to these RA data, while also taking account of pesticide industry's interests?*

First, § 2 will explain the function of environmental RA, the need for public participation in risk management and transparency in RA, and define the right to environmental information. § 3 will outline the registration procedure in EU plant protection product law (hereafter: EU pesticide law). § 4 will discuss the lack of transparency in pesticide RA by referring to the registration of ‘imidacloprid’, a substance belonging to the controversial neonicotinoid pesticides which have been linked to the worldwide decline in honeybees. § 5 will discuss which authorities may hold pesticide RA data and which authorities are competent to rule on a request to disclose such data. § 6 will outline the general EU rules on access to and confidentiality of environmental information, after which § 7 will discuss the specialized rules on access to information and confidentiality in EU food law. § 8 will outline the conflict between the specialized confidentiality regime in the RPPP and the Aarhus Convention. Finally, § 9 will briefly explore the various options to adapt EU pesticide law as to improve access to RA data, while also taking account of the industry's interest in keeping RA data confidential.

## **2. Environmental RA, public participation and the right to information**

The health and environmental risks of new products and processes are not always clear, nor easy to foresee. Environmental RA is a management tool that assists decision-makers in dealing with these risks. This section will first define the concept of RA, set out its objectives and counter the thesis that RA is a sole scientific exercise. Secondly, the procedural right of public participation as an essential element of sound risk management will be discussed. Thirdly, it will be argued that the right to environmental information, in particular RA data, is a prerequisite for public participation in risk management. Next, it will be explained what is understood by “the right to environmental

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<sup>13</sup>EFSA 2014a, p. 1.

<sup>14</sup> Radford 2013.

<sup>15</sup> EFSA 2014a, p. 2-3.

<sup>16</sup> Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters done at Aarhus, Denmark on 25 June 1998, 2161 UNTS 447; 38 ILM 517 (1999). For more on the Aarhus Convention and the right to information, see amongst others: Sands & Peel 2012, p. 652-655 and Pallemarts 2011.

<sup>17</sup> What is understood by the passive right to information will be discussed in §2.4.

information” in this paper. Last, the limitations of the right to environmental information in RA will be discussed, such as the protection of business interests and intellectual property rights.

### ***2.1.Environmental RA: definition, objectives and pitfalls***

Environmental risks relate to the possibility of environmental consequences of a certain product or activity and to uncertainty over the occurrence, magnitude, or timing of those consequences.<sup>18</sup> RA is a regulatory tool that is targeted at these environmental risks. RA is of great importance in EU food law. According to the General Principles of Food Law<sup>19</sup>, EU food law shall normally be based on risk analysis, which consists of three stages: *risk assessment*, risk management and risk communication.<sup>20</sup> Within EU pesticide law, RA should guarantee that the registration of new substances and plant protection products is in accordance with the health and environmental standards of the RPPP.<sup>21</sup> If a substance or product does not seem to comply with the EU safety standards, approval should be subjected to risk-reducing measures<sup>22</sup>, or, ultimately, denied.

Despite the absence of a common definition, RA may be defined as: a systematic process for describing and quantifying the risks associated with hazardous substances, processes, actions, or events.<sup>23</sup> It involves several stages: hazard identification, determining ways of exposure, assessment of the probability of harm and consequences, and an evaluation thereof.<sup>24</sup> An important aspect of RA is the requirement of a *systematic process*, meaning it requires a form of standardised procedure.<sup>25</sup> Thus, RA is not an arbitrary process that is shaped solely on a case-by-case basis.

In relation to pesticides, the US Environmental Protection Agency describes an ecological RA as follows:

*“In an ecological risk assessment, we evaluate the likelihood that exposure to one or more pesticides may cause harmful ecological effects. The effects can be direct [...], or indirect [...]. We determine the likelihood of harmful effects based on scientific measurements and on scientific judgement [...]. An ecological risk assessment employs the most current scientific methods to determine if a pesticide meets the requirements for registration and will not significantly harm wildlife.”*

The General Principles of Food Law refer to RA as “*a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation*”.<sup>26</sup> The RA shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. In the risk management stage, the RA results should be taken into account.<sup>27</sup> Thus, also within EU Food Law, RA should provide a sound scientific basis for risk management decisions.

Although the aims of RA are to be applauded, there has been discussion on whether it is effective in protecting the environment. The fact that an RA has been conducted, does not necessarily guarantee that a product is in conformity with EU environmental standards. If the RA is of a poor quality,

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<sup>18</sup> Covello & Merkhoher 1993, p. 3.

<sup>19</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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 (*OJ* 2002, L 31/1) (hereafter: General Principles of Food Law).

<sup>20</sup> Art. 6(1) and 3(10) General Principles of Food Law.

<sup>21</sup> See in particular art. 4 RPPP.

<sup>22</sup> Art. 6 RPPP.

<sup>23</sup> Covello & Merkhoher 1993, p. 3. For another definition, see: Stirling, Renn & Van Zwanenberg 2006, p. 286.

<sup>24</sup> Ball 2002, p. 529–544. De Sadeleer refers to RA as a four-step approach: 1) hazard identification, 2) dose-response assessment, 3) exposure assessment, and 4) risk characterization (De Sadeleer 2002, p. 181).

<sup>25</sup> De Sadeleer 2002, p. 181. Also see recital 18 of the Preamble of the RPPP.

<sup>26</sup> Art. 3(10) General Principles of Food Law.

<sup>27</sup> Art. 6(2) and (3) General Principles of Food Law.

potential environmental harm and infringements of environmental standards cannot be properly anticipated. “Science” is conventionally held to imply certain key properties, including a systematic methodology, scepticism, transparency, quality control by peer-review, professional independence and accountability, and an emphasis on learning.<sup>28</sup> However, the reliability of science has often been a point of discussion.<sup>29</sup> A poorly conducted RA may wrongly provide decision-makers with an environmental ‘thumbs up’ and a false feeling of scientific certainty. This may lead to infringements of environmental standards. For example, data bias can be seen as a recurrent, though avoidable, pitfall of RA.<sup>30</sup> Scientific conclusions may be influenced by strategic rhetoric and various forms of interests.<sup>31</sup> It is essential to the credibility of RA that the integrity of the professionals involved is maintained and that RA documents are thoroughly reviewed.<sup>32</sup> This bears even more weight if the applicant himself conducts most of the RA research, as is the case in EU pesticide law.<sup>33</sup> For example, in relation to the controversial pesticide “Roundup”, a Member of the EU Parliament asks:

*“Is using Monsanto’s own research data [...] a sound basis scientifically to proceed, given their vested interest and refusal to open test results to inspection in the scientific publication system? [...] Would not the correct scientific response be to repeat the work independently of Monsanto to see if the results are replicated?”*<sup>34</sup>

RA scientists may be tempted to abide to strict standardized and technical RA methods in order to ensure good quality, thereby limiting public involvement.<sup>35</sup> However, the narrow understanding of RA as a sole technical, analytical, and objective instrument, rather than a democratic one, has been criticised.<sup>36</sup> First of all, it is difficult to define what constitutes a sound RA method. Considering the great diversity in potential environmental hazards, no single RA tool can provide for all environmental decisions. There is extensive, and often conflicting, literature on what constitutes good RA practice.<sup>37</sup> Within one RA, scientists from different fields might disagree on the appropriate RA tools and standards. For instance, in the case of long-term effects of the introduction of GMO’s (genetically modified organisms), ecologists and biotechnologists used completely different RA methods. This even led the different disciplines to dismiss the relevance of each others’ findings.<sup>38</sup> Secondly, even if all researchers use one single methodology, they might come to very different conclusions because of their different scientific backgrounds<sup>39</sup> or differences in the framing of research questions and potential environmental risks.<sup>40</sup> Thus, a sole technocratic and scientific view on RA is problematic.<sup>41</sup>

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<sup>28</sup> Stirling 1999a, p. 5.

<sup>29</sup> McDonell 1999, p. 197-199.

<sup>30</sup> Ball 2002, p. 529– 544; O’Brien 2000, p. 27; De Sadeleer 2002, p. 184-185. With regard the environmental impact assessment (EIA) there is a similar risk of data bias: Lawrence 2003, p. 244.

<sup>31</sup> McDonell 1999, p. 199.

<sup>32</sup> De Sadeleer 2002, p. 194. The same can be said for EIA: Lawrence 2003, p. 244.

<sup>33</sup> Again there seems to be a parallel with EIA. In interviews with experts and practitioners from Lithuania “subjectivity in forecasting environmental effects” was ranked the number one shortcoming in environmental impact assessments. This bias was deemed to occur from the fact that EIA practitioners are hired by the developer, thus becoming financially dependent, or from the fact that the developer himself conducted the research (Kruopiene et al. 2008, p.30).

<sup>34</sup> For example see: Parliamentary Question E-007546/2011.

<sup>35</sup> Ball 2002, p. 529; Lee & Abbot 2003, p. 84.

<sup>36</sup> De Sadeleer 2002, p. 184; Peel 2006, p. 202-208.

<sup>37</sup> Ball 2002, p. 529.

<sup>38</sup> Von Schomberg 2006, p. 29-30.

<sup>39</sup> De Sadeleer 2002, p. 185 & 192-194; McDonell 1999, p. 199.

<sup>40</sup> Vaughan & Seifert 1992, p. 119-135.

<sup>41</sup> De Sadeleer 2002, p. 195.

## ***2.2. Public participation: an important aspect of risk management***

The thesis that RA is in essence a scientific procedure, implies that there is little room for public participation or scrutiny.<sup>42</sup> However, RA precedes the risk management stage of which public participation is an important component.<sup>43</sup> Research found that three key factors make risk management decisions acceptable to the public: 1) is the participation procedure acceptable for those who bear the consequences of the action or product?; 2) is there an acceptable rule of liability in case of undesired consequences?; 3) are the institutions who manage and regulate the technology worthy of trust?<sup>44</sup> The first factor shows that the public is only willing to rely on scientific evidence if certain participatory criteria are fulfilled.<sup>45</sup> In addition, inviting a broad range of perspectives in risk management may offset the tendency of experts and policymakers to overestimate the predictive value of science.<sup>46</sup> Public participation in environmental governance is said to improve the quality of the decisions by introducing a wide range of participants with different expertise and perspectives.<sup>47</sup> In addition, it may counter and capture corruption within the public regulatory authorities.<sup>48</sup> Furthermore, the electoral legitimacy of environmental decisions delegated to unelected experts is weak. Therefore, public participation could enhance the procedural legitimacy of risk management decisions.<sup>49</sup>

Strictly speaking, normative decisions should be made in the risk management stage, rather than in the RA stage. After all, RA is aimed at identifying and assessing risks, and not at determining the acceptability of those risks. Thus, one could argue that there is no need for public participation in RA. However, some scholars claim that public participation should be integrated into RA as well. Often the RA stage itself is characterized by uncertainty, different perceptions, and in fact does include value judgements as to which risks are “acceptable”.<sup>50</sup> Within EU pesticide law, the RA needs to establish that there is no *unacceptable* effect on the environment.<sup>51</sup> For example, a pesticide should not have *unacceptable* effects on honeybee colony survival.<sup>52</sup> Assessment of the significance and acceptability of risks involves not only technical matters, but also their social dimensions.<sup>53</sup> This requires a normative, rather than a mere scientific and technical approach.<sup>54</sup> In addition, some argue that in order to integrate the precautionary principle into the RA process, it is necessary to address principles of good governance, such as public participation.<sup>55</sup> Furthermore, the framing of the RA studies - e.g. how research questions and risks are formulated - may highly influence the RA research outcomes.<sup>56</sup> Thus, a sole technocratic view on RA can distract from its social and political dimensions.<sup>57</sup>

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<sup>42</sup> De Sadeleer 2002, p. 195.

<sup>43</sup> Stirling 1999a, p. 34-36; De Sadeleer, p. 184-185 & 195.

<sup>44</sup> McDonell 1999, p. 202.

<sup>45</sup> McDonell 1999, p. 202.

<sup>46</sup> Peel 2006, p. 207.

<sup>47</sup> Lee & Abbot 2003, p. 80-88.

<sup>48</sup> Ayres & Braithwaite 1992, p. 54-100 (chapter 3). Capture is seen as a recurring concern amongst the public regarding the relation between regulators and the chemical industry (Gouldson 2004, p. 141).

<sup>49</sup> Lee & Abbot 2003, p. 84.

<sup>50</sup> De Sadeleer 2002, p. 199; McDonell 1999, p. 202-203.

<sup>51</sup> Art. 4(3)(e) RPPP.

<sup>52</sup> Annex II, par. 3.8.3 RPPP.

<sup>53</sup> Peel 2006, p. 212-213.

<sup>54</sup> Von Schomberg 2006, p. 31-34; Peel 2006, p. 206-208.

<sup>55</sup> Stirling, Renn & van Zwanenberg 2006, p. 290-291.

<sup>56</sup> On the importance of risk framing in environmental law, see: Vaughan & Seifert 1992, p. 119-135.

<sup>57</sup> In this regard see: De Sadeleer 2002, p. 192-195, who advocates in favour of an interdisciplinary approach to RA, with a focus on both natural and social sciences, and broader public consultation. Also see: Stirling 1999b, p. 30; Peel 2006, p. 206-208.



### **2.3. The right to environmental information in RA**

Disclosure of environmental information can be a highly beneficial and cost-effective tool in environmental policy.<sup>58</sup> It is a relatively recent, but now established right in international environmental law.<sup>59</sup> It is closely connected to public participation in environmental decision-making<sup>60</sup>, and is said to contribute to public enforcement of environmental law, both through formal proceedings and through informal mechanisms, such as naming and shaming.<sup>61</sup> Furthermore, it is claimed to enhance the accountability of decision makers.<sup>62</sup> Moreover, the right to information is in line with the idea that those who are potentially exposed to harm, have the right to know about those activities and products.<sup>63</sup>

The right to information in RA may contribute to the quality of the risk governance process in several ways. First of all, it allows for informed public participation in the risk management stage. Public participation in risk management is hindered if the public has no access to the RA data which form the scientific basis for the risk management decisions. The close link between public participation and the right to information appears from several international environmental instruments, such as the Aarhus Convention, the Rio Declaration<sup>64</sup>, and Agenda 21.<sup>65</sup> It must be noted, however, that the right to environmental information is not the only relevant factor in creating public participation, nor is it always successful.<sup>66</sup> Non-legal factors like a lack of time, knowledge and money also affect public participation negatively.<sup>67</sup> Nonetheless, the right to information is an important starting point for effective public participation in risk governance.

Secondly, the right to RA information allows for the implementation of the precautionary principle in the risk management stage, by providing for an open appraisal of risk and scientific uncertainty.<sup>68</sup> Substantial scientific uncertainties should be addressed through explicit, normative

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<sup>58</sup> Sunstein 2002, p. 254-256. On the right to environmental information in international environmental law see: Sands & Peel 2012, p. 624-662 (chapter 15). For an overview of the advantages and disadvantages of the right to information in policy making in general, see: Birkinshaw 2006.

<sup>59</sup> Sands & Peel 2012, p. 648; Partan 1988, p. 43-88; Sand 2005, p. 17-27.

<sup>60</sup> Sands & Peel 2012, p. 648; Lee & Abbot 2003, p. 88; Gouldson 2004, p. 136-149; Gupta 2009, p. 9; Aarhus Implementation Guide 2013, p. 67.

<sup>61</sup> Lee & Abbot 2003, p. 88.

<sup>62</sup> Mason 2010, p. 14.

<sup>63</sup> See Gupta 2009, p. 9 for further references to literature on the aims and advantages of the right to environmental information.

<sup>64</sup> *“Environmental issues are best handled with participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available.”* (Principle 10 of the Rio Declaration on Environment and Development, Rio Janeiro, Brazil, 13 June 1992, UN Doc. A/CONF.151/26 (vol. I); 31 ILM 874 (1992)). For more on the Rio Declaration see amongst others: Porras 1992.

<sup>65</sup> *“One of the fundamental prerequisites for the achievement of sustainable development is broad public participation in decision-making. [...] Individuals, groups and organizations should have access to information relevant to environment and development held by national authorities, including information on products and activities that have or are likely to have a significant impact on the environment, and information on environmental protection measures.”* (par. 23.2 Agenda 21: Programme of Action for Sustainable Development, Rio, Brazil 14 June 1992, U.N. GAOR, 46th Sess., Agenda Item 21, UN Doc A/Conf.151/26 (1992)). Also see: Sands & Peel 2012, p. 44-45.

<sup>66</sup> For example critical on the question whether disclosure of environmental information indeed contributes to attaining desired environmental goals: Gupta 2008; Gupta 2009; Mason 2008.

<sup>67</sup> Heyvaert 2008, p. 21-22.

<sup>68</sup> De Sadeleer 2002, p. 192-193.

choices and not be left to the sole discretion of scientists.<sup>69</sup> Transparency allows for such an open appraisal of risk and scientific uncertainty, thereby contributing to the implementation of the precautionary principle.

Thirdly, transparency in the RA process facilitates public scrutiny and may help to reveal and avoid so-called “home-made, manufactured uncertainty” in relation to health or environmental effects of a product.<sup>70</sup> Examples are the manufactured scientific controversy on the health risks of asbestos<sup>71</sup> and tobacco.<sup>72</sup> If the producer carries out the RA tests or funds the RA-researchers, it is particularly important that the RA studies are open and transparent, thereby allowing for public scrutiny.<sup>73</sup> The infamous EU tobacco advertising affair illustrates how conflict of interest amongst scientists and governmental institutions, in combination with a general lack of transparency, may corrupt the legislative process.<sup>74</sup>

Last, the right to information contributes to public trust in RA.<sup>75</sup> In a white paper on food safety (2000) and on good governance (2001), the European Commission noted a lack of trust amongst the public in RA, scientific experts, and their independence in the field of food safety.<sup>76</sup> According to the Commission, risk communication is therefore a key element in food safety regulation. It requires scientific opinions to be made widely and rapidly available.<sup>77</sup> The establishment of EFSA at the time was supposed to increase transparency and public trust in food safety law.<sup>78</sup>

In sum, the right to environmental information is an important prerequisite for effective public participation, public scrutiny and the implementation of the precautionary principle in the risk management stage. Moreover, transparency may enhance public trust in RA.

#### ***2.4. The passive right to information in the Aarhus Convention***

The various international treaties and codes on access to environmental information do not contain a uniform definition of the right to environmental information.<sup>79</sup> In this paper “the right to information” is understood as the so-called *passive* right to information - the right to obtain information from public authorities - as defined by the Aarhus Convention. Within the EU the Aarhus Convention has been implemented through the Aarhus Directive (2003/4/EC)<sup>80</sup> in relation to Member States, and the

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<sup>69</sup> De Sadeleer 2002, p. 193. Gupta notes that disclosure on its own does not solve normative and political conflicts arising from scientific uncertainty in issue areas such as global warming or biotechnology (Gupta 2009, p. 7).

<sup>70</sup> Sand 2005, p. 18; Beck 1998, p. 12-13.

<sup>71</sup> Gee & Greenberg 2002, p. 52-63.

<sup>72</sup> Sand 2005, p. 25-26.

<sup>73</sup> De Sadeleer 2002, p. 194-195.

<sup>74</sup> US researchers documented various conflicts of interest amongst scientists and national public authorities (with Germany upfront) involved in establishing a European ban on tobacco advertising. More extensively on this affair: Sand 2005, p. 25-26.

<sup>75</sup> De Sadeleer 2002, p. 194-195; Gouldson 2004, p. 136-149.

<sup>76</sup> Commission White Paper, COM(1999) 719 final, p. 7-9; Commission White Paper, COM(2001) 428 final, p. 18-19.

<sup>77</sup> Commission White Paper, COM(1999) 719 final, p. 15.

<sup>78</sup> Commission White Paper, COM(2001) 428 final, p. 19. It was however deemed inappropriate that EFSA itself would carry out the RA, because this might dilute scientific transparency and democratic accountability (Commission White Paper, COM(1999) 719 final, p. 15).

<sup>79</sup> Gupta 2008, p. 2.

<sup>80</sup> Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (*OJ* 2003, L 41/26) (hereafter: Aarhus Directive).

Aarhus Regulation (No. 1367/2003)<sup>81</sup> in relation to EU public authorities. It follows from the case law of the European Court of Justice (ECJ) and EU General Court, that those instruments should be interpreted in conformity with the Aarhus Convention and even be set aside in case of a conflict.<sup>82</sup>

The Aarhus Convention is based on three inter-connected pillars: access to information, public participation, and access to justice in environmental matters. It contains minimum requirements, meaning that treaty parties may opt for broader protection on the national level.<sup>83</sup> Article 4 provides for a right to environmental information held by public authorities<sup>84</sup> without an interest having to be stated.<sup>85</sup> In line with the Aarhus Convention, in this paper, the right to information is understood broadly. It is a right for the general public<sup>86</sup> and includes information relating to substances affecting or likely<sup>87</sup> to affect “*the state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, [...] and the interaction among these elements*”.<sup>88</sup> Thus, environmental information includes all RA data, research and methods relevant to estimate effects of a pesticide on the elements of the environment.<sup>89</sup> It relates only to information held by public authorities<sup>90</sup>: it does not entail the right to gain information from private parties, such as the pesticide producers.<sup>91</sup>

The procedure for requesting environmental information can be found in article 4 of the Aarhus Convention as well. It does not specify the form of the request, thus implying that a request can both be oral or written.<sup>92</sup> The public authority shall either make the information available, or shall (partially) refuse to disclose the information, within one month after the receipt of the request. This period may be extended with one month in case of complex requests or a large quantity of information.<sup>93</sup> In principle, the information requested shall be made available in the form requested by

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<sup>81</sup> Regulation (EC) No 1367/2006 of the European Parliament and of the Council on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (*OJ* 2006, L 264/13) (hereafter: Aarhus Regulation).

<sup>82</sup> ECJ 18 July 2013, C-515/11, *not yet published* (*Deutsche Umwelthilfe eV v Bundesrepublik Deutschland*), par. 32 and General Court EU of 14 June 2012, T-338/08, *not yet published* (*Stichting Natuur en Milieu and Pesticide Action Network Europe v European Commission*), par. 51-59.

<sup>83</sup> Art. 3(5) Aarhus Convention.

<sup>84</sup> Public authority is defined in art. 2(2) Aarhus Convention. Excluded from the definition are bodies operating in a judicial or legislative capacity. Within the EU pesticide approval procedure, it seems highly unlikely that the authorities involved act in a legislative capacity: General Court EU of 14 June 2012, T-338/08, *not yet published* (*Stichting Natuur en Milieu and Pesticide Action Network Europe v European Commission*), par. 65-70.

<sup>85</sup> Art. 4(1)(a) Aarhus Convention.

<sup>86</sup> Defined in art. 2(4) Aarhus Convention as: “*one or more natural or legal persons, and, in accordance with national legislation or practice, their associations, organizations or groups*”.

<sup>87</sup> This wording is in line with the English version of the Aarhus Convention. The English wording refers to substances *likely to affect* the state of elements of the environment, whereas the French and Russian wording refer to substances that *may affect* the state of elements of the environment. According to the Aarhus Implementation Guide, the latter, more inclusive, definition is preferable. However, no formal decision has been made on this matter by the Treaty Parties (Aarhus Implementation Guide 2013, p. 42).

<sup>88</sup> Art. 2(3)(a)(b) Aarhus Convention.

<sup>89</sup> Note that this definition might not entail information on the personal and/or professional background of RA researchers, of which disclosure is required to confirm their expertise or to identify potential conflicts of interest.

<sup>90</sup> A request for information may be refused on the ground that a public authority does not hold the requested information (art. 4(3)(a) Aarhus Convention).

<sup>91</sup> However, it follows from art. 2(2) Aarhus Convention that the definition of public authority is broad, including private parties that have public responsibilities or functions, or provide public services, in relation to the environment, and are under the control of a governmental or administrative body or person.

<sup>92</sup> Aarhus Implementation Guide 2013, p. 73.

<sup>93</sup> Art. 4(2) Aarhus Convention.

the applicant.<sup>94</sup> This should include copies or documents in electronic form, rather than summaries or excerpts, or the opportunity to examine documents on site.<sup>95</sup> Public authorities may make a reasonable charge for supplying environmental information.<sup>96</sup> The ECJ has ruled that the term “reasonable” must be understood as meaning that it does not authorize Member States to pass on the entire amount of the actual costs to the applicants.<sup>97</sup> The public authority may refuse a request for environmental information on certain grounds (discussed hereafter in § 2.5).<sup>98</sup> The grounds for refusal should be interpreted in a restrictive way, taking into account the public's interest in disclosure.<sup>99</sup> If a request for information is refused, the applicant should have access to independent review before a court of law. In addition, he should have access to an expeditious, inexpensive reconsideration procedure before the public authority or an independent and impartial body other than a court of law.<sup>100</sup> In order to guarantee that the public is aware of their rights under article 4 of the Aarhus Convention, the treaty parties should actively inform the public thereof. They should provide sufficient information to the public about the type and scope of environmental information held by the relevant public authorities, the basic terms and conditions under which such information is made available and accessible, and the process by which it can be obtained.<sup>101</sup>

The Aarhus Convention is a leading international instrument on the right to environmental information, and as such provides for a suitable benchmark for assessing EU pesticide law. Nevertheless, many of its provisions are open to interpretation and leave discretion to the treaty parties.<sup>102</sup> In this paper the provisions of the Aarhus Convention will be interpreted by referring to ECJ case law and the Aarhus Implementation Guide.<sup>103</sup>

This paper does not deal with the active right to information in article 5 of the Aarhus Convention.<sup>104</sup> The active right to information deals with the obligation of public authorities or certain private actors, such as industry, to actively disclose environmental information. Although the active right to information may increase public scrutiny and trust in RA, the Aarhus Convention leaves a

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<sup>94</sup> Art. 4(1)(b) Aarhus Convention unless the information is already publicly available in another form (art. 4(1)(b)(i) Aarhus Convention) or if it is reasonable that the authority makes it available in another form, in which case reasons must be given (4(1)(b)(ii) Aarhus Convention). However, the information should still be easily accessible to applicant in its entirety. In addition, “another form” means that the available information is the functional equivalent of the form requested, not a summary (Aarhus Implementation Guide 2013, p. 74).

<sup>95</sup> Aarhus Implementation Guide 2013, p. 73-74. On the other hand, if the requester prefers to inspect the documents on site, in principle, this should be allowed as well (Aarhus Implementation Guide 2013, p. 74).

<sup>96</sup> Art. 4(8) Aarhus Convention.

<sup>97</sup> ECJ 9 September 1999, C-217/97, *ECR* 1999, p. I-05087, *CMLR* 1999-3, p. 277-300 (*Commission v Germany*), par. 47-48.

<sup>98</sup> Art. 4(3) and 4(4) Aarhus Convention list the grounds for refusal.

<sup>99</sup> Art. 4(4) Aarhus Convention. Also see the ECJ's and Court of First Instance's (CFI) case law: ECJ 21 July 2011, C-506/08 *P*, *ECR* 2011, p. I-6237 (*Sweden v MyTravel and Commission*), par. 75 and the case law cited there; CFI 24 May 2011, T 109/05 and T-444/05, *ECR* 2011, p. II 2479 (*NLG v Commission*), par. 123.

<sup>100</sup> Art. 4(7) and 9(1) Aarhus Convention.

<sup>101</sup> Art. 5(2)(a) Aarhus Convention.

<sup>102</sup> Mason 2010, p. 21-23.

<sup>103</sup> Aarhus Implementation Guide 2013 (similar edition (second edition) to the recently published 'interactive' Aarhus Implementation Guide 2014). However, this is not a binding instrument and the ECJ does not need to follow the recommendations in the Implementation Guide. Also see: ECJ 14 February 2012, C-204/09, *ECR* 2012, p. I-0000 (*Flachglas Torgau*), par. 36; General Court EU 8 October 2013, T-545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*), par. 55.

<sup>104</sup> Except for the rights enshrined in art. 5(2)(a) Aarhus Convention which deals with active disclosure duties relating to the passive right to information (see above, n. 101).

wide margin of discretion as to which information is actively disclosed.<sup>105</sup> Since the passive right to information in the Aarhus Convention is much more concrete, it constitutes a more suitable benchmark for assessing EU pesticide law. Furthermore, like article 4 of the Aarhus Convention, this paper does not deal with the manner in which RA data are presented.<sup>106</sup> Raw RA data are often framed in highly technical terms or lost in an overload of scientific information and thus may only be understood by experts in the field. This may limit the discussion to competing experts, while excluding the lay public.<sup>107</sup> Although a serious practical limitation to the right to environmental information, questions of presentation are relevant only once RA data are indeed disclosed. In EU pesticide law, this is often not the case. Therefore, this paper focuses on the disclosure of (raw) RA data as a first step towards more transparency and public participation. Last, this paper does not discuss access to information with regard to the framing of the RA studies. The manner in which research questions and potential environmental risks are formulated can highly influence the RA research outcomes.<sup>108</sup> Thus, public scrutiny in this stage can be very important. However, under the current system the framing of pesticide RA studies is done by the producer. Consequently, as a general rule, this information not held by the relevant public authorities and therefore falls outside the scope of the passive right to information.<sup>109</sup>

### ***2.5. Limitations to the right to information***

The right to environmental information is limited by several grounds for refusal. The Aarhus Convention lists eleven grounds for refusal, such as a manifestly unreasonable or too general request, the protection of international relations and public security, or the protection of the privacy of individuals.<sup>110</sup> An important limitation within EU pesticide law is the protection of business confidentiality and intellectual property rights.<sup>111</sup> In the field of EU food safety law, the Commission emphasizes that the right to scientific information is subject to the “usual requirements of commercial confidentiality”.<sup>112</sup>

Restrictions based on commercial and industrial confidentiality can be found in several international instruments, such as the Convention for the Protection of the marine Environment of the North-East Atlantic (OSPAR Convention)<sup>113</sup> and the 1993 Lugano Civil Liability Convention<sup>114</sup> The well-known Agenda 21<sup>115</sup> states in paragraph 19.16, specifically in relation to chemicals:

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<sup>105</sup> See the active disclosure duties for public authorities mentioned in art. 5 Aarhus Convention stating that “Each Party shall publish the facts and analyses of facts *which it considers relevant*” and “Each Party shall *encourage* operators whose activities have a significant impact on the environment to inform the public”.

<sup>106</sup> Critical in this regard in relation to the Aarhus Convention: Lee & Abbot 2003, p. 93. The active right to information in art. 5 Aarhus Convention only deals with the presentation of environmental information on very limited points. In particular, art. 5(8) states that the treaty parties shall develop mechanisms with a view to ensuring that sufficient product information is made available to the public *in a manner which enables consumers to make informed environmental choices*.

<sup>107</sup> Lee & Abbot 2003, p. 84, 87, 91& 93; Gupta 2008, p. 4; Gupta 2009, p. 7; Gouldson 2004, p. 142-143 & 145.

<sup>108</sup> On the importance of risk framing in environmental law, see: Vaughan & Seifert 1992, p. 119-135.

<sup>109</sup> One could argue that EU pesticide law should be adapted in this aspect and that the public should be involved in the framing of RA studies. Such a change would largely relate to *how* pesticide RA is conducted and does not specifically involve the right to access to RA data. Therefore, although an interesting issue, it will not be discussed in more detail in this paper.

<sup>110</sup> Art. 4(3) and 4(4) Aarhus Convention list the grounds for refusal.

<sup>111</sup> Mason 2008, p. 11. For example, commercial confidentiality is said to be a serious barrier to access to information on pollutants from industrial facilities (Foti et al. 2008, p. 78; Gouldson 2004, 141-142).

<sup>112</sup> Commission White Paper, COM(1999) 719 final, p. 15.

<sup>113</sup> Art. 9(3)(d) Convention for the Protection of the marine Environment of the North-East, Paris, France 22 September 1992, 2354 UNTS 67; 32 ILM 1069 (1993).

*“Industry should provide data for substances produced that are needed specifically for the assessment of potential risks to human health and the environment. Such data should be made available to relevant national competent authorities and international bodies and other interested parties involved in hazard and risk assessment, and to the greatest possible extent to the public also, taking into account legitimate claims of confidentiality”.*

The Aarhus Convention contains a stricter ground for refusal, allowing for commercial confidentiality only in cases: *“where such confidentiality is protected by law in order to protect a legitimate economic interest. Within this framework, information on emissions which is relevant for the protection of the environment shall be disclosed”*.<sup>116</sup> Moreover, treaty parties are under an obligation to interpret grounds for refusal in a restrictive way: *“taking into account the public interest served by disclosure and taking into account whether the information requested relates to emissions into the environment”*.<sup>117</sup> This implies that the exceptions to the right to information should not be applied too liberally. Nonetheless, there is still some room for discretion.<sup>118</sup> Interestingly, an amendment to the Aarhus Convention on the environmental release of GMO’s<sup>119</sup> explicitly states that parties shall in no case consider the RA to be confidential.<sup>120</sup> However, there is no similar amendment regarding pesticides or chemicals.

Another legal instrument providing for confidentiality of commercial and industrial data is the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement<sup>121</sup> drafted by the World Trade Organization (WTO) of which the EU is a member. Article 39(3) TRIPS provides for protection of undisclosed information that has commercial value:

*“ Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”*

Thus, the TRIPS agreement requires data submitted in the course of the pesticide approval procedure to be kept confidential, unless disclosure is necessary to protect the public or steps are taken to prevent unfair commercial use of the data. This is in conflict with the Aarhus Convention, which, for example,

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<sup>114</sup> Art. 14(2) of the Convention on Civil Liability for Damage Resulting from Activities Dangerous to the Environment, CETS No.: 150, Lugano, Italy, 21 June 1993.

<sup>115</sup> Agenda 21: Programme of Action for Sustainable Development, Rio, Brazil 14 June 1992, U.N. GAOR, 46th Sess., Agenda Item 21, UN Doc A/Conf.151/26 (1992).

<sup>116</sup> Art. 4(4)(d) Aarhus Convention.

<sup>117</sup> Art. 4(4) Aarhus Convention.

<sup>118</sup> Although within the EU this discretion is further limited by the General Court, which has adopted a broad interpretation of "emissions into the environment". See General Court EU 8 October 2013, T-545/11, *not yet published (Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission)* further discussed below at § 8.2.

<sup>119</sup> Decision II/1 on genetically modified organisms adopted at the second meeting of the Parties held in Almaty, Kazakhstan, on 25-27 May 2005, ECE/MP.PP/2005/2/Add.2.. The amendment needs another 5 ratification by states that are party to the Aarhus Convention before it enters into force: [www.unece.org/env/pp/gmos.html](http://www.unece.org/env/pp/gmos.html). However, within the EU a similar rule is already in force due to art. 25(4) of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration (*OJ* 2001, L 106/1).

<sup>120</sup> Annex I bis(4)(c). However, it is unclear whether this obligation only relates to the RA report or whether it is also deemed to include all research studies on which the RA report is based.

<sup>121</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, Marrakesh, Morocco 15 April 1994, 1869 UNTS 299; 33 ILM 1197 (1994).

requires environmental information relating to emissions into the environment to be made publicly available under all circumstances. On the EU level, this does not pose a problem, since the ECJ has ruled many times that WTO agreements are not among the rules in the light of which the court reviews the legality of measures adopted by the EU institutions.<sup>122</sup> The Aarhus Convention, on the other hand, forms an integral part of the EU legal order, and needs to be applied by the ECJ.<sup>123</sup> Moreover, article 30 of the Vienna Convention on the Law of Treaties<sup>124</sup> states that between members who are signing parties to successive treaties relating to the same subject matter, the most recent treaty prevails. Thus, within the EU the Aarhus Convention (1998) has priority over TRIPS (1994). It does not surprise therefore, that in a recent ruling the General Court of the EU decided that article 39(3) TRIPS did not alter or limit the EU rules implementing the Aarhus Convention.<sup>125</sup>

Since pesticide RA research often contains very specific information on the chemical properties, structure and safety of a pesticide, it is to be expected that the producer will claim confidentiality. There is a clear tension between commercial confidentiality and transparency in RA. Therefore it is essential that authorities carefully balance the protection of business interests against the public's interest in disclosure. This is in line with EFSA's approach to "Openness, Transparency and Confidentiality".<sup>126</sup> EFSA notes that commercial confidentiality is:

*"clearly a proper device for protecting companies' commercial interests, but care must be taken to ensure that this is not made a pretext for withholding information of legitimate public interest. EFSA proposes to discuss openly with companies how to interpret in a proportionate and balanced manner the concept of commercially sensitive information and is ready to take a challenging approach to issues in the public interest."*<sup>127</sup>

In sum, under international law the right to environmental information may be limited on the basis of various exceptions. In relation to access to pesticide RA data, the most prominent limitation is the protection of commercial interests and intellectual property. As also noted by EFSA, it is important to balance the commercial interests involved against the public right to environmental information.

## ***2.6. Access to information in RA: an important factor in risk governance***

In sum, RA aims to identify environmental risks and is of great importance in EU food law. Although RA is (or should be) largely a scientific procedure, public access to RA data is important for the well-functioning of the risk governance process. In particular, it is a prerequisite for effective public participation, public scrutiny and the implementation of the precautionary principle in the risk management stage. Moreover, transparency may enhance public trust in RA and the decision-making process. The right to environmental information is enshrined in several international treaties. In this paper "the right to information" is understood as the so-called *passive* right to information - the right to obtain information from public authorities - as defined by the Aarhus Convention. Although aiming

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<sup>122</sup> ECJ 12 March 2002, C-27/00 and C-122/00, *ECR* 2002, p. I-2569 (*Omega Air and Others*), par. 93-94; ECJ 9 January 2003, C-76/00 P, *ECR* 2003, p. I-79 (*Petrotub and Republica v Council*), par. 53-54; ECJ 30 September 2003, C-93/02 P, *ECR* 2003, p. I-10497 (*Biret International v Council*), par. 52; CFI 17 September 2007, T-201/04, *ECR* 2007, p. II-03601 (*Microsoft Corp. v Commission of the European Communities*), par. 801.

<sup>123</sup> See: ECJ 8 March 2011, C-240/09, *ECR* 2011, p. I-01255 (*Lesoochránárske zoskupenie VLK v Ministerstvo životného prostredia Slovenskej republiky*), par. 30; ECJ 18 July 2013, C-515/11, *not yet published* (*Deutsche Umwelthilfe eV v Bundesrepublik Deutschland*), par. 32.

<sup>124</sup> Vienna Convention on the law of treaties, concluded at Vienna on 23 May 1969, UN Doc. A/Conf.39/27; 1155 UNTS 331; 8 ILM 679 (1969); 63 AJIL 875 (1969).

<sup>125</sup> General Court EU 8 October 2013, T-545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*), par. 45-46, discussed in more detail below at § 8.2.

<sup>126</sup> EFSA 2003.

<sup>127</sup> EFSA 2003, p. 2.

for wide access to environmental information, the Aarhus Convention provides for various exceptions to this right. In relation to access to pesticide RA data, the most prominent limitation is the protection of commercial interests and intellectual property. After first briefly outlining the EU pesticide approval procedure, this paper will focus on the tension between the right to access to pesticide RA data on the one hand, and the various grounds for refusal that may apply on the other.

### 3. Approval of plant protection products and active substances

For a good understanding of the current debate on access to pesticide RA data, it is necessary to briefly outline the procedure for EU pesticide approval. This approval procedure provides the context in which requests for RA data are made. There is EU legislation on various aspects of pesticides, such as the registration, the import and export of plant protection products and the management of pesticide residues.<sup>128</sup> With regard to pesticide registration, the most important instrument is the RPPP<sup>129</sup>, which recently replaced the old Pesticide Directive (91/414/EEC).<sup>130</sup>

The RPPP contains rules for the approval of plant protection products and the registration of the active substances that plant protection products contain.<sup>131</sup> The approval process under the RPPP is described in more detail in several Commission regulations which provide harmonised criteria for evaluating plant protection products and active substances.<sup>132</sup> The RPPP is based on the implementation of the internal market (article 114 TFEU), a common agricultural policy (article 43 TFEU), and the protection of human health (article 168 TFEU).<sup>133</sup> The purpose of the regulation is twofold: 1) to ensure a high level of protection of both human and animal health and the environment, and 2) to improve the functioning of the internal market, while improving agricultural production.<sup>134</sup> The regulation is underpinned by the precautionary principle and does not prevent Member States to apply this principle in cases of scientific uncertainty as to the health or environmental risks posed by

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<sup>128</sup> See for example: Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (*OJ* 2005, L 70/1); Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC (*OJ* 2002, L 187/30); Regulation 304/2003 (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals (*OJ* 2003, L 63/1). For an overview of EU pesticide law see: Jans & Vedder 2012, p. 457-465.

<sup>129</sup> Regulation (EC) No. 1107/2009 on the registration of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (*OJ* 2009, L 309/1).

<sup>130</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (*OJ* 1991, L 230/1). See for the registration process under this directive: Pallemmaerts 2003, P. 599-604; Voegelzang-Stoute 2004, p. 77-132.

<sup>131</sup> Art. 1(1) and (2) RPPP.

<sup>132</sup> See for example art. 78 RPPP which requires further implementing measures by the Commission. On the basis of this article the Commission adopted, inter alia: Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (*OJ* 2013, L 93/1); 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 (*OJ* 2011, L 155/127).

<sup>133</sup> Unlike Directive 91/414/EEC which was based solely on a common agricultural policy, thereby limiting the influence of the European Parliament and said to place this field of law firmly in the hands of agricultural policy-makers (Pallemmaerts 2003, p. 600).

<sup>134</sup> Art. 1(3) RPPP.



the plant protection products.<sup>135</sup> The regulation deals with the approval of plant protection products, active substances, safeners, synergists and co-formulants.<sup>136</sup> The regulation provides for a two-tier registration procedure. The first tier is the registration of the active substance, safener, synergist or co-formulant on the EU level (§ 3.1). The second tier is the registration of the plant protection product - the end product sold - on the national level (§ 3.2).<sup>137</sup> After first discussing the two tiers, § 3.3. will briefly explain why access to RA data is important in both the European and the national approval procedure.

### ***3.1. Registration of active substances on the European level***

The first tier, the registration procedure for active substances, safeners, synergists and co-formulants at the EU level, is laid down in Chapter II of the RPPP.<sup>138</sup> Being the active element in pesticides, many requests for RA data involve the registration of a new active substance. Therefore this subsection focuses on the registration procedure for active substances.

First approval of an active substance does, in principle<sup>139</sup>, not exceed a time period of ten years. Approval may include restrictions and conditions to ensure conformity with the provisions of the regulation.<sup>140</sup> The approval criteria are listed in article 4 and relate to human and animal health, the environment and the effectiveness of the product. An active substance shall be effective for its purpose and not have any harmful effects, immediate or delayed, on human health, including that of vulnerable groups, or animal health.<sup>141</sup> In addition, they shall not have any *unacceptable* effect on the environment.<sup>142</sup> Particular attention is given to contamination of ground and surface water, air and soil, the impact on non-target species, and the impact on biodiversity and the ecosystem.<sup>143</sup> Annex II stipulates in detail the specific approval criteria. For example, evaluation criteria are given to determine whether an active substance is bio accumulative<sup>144</sup> and whether it has no unacceptable effects on honeybee colony survival.<sup>145</sup>

Article 7 to 21 set out the approval procedure of an active substance.<sup>146</sup> An application for approval is assessed by one Member State, the rapporteur Member State<sup>147</sup>, or by a number of Member States together under a co-rapporteur system.<sup>148</sup> The applicant should enclose a so-called 'summary

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<sup>135</sup> Art. 1(4) RPPP. One must assume that the same is true for the EU, although the General Principles of Food Law only refer to precautionary measures in relation to the protection of human health risks (art. 7 General Principles of Food Law).

<sup>136</sup> Art. 3 RPPP. Safeners, synergists and co-formulants do not have an effect on their own but are added to increase the safety or effectiveness of the plant protection product (Jans & Vedder 2012, p. 457).

<sup>137</sup> This two-stage registration process is similar to the old Directive 91/414/EEC (Pallemarts 2003, p. 600).

<sup>138</sup> Similarly to the old Directive 91/414/EEC (Pallemarts 2003, p. 600).

<sup>139</sup> Art. 5 RPPP. By derogation from art. 5, art. 22 provides for an approval period of 15 years for low-risk active substances and art. 23 provides for an unlimited approval period for basic substances.

<sup>140</sup> Art. 6 RPPP.

<sup>141</sup> Taking into account known cumulative and synergistic effects where the scientific methods accepted by EFSA to assess such effects are available, or on groundwater (art. 4(2)(a) and 4(3)(b) RPPP). However, the established scientific methods do not always suffice to estimate all relevant environmental effect. For example, with regard to neonicotinoid pesticides it has been noted by EFSA that the current scientific methods are not capable of measuring and predicting cumulative and synergistic effects (EFSA Panel on Plant Protection Products and their Residues 2012).

<sup>142</sup> Art. 4(2)(b) and 4(3)(e) RPPP.

<sup>143</sup> Art. 4(3)(e) RPPP.

<sup>144</sup> Annex II, par. 3.7.1.2 and 3.7.3.2 RPPP.

<sup>145</sup> Annex II, par. 3.8.3 RPPP.

<sup>146</sup> Also see: Jans & Vedder 2012, p. 457-460.

<sup>147</sup> Art. 7(1) RPPP.

<sup>148</sup> Art. 7(2) RPPP.

dossier' with the summaries and results of tests and studies that are relevant for the assessment of the approval criteria. In addition, the summary dossier should include an assessment of all the information submitted, and provide relevant, open, peer-reviewed literature published in the last ten years.<sup>149</sup> The summary dossier will be made available to the public, excluding confidential information.<sup>150</sup> Next to the summary dossier, a complete dossier is submitted to the rapporteur Member State, containing the full text of the individual test and study reports.<sup>151</sup>

The summary dossier and the complete dossier form the basis for the Draft Assessment Report (hereafter: DAR) prepared by the rapporteur Member State for the Commission. The DAR assesses whether the substance is expected to meet the approval criteria in article 4.<sup>152</sup> To this purpose, the rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.<sup>153</sup> The DAR is then circulated by EFSA to allow for written comments by other Member States and, provided that the applicant has not requested certain parts of the DAR to be kept confidential, the public. After publication of the DAR, EFSA launches a period of 60 days for public consultation.<sup>154</sup> Where appropriate, EFSA organises a consultation of experts, including experts from the rapporteur Member State<sup>155</sup> In addition, EFSA may ask the Commission to consult a Community reference laboratory to verify the analytical method proposed by the applicant for the determination of the residues.<sup>156</sup>

At the end of the consultation period EFSA adopts a conclusion, based on current scientific and technical knowledge, on whether the active substance is expected to meet the approval criteria.<sup>157</sup> The conclusion of EFSA shall include details on the evaluation procedure and the properties of the active substance and is made publicly available.<sup>158</sup> Six months after receiving EFSA's conclusion, the Commission presents a 'review report' and a Draft regulation in which the active substance is approved, subject to certain conditions and restrictions, or not approved.<sup>159</sup> The Draft regulation is submitted to the Standing Committee on the Food Chain and Animal Health, which, on the basis of the review report, the precautionary principle and all other relevant factors, may adopt the Draft regulation.<sup>160</sup> Approved active substances are included in a Commission regulation, listing all approved active substances.<sup>161</sup>

The procedures for renewal once the approval period has expired and for interim review is listed in articles 14-20. An approval may be reviewed any time, for instance in the light of new scientific and technical knowledge or monitoring data.

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<sup>149</sup> Art. 8 RPPP.

<sup>150</sup> Art. 10 RPPP.

<sup>151</sup> Art. 8(2) RPPP.

<sup>152</sup> Art. 11(1) RPPP.

<sup>153</sup> Art. 11(2) RPPP.

<sup>154</sup> See EFSA's website: [www.efsa.europa.eu/en/pesticides/pesticidesconsultations.htm](http://www.efsa.europa.eu/en/pesticides/pesticidesconsultations.htm). A list of active substances open to public review is to be found on: <http://dar.efsa.europa.eu/dar-web/consultation>. Also see art. 12(1) RPPP.

<sup>155</sup> Art. 12(2) RPPP.

<sup>156</sup> Art. 12(3) RPPP.

<sup>157</sup> Art. 12(2) RPPP.

<sup>158</sup> Art. 12(2) and (4) RPPP.

<sup>159</sup> Art. 13(1) RPPP.

<sup>160</sup> Art. 13(2) RPPP.

<sup>161</sup> Commission Implementing Regulation of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (*OJ* 2011, L 153/1).

### ***3.2. Approval of the plant protection product on the national level***

The authorisation of a plant protection product, the second tier, takes place on the national level and is laid down in Chapter III of the RPPP.<sup>162</sup> In principle a plant protection product may only be used on a national market if it has been approved by the Member State.<sup>163</sup> Article 29 of the RPPP lists the approval criteria. For example, the product's active substance needs to be approved on the EU level and the product should be in conformity with the requirements of article 4(3) RPPP relating to health, environment and effectiveness. Article 29 seems to leave broad discretion to the Member States to approve to a new plant protection product. However, this discretion is seriously limited in two ways.

First, the approval procedure in article 31-39 provides for *zonal approval*. This procedure is new and cannot be found in the old Pesticide Directive (91/414/EEC). The EU is divided in three zones.<sup>164</sup> The applicant has to apply for approval in all Member States in which he intends to market the product.<sup>165</sup> However, only one Member State in the zone assesses the application: the zonal rapporteur Member State (hereafter: the zonal rapporteur).<sup>166</sup> If a pesticide is intended to be used in greenhouses, as post-harvest treatment, for treatment of empty storage rooms, and for seed treatment, only one Member State evaluates the application for all three zones.<sup>167</sup> The applicant may propose which Member State does the assessment, which proposal is normally followed.<sup>168</sup> This has raised concerns with environmental NGO's, as it may encourage forum-shopping by the industry, thereby triggering a race to the bottom amongst competing national authorities.<sup>169</sup> The other Member States within the zone shall refrain from proceeding with the file, pending assessment by the zonal rapporteur.<sup>170</sup> The zonal rapporteur is required to make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.<sup>171</sup> Other Member States in the same zone should be given the opportunity to submit comments to be considered in the assessment.<sup>172</sup>

In principle, the other Member States are required to grant or refuse authorisations on the basis of the assessment of the zonal rapporteur.<sup>173</sup> However, risk mitigation measures deriving from specific conditions of use may be imposed by individual Member States.<sup>174</sup> If the concerns of a Member State relating to human or animal health or the environment cannot be controlled by national risk mitigation measures, authorisation may be refused "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* to human or animal health or the environment".<sup>175</sup> The Member States shall immediately inform the applicant and the Commission of its decision and provide a technical or scientific justification thereof.<sup>176</sup> "Substantiated reasons" and "unacceptable risk" implies that the burden of proof is set higher than the burden of proof under the precautionary principle. However, article 1(4) RPPP states that Member States shall not be prevented from applying the precautionary

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<sup>162</sup> Also see: Pallemarts 2003, p. 600-604; Vogelezang-Stoute 2004, p. 99-107 on the second tier under the old Directive 91/414/EEC.

<sup>163</sup> Art. 28(1) RPPP.

<sup>164</sup> The three zones and countries therein are mentioned in Annex I of the RPPP.

<sup>165</sup> Art. 33(2)(a) RPPP.

<sup>166</sup> Art. 35 RPPP.

<sup>167</sup> Art 33(2)(b) RPPP.

<sup>168</sup> Art. 35(1) RPPP.

<sup>169</sup> Pan Europe on Zonal authorisation: [www.pan-europe.info/Campaigns/pesticides/zonal\\_authorisation.html](http://www.pan-europe.info/Campaigns/pesticides/zonal_authorisation.html).

<sup>170</sup> Art. 35(2) RPPP.

<sup>171</sup> Art. 36(1) RPPP.

<sup>172</sup> Art. 36(1) RPPP.

<sup>173</sup> Art. 36(2) RPPP.

<sup>174</sup> Art. 36(3) RPPP.

<sup>175</sup> Art. 36(3) RPPP.

<sup>176</sup> Art. 36(3) RPPP.

principle where there is scientific uncertainty as to the risks for human or animal health or the environment posed by the plant protection products to be authorised in their territory. One must therefore assume that the terms “substantiated reasons” and “unacceptable risk” are interpreted in line with the precautionary principles. Nonetheless, the zonal registration procedure has been criticised because it could highly increase pesticide use and prevent Member States from adopting pesticide reducing measures.<sup>177</sup> On the other hand - at least in theory - zonal authorisation can also work the other way around. Member States are required to withdraw or amend an authorisation if another Member State in their zone has withdrawn or amended a registration, for example because of serious environmental concerns.<sup>178</sup>

Secondly, the discretion of the Member States is limited by the mutual recognition procedure in article 40-42 RPPP. The applicant, agricultural bodies or professional agricultural organisations may, under certain conditions, apply for authorisation of a product that is already authorised in another Member State.<sup>179</sup> The Member State shall approve the authorisation if the conditions in its territory are similar to the Member State where the product is already authorised.<sup>180</sup> Again, there is a similarly strict escape clause by which Member States may refuse authorisation on the basis of health and environmental concerns.<sup>181</sup> The old Pesticide Directive (91/414/EEC) contained a rather similar mutual recognition procedure.<sup>182</sup> New, however, is article 49 RPPP, with strict mutual recognition for seed treatments, such as many of the controversial neonicotinoid pesticides. If there is a substantial concern that treated seeds are likely to constitute a serious risk to human or animal health or the environment, not the Member States, but the Commission should limit their use. Also the provisions on mutual recognition seem to be in conflict with the fact that the Regulation is underpinned by the precautionary principle. These provisions therefore should not prevent Member States to apply the precautionary principle in cases of scientific uncertainty as to the health or environmental risks posed by a plant protection product.<sup>183</sup>

### ***3.3. Access to RA data - important in both the EU and the national tier***

It is clear from the previous section that RA studies play a vital role in the approval of both active substances and plant protection products. They form an important part of the summary and the complete dossier and lie at the basis of the DAR and EFSA's conclusion. Therefore, public access to RA data is essential to allow for public participation in the approval procedure (through public consultation). Moreover, access to pesticide RA data facilitates public scrutiny and review of the final approval decision. In addition, it allows for scientific discussion and an open appraisal of scientific uncertainty, thereby contributing to the implementation of the precautionary principle which, after all, underpins the RPPP.<sup>184</sup>

Access to RA data is essential both on the EU level and on the national level. However, public access to RA data on the EU level is particularly important, since the approval of an active substance can have major effects for the Member States as well. Once an active substance has been approved on the EU level, there is little room for Member States to refuse the approval of plant protection products

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<sup>177</sup> Danish Eco Council 2010.

<sup>178</sup> Art. 44(3) RPPP.

<sup>179</sup> Art. 40 RPPP.

<sup>180</sup> Art. 41 and 42 RPPP.

<sup>181</sup> Art. 41 RPPP.

<sup>182</sup> Voegelzang-Stoute, p. 105-107.

<sup>183</sup> Art. 1(4) RPPP.

<sup>184</sup> Art. 1(4) RPPP.

containing that substance. If one Member State is willing to approve the plant protection product, in principle other Member States need to follow, either through zonal registration or mutual recognition.

Due to this far degree of harmonisation on the national level, it becomes vital for the protection of human health and the environment that public scrutiny takes place on the EU level. A lack of transparency on the EU level is therefore even more worrying than a lack of transparency on the national level.

#### **4. A case study: confidential RA studies in the approval of imidacloprid**

Although access to pesticide RA data is essential to allow for public participation and scrutiny, the DAR may rely heavily on research for which the pesticide producer has claimed confidentiality. Claims for data protection may severely limit the public's right to environmental information in the field of EU pesticide law. To illustrate the topic, this section will look into the controversial registration of the active substance 'imidacloprid', which was based on largely confidential RA studies.

Imidacloprid belongs to the family of neonicotinoid pesticides: an innovative, highly effective<sup>185</sup>, and relatively new type of pesticide that constitutes a quarter of the pesticides world marketed today.<sup>186</sup> Imidacloprid is the most popular and wide-used neonicotinoid pesticide.<sup>187</sup> From the early 2000's an increasing number of studies indicated neonicotinoids may pose high risks to bees.<sup>188</sup> This makes imidacloprid one of the main suspects in causing so-called 'colony collapse disorder': the unexplained disappearance of honeybees worldwide.<sup>189</sup> However, on the basis of largely confidential research conducted by the producer, EFSA deemed the risks involved acceptable providing certain precautionary measures were taken.<sup>190</sup>

To assess the level of transparency in the RA of imidacloprid, it is worth taking a closer look at the DAR prepared by the rapporteur Member States (Germany).<sup>191</sup> For this purpose, the studies referred to in the DAR have been categorized according to whether they are: confidential, owned by the applicant, and/or published.<sup>192</sup> What stands out is that the vast majority of the RA studies are owned by Bayer, the producer of imidacloprid. Of the approximately 670 studies on which the DAR is based, around 90 % (603 studies) are owned by Bayer. Of the 93 studies relating to bees, 77 % (72 studies) are Bayer-owned.<sup>193</sup> For 97% (585) of the 603 Bayer-owned studies, data protection and confidentiality has been claimed. Consequently, their content is not publicly available and cannot be reviewed by third parties. For the 18 Bayer-owned studies for which no data protection has been

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<sup>185</sup> The newest generation of neonicotinoids is more than 7000 times more toxic than DDT (Bonmatin 2009).

<sup>186</sup> As in 2011 20,000 tonnes annually are emitted into the environment (CCM International 2011).

<sup>187</sup> Easton & Goulson 2013.

<sup>188</sup> See, amongst others: Suchail, Guez & Belzunces 2001; Committee Honeybee Apiaries Decline 2003; Sterk & Benuzzi 2004; Gregorc & Bozic 2004, p. 29–32; Youris 2009. See UNEP 2010 on all potential causes of the worldwide decline in bee numbers, including more references to studies on neonicotinoid pesticides.

<sup>189</sup> Research has shown that some 30 percent of the bee population in the U.S. has been wiped out. In Europe, the losses vary between 1,8 and 53 percent (Neumann & Carreck 2010).

<sup>190</sup> For a critic on the EU RA procedure with regard to neonicotinoid pesticides, see: Kievits 2007, p. 3–5; Kindemba 2009; Letter to the European Commissioner for Health 2009.

<sup>191</sup> DAR imidacloprid 2006.

<sup>192</sup> Since the DAR consists out of 3 Volumes and 7 documents with a total amount of 1400 pages, the categorization has been done digitally, using ABBYY Fine Reader, Microsoft Word and Excel. Although this is a rather accurate way of classifying the studies, it cannot be ruled out that the actual numbers and percentages differ slightly.

<sup>193</sup> However, out of the 21 independent studies relating to bees, 7 studies (33%) were carried out (partly) by researchers that were also involved in Bayer-owned imidacloprid studies.

claimed, none were published at the time the DAR was drafted. Only 10 % of the studies (67 studies) constitute independent, published research not conducted on behalf of Bayer.

From this small inquiry, it is clear that a DAR may be largely based on studies that are confidential and owned by the applicant. This is not surprising, considering that EU pesticide law requires the applicant to provide a summary dossier proving that all approval criteria are met. This procedure is quite economical, because it would be virtually impossible, both financially and time-wise, for the rapporteur Member State and EFSA to conduct all required RA research. Problematic, however, is that the applicant has an interest in providing data that are favourable for the application. There is a risk that the RA studies are biased, making public scrutiny all the more important.<sup>194</sup>

In view of the various studies indicating negative effects of neonicotinoids on bees, the Commission requested EFSA in April 2012 to provide a conclusion regarding the risk of neonicotinoid active substances for bees. Early in 2012 three independent studies on the sub-lethal effects of certain neonicotinoids in bees were published.<sup>195</sup> Those studies indicated several negative sub-lethal effects in bees and triggered a chain of reactions on the EU level. In a reaction to these studies, EFSA stated that further data were required before drawing a definite conclusion.<sup>196</sup> In May 2012, a scientific panel of EFSA concluded that the established RA methods were incapable of sufficiently determining the effects of pesticides on bees.<sup>197</sup> In July 2012 EFSA received an updated request from the Commission to prioritise the review of three neonicotinoids, including imidacloprid.<sup>198</sup> In January 2013 EFSA concluded that severe data gaps in the initial RA of imidacloprid exist and that a high risk for bees could not be excluded.<sup>199</sup> A few months later, the Commission adopted a temporary European ban on various uses of imidacloprid and three other types of neonicotinoids.<sup>200</sup> Although this ban shows that EU law can adapt fast to environmental concerns, the safety of imidacloprid for bees had been a point of discussion from the early 2000's. It is therefore remarkable that EFSA did not identify the severe data gaps and possible high risks for bees during the initial approval of imidacloprid in 2008.<sup>201</sup> Public disclosure of the RA studies could have fuelled and speeded up the scientific discussion. It could have triggered useful criticism on the Bayer-owned studies by independent scientists, assisting EFSA and the Commission in recognizing the flaws in the initial RA in an earlier stage.

The case of imidacloprid shows that it is important that RA studies are open to public scrutiny, ensuring that it is not solely at the discretion of EFSA, the Commission and national authorities to

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<sup>194</sup> In this light, it is remarkable that the DAR can only be obtained by first filling out an application with personal details through EFSA's website (see: <http://dar.efsa.europa.eu/dar-web/provision/request/subid/80>). The same is true for other active substances, see: <http://dar.efsa.europa.eu/dar-web/provision>

<sup>195</sup> Henry et al. 2012; Whitehorn et al. 2012; Schneider et al. 2012.

<sup>196</sup> EFSA 2012b.

<sup>197</sup> EFSA Panel on Plant Protection Products and their Residues 2012. In reaction to these concerns, EFSA has adopted a new guidance document on the risk assessment of plant protection products on bees (EFSA 2013a), and recommendations for future research in the field (EFSA 2014b).

<sup>198</sup> The process which has led to the temporary ban on imidacloprid, is described in more detail in EFSA 2013b, p. 5-6.

<sup>199</sup> EFSA 2013b.

<sup>200</sup> Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (*OJ* 2013, L 139/12); Commission Implementing Regulation (EU) No. 781/2013 amending Implementing Regulation (EU) No. 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance (*OJ* 2013, L 219/22). Although fipronil officialy is not a neonicotinoid, it has similar properties to the neonicotiod pesticidesa.

<sup>201</sup> EFSA 2008.

assess RA data. Since for many RA studies confidentiality is requested, meaning they are not automatically disclosed to the public, the passive right to information becomes especially important.

## 5. Authorities holding pesticide RA data

Under the Aarhus Convention, a request for environmental information may be refused if the authority does not hold the environmental information.<sup>202</sup> Thus, before further discussing whether EU pesticide law sufficiently guarantees access to RA data, it is essential to establish to which authority a request for information needs to be made. This section will discuss which authorities hold the pesticide RA studies. Secondly, it will discuss which authority has the power to decide upon the merits of a request for access to these data.

### 5.1. Authorities holding pesticide RA data

On the EU level a potential obstacle to access to RA data, is that it can be rather unclear which authorities hold the information. This is a practical, rather than a legal problem. Nonetheless, it is highly relevant for persons who wish to file a request for pesticide RA data.

From the RPPP it follows that the applicant has to submit a summary and a complete dossier for approval of an active substance.<sup>203</sup> The full text of the individual RA tests and study reports are submitted by the applicant to the rapporteur Member State as part of the complete dossier.<sup>204</sup> Contrary to the summary dossier, the complete dossier is not made available to the public.<sup>205</sup> In case the application for approval is admissible, the applicant shall immediately forward the *complete and the summary dossier* to the other Member States, the Commission and EFSA: "*including the information about those parts of the dossiers in respect of which confidentiality has been requested*".<sup>206</sup> EFSA recommends that the applicant provides the Commission, all other Member States and EFSA with the (non-sanitised) complete dossier and summary dossier.<sup>207</sup> In addition, all confidential information taken into account by the rapporteur Member State is reported in the separate volume 4 (or Annex C) of the DAR.<sup>208</sup> Volume 4 is not included in any version public version of the DAR.<sup>209</sup> However, a non-sanitised version of the DAR is sent by the rapporteur Member State to EFSA and the Commission.<sup>210</sup> Subsequently, EFSA circulates the complete, non-sanitised DAR to the other Member States.<sup>211</sup> Thus, through the circulation of both the complete dossier and the DAR, the submitted RA studies are held by EFSA, the Commission, the rapporteur Member State and all other Member States. Furthermore, the rapporteur Member State should prepare a list of the test and study reports necessary for first approval of the active substance and circulate it to the Commission and other Member States.<sup>212</sup>

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<sup>202</sup> Art. 4(3)(a) Aarhus Convention.

<sup>203</sup> Art. 8 RPPP.

<sup>204</sup> Art. 8(2) RPPP.

<sup>205</sup> See art. art. 10 RPPP.

<sup>206</sup> Art. 9(3) RPPP.

<sup>207</sup> EFSA Guidance on Identification and removal of confidential information.

<sup>208</sup> European Commission Directorate-General Health & Consumer Protection SANCO/12580/2012 – rev 3.1, p. 4-5; European Commission Directorate-General for Agriculture, Document 1654/VI/94, Rev 7, p. 27.

<sup>209</sup> European Commission Directorate-General for Agriculture, Document 1654/VI/94, Rev 7, p. 27 (point 4.7.4), also see art. 12(1) RPPP.

<sup>210</sup> Art. 11(1) RPPP.

<sup>211</sup> Art. 12(1) RPPP..

<sup>212</sup> Art. 60(1) RPPP.

Although it seems clear that all authorities involved should in theory hold RA data relating to active substances, from the General Court's recent ruling in *Stichting Greenpeace Nederland & PAN Europe v. Commission*<sup>213</sup> it follows that in practice the situation can be rather unclear. In this case two environmental NGO's requested under the old Pesticide Directive (91/414/EEC) from the Commission access to confidential RA data relating to the active substance glyphosate. The Commission invited the applicants to file a request at the rapporteur Member State, stating that the Commission itself did not hold the part of the DAR (volume 4) with the confidential test and study reports.<sup>214</sup> The Commission did not consider itself capable of refusing the requested RA information, since it did not possess the information.<sup>215</sup> According to the Commission this was in conformity with the approval procedure for active substances.<sup>216</sup> This is remarkable, since the old Pesticide Directive does require that the applicant provides all Member States and the Commission with a dossier containing a detailed and full description of the studies conducted and of the methods used.<sup>217</sup> Thus, it follows from *Stichting Greenpeace Nederland & PAN Europe v. Commission* that practice may differ from the letter of the law. If in fact only the rapporteur Member States would hold the confidential RA studies, this could seriously limit the public's access to confidential RA data. After, all if a member of the public has to request RA data from a foreign rapporteur Member State, through an unfamiliar procedure and possibly in an unfamiliar language, this could seriously hinder access to RA data.

In relation to the approval of plant protection products on the national level, the applicant is under the obligation to provide the full dossier and the summary dossier to all Member States in which he seeks approval.<sup>218</sup> Thus, all Member States in which a request for approval is filed, should hold the confidential RA studies. However in case of a request for mutual recognition a Member State can choose not to ask for the submission of the complete and summary dossier.<sup>219</sup> However, all Member States, when authorising a plant protection product, are obliged to keep and make available to any interested party upon request: (a) a list of the test and study reports concerning the active substance, safener or synergist, adjuvant and the plant protection product necessary for authorisation; and (b) a list of test and study reports for which the applicant claimed data protection under article 59 RPPP and the reasons to support that claim.<sup>220</sup>

Even if the different authorities involved do not all hold the confidential RA information, it follows from the RPPP that they *could* require the information to be submitted to them. The Aarhus Implementation Guide states that if an authority does not physically possess information, it can still be said to effectively hold information it is entitled to possess:

*"In practice, for their own convenience, public authorities do not always keep physical possession of information that they are entitled to have under their national law. For example, records that the authority has the right to hold may be left on the premises of a regulated facility. This information can be said to be "effectively" held by the public authority."*<sup>221</sup>

Thus, one may argue that all authorities which are entitled to require the RA studies to be submitted to them, can be said to effectively hold the RA studies. For example, this would include a Member State

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<sup>213</sup> General Court EU 8 October 2013, T 545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*).

<sup>214</sup> *Ibid.*, par. 2 and 6.

<sup>215</sup> *Ibid.*, par. 21.

<sup>216</sup> *Ibid.*, par. 20.

<sup>217</sup> Art. 6(2) in combination with Annex II and III of Directive 91/414/EEC.

<sup>218</sup> Art 33(1) and (3) RPPP.

<sup>219</sup> It follows from art. 42(2)(c) RPPP that the Member State to which a request for mutual recognition is made, *may* require the submission of a complete *or* summary dossier, but is not under an obligation to do so.

<sup>220</sup> Art. 60(2) RPPP.

<sup>221</sup> Aarhus Implementation Guide 2013, p.77.



to which a request for mutual recognition is made and which chooses not to ask for the complete dossier. However, this is not a settled matter, since the Aarhus Implementation Guide is not binding.<sup>222</sup> If an authority is deemed not to hold the relevant RA data, it has a duty under the Aarhus Convention to inform the applicant which public authority may have the information. Alternatively, it may transfer the request to that authority and inform the applicant thereof.<sup>223</sup>

In sum, although the RPPP suggests that in most cases all Member States, the Commission and EFSA hold the confidential RA study reports, it is unclear whether this is also the case in practice. In particular, it is rather unclear in which cases other Member States, EFSA and the Commission hold confidential RA data relating to a new active substance.<sup>224</sup> The unclear situation can be problematic for members of the public trying to gain access to pesticide RA data.<sup>225</sup> Moreover, it is at odds with the Aarhus Convention, which requires public authorities to provide sufficient information to the public about the type and scope of environmental information held by them.<sup>226</sup>

### ***5.2. Authorities deciding upon a request for pesticide RA data***

Even if the Member States, the Commission and EFSA all hold the confidential RA data, this does not mean that under the RPPP they all have the authority to decide on the merits of a request for this information. In relation to active substances, article 7(3) RPPP states: "*Upon a request for access to information, the rapporteur Member State shall decide what information is to be kept confidential.*" Article 33(4) RPPP provides for a similar procedure in relation to plant protection products, where the zonal rapporteur decides upon a request for confidential information.<sup>227</sup>

Since the rapporteur Member State grants the initial confidentiality, one may argue that it is in the best position to decide upon data requests. The Aarhus Convention does not prescribe that the authority to which an information request is made should also decide on the merits of the request. The Aarhus Implementation Guide does not discuss the possibility to delegate the substantive decision to another authority. Thus, it seems that the procedure in the RPPP is not prohibited by the Aarhus Convention.

The ECJ has limited the discretion of Member States to object against the disclosure of information held by an EU institution. EU law contains a provision on access to information held by an EU institution but originating from a Member State. Article 4(5) of the Access to Documents Regulation<sup>228</sup> (discussed hereafter in § 6) specifically entitles a Member State to object to the disclosure by an EU institution of documents originating from that State. The ECJ has clarified that a Member State may only object on the basis of the exceptions laid down in article 4(1) to (3) of the Access to Documents Regulation and that it should give proper reasons for its position.<sup>229</sup> In addition, the Member State should cooperate with the EU institution in order to facilitate timely decision-making.<sup>230</sup> Moreover, it should examine whether there is an overriding public interest in disclosure of

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<sup>222</sup> General Court EU 8 October 2013, T-545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*), par. 55; ECJ 14 February 2012, C 204/09, *ECR* 2012, p. I-0000 (*Flachglas Torgau*), par. 36.

<sup>223</sup> Art. 4(5) Aarhus Convention.

<sup>224</sup> Therefore, for the purpose of this paper, EFSA has been asked through to comment on this matter by request on 8 February 2014 on EFSA's website, but no reply has been received.

<sup>225</sup> Private correspondence with Hans Muilerman of PAN Europe on 1-2 February 2014.

<sup>226</sup> Art. 5(2)(a) Aarhus Convention.

<sup>227</sup> Art. 33(4) RPPP.

<sup>228</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (*OJ* 2001, L 14/43).

<sup>229</sup> ECJ 18 December 2007, C-64/05 P, *ECR* 2007, p. I-11389 (*Sweden v Commission*), par. 85-87 and 99.

<sup>230</sup> *Ibid.*, par. 86.

the documents concerned.<sup>231</sup> If the Member State does not sufficiently motivate its objections, the EU institution should disclose the information anyway.<sup>232</sup> This is in line with *Stichting Greenpeace Nederland & PAN Europe v. Commission*<sup>233</sup> in which the Commission refused to disclose pesticide RA studies. The General Court annulled the Commission's decision which violated the Aarhus Regulation, even though the Commission had based its refusal on the decision by the rapporteur Member State not to disclose the requested information in order to protect the commercial interests of the producers.

In sum, under the RPPP the substantive decision on a request for RA data is assigned to the rapporteur Member State or zonal rapporteur. Nonetheless, members of the public may choose to file a request for such information to any other authority holding the information, such as EFSA, the Commission or other Member States. It follows from *Stichting Greenpeace Nederland & PAN Europe v. Commission*<sup>234</sup> that an authority remains responsible for the final decision to (partially) refuse access to pesticide RA data. Therefore, it is advisable that an authority to which a request for information is addressed, independently reviews the decision made by the rapporteur Member State or zonal rapporteur. If a refusal seems unjustified, the authority should grant access nevertheless. This provides for an extra safeguard in assuring conformity with the Aarhus Convention.

## 6. Access to pesticide RA data and confidentiality under general EU law

There is a vast body of EU law on access to environmental information. Particularly relevant are the Aarhus Directive, the Aarhus Regulation (together: the Aarhus legislation), and the Access to Documents Regulation.<sup>235</sup> The Aarhus Directive, governs the right to environmental information at Member State level and implements the Aarhus Convention.<sup>236</sup> The right to information at the EU level is governed by the Access to Documents Regulation and the Aarhus Regulation.<sup>237</sup> The Aarhus Regulation aims to align the Access to Documents Regulation with the Aarhus Convention.<sup>238</sup>

This section discusses these general (non sector-specific) rules on access to environmental information and assesses their conformity with the Aarhus Convention. Firstly, it will be discussed to what extent pesticide RA data qualify as environmental information within the meaning of the Aarhus legislation. Secondly, the procedure for requesting environmental information will be explained briefly. Thirdly, the exceptions to the right to environmental information will be discussed as far as they are relevant in relation to pesticide RA data. Next to the general rules on access to environmental

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<sup>231</sup> General Court ECJ 8 October 2013, T-545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*), par. 33.

<sup>232</sup> ECJ 18 December 2007, C-64/05 P, *ECR* 2007, p. I-11389 (*Sweden v Commission*), par. 88.

<sup>233</sup> General Court EU 8 October 2013, T-545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*).

<sup>234</sup> *Ibid.*

<sup>235</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (*OJ* 2001, L 145/43).

<sup>236</sup> Jans & Vedder 2012, p. 369. Also see recital 5 of the Aarhus Directive.

<sup>237</sup> Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (*OJ* 2006, L 264/13).

<sup>238</sup> See in particular art. 3 Aarhus Regulation and recital 12 of the Preamble.

information, there are specialized rules on access to information in EU food law. These specialized rules will be discussed in § 7.<sup>239</sup>

### **6.1. The definition of environmental information in relation to pesticide RA**

Like in the Aarhus Convention, the definition of “environmental information” in the Aarhus Directive and the Aarhus Regulation is broad including information on “*factors, such as substances [...] emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment*”.<sup>240</sup> Information on pesticides clearly falls into this category, since pesticides are specifically designed to affect elements of the environment.

Interesting in relation to pesticide RA data is the ruling of the ECJ in *Stichting Natuur en Milieu and Others v. Ctgb*.<sup>241</sup> At issue was the refusal by the Dutch Board for the Authorisation of Plant Protection Products (Ctgb) to disclose certain studies and reports on field trials concerning residues of the active substance *propamocarb* on or in lettuce. The ECJ ruled that “environmental information” includes studies containing information on the setting of a maximum quantity of a pesticide or component thereof and information on the presence of residues in a product.<sup>242</sup> According to the Court, those studies form part of an authorisation procedure whose purpose is precisely to prevent risks and hazards for humans, animals and the environment.<sup>243</sup> The ECJ ruled that, although information on the presence of residues does not directly involve an assessment of the consequences for human health, it does concern “*elements of the environment which may affect human health if excess levels of those residues are present, which is precisely what that information is intended to ascertain*”.<sup>244</sup> Thus, “environmental information” within the meaning of the Aarhus Directive encompasses not only information directly relating to effects on elements of the environment, but also information required to estimate those effects. Most RA studies aimed at one of the evaluation criteria for approval mentioned in Annex II of the RPPP will therefore qualify as environmental information.

In *Glawischnig* the ECJ clarified that the old Environmental Information Directive (Directive 90/313/EEC) does not give a general and unlimited right of access to all information held by public authorities which has a connection, however minimal, with one of the elements of the environment.<sup>245</sup> In this light, an interesting question is whether RA data, including highly technical information such as information on the methods of analysis<sup>246</sup>, are considered to constitute environmental information. One could argue that such information only has a minimal connection to elements of the environment.

On the other hand, the public needs access to all RA data to be able to fully review the approval procedure. Therefore, all information submitted for approval constitutes environmental information within the meaning of article 2(1)(c) Aarhus Directive and article 2(1)(d)(iii) Aarhus Regulation. These articles refer to information on (*administrative*) *measures* affecting or likely to affect the elements of the environment or factors, such as substances, emissions, and discharges affecting or likely to affect those elements. This information category also includes measures or activities designed

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<sup>239</sup> See Vogelegang-Stoute 2004, p. 226-233 on access to information under the old Pesticide Directive (Directive 91/414/EC) and the old Access to Information Directive (Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment) (*OJ* 1990 L 158/56).

<sup>240</sup> Art. 2(1)(b) Aarhus Directive and 2(1)(d)(ii) Aarhus Regulation.

<sup>241</sup> ECJ 16 December 2010, C-266/09, *ECR* 2010, p. I-13119 (*Stichting Natuur en Milieu and Others v College voor de toelating van gewasbeschermingsmiddelen en biocide*).

<sup>242</sup> *Ibid.*, par. 37-43.

<sup>243</sup> *Ibid.*, par. 39.

<sup>244</sup> *Ibid.*, par. 42.

<sup>245</sup> ECJ 12 June 2003, C- 316/01, *ECR* 2003, p. I-05995 (*Eva Glawischnig v Bundesminister für soziale Sicherheit und Generationen*), par. 25.

<sup>246</sup> See Annex II, par. 3.5 RPPP.

to protect the elements of the environment. In *Stichting Natuur en Milieu and Others v. Ctgb*, Advocate General Kokott points out that certain studies *must* be submitted in the authorisation procedure and therefore form part of the basis for any authorisation. She argues that the decision on the authorisation of plant protection products is an administrative measure likely to affect the state of the elements of the environment within the meaning of article 2(1)(c) the Aarhus Directive.<sup>247</sup> In order to be able to fully assess this measure, it is reasonable in principle to regard *all* information submitted during the authorisation procedure as environmental information.<sup>248</sup> She concludes: “*Information which is submitted in the authorisation procedure is therefore information on that administrative measure, that is to say also environmental information within the meaning of Article 2(1)(c) of the Environmental Information Directive.*”<sup>249</sup>

Advocate General Kokott’s line of reasoning seems plausible. Nonetheless, some have argued that not all submitted RA data constitute environmental information, but only information dealing with identifying effects on humans and the environment.<sup>250</sup> However, this fails to take into account that under article 2(1)(c) Aarhus Directive it is irrelevant whether the information relates directly to the environment: it suffices that the information relates to *an administrative measure* likely to affect the elements of the environment. Moreover, Advocate General Kokott’s conclusion is in line with the broad interpretation of “*administrative measure for the protection of the environment*” under the old Environmental Information Directive (90/313/EEC) as established in the *Mecklenburg* case.<sup>251</sup>

An indication that information on the RA research methods does indeed constitute “environmental information” within the meaning of the Aarhus legislation, can be found in *Stichting Greenpeace Nederland & PAN Europe v. Commission*.<sup>252</sup> In this case, the General Court ruled that information on the methods of analysis and validation of data does not constitute “*information relating to emissions into the environment*”.<sup>253</sup> Under the Aarhus legislation, information relating to emissions into the environment needs to be disclosed to the public, regardless of claims for commercial confidentiality.<sup>254</sup> According to the General Court no such overriding public interest exist in relation to information on the methods of analysis and validation, which did not relate sufficiently direct to emissions into the environment. This consideration would have been irrelevant, if information on the RA research methods does not constitute environmental information in the first place. This is an indication that information on the RA research methods constitutes environmental information.

An overly restrictive interpretation of what constitutes environmental information may devoid the Aarhus Convention of much of its meaning. If information on the research methods would be excluded from the definition of environmental information, this would seriously impede the possibility to review or reproduce the RA studies by members of the public. Moreover, such a restrictive

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<sup>247</sup> AG Kokott in Case C-266/09 (*Stichting Natuur en Milieu and others vCtgb*), at. 69.

<sup>248</sup> *Ibid.*, at. 70.

<sup>249</sup> *Ibid.*, at. 71.

<sup>250</sup> Von Holleben 2013, p. 570, who states that the information needs to relate to harmful effects on human health or elements of the environment; Garçon 2012, p. 395 who states that the information needs to concern, either directly or indirectly, the affection of the elements of the environment or human health. She considers that most (but not all) information submitted in the approval procedure will constitute environmental information.

<sup>251</sup> ECJ 17 June 1998, C-321/96, ECR 1998, p. I-3809 (*Mecklenburg v Kreis Pinneberg-Der Landrat*), par. 21, in which the ECJ ruled that to constitute *environmental information*: “*it is sufficient [...] to be an act capable of adversely affecting or protecting the state of one of the sectors of the environment covered by the directive.*”

<sup>252</sup> General Court EU 8 October 2013, T 545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*).

<sup>253</sup> *Ibid.*, par. 72.

<sup>254</sup> Art. 4(2)(d) Aarhus Directive and art. 6(1) Aarhus Regulation (§ 8.2 below discusses what is to be understood by “emissions into the environment ” in EU pesticide law). Similarly, see: art. 4(4)(d) Aarhus Convention, discussed above in § 2.5

interpretation seems to be at odds with the General Courts ruling in *Stichting Greenpeace Nederland & PAN Europe v. Commission*.<sup>255</sup> Therefore, in line with Advocate General Kokott, in this paper it is assumed that all RA data submitted in the approval procedure constitutes environmental information within the meaning of the Aarhus legislation.<sup>256</sup>

## **6.2. Procedure for requesting environmental information**

The procedure for requesting pesticide RA data can be found in the Aarhus Directive and the Access to Documents Regulation; the RPPP does not provide for a specialized procedure. Because the Aarhus Directive is in line with the procedure prescribed by the Aarhus Convention as set out above in § 2.4, it will be discussed only briefly here. The Access to Documents Regulation will be discussed with a focus on its differences with the Aarhus Convention and Aarhus Directive.

Article 3 of the Aarhus Directive requires Member States to make environmental information available upon request without an interest needed to be stated. Public authorities shall make the information available within one month after the receipt of the request, to be extended with one month in case of complex or a large quantity of information.<sup>257</sup> The same time limits apply to a (partial) refusal.<sup>258</sup> In principle, the information requested shall be made available in the form requested by the applicant.<sup>259</sup> The public authority shall make reasonable efforts to maintain environmental information in a format that is readily reproducible and accessible by electronic means.<sup>260</sup> Public authorities may make a reasonable charge for supplying environmental information.<sup>261</sup> According to the ECJ a charge may not include the entire amount of the costs actually made in conducting an information request, if this would dissuade people from seeking to obtain information or restrict their right of access to information.<sup>262</sup> This is of particular importance to EU pesticide law. After all, RA data usually involve a huge amount of research information, as illustrated by the DAR on imidacloprid. This DAR consists of a total amount of 1400 pages, with reference to approximately 585 confidential studies. A request to disclose such a large number of studies, may lead to considerable costs for the authority conducting the information request. In case of a refusal, article 6 provides for access to an inexpensive administrative review procedure and a procedure before a court of law or other independent and impartial body established by law.<sup>263</sup> Furthermore, Member States may provide that third parties incriminated by the disclosure also have access to justice.

The procedure for a request for access to information held by EU institutions is to be found in the Access to Documents Regulation. An application shall be made in written form, including electronic form, and does not need to state the reasons for the application.<sup>264</sup> The Aarhus Convention and Aarhus

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<sup>255</sup> General Court EU 8 October 2013, T 545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*), par. 72.

<sup>256</sup> As will be discussed in § 6.3. below, this does not mean that all RA information must automatically be disclosed upon request.

<sup>257</sup> Art. 3(2) Aarhus Directive. Also see art. 4(2) Aarhus Convention.

<sup>258</sup> Art. 4(5) Aarhus Directive.

<sup>259</sup> Art. 3(4) Aarhus Directive, unless the information is already publicly available in another form (art. 3(4)(a) Aarhus Directive) or if it is reasonable that the authority makes it available in another form, in which case reasons must be given (art. 3(4)(b) Aarhus Directive).

<sup>260</sup> Art. 3(4) Aarhus Directive.

<sup>261</sup> Art. 5(2) Aarhus Directive.

<sup>262</sup> ECJ 9 September 1999, C-217/97, *ECR* 1999, p. I-05087, *CMLR* 1999-3, p. 277-300 (*Commission v Germany*), par. 47-48.

<sup>263</sup> Art. 4 Aarhus Directive contains the grounds for refusal and will be discussed in the next subsection.

<sup>264</sup> Art. 6 Aarhus Directive.

Directive do not prescribe that a request is made in written form.<sup>265</sup> Within 15 working days from registration of the application, the EU institution or body shall either grant access or state the reasons for a total or partial refusal.<sup>266</sup> This may be extended with 15 working days in exceptional cases.<sup>267</sup> This time-limit is shorter than the month (extendable with another month) under the Aarhus Convention and the Aarhus Directive. If a request is (partially) refused or if the institution fails to reply within the prescribed time-limit, the applicant may make a confirmatory application.<sup>268</sup> If a confirmatory application is made, the institution shall grant access or state the reasons for the total or partial refusal. In case of a (partial) refusal or a failure to reply, the applicant may make a complaint to the European Ombudsman and/or start proceedings before the ECJ in accordance with article 228 and 263 TFEU.<sup>269</sup> This procedure is largely in line with the requirements for access to justice under the Aarhus Convention.<sup>270</sup> However, the General Court ruled that a suit against a failure to reply timely, is admissible only if the public authority has not decided upon the request at a later stage. If at the time of the judgement a decision has been made - despite being for example five months too late - the applicants have no interest in pursuing their claim.<sup>271</sup> This line of jurisprudence does not promote timely decision-making by EU institutions. Moreover, it is highly questionable whether it is in conformity with article 9(1) Aarhus Convention, which requires effective access to an independent court in case of a failure to decide timely upon a request for environmental information. Also article 10(1) of the Access to Documents Regulation may be in conflict with the Aarhus Convention. This article states that the charge made for an application shall not exceed the real cost of producing and sending the copies. Member States, on the other hand, are not allowed to pass on the entire amount of the costs.<sup>272</sup> It is questionable whether this provision is in conformity with article 4(8) of the Aarhus Convention which only allows for reasonable charges.<sup>273</sup> Moreover, the Aarhus Convention requires that public authorities intending to make such a charge, make available to applicants a schedule of charges which may be levied.<sup>274</sup> From this it follows that charges should be set in advance, precluding authorities to redeem the actual costs.

In sum, although the Aarhus Directive has implemented the Aarhus Convention effectively in relation to Member States, the Aarhus Regulation deviates from the Aarhus Convention on certain points. In particular, the right to RA data may be severely restricted if EU institutions do not observe the time limits for deciding upon a request for environmental information or if they would levy charges equalling the actual costs of conducting a request for pesticide RA data.

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<sup>265</sup> Also see the Aarhus Implementation Guide 2013, p. 73. The Commission notes in its Aarhus Implementation Report that: "*Freedom of forms prevails, so a simple letter or email is sufficient to register an application*" (Commission Aarhus Implementation Report, COM(2011) 208 final, p. 8). The Commission does not refer to oral requests. One could argue that the Aarhus Regulation is supposed to solve this discrepancy by providing in art. 3 that the Access to Documents Regulation applies to *any* request for environmental information. However, strictly speaking, this implies that the requirement of a written request in the Access to Documents Regulation applies to any request for environmental information.

<sup>266</sup> Art. 7(1) Access to Documents Regulation.

<sup>267</sup> Art. 7(3) Access to Documents Regulation.

<sup>268</sup> Art. 7(2) and (4) Access to Documents Regulation.

<sup>269</sup> Art. 8 Access to Documents Regulation.

<sup>270</sup> See § 2.4 of this paper on the requirements for access to justice in art. 9(1) of the Aarhus Convention.

<sup>271</sup> General Court EU 9 November 2011, T-120/10, *not yet published (ClientEarth & others v Commission)*, par. 46-56.

<sup>272</sup> ECJ 9 September 1999, C-217/97, *ECR* 1999, p. I-05087, *CMLR* 1999-3, p. 277-300 (*Commission v Germany*), par. 47-48.

<sup>273</sup> Likewise: Jans & Vedder 2012, p. 375.

<sup>274</sup> Art. 3(8) Aarhus Convention.

### **6.3. Grounds for refusal**

Both the Aarhus Directive and the Access to Documents Regulation list the grounds for refusal of a request for environmental information.<sup>275</sup> Article 4(1) and (2) of the Aarhus Directive list thirteen grounds for refusal of which four are of particular relevance in relation to disclosure of pesticide RA data. Those four exceptions will be discussed in more detail below. The grounds shall be interpreted restrictively, taking into account the public interest served by disclosure.<sup>276</sup> More than one ground for refusal may apply simultaneously to an information request. For example, disclosure of RA data may at the same time adversely affect the confidentiality of commercial information, the confidentiality of personal data and the protection of intellectual property rights. In *Office of Communications v The Information Commissioner*<sup>277</sup> the ECJ ruled that if several grounds for refusal overlap, the public interests served by disclosure may be weighed against the interests served by refusal, taking into account cumulatively a number of the grounds for refusal.<sup>278</sup>

The grounds for refusal in article 4 of the Access to Documents Regulation need to be read in conjunction with article 6(1) of the Aarhus Regulation. The latter provides that the grounds for refusal in the Access to Documents Regulation need to be interpreted in a restrictive way, taking into account the public interest served by disclosure and whether the information requested relates to emissions into the environment. On some points, the Access to Documents Regulation deviates from the Aarhus Directive and the Aarhus Convention. For example, the Access to Documents Regulation contains a ground for refusal based on the protection of the financial, monetary or economic policy of the EU or a Member State.<sup>279</sup> This exception cannot be found in the Aarhus Convention (or the Aarhus Directive).<sup>280</sup> Overall, however, the exceptions in the Access to Documents Regulation largely overlap with the Aarhus Directive and will be discussed separately only as far as these two instruments differ.

#### **6.3.1. Material in the course of completion or unfinished documents and internal communications**

Interesting in relation to pesticide RA is article 4(1)(d) Aarhus Directive, which states that a request may be refused if it concerns material in the course of completion or unfinished documents or data. This exception is in conformity with the Aarhus Convention.<sup>281</sup> Under EU pesticide law, the rapporteur Member State or the zonal rapporteur is required to make an independent, objective and transparent assessment in the light of current scientific and technical knowledge.<sup>282</sup> As long as that assessment is not completed, one could argue that a request for RA data may be refused on the basis of article 4(1)(d) Aarhus Directive. This has the clear disadvantage that public participation may only fully take place after completion of the assessment, which decreases the change that the rapporteur Member State or the zonal rapporteur integrates environmental concerns amongst the public in its assessment. However, although the Aarhus Convention does not clearly define “material in the course of completion”, the Aarhus Implementation Guide clarifies that this notion solely relates to the process of preparation of the information. It does not include any decision-making process for the purpose of

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<sup>275</sup> Art. 4 Aarhus Directive and art. 4 Access to Documents Regulation.

<sup>276</sup> Art. 4(2) Aarhus Directive.

<sup>277</sup> ECJ 28 July 2011, C-71/10, ECR 2011, p. I-07205 (*Office of Communications v Information Commissioner*).

<sup>278</sup> *Ibid.*, par. 28-32.

<sup>279</sup> Art. 4(1)(a), fourth indent Access to Documents Regulation.

<sup>280</sup> Nonetheless, the ECJ has occasionally allowed for EU institutions to rely on this ground for refusal in relation to environmental information. See: Jans & Vedder 2012, p. 373 with reference to General Court EU 13 January 2011, T-362/08, ECR 2011, p. II-00011 (*IFAW Internationaler Tierschutz-Fonds*).

<sup>281</sup> See art. 4(3)(c) Aarhus Convention.

<sup>282</sup> Art. 11(2) and 36(1) RPPP.

which the information has been prepared. Moreover, raw environmental data, such as raw RA data, do not fall under this exception.<sup>283</sup> The interpretation in the Aarhus Implementation Guide seems justified, because a broader interpretation of “material in the course of completion” would unduly limit the public's right to effectively participate in the decision-making process.

A related ground for refusal can be found in article 4(1)(e) of the Aarhus Directive and involves internal communications. Under this exception disclosure of internal communications on the approval of a pesticide may be refused. Such internal communications may also relate to the pesticide RA studies. What is understood by “internal communications” is again not clearly defined in the Aarhus Convention. The Aarhus Convention Implementation Guide favours a restrictive interpretation, stating that the exception is mainly intended to protect the personal opinions of government staff : “*It does not usually apply to factual materials even when they are still in preliminary or draft form.*”<sup>284</sup> Thus, disclosure of internal communications cannot be refused as far as it contains factual RA data. In addition, according to the Implementation Guide: “*Opinions or statements expressed by public authorities acting as statutory consultees during a decision-making process cannot be considered “internal communications”. Neither can studies commissioned by public authorities from related, but independent, entities.*” This could mean that opinions expressed by the rapporteur Member State cannot be considered “internal communications”. In addition, it follows from the Implementation Guide that once particular information has been disclosed by the authority to a third party, it does not qualify as “internal communications”. Thus, if for example certain (interim) conclusions or opinions on the RA are shared with the applicant, this cannot be regarded as internal communications. If the interpretation favoured by the Implementation Guide is followed, this would mean that mainly personal opinions of staff that are not shared with third parties fall under the scope of article 4(1)(e) Aarhus Directive. Most RA data will therefore not fall under this exception.

The Access to Documents Regulation contains a slightly different ground for refusal in article 4(3) relating to the internal communications and the protection of the EU institutions' decision-making process. It is one of the most common grounds on which the Commission bases refusals.<sup>285</sup> Information may be refused if it is drawn up for internal use or is received by the authority on a matter in which the authority still needs to make a decision and disclosure of the information would seriously undermine the authority's decision-making process. This provision refers to documents drafted by the public authority as well as documents *received* by the authority. However, the EU Ombudsman decided that the exception does not apply to documents sent to the Commission by Member States.<sup>286</sup> This interpretation is in line with the Aarhus Convention, which does not contain an exception regarding documents that are received by the authority on a matter in which the authority still needs to make a decision. The second paragraph of article 4(3) of the Access to Documents Regulation provides that information containing opinions for internal use as part of deliberations and preliminary consultations within the authority shall be refused, even after the decision has been taken, if disclosure of the document would seriously undermine the authority's decision-making process.

By requiring that the EU public authority's decision-making process would be *seriously undermined*, the Access to Documents Regulation is in fact more restrictive than the Aarhus Convention, which merely refers to unfinished documents and internal communications.<sup>287</sup> It follows

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<sup>283</sup> Aarhus Implementation Guide 2013, p. 79.

<sup>284</sup> Aarhus Implementation Guide 2013, p. 79.

<sup>285</sup> Commission Aarhus Implementation Report, COM(2011) 208 final, p. 11-12.

<sup>286</sup> European Ombudsman 12 December 2006, case nr. 1463/2005/TN against the European Commission, point 1.14. Also see in this regard the Commission Aarhus Implementation Report, COM(2011) 208 final, p.13.

<sup>287</sup> Art. 4(3)(c) Aarhus Convention.



from settled case law that the risk of the decision-making process being undermined must be reasonably foreseeable and not purely hypothetical.<sup>288</sup> Consequently, the authority should specify how disclosure of the information would concretely and effectively undermine its decision-making process.<sup>289</sup> In a complaint brought before the European Ombudsman, the Commission argued that revealing the names of civil servants participating in a Commission working group would facilitate criticism against them. This would limit the Commission's capacity to adopt its position free from external influences.<sup>290</sup> The Ombudsman, however, found that the Commission's statement was "*not supported by any properly reasoned argument*" and "*based on a purely hypothetical assumption*".<sup>291</sup>

Thus, the purely hypothetical undermining of the decision-making process does not justify a refusal on the grounds of article 4(3) of the Access to Documents Regulation. Even if a refusal under article 4(3) of the Access to Documents Regulation seems justified, this needs to be balanced against the public interest in disclosure and the exception needs to be interpreted restrictively.<sup>292</sup> The decision should be based on a genuine examination of the particular circumstances of the case.<sup>293</sup>

In conclusion, disclosure of unfinished documents and internal communications may be refused on certain grounds on both the national and the EU level. Taking note of the Aarhus Implementation Guide, relevant EU case law and the EU Ombudsman's decisions it seems that a refusal to disclose pesticide RA data may not be based on these grounds easily.

### **6.3.2. Confidentiality of commercial or industrial information**

In line with the Aarhus Convention<sup>294</sup>, article 4(2)(d) of the Aarhus Directive provides for confidentiality of commercial or industrial information provided for by national or Community law to protect a legitimate economic interest. Likewise, article 4(2) of the Access to Documents Regulation provides for a ground for refusal based on the protection of commercial interests of a natural or legal person. Next to these general rules on commercial confidentiality, the RPPP contains a specialized confidentiality regime in article 63, which will be discussed hereafter in § 7.

According to the Aarhus Implementation Guide, the commercial confidentiality exception requires that a legitimate economic interest is established. This implies that the information is not already in the public domain and that the body whose interests are at stake took reasonable measures to protect the information. Moreover, it implies that disclosure would significantly damage the economic interests involved and assist competitors.<sup>295</sup> These requirements will often be fulfilled in relation to pesticide RA data. There is a clear economic interest for pesticide producers to keep RA information confidential. Once disclosed, RA information may be used by any competitor, saving them the effort of conducting expensive and time-consuming RA research themselves. This could give competitors an unfair commercial advantage and could make it unprofitable for producers to spend their resources on innovative research and the development of new products.

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<sup>288</sup> ECJ 17 October 2013, C-280/11, *not yet published (Council v Access Info Europe)*, par. 31; CFI 7 February 2002, T-211/00 *ECR* 2002, p. II-485 (*Kuijer v Council*), par. 56; CFI 13 April 2005, T-2/03, *ECR* 2005, p. II-1121 (*Verein für Konsumenteninformation v Commission*), par. 69.

<sup>289</sup> Commission Aarhus Implementation Report, COM(2011) 208 final, p. 13.

<sup>290</sup> European Ombudsman 4 July 2012, case nr. 127/2010/VIK against the European Commission, par. 30.

<sup>291</sup> *Ibid.*, par. 57(ii).

<sup>292</sup> For example, see: ECJ 17 October 2013, C-280/11, *not yet published (Council v Access Info Europe)*, par. 32.

<sup>293</sup> See inter alia: CFI 19 July 1999, T-14/98, *ECR* 1999, p. II-2489 (*Hautala v Council*), par. 67.

<sup>294</sup> Art. 4(4)(d) Aarhus Convention.

<sup>295</sup> Aarhus Implementation Guide 2013, p. 82.

In conformity with the Aarhus Convention, the commercial confidentiality exception in the Aarhus Directive and the Access to Documents Directive<sup>296</sup> is subject to an overriding public interest in disclosure if the information relates to emissions into the environment. This 'exception to the exception' is based on the idea that information about emissions loses its proprietary character once the emissions enter the public domain.<sup>297</sup> In relation to RA pesticide data, there may be an overriding public interest in disclosure if the data relate, for example, to the determination of impurities, which will be eventually emitted into the environment.<sup>298</sup>

### 6.3.3. *Intellectual property rights*

A third relevant ground for refusal can be found in article 4(2)(e) of the Aarhus Directive in case disclosure of environmental information would adversely affect intellectual property rights. Intellectual property rights are granted for original human work and include, amongst others, copyrights, patents, and trademarks.<sup>299</sup> A similar ground for refusal can be found in article 4(2) of the Access to Documents Regulation. Several intellectual property rights may be affected by the publication of pesticide RA data, such as copyrights on RA reports and patents on testing methods.

One could argue that publication of copyrighted RA study reports, in itself, would be a violation of the copyright. After all, once disclosed, anyone could (illegally) copy, use and distribute the RA study report. However, as said, the grounds for refusal in the Aarhus Directive and Access to Documents Regulation need to be interpreted in a restrictive way, taking into account the public interest served by disclosure. Thus, the sole risk of a violation of intellectual property rights in itself should not outweigh the public interest in disclosure. The UK's Information Commissioner's Office takes a similar position, stating that intellectual property rights should generally not prevent a public authority from disclosing the information. To apply the exception, it must be shown that disclosing environmental information will actually harm the ability of the rights holder to exploit or control their intellectual property right. Technically infringing intellectual property rights is not enough.<sup>300</sup> This approach is in line with the broad access to environmental information aimed for by the Aarhus Convention.

Under the Access to Documents Regulation, the intellectual property exception is subject to an overriding public interest in disclosure if the information requested relates to emissions into the environment.<sup>301</sup> Interestingly, this goes further than what is required under the Aarhus Convention.<sup>302</sup> No similar overriding public interest exists under the Aarhus Directive.<sup>303</sup> This means that Member States always have to weigh the public interest in disclosure against the protection of the intellectual property rights, also if the information relates to emissions into the environment.<sup>304</sup> Thus, although RA data relating to emissions into the environment cannot not enjoy commercial confidentiality under the Aarhus Directive, Member States may refuse to disclose the information anyway in order to protect intellectual property. Therefore, if there is a change that RA data may be protected under the

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<sup>296</sup> Through art. 6(1) Aarhus Regulation.

<sup>297</sup> Aarhus Implementation Guide 2013, p. 83.

<sup>298</sup> See: General Court EU 8 October 2013, T-545/11, *not yet published* (*Stichting Greenpeace Nederland and PAN Europe v European Commission*), par. 69-71, 73 & 75.

<sup>299</sup> For an extensive overview of the different types of intellectual property rights in the EU, see: Seville 2009.

<sup>300</sup> UK's Information Commissioner's Office 2013, p. 10.

<sup>301</sup> See art. 6(1) Aarhus Regulation.

<sup>302</sup> The Aarhus Convention only provides for an overriding public interest in disclosure in case of emissions into the environment in relation to commercial confidentiality (see art. 4(3)(d) Aarhus Convention).

<sup>303</sup> Likewise: Jans & Vedder 2012, p. 373.

<sup>304</sup> Garçon 2012, p. 396.

intellectual property exception, it is advisable to file a request for access to these data always also at the EU level.

The regime in the RPPP already (partially) protects producers against infringements of intellectual property rights by competitors. Article 59 RPPP provides for a specialized data protection regime with a view on protecting the financial interests of the information holder. A justified claim for data protection under article 59 prevents Member States from using the study reports in another authorisation procedure for the benefit of competitors. Thus, if RA data are publicly disclosed, the holder of the information is, for a certain time period, protected against competitors using those studies. Data protection is granted for a period of ten, thirteen or, in exceptional cases, fifteen years. These time-limits show that the protection of intellectual property rights in the field of EU pesticide law is limited by law. Furthermore, to prevent duplication of tests on vertebrate animals, data protection does not apply to studies involving vertebrate animal testing. Article 62 RPPP provides that the holder shall endeavour to share such tests with other applicants, who then should share in the costs. If the holder and prospective applicant fail to reach agreement on the sharing of the studies, this does not prevent the Member State from using the test and study reports for the purpose of the application of the competitor.

From article 59 and 62 RPPP it follows that within EU pesticide law, intellectual property rights can make way for other interests involved, such as animal wellbeing. Therefore, a refusal to disclose pesticide RA data on the basis of intellectual property rights should not be approved easily. In addition, under the Access to Documents Regulation there is an overriding public interest in disclosure if the RA data relate to emissions into the environment.<sup>305</sup>

#### **6.3.4. Protection of personal data**

A fourth interesting ground for refusal can be found in article 4(2)(f) of the Aarhus Directive involving the protection of personal data. This exception covers personal data relating to a natural person where that person has not consented to the disclosure of that information. A slightly broader exception can be found in article 4(1)(b) of the Access to Documents Regulation relating to the protection of the privacy and the integrity of individuals. Personal data may include information on the identity of the RA researchers or the national officials involved in drafting the DAR. Such information might be relevant to the public, since it allows for review of the independence, affiliations and expertise of the RA researchers.

Interesting is a recent case where the ECJ had to rule on a request for information on experts involved in the preparation of an EFSA draft guidance document.<sup>306</sup> Two environmental NGO's applied for access to information on the preparation of the draft guidance document. The names, biographies and declarations of interests in respect of each of the experts were disclosed on EFSA's website. Moreover, EFSA disclosed, amongst others, the comments of the consulted expert panels. However, EFSA refused to disclose the individual author of each comment. The ECJ ruled that such information is protected from disclosure under Regulation No 45/2001 on the protection of personal data.<sup>307</sup>

By analogy, this judgement could apply to data on scientists involved in RA studies and individuals involved in drafting the DAR. In addition, article 63(2)(g) RPPP provides that

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<sup>305</sup> This will often be the case, see the discussion hereafter in § 8.2.

<sup>306</sup> General Court EU 13 September 2013, T-214/11, *not yet published (ClientEarth and PAN Europe v EFSA)*.

<sup>307</sup> Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (*OJ* 2001, L 8/1).

confidentiality may be presumed if it concerns data on researchers involved in vertebrate animal testing (discussed hereafter in § 7). On the other hand, one could argue that, vice versa, such a presumption suggests that data on researchers involved in other kinds of RA studies are not necessarily confidential. Moreover, on the national level, the Aarhus Directive provides for an overriding public interest in disclosure if the information relates to emissions into the environment.<sup>308</sup>

In sum, disclosure of RA data containing personal information on individuals may be refused in order to protect their integrity and privacy, providing there is no overriding public interest in disclosure. Although this may be worrying in cases where the independence and expertise of RA researchers or the authority's officials is questioned, this is in line with the Aarhus Convention.<sup>309</sup>

#### **6.4. Discrepancies with the Aarhus Convention?**

The Aarhus Directive seems to be in line with the Aarhus Convention, and even provides for wider access to environmental information in certain cases. Moreover, the ECJ has ruled that the Aarhus Directive needs to be interpreted in conformity with the Aarhus Convention.<sup>310</sup> Thus, even if there were discrepancies between the Aarhus Directive and the Aarhus Convention, this should not lead to a violation of the latter in practice. The Access to Documents Regulation and the Aarhus Regulation, however, do deviate from the Aarhus Convention on certain points. In particular, the right to RA data may be restricted if EU institutions do not observe the time limits for deciding upon a request for environmental information<sup>311</sup> or if they would levy charges equalling the actual costs of conducting an information request. This could lead to infringements of the Aarhus Convention, until the EU courts rule otherwise.<sup>312</sup> But in most cases, also these EU instruments are in line with the Aarhus Convention, providing for wide access to environmental information. Since this is an observation not typical to EU pesticide law, the next section will discuss the specialized rules on the right to information and confidentiality in EU food law.

### **7. Confidentiality of RA studies under the RPPP and EU food law**

Next to the general EU rules on access to environmental information, the RPPP and other instruments of EU food law contain specialized rules on access to documents and confidentiality. This section will discuss article 63 RPPP, which contains a specialized confidentiality regime for information submitted by applicants in the approval procedure. Secondly, other relevant instruments of EU food law and the internal rules of EFSA on access to documents will be discussed.

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<sup>308</sup> In this regard, the Aarhus Directive goes further than what is required by the Aarhus Convention and a similar provision cannot be found in the Access to Documents Regulation or Aarhus Regulation. However, in most cases personal data relating to RA researchers will not constitute "information relating to emissions into the environment".

<sup>309</sup> Art. 4(4)(f) Aarhus Convention. See on this article: Aarhus Implementation Guide 2013, p. 84.

<sup>310</sup> ECJ 18 July 2013, C-515/11, *not yet published (Deutsche Umwelthilfe eV v Bundesrepublik Deutschland)*, par. 32.

<sup>311</sup> General Court EU 9 November 2011, T-120/10, *not yet published (ClientEarth & others v Commission)*, par. 46-56.

<sup>312</sup> The EU courts may rule that the Aarhus Regulation and Access to Documents Regulation are set aside by the provisions of the Aarhus Convention, as was the case in: General Court EU of 14 June 2012, T-338/08, *not yet published (Stichting Natuur en Milieu and Pesticide Action Network Europe v European Commission)* and General Court EU of 14 June 2012, T-396/09, *not yet published (Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht v European Commission)*.

### **7.1. Article 63 RPPP**

When submitting the application for national authorisation, the applicant may request certain information, including certain parts of the dossier, to be kept confidential pursuant article 63 RPPP. Article 63 provides for a specialised confidentiality regime, but explicitly states that it is without prejudice to the provisions of the Aarhus Directive.<sup>313</sup> The applicant shall physically separate the confidential information. Upon a request for access the rapporteur Member State or zonal rapporteur shall decide what information is to be kept confidential.<sup>314</sup> In addition, the RPPP contains various active disclosure duties that may be restricted on the basis of article 63. For example, article 10 states that EFSA shall without delay make the summary dossier available to the public, providing no confidential treatment has been requested and justified, unless there is an overriding public interest in disclosure. Similarly, article 12 provides that the DAR shall be made public by EFSA, after giving the applicant two weeks to request that certain parts of the DAR be kept confidential.<sup>315</sup>

If an applicant requests confidentiality under article 63, he should provide verifiable evidence that disclosure would undermine his commercial interests or the protection of the privacy and the integrity of individuals.<sup>316</sup> One may think of data relating to the research methods and the layout of the RA studies. For example, EFSA states that disclosure of information may undermine the commercial interest of the applicant if the information relates to specific analytical methods based on novel technology used for generating residue data.<sup>317</sup> With such information, competitors could simply replicate the RA studies, without spending time and resources on developing research methods and necessary technology. As said before, this could lead to an unfair commercial advantage for competitors over the primary holder of the RA studies.

The second paragraph of article 63 lists seven specific types of information which shall normally be deemed confidential:

- a) the method of manufacture;
- b) the specification of impurity<sup>318</sup> of the active substance;
- c) results of production batches;
- d) methods of analysis for impurities;
- e) links between a producer/importer and the applicant/ authorisation holder;
- f) information on the complete composition of a plant protection product; and
- g) names and addresses of persons involved in vertebrate testing.

The exceptions under a) and d) relating to information on impurities, do not apply if the information relates to impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant. However, a similar exception does not apply to the other types of information that can be environmentally relevant, such as information on the complete composition of a plant protection product. Most of the information listed in article 63(2) also fall under the grounds for refusal relating to the protection of commercial interests and intellectual property in the Aarhus legislation. The information listed under e) (links between a producer/importer and the applicant/ authorisation holder)

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<sup>313</sup> Art. 63(3) RPPP.

<sup>314</sup> Art. 7(3) and 33(4) RPPP.

<sup>315</sup> Also see for example art. 16 RPPP that stipulates that EFSA shall without delay make available to the public renewal information provided by the applicant, again with the exception that no confidential treatment has been requested.

<sup>316</sup> Art. 63(1) RPPP.

<sup>317</sup> EFSA 2011, p. 2.

<sup>318</sup> "Impurity means any component other than the pure active substance and/or variant which is present in the technical material (including components originating from the manufacturing process or from degradation during storage)" (art. 3(33) RPPP).

and g) (names and addresses of persons involved in vertebrate testing) are exceptions. These two types of information relate to the protection of the privacy and integrity of legal or natural persons.

There is a clear tension between article 63 and the Aarhus Convention and, by the same token, the Aarhus legislation. Article 63(1) provides for a rather open provision under which various requests for confidentiality may be launched. If it concerns information listed in article 63(2), the applicant does not need to prove that his commercial interests or the privacy and integrity of individuals would be undermined by disclosure. Rather, it seems that the individual requesting the information needs to establish that confidentiality is not justified. Thus, the burden of proof is shifted. The phrase “shall normally be deemed” leaves a small amount of discretion to the national authorities to disclose the information in exceptional cases. Nonetheless, the presumption in article 63(2) seems to be in conflict with the discretionary power for authorities to allow or refuse a claim for confidentiality under the Aarhus Convention. Moreover, the grounds for refusal in the Aarhus Convention shall be interpreted restrictively, taking into account the public interest served by disclosure and whether the information relates to emissions into the environment.<sup>319</sup> Moreover, the Aarhus Convention does not allow for commercial confidentiality if the information requested relates to emissions into the environment. On top of that, the Aarhus Regulation also provides for a similar overriding public interest in disclosure in relation to the protection of intellectual property and the Aarhus Directive in relation to the protection of personal data.<sup>320</sup>

Article 63 seems to be largely drafted with an eye on protecting the applicants interests. It is strikingly different from the confidentiality regime in article 14 of the old Pesticide Directive (91/414/EEC). This article contained a negative list, listing information that could *not* be regarded as confidential, rather than information that is normally considered confidential. Information that could not be regarded as confidential included information on physico-chemical data, information on the methods relating to impact on human and animal health and the environment, and information on the methods relating to the presence, quantities and environmental effects of residues. Thus, under article 14 of the old Pesticide Directive most of the environmentally relevant information relating to the RA methodology could *not* be considered confidential. It is clear that article 63 RPPP is a considerable change to article 14 of the old Pesticide Directive. Advocates of the pesticide industry consider this an indication that, compared to the old Pesticide Directive, article 63(2) RPPP aims for an increased level of protection of the information listed, which cannot be set aside by the Aarhus legislation.<sup>321</sup> Indeed, article 63(2) RPPP could potentially seriously limit the right to information in EU pesticide law.<sup>322</sup> It is therefore interesting to look at the legislative and political background of article 63.

The final text of article 63 is surprisingly different from the initial proposal. The initial article 60(2) stated:

*"As regards the commercial interests referred to in paragraph 1, only the following elements shall be considered confidential:*

*(a) the method of manufacture;*

*(b) the specification of purity of the active substance except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant;*

*(c) information on the complete composition of a plant protection product."<sup>323</sup>*

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<sup>319</sup> Art. 4(4) Aarhus Convention.

<sup>320</sup> In this regard, the Aarhus legislation goes further than the Aarhus Convention. It must be said, however, that the tension between the RPPP and the Aarhus Directive is largely of a theoretical nature, since the names and addresses of RA researchers will usually not qualify as "information relating to emissions into the environment".

<sup>321</sup> Garçon 2012, p. 397.

<sup>322</sup> In this regard, also see Garçon 2012, p. 397.

<sup>323</sup> Commission Proposal, COM(2006) 388 final, p. 54.

This list is considerably shorter than the list in article 63(2) RPPP. Moreover, this article limits the scope of commercial confidentiality to three specific types of information, excluding all other types of RA data from confidentiality. In its Common Position, the Council included the current article 63(2), shifting the burden of proof in relation to considerably more types of RA information.<sup>324</sup> In its communication to the European Parliament, the Commission commented on these changes:

*“Some changes have been done in Article 60, setting out the rules on confidentiality. These amendments are mostly technical and clarify the difference between the protection of commercial rights of companies and the protection of privacy and integrity of individuals.”*<sup>325</sup>

It is difficult to understand why the Commission states that the Council's amendment is mostly technical in nature. The amended article 63(2) lists four more types of, presumably confidential, RA data. Moreover, applicants can now claim commercial confidentiality for any type of RA data, rather than only for the three specific types of information initially listed in article 60(2) of the proposal. In addition, the amendment is at odds with the Commission initial statement that there was no reason to explicitly protect the privacy of individuals involved in vertebrate testing, since such information may already be protected under the general rules on access to information.<sup>326</sup> In sum, the Council's amendment would have benefited from a more elaborated and clearer explanation than the Commission's flawed reference to its technical nature.

It is clear that the right to environmentally relevant RA data may be severely restricted by article 63 RPPP. On several points, article 63 seems to be in conflict with the Aarhus Convention. However, before discussing this tension in more detail in §8, the next subsection will discuss other rules of EU food law which are relevant in relation to requests for pesticide RA data.

## ***7.2. Access to documents held by EFSA under EU food law***

The General Principles of Food Law contain provisions on transparency specifically addressed to EFSA. It provides that the Access to Documents Regulation, which only applies to the Commission, the Parliament and the Council, is to apply to applications for access to documents held by EFSA.<sup>327</sup> Nowadays, this article is of little value since the Aarhus Regulation contains a similar provision in article 3.<sup>328</sup> However, the General Principles of Food Law contain other interesting provisions on access to information held by EFSA.

First of all, section 2 of the General Principles of Food Law contains principles of transparency to which EFSA must adhere. Article 10 provides for an active disclosure duty in case that food poses a suspected risk for human or animal health. Article 9 stipulates that, as a starting point, there shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law. In relation to active substances, EFSA launches a period of 60 days for public consultation after publication of the DAR.<sup>329</sup> In addition, the EFSA may

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<sup>324</sup> Council Common Position (EC) No 25/2008.

<sup>325</sup> Commission Communication, COM(2008) 578 final, p. 8

<sup>326</sup> Amended Commission Proposal, COM(2008) 93 final, p. 9 and 63.

<sup>327</sup> Art. 41(2) General Principles of Food Law.

<sup>328</sup> A proposal of the Commission (2011) aims to make the Access to Documents Regulation directly applicable to other EU agencies, aligning it with art. 5(3) of the Treaty on the Functioning of the European Union (see Commission Proposal, COM(2011) 137 final).

<sup>329</sup> See EFSA's website: [www.efsa.europa.eu/en/pesticides/pesticidesconsultations.htm](http://www.efsa.europa.eu/en/pesticides/pesticidesconsultations.htm). A list of active substances open to public review is to be found here: <http://dar.efsa.europa.eu/dar-web/consultation>. Also see art. 12(1).

launch public consultations on scientific topics.<sup>330</sup> It is clear that such public consultations has little effect if the public does not have prior access to the relevant scientific data on the environmental risks involved. However, it must be said that even if access to RA data is granted, it is questionable whether the public may take account of this information timely as to comment within the 60 day period for public consultation. EFSA may take more than a month to reply to a request for information<sup>331</sup>, leaving only a month or less for the public to examine a large amount of complex RA data. In case of a (partial) refusal the consultation period is long closed before a court has the chance to rule on the legitimacy of the refusal. Therefore, although the right to RA data is a prerequisite for public scrutiny of RA, other procedural changes to EU pesticide law may be required in order to fully integrate public viewpoints and concerns into the decision-making process.

Section 4 of the General Principles of Food Law contains provisions on independence, transparency, confidentiality and communication by EFSA. Article 38(1) states that EFSA shall ensure that it carries out its activities with a high level of transparency. This includes the obligation to make public without delay the information on which the EFSA's opinions are based, without prejudice to article 39 and article 41 of the General Principles of Food Law. Article 41(1) provides that EFSA shall ensure wide access to documents it possesses. Article 39 contains a rather broad and general confidentiality provision. EFSA's Management Board shall adopt more detailed provisions on access to documents, taking full account of the EU principles and conditions applicable to access to EU institutions' documents.<sup>332</sup>

EFSA's Management Board has done so in its Decision Concerning Access to Documents.<sup>333</sup> There are some striking discrepancies between this Decision on the one hand, and the Aarhus legislation and the Access to Documents Regulation on the other. Firstly, while the Access to Documents Regulation provides for a time-limit of 15 working days for the authority to reply to an application for information, the EFSA's Management Boards Decision provides for a time-limit of a month.<sup>334</sup> Secondly, article 3 states that EFSA "*shall* refuse access to certain documents" in case of one of the exceptions mentioned in article 4 of the Access to Documents Regulation. In particular, it *shall* refuse access where the disclosure would undermine:

- a) the privacy and integrity of individuals;
- b) commercial interests of a natural or legal person;
- c) the EFSA's decision-making process, internal or preliminary consultations and deliberations, with a view to safeguard the freedom of the scientific debate and guarantee the independence vis-à-vis external influence; and,
- d) the EU or EFSA's public interests, international relations or financial interests.<sup>335</sup>

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<sup>330</sup> [www.efsa.europa.eu/en/calls/consultations.htm](http://www.efsa.europa.eu/en/calls/consultations.htm). For example, it has launched an open consultation on the Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile: [www.efsa.europa.eu/en/consultationsclosed/call/130717.htm](http://www.efsa.europa.eu/en/consultationsclosed/call/130717.htm).

<sup>331</sup> The time limits for EFSA to reply, are 15 respectively a month (art. 7(1) Access to Documents Regulation art. 5 (3) of the EFSA Decision Concerning Access to Documents, nr. MB 16.09.2003). Both time periods may be extended with 15 working days in exceptional cases (art. 7(2) Access to Documents Regulation and art. 5(4) EFSA Decision Concerning Access to Documents, nr. MB 16.09.2003).

<sup>332</sup> Art. 41(2) General Principles of Food Law.

<sup>333</sup> EFSA Decision Concerning Access to Documents, nr. MB 16.09.2003.

<sup>334</sup> Compare art. 7(1) Access to Documents Regulation and art. 5 (3) EFSA Decision Concerning Access to Documents, nr. MB 16.09.2003. Both time periods may be extended with 15 working days in exceptional cases (art. 7(3) Access to Documents Regulation and art. 5(4) EFSA Decision Concerning Access to Documents, nr. MB 16.09.2003). Although the EFSA Decision Concerning Access to Documents derogates from the Access to Documents Regulation, it is in line with art. 4(2) Aarhus Convention.

<sup>335</sup> Also other exceptions are mentioned, such as the protection of court proceedings and the fact that disclosure would undermine the protection of public security, defence and military matters.



Except for the protection of the EU or EFSA's financial interests, these exceptions are in line with the Aarhus Convention.<sup>336</sup> Not in conformity, however, is that EFSA *shall* refuse access. In particular, it shall refuse access where the disclosure would undermine amongst others: the privacy and integrity of individuals, commercial interests, or the EFSA's decision-making process. On the basis of these exceptions disclosure of virtually all RA data could be refused. The use of "*shall*" leaves little room for a restrictive interpretation, taking into account the public interest in disclosure, as required by the Aarhus Regulation<sup>337</sup> and the Aarhus Convention.<sup>338</sup> In addition, in the commercial confidentiality clause under b) there is no mention of an overriding public interest if information relates to emissions into the environment. Last, in conformity with the Aarhus Regulation, but in contrast with the Aarhus Convention<sup>339</sup>, the Decision specifically allows EFSA to redeem all costs actually incurred by conducting the information request if it involves a document of more than 20 pages.<sup>340</sup>

EFSA's Decision does not refer to the Aarhus Regulation, unlike for example the Management Decision of the European Chemicals Agency (ECHA) on access to documents.<sup>341</sup> This can be explained by the fact that EFSA's Decision (2003) precedes the Aarhus Regulation (2006). One must assume that EFSA will take full account of the provisions of the Aarhus Regulation, being higher in rank than EFSA's Decision Concerning Access to Documents. As far as it concerns environmental information, the Decision should be carried out in conformity with the Aarhus Regulation and the Aarhus Convention. After all, as stated by the General Principles of Food Law, EFSA should take full account of the EU principles and conditions applicable to access to EU institutions' documents.<sup>342</sup> In practice, it seems that EFSA often refers to the Access to Documents Regulation, rather than to its Decision Concerning Access to Documents.<sup>343</sup> Nonetheless, it would be better if EFSA updated the Decision as to align it with the Aarhus Convention. The announced revision of EFSA's policy on openness and transparency, would be an excellent opportunity to do so.<sup>344</sup>

### ***7.3. Discrepancies with the Aarhus Convention?***

It is striking that both the RPPP and EFSA's internal rules on access to documents, seem to be in conflict with the right to environmental information as enshrined in the Aarhus Convention. They deviate from the Aarhus Convention by either presuming confidentiality in relation to certain types of RA data or by providing for largely mandatory grounds for refusal. The RPPP and EFSA's Decision Concerning Access to Documents do not require the ground for refusal to be interpreted restrictively, taking into account the public's interest in disclosure. In addition, they do not distinguish between environmental information and other information, nor do they provide for an overriding public interest in disclosure if commercial information relates to emissions into the environment. It is difficult to see why the RPPP does not address these issues, since it has been drafted after the EU became a signing

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<sup>336</sup> See Art. 4(3) and (4) Aarhus Convention.

<sup>337</sup> Art. 6(1) Aarhus Regulation.

<sup>338</sup> See art. 4(4) Aarhus Convention and in particular art 4(4)(d).

<sup>339</sup> Although it is not clear from the Aarhus Convention what is understood by "a reasonable amount" it follows from the Aarhus Implementation Guide 2013, p. 89-90 that financial barriers should not form an impediment to access to information.

<sup>340</sup> Art. 6(2) EFSA Decision Concerning Access to Documents, nr. MB 16.09.2003. See on the tension with the Aarhus Convention § 6.2. above.

<sup>341</sup> Compare to recital 3 of the preamble and art. 1 of ECHA's Management Board Decision MB/12/2008.

<sup>342</sup> Art. 41(2) General Principles of Food Law.

<sup>343</sup> See for example: EFSA's Executive Director 2011; EFSA's Head of the Legal and Regulatory Affairs Unit 2012. However, in these replies to information requests by EFSA there is virtually no consideration given to the Aarhus Regulation.

<sup>344</sup> EFSA 2014a, p. 2-3.

party to the Aarhus Convention<sup>345</sup> and after adoption of the Aarhus legislation. EU pesticide law is inherently linked to environmental issues, and should therefore give special consideration to transparency and public participation. However, it seems that these procedural concerns still need to be integrated into EU pesticide law.

## 8. EU food law and the Aarhus Convention: which takes priority?

There is a clear tension between article 63 RPPP on the one hand and the Aarhus Convention and the Aarhus legislation on the other. As said, the presumptions of confidentiality in article 63(2) RPPP seem to be in conflict with the discretion of authorities to grant or decline confidentiality and with the required restrictive interpretation of the exceptions, taking into account the public interest served by disclosure.<sup>346</sup> The ECJ has clarified the hierarchy between article 63 RPPP and the Aarhus legislation. This section will first address the relation between the Aarhus Directive and article 63 RPPP. Secondly, the relation between the Aarhus Regulation and article 63 RPPP will be discussed.

### 8.1. The relation between the Aarhus Directive and article 63 RPPP

In the view of the Commission, as a general rule sector-specific acts, being "lex specialis", overrule the general provisions of the Aarhus Directive.<sup>347</sup> Article 63(3) RPPP, however, explicitly states that it is without prejudice to the Aarhus Directive. Therefore article 63 RPPP must be interpreted in conformity with the Aarhus Directive.<sup>348</sup> According to Garçon the RPPP prevails over the Aarhus Directive regardless of article 63(3) RPPP. She argues that this article merely clarifies that the Aarhus Directive is applicable, but does not set aside the specialized confidentiality regime in article 63(1) and (2) RPPP.<sup>349</sup> This means, she argues, that any grounds for a public interest in disclosure should be interpreted restrictively. This interpretation of article 63(3) RPPP clearly goes against the wording of that article<sup>350</sup> and is not supported by the judgement of the ECJ in *Stichting Natuur en Milieu and Others v. Ctgb*.<sup>351</sup>

*Stichting Natuur en Milieu and Others v. Ctgb* dealt with the relationship between the confidentiality regime in article 14 of the old Pesticide Directive (Directive 91/414/EC) and the Aarhus Directive. Article 14 of the old Pesticide Directive states explicitly that it is without prejudice to the old Environmental Information Directive (Directive 90/313/EEC). From this, the ECJ concluded that where commercial confidentiality seems justified, the authorities are nevertheless obliged to disclose information relating to emissions into the environment or if the public interest in disclosure outweighs the interest served by the ground for refusal.<sup>352</sup> The balancing of the public interest served

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<sup>345</sup> Which was in 2005: Council Decision 2005/370/EC of 17 February 2005 on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters (*OJ* 2005, L 124/1).

<sup>346</sup> See art. 4(4) Aarhus Convention, 4(2) Aarhus Directive and 6(1) Aarhus Regulation.

<sup>347</sup> Commission Report, COM(2012) 774 final, p. 9.

<sup>348</sup> Also the Commission notes that the general rule that a 'lex specialis' overrules the Aarhus Directive, may not apply if the sector-specific act contains provisions on its relationship to the Aarhus Directive (Commission Report, COM(2012) 774 final, p. 9).

<sup>349</sup> Garçon 2012, p. 397.

<sup>350</sup> For example, the English version of art. 63 RPPP states: "This article is without prejudice to Directive 2003/4/EC". The French version states: "Le présent article s'entend sans préjudice de la directive 2003/4/CE". The Dutch version states: "Dit artikel doet geen afbreuk aan Richtlijn 2003/4/EG".

<sup>351</sup> ECJ 16 December 2010, C-266/09, *ECR* 2010, p. I-13119 (*Stichting Natuur en Milieu and Others v College voor de toelating van gewasbeschermingsmiddelen en biocide*).

<sup>352</sup> *Ibid.*, par. 53.

by the disclosure and the specific interest served by confidentiality must be carried out in each individual case.<sup>353</sup> Moreover, the ECJ clarified that the processing of a request for confidentiality may not lead the authority to disregard its obligations under the Aarhus Directive.<sup>354</sup>

It follows from *Stichting Natuur en Milieu and Others v. Ctgb* that the national authority's obligations deriving from the Aarhus Directive prevail over the obligations deriving from the confidentiality regime in the old Pesticide Directive (Directive 91/414/EC). Unlike article 63(2) of RPPP, article 14 of the old Pesticide Directive contains a list of information which cannot be treated as confidential, rather than listing types of information that are presumed to be confidential. Nevertheless, it seems consistent that also article 63(2) RPPP must be applied in accordance with the Aarhus Directive, because it is explicitly stated that the article is without prejudice to the Aarhus Directive.

Thus, in case of a conflict between article 63 RPPP and the Aarhus Directive, the Aarhus Directive prevails. Nonetheless, the current legal situation is far from clear. After all, if the Aarhus Directive has priority, the presumption of confidentiality in article 63(2) RPPP is deprived of much of its meaning. Therefore, one could rightly wonder why article 63(2) RPPP has been adopted in its current form.

## **8.2. The relation between the Aarhus Regulation and the RPPP**

Article 63(3) RPPP only states that it is without prejudice to the Aarhus Directive. This does not mean, a contrario, that article 63 does prevail over the Aarhus Regulation. It has been pointed out that, whereas the Aarhus Directive needs to be implemented by the Member States, the Aarhus Regulation applies directly to EU institutions and therefore an express reference in article 63 RPPP is not necessary.<sup>355</sup> It follows from the recent ruling by the General Court in *Greenpeace Nederland and PAN Europe v Commission*<sup>356</sup> that article 63 RPPP is indeed also without prejudice to the Aarhus Regulation. However, it would be clearer if article 63(3) RPPP also referred to the Access to Documents Regulation and the Aarhus Regulation. For example, Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) does explicitly refer to the applicability of the Access to Documents Regulation and even to the Aarhus Convention.<sup>357</sup>

*Greenpeace Nederland and PAN Europe v Commission* involved a request filed with the Commission for access to several documents relating to the authorisation of the active substance glyphosate. Greenpeace and PAN Europe argued that information on the exact composition of the products developed and tested, data on impurities and metabolites, and data on the analytical profile of the test batches, constitute information relating to emissions into the environment. These data, they argue, are required in order to interpret the RA tests and to verify whether they are representative of the emissions that will occur during the actual use of the product in practice.<sup>358</sup>

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<sup>353</sup> Ibid., par. 55-59.

<sup>354</sup> Ibid., par. 51 & 54.

<sup>355</sup> Von Holleben 2013, p. 572, footnote 20.

<sup>356</sup> General Court EU 8 October 2013, T-545/11, *not yet published* (*Stichting Greenpeace Nederland and PAN Europe v European Commission*).

<sup>357</sup> Recital 117-118 of the preamble and art. 118(1) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (*OJ* 2006, L 396/1).

<sup>358</sup> Ibid., par. 61-63.

The Commission refused access to the RA tests and studies submitted by the producer. In the Commission's view, the tests did not relate to emissions into the environment but rather involved information relating to the production process of glyphosate. Disclosure of that information would allow competing undertakings to copy the production method, leading to considerable loss for the producer. The Commission found that the need to protect the producer's intellectual property rights outweighed the public interest in disclosure of the information.<sup>359</sup>

The General Court emphasizes that article 6(1) of the Aarhus Regulation requires authorities to disclose information upon request if it relates to emissions into the environment: "*even if such disclosure is liable to undermine the protection of the commercial interests of a particular natural or legal person, including that person's intellectual property*".<sup>360</sup> This is no different if the commercial interests and intellectual property are protected under the old Pesticide Directive or under article 63(2) RPPP.<sup>361</sup> According to the General Court such specialized confidentiality regimes merely presume that disclosure of the information would undermine the interests protected by these regimes. Article 63 RPPP does not, however, overrule the irrefutable presumption in the Aarhus Regulation that an overriding public interest in disclosure exists if information relates to emissions into the environment.<sup>362</sup> Furthermore, the Court states that this interpretation cannot be called into question on the basis of article 16 and 17 of the Charter of Fundamental Rights of the EU (the freedom to conduct a business and the right to property) or article 39 of the TRIPS Agreement relating to the protection of intellectual property of agricultural chemical products.<sup>363</sup>

The Commission argues that the notion of "information relating to emissions into the environment" needs to be interpreted restrictively. This argument is rejected by the General Court.<sup>364</sup> The Court considers that the plant protection product will be released into the environment by spraying. Therefore, the composition of the plant protection products constitutes information relating, in a sufficiently direct manner, to emissions into the environment. The same is true for information on the identity and quantity of the impurities present in the active substance and the test batches.<sup>365</sup> The General Court concludes that the Commission erred by refusing to disclose this information, because there is an irrefutable overriding public interest in disclosure under the Aarhus Regulation.<sup>366</sup> However, the methods of analysis and validation of the test batches do not constitute information relating to emissions into the environment. In the Court's view, those data do not allow for the determination, in a sufficiently direct manner, of the level of emission into the environment of the active substance.<sup>367</sup>

*Greenpeace Nederland and PAN Europe v Commission* clarifies that the RPPP does not alter the provisions of the Aarhus Regulation. This is striking, since the information refused related to the complete composition of the plant protection product, the identity and quantity of impurities and the impurities in the various batches. Exactly these types of information are listed in article 63(2) RPPP under b, c and f. The General Court resolves this conflict by stating that article 63(2) RPPP merely indicates in which cases the undermining of a commercial interest is presumed. Article 63 RPPP does

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<sup>359</sup> Ibid., par. 9 and 64.

<sup>360</sup> Ibid., par. 38.

<sup>361</sup> Ibid., par. 40-41.

<sup>362</sup> Ibid., par. 42.

<sup>363</sup> Ibid., par. 44-46.

<sup>364</sup> Ibid., par. 49-53.

<sup>365</sup> Ibid., par. 69-71 and 73.

<sup>366</sup> Ibid., par. 75.

<sup>367</sup> Ibid., par. 72.

not, however, strike a balance between these commercial interests and the public interest in disclosure. These interests should be balanced taking *full* account of the Aarhus Regulation.

The decision of the General Court has been criticized by Von Holleben.<sup>368</sup> He opposes the General Court's wide interpretation of "information relating to emissions into the environment". Von Holleben argues that in substance law, one easily runs the risk of classifying the entire use of chemicals as emissions.<sup>369</sup> He submits that the notion of "submission into the environment" should be limited to emissions from installations<sup>370</sup>, in accordance with the Industrial Emissions Directive (96/61/EC) to which the Aarhus Implementation Guide refers.<sup>371</sup> This argument is unconvincing, since this reference in the Aarhus Implementation Guide is clearly meant as just an example of what can constitute information relating to emissions into the environment.<sup>372</sup>

In addition, Von Holleben argues that a wide interpretation of "emissions into the environment", which turns the special exception into a rule, is incompatible with the RPPP.<sup>373</sup> Being right on this point, he fails to mention that, vice versa, the RPPP is incompatible with the Aarhus Convention and Aarhus legislation. Indeed, as Von Holleben states, many of the pesticide RA studies will deal with the effects of (future) emissions into the environment. Therefore, pesticide RA studies constitute important information for the public. Although this may indeed mean that large parts of the application dossier must be automatically disclosed upon request, this is nothing but a consequence of the Aarhus Convention. It would be unacceptable if in various subfields of law, lower legislation such as the RPPP would alter the interpretation of the Aarhus Convention. This could not only potentially severely restrict the wide access to environmental information aimed for by the Aarhus Convention, but could also lead to an inconsistent interpretation of the Aarhus Convention across different fields of law. It would be hard to explain why the right to access to environmental information is more restricted in relation to pesticides as compared to other types of environmental information. Furthermore, if the General Court would have allowed the RPPP to dictate and limit the scope of the Aarhus Regulation, this could have set an unwanted precedence. By doing so, the Court would signal - also to Member States - that specialized confidentiality regimes may legally limit the rights in the Aarhus Convention. This could deprive the Aarhus Convention of much of its meaning.<sup>374</sup>

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<sup>368</sup> Von Holleben 2013. Although not mentioned in his article, Von Holleben has a history of working for bodies known to represent the chemical industry, amongst which: Managing Director of the German chemical industry association VCI in the area of "Technology and Environment" (1987-2001), Formerly Chairman of the Environment Committee of Chemical Associations ICCA, Member of the Environment Committee of the European Chemical Industry Council CEFIC (source: [www.ask-eu.de/Experten/3505/Dr-Horst-von-Holleben.htm](http://www.ask-eu.de/Experten/3505/Dr-Horst-von-Holleben.htm)).

<sup>369</sup> Von Holleben 2013, p. 575.

<sup>370</sup> A similar argument is made by Garçon in the more general context of the Aarhus legislation, the RPPP and the relation between those instruments (Garçon 2012, p. 396).

<sup>371</sup> Aarhus Implementation Guide 2013, p. 83.

<sup>372</sup> This is in line with the consideration in the Aarhus Implementation Guide that: "In view of the Convention's principles and objectives, it would seem that any information on emissions that may affect the quality of the environment should be considered relevant for environmental protection, irrespective of the quantities of the emissions involved. Indeed, a case can be made that all information on emissions is relevant to the protection of the environment" (Aarhus Implementation Guide, p. 83). On this matter, also see: • General Court EU 8 October 2013, T 545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*), par. 55-56.

<sup>373</sup> Von Holleben 2013, p. 571.

<sup>374</sup> Nevertheless, regarding information on emission trading, the ECJ ruled that specialized confidentiality regime excluded the application of the Aarhus Directive: ECJ 22 December 2010, C-425/09, *ECR* 2010, p. I-14115 (*Ville de Lyon v Caisse des dépôts et consignations*), par. 34-41. This is in line with the Commission's statement that, as a general rule, the sector-specific acts, being "lex specialis", overrule the general provisions of the Aarhus Directive (Commission Report, COM(2012) 774 final, p. 9). This could lead to a violation of the Aarhus Convention, which seems unjustified unless the specialized confidentiality regime is based on higher

The ruling of the General Court seems to be in line with the Aarhus Convention, which is higher on the international legal ladder than the RPPP. In order to secure the effectiveness of the Aarhus Convention, one may hope that the General Court will uphold its line of reasoning in *Greenpeace Nederland and PAN Europe v Commission* in a similar case under REACH (still pending).<sup>375</sup> In addition, it needs to be seen whether the ECJ will confirm the General Court's ruling in *Greenpeace Nederland and PAN Europe v Commission* in the appeal recently filed by the Commission. In appeal the Commission argues that the General Court failed to take due account of the confidentiality regime in the RPPP.<sup>376</sup>

### **8.3. The tension between article 63 RPPP and the Aarhus Convention resolved?**

From *Stichting Natuur en Milieu and Others v. Ctgb*<sup>377</sup> and *Greenpeace Nederland and PAN Europe v Commission*<sup>378</sup> it follows that the Aarhus legislation prevails over article 63 RPPP. This largely aligns the right to environmental information in EU pesticide law with the Aarhus Convention. However, not all the discrepancies with the Aarhus Convention are resolved, since the Aarhus Regulation itself is not on all points in conformity with the Aarhus Convention (as discussed in § 6).

There is a clear conflict between the RPPP and the Aarhus Regulation. One could wonder why article 63(2) RPPP has been drafted, if much of the information listed needs to be disclosed anyway in accordance with the Aarhus legislation. Moreover, if article 63(2) RPPP is largely overruled by the Aarhus legislation, it is questionable whether the RPPP still sufficiently protects the industry's commercial interests.

In the current system it is rather unclear under which conditions pesticide RA data are disclosed. This is in itself a violation of the Aarhus Convention, which requires public authorities to provide sufficient information to the public about the basic terms and conditions under which environmental information is made available and accessible.<sup>379</sup> The next section will discuss what alterations to EU pesticide law could contribute to more clarity in the field.

## **9. Recommendations**

EFSA is aware of the importance and complexity of the dilemma of transparency versus the protection of commercial interests and is said to prepare a new policy in this field.<sup>380</sup> In view of these upcoming changes, this section will contain some basic proposals on how to align EU pesticide law with the Aarhus Convention while still protecting industry's commercial interests. These proposals are meant as

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international law which prevails over the Aarhus Convention. This could have been the rationale behind the ECJ's judgement in *Ville de Lyon v Caisse des dépôts et consignations*, where the specialized confidentiality regime was an implementation of the Kyoto Protocol (entry into force in 2005 and thus prevailing over the 1998 Aarhus Convention), see art. 30 Vienna Convention on the law of treaties).

<sup>375</sup> See General Court, T-245/11, *pending (ClientEarth and International Chemical Secretariat v ECHA)*, concerning access to documents under REACH related to names of registrants and to tonnages of dangerous substances placed on the market.

<sup>376</sup> Appeal brought on 17 December 2013 by European Commission against the judgment of the General Court (Second Chamber) delivered on 8 October 2013 in Case T-545/11 (*Stichting Greenpeace Nederland and Pesticide Action Network Europe (PAN Europe) v European Commission*), C-673/13 P.

<sup>377</sup> ECJ 16 December 2010, C-266/09, ECR 2010, p. I-13119 (*Stichting Natuur en Milieu and Others v College voor de toelating van gewasbeschermingsmiddelen en biocide*).

<sup>378</sup> General Court EU 8 October 2013, T 545/11, *not yet published (Stichting Greenpeace Nederland & PAN Europe v Commission)*.

<sup>379</sup> Art. 5(2)(a) Aarhus Convention.

<sup>380</sup> Radford 2013; EFSA 2014a.

a starting point for discussion only, and would need further deliberation and research in order to assure their effectiveness and their conformity with other fields of law. Furthermore, the discussion in this paper is limited to access to pesticide RA data. It is, however, important to realize that more procedural barriers to public participation and public scrutiny may apply. For example, a severe limitation to public scrutiny are the overly strict standing conditions for private parties who wish to challenge EU decisions before the ECJ.<sup>381</sup> Thus, although increased transparency would be a step in the right direction, more barriers to public participation and scrutiny may need to be resolved.

### **9.1. Clarification of the hierarchy between the RPPP and the Aarhus legislation**

As discussed in the previous section, the ECJ and the General Court have clarified that the Aarhus legislation prevails over article 63 RPPP. Nonetheless, the current legal situation is far from pretty. By looking at article 63(2) RPPP one gets the impression that certain RA data are deemed confidential. However, from *Stichting Natuur en Milieu and Others v. Ctgb*<sup>382</sup> and *Greenpeace Nederland and PAN Europe v Commission*<sup>383</sup> it follows that article 63 RPPP is subject to the Aarhus legislation and to the overriding presumptions therein. It would be much clearer if this hierarchy would be made apparent from article 63 RPPP.

This could be done by amending article 63(3) RPPP, which states that article 63 is without prejudice to the Aarhus Directive. It would be clearer if article 63(3) RPPP would also refer to the Aarhus Regulation and preferably also to the Aarhus Convention. REACH, for example, explicitly refers to the Aarhus Convention in its preamble.<sup>384</sup> Moreover, article 63 RPPP could benefit from including the requirements mentioned in the Aarhus legislation. For example, one could include that “information relating to emissions into the environment must be disclosed even if this would undermine the protection of commercial interests”. This way, it is made explicit that article 63 RPPP does not alter the meaning of the Aarhus legislation in this respect.

Secondly, it would be better if article 63(2) RPPP would not list types of information that often relate to emissions into the environment. This includes information relating to the specification of impurity, results of production batches, and the complete composition of a plant protection product. Similarly, EFSA's Decision Concerning Access to Documents<sup>385</sup> should be updated in order to bring it in conformity with the Aarhus Convention and Aarhus Regulation. This would contribute to legal certainty amongst members of the public seeking access to pesticide RA data, as well as amongst the pesticide industry seeking confidentiality of those data.

Thirdly, it would be advisable if article 63 RPPP, as well as article 6(2) of EFSA's Decision Concerning Access to Documents, would clarify that the charge for conducting an information request

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<sup>381</sup> This limitation has been exhaustively discussed and criticised in legal literature. See for example: Usher 2003, p. 575; Koch 2005; Also see: AG Jacobs in Case C-50/00 (*Unión de Pequeños Agricultores v Council*). Recently, however, the General Court found a strict interpretation of "measure of individual scope" in art. 10(1) Aarhus Regulation to be a violation of the Aarhus Convention (General Court EU of 14 June 2012, T-338/08, *not yet published* (*Stichting Natuur en Milieu and Pesticide Action Network Europe v European Commission*), par. 79-83; General Court EU of 14 June 2012, T-396/09, *not yet published* (*Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht v European Commission*), par. 59-69. Although these cases relate to a request for internal (administrative) review, and not to access to the EU courts, they may indicate a step in the direction of a more liberal standing doctrine.

<sup>382</sup> ECJ 16 December 2010, C-266/09, ECR 2010, p. I-13119 (*Stichting Natuur en Milieu and Others v College voor de toelating van gewasbeschermingsmiddelen en biocide*).

<sup>383</sup> General Court EU 8 October 2013, T 545/11, *not yet published* (*Stichting Greenpeace Nederland & PAN Europe v Commission*).

<sup>384</sup> Recital 117 of the preamble of REACH.

<sup>385</sup> EFSA Decision Concerning Access to Documents, nr. MB 16.09.2003.

must be reasonable and set in advance. This would align EU pesticide law with the Aarhus Convention, even though the Access to Documents Regulation is not in conformity on this point.<sup>386</sup>

### ***9.2. How to protect the producers business interests?***

If the Aarhus Convention has priority over the confidentiality regime in article 63 RPPP, business interests may be not sufficiently protected under the RPPP. Therefore, three options will be discussed to better protect the producer against competitors misusing disclosed RA data.

#### ***9.2.1. Article 62 RPPP: obliged sharing in RA costs***

Article 62 RPPP can provide inspiration for an alternative to commercial confidentiality. Rather than providing for confidentiality, this provision provides for the obliged sharing of studies that involve vertebrate animal testing. The holder of these studies can claim a fair share in the testing costs from the prospective applicant who uses these studies for a new registration. Disputes can be resolved through binding arbitration or through litigation on the national level. Awards from arbitration or litigation shall be enforceable in the courts of all Member States.<sup>387</sup>

It is questionable whether competitors would indeed share in the costs if they can just repeat the RA studies, without spending time and money on developing research methods and a research design. In order to promote that competitors indeed fairly share in the costs, effective sanctions should be in place against the copying of RA studies. This can be done, for example, by providing that if RA material, including research methodology and design, is proven to be illegally used or copied, the user should pay a considerable fine to the original owner. Another option would be to revoke the approval of an active substance if it appears to be based on “stolen” RA information.

A problem with extending article 62 RPPP to publicly available RA data is that it would be problematic to enforce it outside the EU. Once RA information has been publicly disclosed, what is there to prevent competitors from using that information outside the EU without sharing in the costs? This is a clear disadvantage of the system in article 62 RPPP, which is hard to overcome. It may be solved by denying such competitors access to the EU market or by fining them, although this may very well be against various international trade agreements.

#### ***9.2.2. Intellectual property rights***

A second manner to protect the commercial interests of producers is through intellectual property rights. If RA studies are copyrighted or if certain testing methods are patented, this can provide producers with effective means to protect their commercial interests. After all, that is exactly what intellectual property rights aim to do. Problematic in this regard are non-patented research methods. Such tests may be easily repeated by competitors, saving time and money developing a research design and giving them an unfair advantage over the original owner of the studies.

#### ***9.2.3. Reading room***

A third, often mentioned option to protect the commercial interests of the industry while allowing members of the public to access pesticide RA data is the so-called reading room. A reading room would allow members of the public to freely examine the RA information, while protecting confidential information against unwanted attention from competitors. During the drafting of the

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<sup>386</sup> Compare art. 10(1) Access to Documents Regulation with art. 3(8) Aarhus Convention.

<sup>387</sup> Art. 62(6) RPPP.



RPPP, the EU Parliament Committee on the Environment, Public Health and Food Safety proposed a paragraph 2a to article 63 RPPP introducing the reading room concept:

*"For test data, including study reports, which have been provided by an applicant to support a decision to authorise or amend a plant protection product under this Regulation, such data may be viewed by interested parties in specific locations identified by the Commission, the Authority or the Member States. Such data shall not be made public through the provision of copies or through any other means of publication (including electronic publication)."*<sup>388</sup>

According to the Parliament, the proposal aimed to strike a balance between access to information for the public and protection against competitors misusing the system in order to obtain sensitive commercial data.

The amendment was not integrated in the final version of article 63 RPPP. Recently however, in light of EFSA's revision of its transparency policy, the reading room concept has again been named as a way to balance the public's right to information against the industry's commercial interests.<sup>389</sup> One clear disadvantage of the reading room concept, is that it requires members of the public to travel to a particular location in order to examine the RA data. This will often lead to costly and time-consuming travel arrangements. Another problem is that if the documents may only be examined on the spot, this could hinder a thorough and careful examination. After all, there is usually a major body of RA data submitted in the approval procedure and it would be virtually impossible to thoroughly review all this information in a short period of time. Researchers would thus be required to spend a considerable amount of time in the reading room, possibly spread over multiple visits. Moreover, a reading room does not fully support an open scientific discussion. Even if scientists would use the reading room to review and comment on the RA studies, their peers would also have to use the reading room in order to be able to react on their findings and to participate fully in the scientific discussion. Therefore, a reading room is less likely to facilitate a (global) scientific discussion than full disclosure which allows for publication on the internet or in journals.

From a legal point of view, the reading room concept is not in conformity with the Aarhus Convention, which provides access to *all* members of the public, including competitors, without an interest needing to be stated.<sup>390</sup> Moreover, in principle the information should be provided in the form requested, unless it is reasonable for the public authority to make it available in another form.<sup>391</sup> Although the reading room concept would improve transparency in the field of EU pesticide law, it cannot serve as a substitute to the passive right to information under the Aarhus Convention. Nonetheless, it may be an interesting option for the industry. After all, if access to RA data can be obtained fast and easy through a reading room, members of the public may decide not to request the information from the authorities through a potentially time-consuming procedure. This could save them time and money, while protecting the industry's commercial interests. Therefore, a reading room would be a welcome step in the direction of more transparency in EU pesticide law, providing it is not considered a substitute for the right to environmental information in the Aarhus Convention.

## 10. Conclusion

This paper has discussed the importance of transparency in pesticide RA. The RA studies submitted by the producer form the basis of the approval of new active substances and plant protection products.

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<sup>388</sup> European Parliament Committee on the Environment, Public Health and Food Safety 2008, p. 96-97.

<sup>389</sup> For example see: Radford 2013 and Jones 2013.

<sup>390</sup> Art. 4(1) Aarhus Convention.

<sup>391</sup> Art. 4(1)(b) Aarhus Convention.

This makes transparency in RA a prerequisite for public scrutiny and participation, public trust, and the implementation of the precautionary principle in EU pesticide law. However, the public interest in disclosure of pesticide RA data will often conflict with the interests protected by several exceptions to the right to environmental information. In particular, there will often be a conflict with the protection of the producer's commercial interests. Disclosed RA data may give competitors an unfair commercial advantage over the producer who conducted the studies. As shown by the DAR on imidacloprid, most of the RA studies used for assessing the safety of new pesticides are confidential and are not automatically disclosed to the public.

While the Aarhus Convention, the Aarhus Directive and (more or less) the Aarhus Regulation focus on broad access to environmental information, article 63 RPPP focuses on protecting the industry's commercial interests and the privacy of individuals. Article 63(2) RPPP seems to imply that certain types of RA data are deemed confidential, although such a presumption would be in conflict with the Aarhus Convention. Most types of RA data listed in article 63(2) RPPP will relate to emissions into the environment, in which case there is often an overriding public interest in disclosure under the Aarhus Convention and the Aarhus legislation. It follows from the ECJ's and General Court's case law that in case of a conflict, these instruments prevail over article 63 RPPP. This case law largely aligns EU pesticide law with the Aarhus Convention. Nevertheless, there are still some discrepancies between the Aarhus Regulation and the Aarhus Convention which may remain until the EU courts rule otherwise. But overall, there is broad access to pesticide RA data relating, in a sufficiently direct manner, to emissions into the environment. In relation to other RA data, the public interest in disclosure needs to be weighed against the interests protected by the grounds for refusal. These grounds should be interpreted restrictively. The ECJ's and General Court's case law shows that confidentiality should not be granted easily, also in relation to EU pesticide law. This is to be applauded, since it guarantees the effectiveness of the Aarhus Convention and contributes to uniformity by rejecting sector specific restrictions to the right to environmental information.

Nevertheless, the current legal situation is rather unclear. Looking at article 63 RPPP, one cannot but conclude that the Aarhus Convention has not been taken sufficiently into account during its drafting. This has resulted in conflicting bodies of law, potentially causing legal uncertainty amongst industry and members of the public. In addition, it is questionable whether the industry's interests are sufficiently protected if article 63 RPPP is overruled by the Aarhus Convention and thereby deprived of much of its meaning.

In this paper some (basic) options have been proposed to bring the RPPP in conformity with the Aarhus Convention, while at the same time protecting business interests. First of all, article 63 RPPP should be brought in conformity with the Aarhus Convention. Furthermore, industry interests could be protected by (partially) extending article 62 RPPP to all environmentally relevant RA studies. Such a system would provide for the obliged sharing in RA costs by competitors who wish to use another producer's RA studies. Moreover, where the owner of RA studies is not sufficiently protected by intellectual property law, other sanctions against the misuse of RA data by competitors could be installed, such as fines and the withdrawal of an approval. Last, the reading room concept could improve transparency in EU pesticide RA, but does not serve as a substitute for the right to environmental information under the Aarhus Convention. It is clear that balancing the different interests involved is not an easy task. The proposed options do not address all potential problems and pitfalls when balancing the public's right to information against the industry's interest in keeping RA studies confidential. Therefore, more research on possible policy options would be welcome.

It might prove impossible to find a solution that suits everyone. In many cases, the Aarhus Convention will then decide in favour of access to RA information which relates to emissions into the

environment. Regarding other environmentally relevant RA data, the grounds for refusal should be interpreted restrictively, as prescribed by the Aarhus Convention. After all, considering the major impact pesticides may have on consumer health and the environment, the public right to know should be the rule and confidentiality the exception.

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