# Atrazine: A Case Study in the Differences Between Regulations of Endocrine Disrupting Chemicals in the EU and the US

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### I. INTRODUCTION:

The discovery of endocrine disruptors (EDCs)<sup>1</sup> in the environment combined with the recent decision by the Environmental Protection Agency ("EPA") to reregister Atrazine, a widely used herbicide and a highly controversial suspected endocrine disruptor, presents a new challenge to environmental regulatory agencies everywhere.<sup>2</sup> Part of the reason that EDCs represent such a unique challenge is their scientific complexity and the related uncertainty in establishing exactly how they work.

This paper will examine the different ways in which the European Union (EU)

<sup>&</sup>lt;sup>1</sup> See WHO INT'L PROGRAMME ON CHEM. SAFETY (IPCS), Global Assessment of the State of Science of Endocrine Disruptors, (Terrii Damstra, Sue Barlow, Aeke Bergman, Robert Kavlock & Glen Van Der Kraak, eds.) (2002), available at http://www.who.int/entity/ipcs.publications/en/ch1.pdf (Endocrine disruptors as exogenous substances which alter functions of the endocrine system and consequently cause adverse health effects in an intact organism, or its progeny, or subpopulations).

<sup>&</sup>lt;sup>2</sup> See Press Release, NATURAL RES. DEF. COUNCIL, EPA REFUSAL TO RESTRICT ATRAZINE DESPITE HEALTH THREAT IGNORES SCIENTIFIC EVIDENCE SAYS NRDC (Oct. 31, 2003), http://www.nrdc.org/media/pressreleases/031031.asp (explaining that the EPA's decision to allow chemical companies to continue to sell atrazine conflicts with the chemical's severe medical effects and other countries' rejection of the chemical). Recent studies show that Atrazine seriously disrupts frogs' hormone systems and ability to reproduce. *Id.* Despite these studies, and despite the EPA's own conclusions that existing Atrazine contamination may jeopardize the survival of dozens of endangered specifies, the EPA continues to ignore its obligations under the Endangered Species Act. *Id.* The EPA has failed to consult with the Fish and Wildlife Service or the National Marine Fisheries Service on Atrazine's risks to endangered species. *Id.* The NRDC sued the EPA in August 2003, charging that the agency is permitting widespread use of Atrazine even though it acknowledges the weed-killer might harm endangered species. *Id.* 

and the United States (US) have chosen to deal with the problems that EDCs represent within their respective legal systems. Specifically the paper will use Atrazine as a case study to illustrate these differences. Tyrone Hays was the first to suspect that Atrazine was an EDC and brought this to media attention by publishing a paper on the topic in *Nature*, in October 2001.<sup>3</sup> At the time of his initial study he was working at Syngenta, one of the world's largest producers of the herbicide, Atrazine.<sup>4</sup> In response Syngenta created its own panel of scientists, called *EcoRisk*, which produced several studies that refuted Hays' findings.<sup>5</sup> Ever since, there has been a huge amount of controversy over whether or not Atrazine is an EDC and presents a threat to the health and the environment at its present concentrations in groundwater, drinking water, etc. The EPA's Scientific Advisory Panel (SAP) has since reviewed all of the *EcoRisk* studies and discovered each of them to be scientifically and methodologically flawed; some on levels as basic as separating control and test subjects.<sup>6</sup>

Based on the information in these studies and the SAP's report, the US and the EU have taken radically different approaches to their regulation of Atrazine. This paper will begin with a brief overview of the EU regulatory system, followed by a

<sup>&</sup>lt;sup>3</sup> Tyrone Hayes, Kelly Haston, Mable Tsui, Anhthu Hoang, Cathryn Haeffele & Aaron Vonk, Feminization of Male Frogs in the Wild, 419 NATURE 895, 895-96 (Oct. 2002).

<sup>&</sup>lt;sup>4</sup> See Syngenta Crop Protection, Atrazine's Safety, http://www.syngentacropprotection-us.com/prod/herbicide/Atrazine/index.asp?nav=FSheet2 (last visited Sept. 16, 2006) (supporting the use of Atrazine, arguing the herbicide is the most thoroughly tested product ever used in crop protection. Syngenta emphasizes that in the last four decades, universities, government agencies, the crop protection industry, and independent laboratories conducted more than eight hundred scientific studies evaluating Atrazine's potential effects on health and the environment. More than two hundred of these studies were completed after 1995, ensuring Atrazine has passed the most recent scientific tests and reviews. Thus, Syngenta concludes, the overwhelming body of research supports the safety of Atrazine to humans and the environment).

<sup>&</sup>lt;sup>5</sup> PRESS RELEASE, NATURAL RES. DEF. COUNCIL, *supra* note 2. *See* Jennifer Lee, *Popular Pesticide Faulted for Frogs Sexual Abnormalities*, N.Y. TIMES, June 19, 2003, *available at* http://www.mindfully.org/Pesticide/2003/Atrazine-Frog-Sexual19jun03.htm (explaining that scientists from the Environmental Protection Agency say there is "sufficient evidence" to conclude Atrazine, the country's most widely used pesticide, causes sexual abnormality in frogs); Goldie Blumenstyk, *The Story of Syngenta & Tyrone Hayes at UC Berkley: The Price of Research*, THE CHRONICAL OF HIGHER EDUCATION, v.50, i.10 (Oct. 31, 2003), *available at* http://www.mindfully.org/Pesticide/2003/Syngenta-Tyrone-Hayes31oct03.htm (reporting on the details of Haye's connection with Syngenta during his initial findings); Carl T. Hall, *From Boyhood Curiosity to Scientific Discovery: Biologist Tyrone Hayes Links Pesticides to Amphibian Deformities*, S.F. CHRONICLE, NOV. 4, 2002, *available at* http://www.mindfully.org/Pesticide/2002/Tyrone-Hayes-Curiosity4nov02.htm (reporting on Tyrone Hayes, a professor of biology at the University of California, Berkley. Hayes produced a series of highprofile studies challenging the ecological safety of Atrazine, the most widely used pesticide in the United States. His latest research suggested the product may be harming the reproductive functioning of amphibians exposed to farm chemicals in the spring runoff); Bijal P. Trivedi, *Hermaphroditic Frogs Caused by Popular Weed Killer*, NATIONAL GEOGRAPHIC TODAY, Apr. 16, 2002, *available at* 

http://news.nationalgeographic.com/news/2002/04/0416\_020416\_TVfrog.html (discussing the effect of Atrazine, a top selling weed killer throughout the United States, on the sexual development of male frogs, turning them into hermaphrodites at concentrations thirty times higher than those deemed safe by the EPA).

<sup>&</sup>lt;sup>6</sup> See THOMAS STEEGER & JOSEPH TIETGE, ENV'T PROT. AGENCY, OFFICE OF PREVENTION, PESTICIDES & TOXIC SUBSTANCES, WHITE PAPER ON THE POTENTIAL DEVELOPMENTAL EFFECTS OF ATRAZINE ON AMPHIBIANS 16-17 (June 17, 2003), available at http://www.epa.gov/scipoly/sap/meetings/2003/june/finaljune2002telconfreport.pdf (summarizing the EcoRisk studies); Atrazine: Frogs, Farms, and Pharmaceuticals (Link TV broadcast Aug. 2004) (focusing on the recent controversies surrounding Syngenta, Dr. Ron Kenddell, the EcoRisk Panel, and Tyrone Hayes, and the effect of these controversies on farmers and the general public).

discussion of the current EU regulations and directives governing Atrazine. Then the paper will lay out the framework for the regulatory system in the US. Lastly the US regulations on Atrazine will be contrasted with those in the EU and some possibly important implications for the future regulation of EDCs from these differences will be described.

### II. EU REGULATION OF EDCS

# A. EU Policy Making Procedures and Authority

Environmental legislation was passed in the 1970s as part of economic reforms in the EU, often justified as a part of market harmonization. Without an express grant of power to legislate on solely environmental concerns, the legislation of the 1970s required using cooperation procedures- a unanimous vote of approval from the Commission after consultation with the Parliament. Not until 1987 with the advent of the Single European Act (SEA) did the EU have explicit power to legislate on environmental issues. Thus, the SEA shows a recognition of the shift of balance between the economy and the environment within the EU. Many view the SEA as a key turning point in environmental legislation.

The EU treaty of 1993 made progress by referring to sustainable development, but did not commit to it. In addition, the treaty did not provide for simplification of the procedures to implement environmental legislation. The EU came under public criticism because of the inherent conflict between Article 175 of the European Commission ("EC") treaty, which set out a cooperation procedure for environmental legislation, and Article 95 of the EC treaty, which set codecision procedures for the internal market. This conflict was seen as the main justification for promoting economic issues over environmental ones. The Treaty of Amsterdam sought to resolve this problem. The Amsterdam treaty introduced the doctrine of incorporation and set out sustainable development as a principle task of the EU. It also replaced the cooperation procedures with simpler codecision procedures. Supplementation of the cooperation procedures with simpler codecision procedures.

The codecision procedure is still used by the EU for environmental regulations today. First, the Commission proposes environmental legislation. The Commission is composed of 20 members with 25 directorates- general (DG) each headed by a Director- General.<sup>14</sup> Then decision-making power is shared equally by Parliament

<sup>12</sup> *Id*.

<sup>&</sup>lt;sup>7</sup> See EUROPEAN COMM'N, THE AMSTERDAM TREATY, A COMPREHENSIVE GUIDE, http://europa.eu.int/scadplus/leg/en/lvb/a15000.htm (discussing the history of the environmental movement since the 1970's and the criticisms the EU received for putting economic aspects of trade before protection of the environment, the latter being perceived as a potential barrier to trade rather than a separate goal. In response to criticisms, the Treaty on European Union upgraded the environment to a Community policy and no longer simply action by Government) (last visited Sept. 17, 2006).

<sup>&</sup>lt;sup>8</sup> See id. (describing consultation to be the process by which Parliament may amend or modify legislation proposed by the Commission).

<sup>&</sup>lt;sup>9</sup> P.S.R.F. MATHIJSEN, A GUIDE TO EUROPEAN UNION LAW 19 (8th ed. 2004).

 $<sup>^{\</sup>rm 10}$  European comm'n, The Amsterdam Treaty: A Comprehensive Guide,  $\it supra$  note 7.

<sup>&</sup>lt;sup>11</sup> *Id*.

<sup>&</sup>lt;sup>13</sup> *Id*.

 $<sup>^{14}</sup>$  European Community, Serving the European Union: A Citizen's Guide to the Institutions of the European Union 13-14 (1999).

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and the Council of Ministers through a conciliation committee, composed of an equal number from members of the Parliament and of the Council with the Commission present. The conciliation committee then attempts to create a text, which everyone may agree to support. If no agreement can be reached Parliament may reject the proposed regulations outright. Stavros Dimas is the current Commissioner for the Environment at the head of the Environment Director-General of the Environment.

# B. EU Regulatory Framework for EDCs and other Harmful Chemicals

In 1999, the EU proposed and accepted a system for regulating hazardous chemicals including EDCs.<sup>17</sup> The system consisted of a prioritized list of substances that are divided into categories based on the amount of scientific evidence of 1) endocrine disruption in humans, 2) endocrine disruption in animals, 3) the potential for exposure due to persistence in the environment and 4) amount of the substance being produced.<sup>18</sup> The three categories used are:

Group 1: A minimum of one study demonstrating endocrine disruption in an intact organism. This is not a weight of evidence approach.

Group 2: Substances that present potential endocrine disruptors. In vitro experiments shows disruption in intact organisms; also, possibly some in vitro experiments as well as structural analysis and metabolic considerations.

Group 3: Substances that are persistent in the environment or are produced in high volumes that either have insufficient data gathered about them or are not presently considered to be EDCs<sup>19</sup>

The EU created the following guidelines to determine which group a suspected EDC should be classified under:

If reliable in-vivo evidence for endocrine disruption is available, the substance is placed in Group I;

If less reliable in-vivo evidence for endocrine disruption is available (for example in case of contradictory test results), the substance is placed in Group II;

If only in-vitro evidence for endocrine disruption is available and test results are positive, the substance is placed in Group II;

Substances with no data but closely related to substances categorized as Category I are placed in Group II;

Substances with no data but closely related to substances categorized as Category II are placed in Group II;

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<sup>&</sup>lt;sup>15</sup> *Id*. at 6

Commissioner Stavros Dimas' website, available at http://europa.eu.int/comm/commission\_barroso/dimas/index\_en.htm (last visited Sept. 28, 2006).

<sup>&</sup>lt;sup>17</sup> See Pesticide Action Network Pesticide Database, Endocrine Disruptors http://docs.pesticideinfo.org/Docs/ref\_toxicity5.html (modified June 13, 2005) (discussing the regulation of Endocrine disruptors in different countries).

<sup>&</sup>lt;sup>18</sup> *Id*.

<sup>&</sup>lt;sup>19</sup> *Id*.

Substances with no evidence for endocrine disruption or no data and not related to Group I or II are placed in Group III.<sup>20</sup>

It is important to note that this system of creating a prioritized list overlaid previous regulations such as the 1998 Directive 98/83/EC on the quality of drinking water, which set the maximum admissible concentrations (MACs) of each substance at 0.1  $\mu$ g/l and the total concentration of all pesticides at 0.5  $\mu$ g/l.<sup>21</sup> This system using MACs is not unlike the Safe Drinking Water Act restrictions in the US. 22 All pesticides must still meet these minimum MAC requirements regardless of their ranking as a hazardous EDC.<sup>23</sup>

Similarly, one of the most important directives in terms of herbicide and pesticide regulations Directive 91/414 acts like Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") in the U.S.<sup>24</sup> Just as FIFRA regulates pesticides through registration at the federal level in the U.S., Directive 91/414 creates a unified system for the registration, sale and use of pesticides at the EU level. Unlike FIFRA the directive includes the same sort of unfair competition and free trade justifications as used by the Organization for Economic Cooperation and Development ("OCED") to justify the polluter having to pay the principle.<sup>25</sup>

In addition to Directive 91/414, the EU has enacted legislation focusing solely on water contaminants like Atrazine. Entering into force in 2001, the Water Framework Directive (Directive 2000/60/EC) focuses on the protection of rivers, lakes, coastal waters and the seas from hazardous substances and was the result of the EU's new push towards an integrated, holistic and sustainable approach to regulation.<sup>26</sup> The objective was to obtain the ecological and chemical river system throughout Europe within 15 years, treating each river basin as an indivisible whole within its basin. Individual plans for each river basin were to be targeted by 2009.<sup>28</sup>

Together these directives: maximum allowable concentrations, registration, the prioritized list and the Water Framework Directive— create the broad regulatory framework under which EDCs and water contamination fall in the EU. However, the task of specifically registering pesticides for use in the EU is under the control of

<sup>&</sup>lt;sup>20</sup> Id.

<sup>&</sup>lt;sup>21</sup> Grada A. Wossink & Theodore A. Feitshans, *Pesticide Policies in the European Union*, 5 DRAKE J. AGRIC L. 223, 224 (2000).

<sup>&</sup>lt;sup>22</sup> Safe Drinking Water Act, 42 U.S.C.A. § 300(g)(1) (2003).

<sup>&</sup>lt;sup>23</sup> Wossink & Feitshans, *supra* note 18, at 228.

<sup>&</sup>lt;sup>24</sup> L. SMEETS, EUROPEAN AND MEDITERRANEAN PLANT PROT. ORG., REVISION OF THE COUNCIL DIRECTIVE 91/414 AND CURRENT PROGRESS WITH THE EU. REVIEW OF EXISTING ACTIVE SUBSTANCES (Apr. 2006), http://www.eppo.org/PPPRODUCTS/eureport.htm (setting federal regulations of plant protection products).

<sup>&</sup>lt;sup>25</sup> Compare Smeets, supra note 24, with U.S. Env't Prot. Agency, supra note 6.

Framework Directive on the EUROPA page. available http://europa.eu.int/comm/environment/water/water-dangersub/press\_en.pdf

<sup>&</sup>lt;sup>27</sup> See Press Release, Natural Res. Def. Council, EPA Refusal to Restrict Atrazine Despite Health Threat NRDC, Scientific Evidence, Ignores available savs http://www.nrdc.org/media/pressreleases/031031.asp (discussing the European Union's ban of atrazine, to be complete and in effect within eighteen months); Council Directive 2000/60, art. 4, 5, 11, 13, 2000 O.J. (L 327) 1 (EC) (addressing the uniqueness of each river basin, and calling for individual preservation plans for each).

<sup>&</sup>lt;sup>28</sup> *Id*.

the EU Standing Committee on the Food Chain and Animal Health, which was created by Parliament and the Council as part of the Committee on Plant Health (which works with the Commission on herbicides and pesticides) to aid and advise the Commission in creating specific procedures not unlike a Senate committee in the US.<sup>29</sup> Members are selected from representatives of member countries and a representative of the Commission chairs the committee. This Committee must review and approve of all new pesticides and herbicides through a registration process before their production and distribution. In addition, the committee is responsible for periodically re-evaluating existing pesticides and herbicides already on the market in light of any new scientific evidence through a similar re-registration process.<sup>30</sup> The goals of the committee include a strong emphasis on human and animal health and safety throughout the food chain and food production process, which is different from FIFRA's human health and environment focus. Members of the committee are of various and diverse backgrounds just as those working for the EPA here in US.<sup>31</sup> The commissioner and decisions by the committee come under the authority of the European Commission of the EU's executive branch. Decisions are subject to suit brought by citizens under the jurisdiction of the European Court of Justice. Since, Atrazine is the most widely used herbicide and at the time of the publication of Hays' study already in use both in the US and in the EU, it was subject to the Food Chain and Animal Health Committee (FCAHC) re-registration process.

It is important to note that Council Regulation (EEC) No 793/93 requires industry to provide information, data, models and statistics to the European Commission.<sup>32</sup> In addition to just requiring that manufacturers provide information on the chemicals they sell the council regulation also requires that the information provided complies with "good laboratory" practices as set out in Council Directive 87/18/EEC.<sup>33</sup> The US does have corresponding "Good Laboratory Practices" in 40 CFR §160.1, with specific provisions applying to FIFRA sections 136(a), 136(c), 136(f), 136(q) and 136(v), however, these guidelines do not seem to be as rigorous as those in Directive 87/18/EEC.<sup>34</sup> Moreover, Regulation (EEC) No 793/93 also sets out the specific types of data manufacturers must supply, such as: name and identifying number, quantity produced or imported, current classification, foreseeable uses, physicochemical properties, environmental pathways and environmental fate of the substance, eco-toxicity, acute and sub-acute toxicity, carcinogenic properties, mutagenic properties, reproduction and other relevant risk evaluation factors.<sup>35</sup> If a

<sup>34</sup> 40 C.F.R. § 160.1 (2005) (intended to assure the quality and integrity of data submitted pursuant to sections of FIFRA).

<sup>&</sup>lt;sup>29</sup> See generally European Comm'n Food Safety Regulatory Comms., Food Safety: From the Farm to the Fork, http://ec.europa.eu.int/comm/food/fs/rc/index\_en.html (last visited Sept. 18, 2006) (stating the European Parliament and the Council established the Standing Committee on the Food Chain and Animal Health, consisting of representatives having key roles in decision-making on food safety issues).

<sup>30</sup> Id.

<sup>&</sup>lt;sup>31</sup> European Comm'n, Health and Consumer Prot. Directorate-Gen., http://europa.eu.int/comm/dgs/health\_consumer/weare.htm (last visited Sept. 17, 2006) (describing diverse backgrounds of committee members).

<sup>&</sup>lt;sup>32</sup> Council Regulation, 793/93, art.10 1 O.J. (L 84).

<sup>&</sup>lt;sup>33</sup> *Id.* at 3.

<sup>&</sup>lt;sup>35</sup> Council Regulation 793/93 EEC, supra note 29, at art. 4-5.

manufacturer does not provide enough information they may be asked to carry out tests and studies to provide more information.<sup>36</sup> This is similar to FIFRA's data callin provision discussed later. When deciding the classification of a chemical the FCAHC may look to not only the effects on humans and the environment, but also the exposure to humans and the environment, the lack of data on the substance's effects, work carried out internationally and other Community regulations.<sup>37</sup> It is important to realize that the EU Parliament may veto categorizations made by the European Commission.

## C. EU Regulation of Atrazine

After the creation of the Water Framework Directive the EU has followed up with the creation of a list of 32 substances to be phased out. <sup>38</sup> These substances include 11 that are classified as priority hazardous substances to be phased out over the next 20 years and an additional 11 substances that may be classified as priority hazardous substances after thorough scrutiny. This included Atrazine because of its risk as a possible carcinogen.<sup>39</sup> However, once the Hays and Syngenta studies came to light and were evaluated by the SAP, the FCAHC decided to deny the re-registration of Atrazine. 40 FCAHC's decision is not surprising because many EU countries had already individually taken steps to ban or phase out Atrazine. 41 It is not clear whether the individual countries within the EU banned Atrazine whether for human health or environmentally related concerns. For example, both Denmark and Sweden were some of the first countries to ban Atrazine, but it is unclear if the Syngenta controversy and Hays studies played an influential role. The FCAHC used the risk of leaching to ground water as its main justification for its decision and surprisingly cites directly to EPA data and research to support their decision because their own SAP report showed no significant risk.<sup>42</sup> Specifically, the FCAHC says, that it is Atrazine's potential to pollute groundwater and its persistence once groundwater is contaminated, that is the main justification for the ban. However,

<sup>38</sup> Press Release, European Comm'n, Water Policy: Commission Identifies Priority Substances and Proposes to Phase Out Eleven Hazardous Substances (Jan. 18. 2001), http://europa.eu.int/rapid/searchAction.do (search and set date range from 8/01/2001 to 8/01/2001, then follow "Water Policy: Commission Identifies Priority Substances and Proposes to Phase Out Eleven Substances" hyperlink) (last visited Sept. 7, 2006).

<sup>39</sup> Id.

<sup>&</sup>lt;sup>36</sup> *Id.* at art. 10.

<sup>&</sup>lt;sup>37</sup> *Id.* at art. 6.

See Syngenta Crop Protection, http://www.syngentacropprotection-us.com/prod/herbicide/Atrazine/index.asp?nav=reregistration#10 (last visited Sept. 16, 2006) (criticizing the re-registration denial as not health-based or scientifically supported, but instead as contrary to the EU's own positive reviews).

<sup>&</sup>lt;sup>41</sup> See e.g., PRESS RELEASE, NATURAL RES. DEF. COUNCIL, EPA REFUSAL TO RESTRICT ATRAZINE DESPITE HEALTH THREAT IGNORES SCIENTIFIC EVIDENCE, SAYS NDRC (Oct. 31, 2003), http://www.nrdc.org/media/pressreleases/031031.asp (noting the tight restrictions that exist in Switzerland).

<sup>&</sup>lt;sup>42</sup> See Council Regulation, supra note 29 (stating that the results of the study showed no reasonable risk), and Official Journal of the European Union, Commission Decision of 10 March 2004 concerning the non-inclusion of atrazine in Annex I to Council directive 91/414/EEC and the withdrawal of authorization for plant protection products containing this active substance (notified under document number C(2004) 731), at Section 6.1 available at http://www.syngenta.com/en/media/article.aspx?article\_id=325, http://www.syngentacropprotection-us.com/prod/herbicide/Atrazine/index.asp?nav=reregistration

there may be other factors that influenced their decisions since there are many toxins like gasoline that have the same properties and have not been banned.

In the case of Atrazine the EU ran its own scientific review of the available data. Ironically despite a finding that Atrazine is not dangerous if used properly the EU went ahead with banning it.<sup>43</sup> Therefore, circumstantial evidence points to the recent scientific and political controversy in the U.S. combined with an application of the precautionary principle as the primary sources of justification.

A few exceptions to the complete ban of Atrazine have been made for "essential uses." Essential uses are defined as crops that cannot otherwise be grown without the use of Atrazine. These include major exceptions in the UK and Ireland (until 2007 only) for forestry and maize. Individual countries are allowed to apply for exceptions to environmental regulations provided they can show special harm or make special distinctions. In these cases the UK and Ireland were successful in showing both essential use and special harm. All other uses are strictly banned and are now illegal.

### III. US REGULATIONS OF EDCS

### A. US Regulatory Framework: FIFRA

The EPA regulates EDCs and other hazardous chemicals that pose environmental risks in the US. FIFRA is the central federal statute for pesticides (including herbicides) like Atrazine. EDCs may also be regulated under the Toxic Substances Control Act ("TSCA"), the Endangered Species Act ("ESA"), the Safe Drinking Water Act "(SDWA"), Clean Air Act ("CAA"), Clean Water Act ("CWA"), and Food and Drug Administration ("FDA"), depending upon the particularly EDC and its use. This paper will focus on regulations under FIFRA because it is most relevant to the Atrazine case.

FIFRA creates two categories of chemicals; new chemicals to the market and those that are already in circulation.<sup>47</sup> New chemicals are subject to higher standards than those already in use. FIFRA allows older chemicals to be grandfathered in. This kind of system may create problematic results where older suspected EDCs are under less regulation than newer, safer chemicals, which might be available substitutes.

As an older chemical that is already being used in the market place, Atrazine may be regulated under FIFRA 7 USCA §136(g)(A) as a pesticide that is already in use, but subject to periodic review. Section 138(c)(A) of FIFRA states that the burden of proof in the registration process for a chemical like Atrazine lies with the

<sup>46</sup> *Id*.

<sup>47</sup> 7 U.S.C. § 136(a)(1) (2000 & Supp. 2006).

 <sup>43</sup> See Syngenta Crop Protection, supra note 37 (discussing Atrazine controversy in the U.S. and E.U.).
 44 Council Directive 91/414, 1991 O.J. (L230) 1, available of http://www.dgsgardening.btinternet.co.uk/EUdirective.htm (last visited Sept. 6, 2006).

<sup>&</sup>lt;sup>45</sup> *Id*.

<sup>&</sup>lt;sup>48</sup> U.S. ENVT'L PROT. AGENCY, ATRAZINE INTERIM REREGISTRATION ELIGIBILITY DECISION (IRED) Q&A'S (Jan. 2003), http://www.epa.gov/pesticides/factsheets/Atrazine.htm (last visited Sept. 17, 2006); 7 U.S.C. § 136(a)(g)(1)(A).

registrant or manufacturer;<sup>49</sup>In this case, the burden lies with companies like Syngenta.

EPA had the discretion to renew Atrazine's registration or to re-classify it under \$136(d)(2) or \$136(d)(3) due to a finding of unreasonable risk to the environment. To summarize, the EPA, under FIFRA could have: (1) banned Atrazine, (2) classified Atrazine for restricted use, (3) modified the labeling requirements, instructions and warnings required for Atrazine, (4) limited sales to reserve stocks, (5) suspend sales or (6) renewed the registration on the basis of the scientific uncertainty surrounding evidence that Atrazine is an EDC presenting an unreasonable risk to the environment. St

In the case of scientific uncertainty concerning the regulations of a known EDC like Atrazine the EPA's options seem limited. This is in part because without scientific certainty the EPA will not be able to justify deciding what uses and what concentrations of a particular pesticide to permit. If the exact mechanism through which the EDC, in this case Atrazine, harms human health or the environment is uncertain, then the EPA cannot know if some or all uses are unsafe. So, how does the EPA deal with this lack uncertainty? One tool that might be used by the EPA can be found in §136. The EPA is entitled to carry out "data-call-ins" under §136(c)(2)(B). Data-call-ins allow the EPA to give the manufacturer a reasonable amount of time to come up with the information they need. This provision of FIFRA is supposed to shift burden onto the manufacturer, who is theoretically in the best position to research and provide accurate information about the substance in question. This creates a situation where the EPA is not able to always react in the most precautionary way.

### B. Atrazine Case Study

Tyrone Hays' study published in *Nature* in 2001 was the first to suggest that Atrazine may be an EDC.<sup>53</sup> The study found that Atrazine concentrations lower than those presently found in groundwater in many states caused greater instances of hermaphrodites amongst the test subjects, frogs.<sup>54</sup> Syngenta one of the largest manufacturers of Atrazine created a panel of scientists to do more research on Atrazine's endocrine disrupting abilities. The panel was called EcoRisk and all of

<sup>52</sup> See FIFRA, 7 USC §136(a)(c)(2)(B) ("Data-call-in" (DCI) is a term used for the EPA's ability to request specific additional data from a registrant to support an existing registration). See generally U.S. Envt'l Prot. Agency Office of Pesticide Programs, Staff Background Paper #3.1 (2003), available at http://www.epa.gov/oppfead1/trac/dci.htm (providing more detail about the DCI process).

<sup>&</sup>lt;sup>49</sup> 7 USC §138(a)(c)(1)(F).

<sup>&</sup>lt;sup>50</sup> FIFRA, 7 USC §136(a)(d)(2)-(3).

<sup>&</sup>lt;sup>51</sup> Id

<sup>&</sup>lt;sup>53</sup> Hayes, et. al., *supra note* 3, at 895.

<sup>&</sup>lt;sup>54</sup> See Atrazine: Frogs, Farms & Pharmaceuticals (Link TV television broadcast Aug. 2004) (focusing on the recent controversies surrounding Syngenta, Dr. Ron Kendell, the EcoRisk Panel and Tyrone Hayes. The documentary also focuses on how these controversies affect farmers as well as general public); see Hayes et. al., supra note 3, at 895 (stating that detectable amounts of Atrazine were present in states like Utah, Wisconsin, and Nebraska, non-agricultural states with sales of Atrazine below 4 kilograms per square kilometer); Tyrone Hayes, Kelly Haston, Mable Tsui, Anhthu Hoang, Cathryn Haeffele & Aaron Vonk, Feminization of Male Frogs in the Wild, 419 NATURE 895, 895-96 (Oct. 2002) (stating that detectable amounts of Atrazine were present in states like Utah, Wisconsin and Nebraska which were non-agricultural states with sales of Atrazine below 0.4 kg km²).

their studies found Atrazine to not be an EDC in direct opposition to the Hayes experiment. In the meantime Hays claims to have reproduced the same results of his original experiment confirming that Atrazine is an EDC. This created a great deal of controversy amongst the scientific community. Due to the concern and the level of apparent scientific uncertainty courts granted the EPA a time extension for the FIFRA re-registration process allowing for the SAP to review all of the Hays' and EcoRisk studies. Funding of all of the EcoRisk studies by Syngenta, which had a vested interested in showing Atrazine was not an EDC also called many of the studies into question.

After 9 months of analysis, the SAP found each and every one of the EcoRisk studies to be fundamentally or methodologically flawed, some containing defects as egregious as allowing control and test subjects to intermix.<sup>58</sup> Having discredited the EcoRisk studies the EPA found insufficient evidence to block Atrazine's reregistration due to the uncertainty surrounding whether Atrazine posed a human health or environmental risk. So in October of 2003 EPA finalized the Interim Registration Eligibility Decision ("IRED") allowing Atrazine to be approved.<sup>59</sup> Moreover, it is not clear why EcoRisk and Syngenta were not found to be in violation of the Code of Federal Regulations ("CFR") "good laboratory practices," given the SAP findings.<sup>60</sup>

This is problematic when the chemical toxins are as complicated as EDCs. Unlike other types of toxins can disrupt hormonal systems in a variety of different ways that may have vastly different affects in organisms of the same species that are at different stages of development or simply different sizes.<sup>61</sup> This makes clear scientific consensus especially difficult. U-shaped dose-response curves that are

<sup>57</sup> See Press Release, U.S. Envy'l Prot. Agency, Office of Pesticide Programs, Atrazine Evaluation Deadline Extension (2003), http://www.epa.gov/oppfead1/cb/csb\_page/updates/Atrazinext.htm (providing notice of the extension and its new relevant dates); Envy'l Prot. Agency, Atrazine Interim Reregistration Eligibility Decision (IRED) Q&A's (Jan. 2003), http://www.epa.gov/pesticides/factsheets/Atrazine.htm (supplying "technical and general information about Atrazine and its [then] current regulatory status under pesticide and water laws); 7 U.S.C. § 136a(g)(2)(A) (authorizing review of data submitted for reregistration by the EPA)

<sup>&</sup>lt;sup>55</sup> Council Directive 01/414, *supra* note 41.

<sup>&</sup>lt;sup>56</sup> Id

<sup>&</sup>lt;sup>58</sup> See Jennifer E. Lee, Popular Pesticide Faulted for Frog's Sexual Abnormalities, NY TIMES,

June 19, 2003 at A20 (detailing EPA's conclusions about the effects of Atrazine on frogs); Rebecca Renner, *Controversy Clouds Atrazine Studies*, ENVTL. SCI. & TECH., Feb. 19, 2004, http://pubs.acs.org/subscribe/journals/esthag-w/2004/feb/science/rr\_controversy.html (detailing the "allegations of ethical misconduct and bad science" involved with Atrazine registration); Pharyngula, http://scienceblogs.com/pharyngula/2006/02/tyrone\_hayes\_at\_umm.php (Feb. 6, 2006, 10:33 CTS) (Pharyngula is a blog maintained by Professor Paul Z. Myers a Biology Professor at the University of Minnesota. His posting focuses on Tyrone Hayes and the Atrazine controversy); Kerry Tremain, *Hopping Mad: A Frog Biologist Battles an Agrichemical Giant*, SIERRA MAGAZINE (July/Aug. 2004), http://www.sierraclub.org/sierra/200407/profile.asp (last visited February 7, 2007) (providing extensive details on the Atrazine controversy and comments from Hayes).

<sup>&</sup>lt;sup>59</sup> Council Directive 793/93, *supra* note 30.

<sup>&</sup>lt;sup>60</sup> Good Laboratory Practices, 40 CFR §160 (2005).

<sup>&</sup>lt;sup>61</sup> See ENVT'L PROT. AGENCY, ENDOCRINE DISRUPTOR SCREENING AND TESTING ADVISORY COMM., FINAL REPORT, 21-25 (Aug. 1998), available at http://www.epa.gov/scipoly/oscpendo/docs/edstac/chap2v14.pdf (providing background information on how the endocrine system functions, discussing issues endocrine disruptors present, and the creation of the Endocrine Disruptor Screening and Testing Advisory Committee in 1996).

now commonly accepted to be accurate for many toxins by toxicologists makes experimentation more complicated as well.

Despite all the options FIFRA provides the EPA still concluded that the toxicity of a Atrazine is too controversial to be regulated without stronger and clearer evidence. However, EDCs are so complicated that clear uncontroversial evidence may take decades to prove. This demonstrates that though FIFRA appears to place the burden upon industry in practice, this places industry in a great deal of control because industry is essentially in control of much of the information. Only in rare instances do you have scientists who are willing to take on industrial giants, as was the case with Tyrone Hays, and risk large well organized campaigns to discredit their work.

In contrast, on October 15<sup>th</sup>, European Union nations announced that they would ban Atrazine over the course of 18 months.<sup>62</sup> This does imply that European countries have a regulatory system better able to err on the side of precaution when dealing with toxins that are so complex. It also implies that the EU system and the FCAHC are better able to use discretion to disregard industry-funded science. Much of the reason that the EU is able to do this can be attributed to different evidentiary standards under the court system, the incorporation of economic free trade arguments into justifications, the explicit use of precautionary principle language in the EU Treaty, different political actors and the use of different policy tools. All of these factors will be discussed in the following section.

In October, the Natural Resource Defense Council ("NRDC") claimed that the EPA had failed to consider the Endangered Species Act ("ESA") implications of the Atrazine animal studies and that the EPA had failed to communicate with the Fish and Wildlife Service and the National Marine Fisheries Service. Based on this accusation the NRDC filed suit against the EPA in August of 2003 for failing to carry out its obligations under the ESA (Endangered Species Act) given the scientific evidence presented in the Atrazine animal studies. The ESA is perhaps the most precautionary environmental regulation in the US. It requires any action that threatens an endangered species or their habitat to be stopped. NRDC is claiming that the animal studies on Atrazine show that its use threatens endangered species and their habitat. This is an interesting loophole, which circumvents FIFRA under which pesticides are normally regulated. However, in order to be

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<sup>&</sup>lt;sup>62</sup> See PRESS RELEASE, NATURAL RES. DEF. COUNCIL, supra note 41 (contrasting the U.S. and E.U. stances on Atrazine regulation).

<sup>&</sup>lt;sup>63</sup> U.S. ENVT'L PROT. AGENCY, ATRAZINE INTERIM REREGISTRATION ELIGIBILITY DECISION (IRED) http://www.epa.gov/pesticides ADDENDUM, Q&A'S OCTOBER 2003, /factsheets/Atrazine addendum.htm (last visited Sept. 17, 2006); PRESS RELEASE, NATURAL RES. DEF. COUNCIL, EPA REFUSAL TO RESTRICT ATRAZINE DESPITE HEALTH THREAT IGNORES SCIENTIFIC EVIDENCE, SAYS NRDC, (Oct. 31, 2003), http://www.nrdc.org/media/pressreleases/031031.asp. See also PRESS RELEASE, NATURAL RES. DEF. COUNCIL, NRDC SUES EPA FOR FAILING TO PROTECT ENDANGERED WILDLIFE FROM HERBICIDE (Aug. 2.0 http://www.nrdc.org/media/pressreleases/030820.asp (discussing NRDC suit against EPA for failing to protect endangered species).

64 See Press Release, Natural Res. Def. Council, supra note 41 (noting that scientific studies have

See PRESS RELEASE, NATURAL RES. DEF. COUNCIL, *supra* note 41 (noting that scientific studies have shown atrazine may cause cancers and harm reproductive and hormone systems in humans and animals). <sup>65</sup> See PRESS RELEASE, NATURAL RES. DEF. COUNCIL, EPA REFUSAL TO RESTRICT ATRAZINE DESPITE HEALTH THREAT IGNORES SCIENTIFIC EVIDENCE, SAYS NRDC (Oct. 31, 2003), http://www.nrdc.org/media/pressreleases/031031.asp (charging EPA with ignoring the harmful affects of Atrazine to animals).

successful the NRDC will have to show that Atrazine harms a specific endangered species in some way otherwise there will be no case. This may be one possible source of regulating EDCs, like Atrazine, even though the ESA was clearly not legislated with such a purpose in mind.

It is likely that in this litigation the NRDC will come across the same problems as the EPA in interpreting the science to meet the evidentiary standards to justify regulation. Without a clear scientifically supported connection between Atrazine and endangered species or their habitat this legal claim is undercut by the scientific uncertainty. Therefore, NRDC will not be able to avoid the same problems the EPA ran into because EDCs are complex, the science is disaggregated, the studies use different methodologies, have different endpoints and the studies are on different species at different stages of development. Not to mention that a U-shaped dose response curve makes it unclear what the EPA should have done even if there was clear evidence that Atrazine is a human health and environmental risk. Even if there is risk the U-shaped curve suggests lower levels are just as dangerous as high levels of the particular toxin.

Raw	Data

Dose	1	1.5	2.5	4	5.5	6.5	7
Response	90	60	25	10	24	60	90

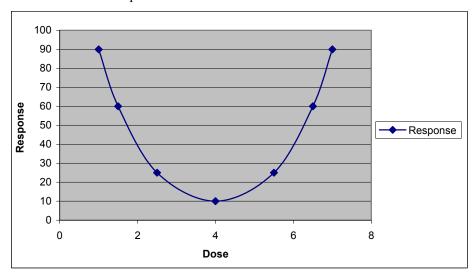
Long-Evans rats according to different levels of Atrazine exposure).

<sup>&</sup>lt;sup>66</sup> See generally Simiäc B, Kniewald J & Kniewald Z, Effects on Atrazine on Reproductive Performance of the Rat, 14(6) J. APPL. TOXICOL. 401-04 (1994) (explaining the ingestion of Atrazine by rats for seven days and resulting in loss of body weight and prolonged oestrous cycle in the female rats); Kavlock R.J., Exposure to Pesticides, 24(4) J. TOXICOL. SCI. 265, 265 (1999); Bishop C.A., Mahony N.A., Struger J., N. G. P, & Pettit K.E., Anuran Development, Density and Diversity to Agricultural Development in the Holland River Watershed, Ontario, Canada (1990-1992), 57(1) ENNT'L MONITORING AND ASSESSMENT 21-43(1999) (suggesting that herbicide Atrazine, ammonia, phosphorus particulates and other substances may contribute to lower anuran diversity, density, and reproductive success of American toads and green frogs); See e.g., Fenton S.E., Greiner S.N., Youngblood G.L., & Davis C.C., Effects from Gestational Exposure to a Mixture of Atrazine and its Biological Metabolites in Male Long-Evans Rats, 66 BIOL. REPOD. 199, 200 PINCITE (2002) (explaining the different effects in

<sup>&</sup>lt;sup>67</sup> See Edward J. Calabrese and Linda A. Baldwin, Toxicology Rethinks its Central Belief: Hormesis Demands a Reappraisal of the Way Risks Are Assessed, 421 NATURE 691, 691 (Feb. 13, 2003) (explaining that the EPA has been struggling to harmonize how the agency assesses risks using the U-shaped dose response curve, also known as the hormetic paradigm).

<sup>&</sup>lt;sup>68</sup> THOMAS STEEGER & JOSEPH TIETGE, ENVT'L PROT. AGENCY, OFFICE OF PREVENTION, PESTICIDES, & TOXIC SUBSTANCES, WHITE PAPER ON POTENTIAL DEVELOPMENT, EFFECTS OF ATRAZINE ON AMPHIBIANS 54 (2003), available at http://www.epa.gov/scipoly/sap/meetings/2003/june/finaljune2002telconfreport.pdf; Sarah I. Storrs & Joseph M. Kiesecker, Survivorship Patterns of Larval Amphibians Exposed to Low Concentrations of Atrazine, 112 ENVIRON. HEALTH. PERSP. 1054, 1056 (July 2004), http://www.ehponline.org/members/2004/6821/6821.pdf (last visited February 7, 2007).

### U- Curve Relationship



The EPA has taken some action by setting Maximum Contamination Levels ("MCL") for Atrazine under the Safe Drinking Water Act. <sup>69</sup> These function in the same way as the 1998 Directive 98/83/EC on the quality of drinking water, which set the maximum admissible concentrations (MACs) for all pesticides regardless of scientific evidence as a general precautionary standard. <sup>70</sup> If MCLs for Atrazine are exceeded, EPA has charged Syngenta with aiding community water systems with coming into compliance. <sup>71</sup>

### IV. DIFFERENCES-POSSIBLE EXPLANATIONS

Many people have tried to explain why the EU has taken a more precautionary stance on environmental regulations. To really understand why, this section will look at the central differences between the two sets of environmental regulations.

### A. Free Trade

The EU was founded upon principles of tree trade and the creation of a unified European market. Therefore, regulations that can be based on correcting unfair

<sup>&</sup>lt;sup>69</sup> See U.S. ENVT'L PROT. AGENCY, ATRAZINE INTERIM REREGISTRATION ELIGIBILITY DECISION (IRED) ADDENDUM, Q&A'S – OCTOBER 2003, http://www.epa.gov/pesticides/factsheets/Atrazine\_addendum.htm (last visited Sept. 17, 2006) (stating that drinking water is monitored under SDWA, where detections of Atrazine approaching the MCL will trigger further action); PRESS RELEASE, ENVT'T PROT. AGENCY, OFFICE OF PESTICIDE PROGRAMS, ATRAZINE EVALUATION DEADLINE EXTENSION, http://www.epa.gov/oppfead1/cb/csb\_page/updates/Atrazinext.htm (stating the EAP and the NRDC jointly requested that the court extend the deadline for the IRED to January 31, 2003).

<sup>&</sup>lt;sup>70</sup> Wossink & Feitshans, *supra* note 18, at 224.

<sup>&</sup>lt;sup>71</sup> U.S. ENVT'L PROT. AGENCY, ATRAZINE INTERIM REREGISTRATION ELIGIBILITY DECISION (IRED) ADDENDUM, Q&A'S (OCTOBER 2003), http://www.epa.gov/pesticides/factsheets/Atrazine\_addendum.htm (last visited Sept. 17, 2006); PRESS RELEASE, ENVT'L PROT. AGENCY, OFFICE OF PESTICIDE PROGRAMS, ATRAZINE EVALUATION DEADLINE EXTENSION, http://www.epa.gov/oppfead1/cb/csb page/updates/Atrazinext.htm.

competition between member states are easily justified under the EU Treaty. This may have played an important role in the EU's regulation of Atrazine, since many member states had already made declarations banning Atrazine. So, phasing out Atrazine use in the EU essentially levels the playing field by not allowing those countries that have decided to err on precaution from being competitively disadvantaged. This is in sharp contrast to the US regulatory systems where free trade is not listed as a strong justification for regulating pesticides. States are still free to ban a pesticide even if the EPA has not, but the fact that states have banned a pesticide is not reason the EPA may use to ban the pesticide at a federal level.

Free trade principles in EU regulations must be taken in the context of the principle of Subsidiary, which states the EU, "shall take action only if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effect of the proposed action, be better achieved by the community." This means that issues of scale are a factor in deciding whether or not action is taken at the EU level. Environmental problems that affect groundwater like Atrazine are an ideal example of regulations, which are best addressed at the EU level because of their transboundary affects. Based on these concepts if several countries within the EU ban a pesticide, the EU may decide that for issues of free trade and leveling the economic playing field within the EU market that the pesticide should be banned at the EU level.

### B. Formal Adoption of Principle of Precaution

Unlike in the U.S., the EU has formally adopted the precautionary principle in the EU Treaty and the Treaty of Amsterdam. In addition, the European Environmental Protection Agency ("EPA") uses the principle of precaution as part of its general agency policies. This allows the EU to base decisions in the face of scientific uncertainty, whereas the EPA must justify regulations based on scientific consensus.

One could describe the difference between US and EU environmental policies as the difference between prevention and precaution best described by European Union Trade Commissioner Pascal Lamy "in the US they believe that if no risks have been proven about a product, it should be allowed. In the EU we believe something should not be authorized if there is a chance of risk." Despite this express authorization of the precautionary principle it is not applied evenly in all EU

<sup>77</sup> Treaty of Amsterdam Amending the Treaty on European Union, the Treaties Establishing the European Communities, and Certain Related Acts, art. 34, Oct. 2, 1997, available at http://www.europarl.europa.eu/topics/treaty/pdf/amst-en.pdf (last visited Feburary 12, 2007).

<sup>&</sup>lt;sup>72</sup> P.S.R.F. Mathijsen, A Guide to European Union Law 19 (8th ed. 2004).

<sup>&</sup>lt;sup>73</sup> FIFRA, 7 USC §136(a)(c)(2)(B). "Data-call-in" (DCI) is a term used for the EPA's ability to request specific additional data from a registrant to support an existing registration. *See generally* U.S. ENVT'L PROT. AGENCY OFFICE OF PESTICIDE PROGRAMS, STAFF BACKGROUND PAPER #3.1 (2003), available at http://www.epa.gov/pesticides/factsheets/Atrazine.htm (providing more detail about the DCI process).

<sup>&</sup>lt;sup>74</sup> Jonathan B. Wiener, Whose Precaution After All? A Comment on the Comparison and Evolution of Risk Regulatory Systems, 207 DUKE J. COMP. & INT<sup>2</sup>L. L. 207, 212 (2003).

<sup>&</sup>lt;sup>75</sup> Wossink & Feitshans, *supra* note 18, at 236.

<sup>&</sup>lt;sup>76</sup> Id

<sup>&</sup>lt;sup>78</sup> Wossink & Feitshans, *supra* note 18, at 212.

<sup>&</sup>lt;sup>79</sup> *Id.* at 213-214.

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regulations. It is simply one of many different arguments that policy makers may make to challenge or support legislation.

### C. Differences between Precaution in Environmental Issues

US and Europe do not always diverge in the same directions over the precautionary principle. For example, while in the case of Atrazine the EU has been more precautionary there are other areas where the US has taken a more precautionary approach such as the Bush doctrine of preemption for terrorism and homeland security. 80 In the area of environmental law there may be a pattern that explains the differences for why sometimes the US is more precautionary and sometimes the EU is more precautionary. In instances where environmental regulations are supported by human health concerns such as with diesel fuel the US takes a fairly precautionary stance, however, when concerns are primarily environmental as with CFC or Atrazine the EU takes a more precautionary approach.<sup>81</sup> Whether this pattern holds true will require more evidence. It remains to be seen if the EPA will take a more precautionary approach when faced with an EDC like Atrazine, which is proposed to have serious, but controversial human health risks.

### D. Enforcement and Different legal systems- Torts and the Role of Courts

The role of the court system in the US today may explain part of the differences between the two systems of regulation. Cases such as Chevron and Industrial Union Dep't (from now on referred to as Benzene) place much higher evidentiary burdens upon the EPA's actions. 82 Chevron states that deference will be given to the agency if the statute is clear or if there is a reasonable interpretation, which is neither arbitrary nor capricious. 83 This sets a precedent that is quite generous to agency decisions in absence of clear statutory language indicating otherwise, however, when read in light of *Benzene* there is some limitation to this deference when making scientifically based decisions. Benzene implies minimum thresholds of evidence that must be met in order to show causation.<sup>84</sup> Specifically in *Benzene* the court stated that "the Agency [must] show, on the basis of substantial evidence, that it as least more likely."85 In this case it would suggest that the EPA must show by substantial evidence that Atrazine is more likely to be an EDC. 86 This creates an incentive for the EPA not to take action in the face of scientific uncertainty because of the high risk that courts will overturn such decisions. In addition, it shifts the financial and informational burdens of litigation to disfavor the EPA and increases industry's

<sup>&</sup>lt;sup>80</sup> PRESS RELEASE, NATURAL RES. DEF. COUNCIL, supra note 60, at 239-40.

<sup>81</sup> Id. at 230 (describing the hypothesis that precautionary differences are based on regulatory focus on human health in the US versus a regulatory focus on environment in the EU and describing several regulations to support this idea).

Wendy Wagner, The Science Charade in Toxic Risk Regulation, 95 COLUM. L. REV. 1613, 1661-1664; Chevron USA Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984); Industrial Union Department v. American Petroleum Institute, 448 U.S. 607, 653-54 (1980).

<sup>83</sup> Chevron USA Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984).

<sup>&</sup>lt;sup>84</sup> Industrial Union Department v. American Petroleum Institute, 448 U.S. 607, 653-54 (1980).

<sup>&</sup>lt;sup>85</sup> *Id*.

<sup>&</sup>lt;sup>86</sup> Wendy Wagner, The Science Charade in Toxic Risk Regulation, 95 COLUM. L. REV. 1613, 1661-1664 (1995); Industrial Union Department v. American Petroleum Institute, 448 U.S. 607, 653 (1980).

incentive to withhold damaging evidence or simply not carry out studies that might be damaging. Therefore, even though statutes like FIFRA may seem on their face to place the burden of evidence upon industry, the current trend in jurisprudence places a high burden upon the EPA.

In contrast the recent EU cases seem to be moving in a slightly different direction. The judgment by the Court of First Instance in Pfizer Animal Health SA v. Council of the European Union set out the standards for scientific evidence for environmental restrictions.<sup>87</sup> The court states, "where there is scientific uncertainty as to the existence or extent of risks to human health, the Community institutions may, by reason of the precautionary principle, take protective measures without having to wait until the reality and seriousness of those risks become fully apparent [citation omitted]."88 The opinion also states that risk assessments cannot be required for the purposes of providing conclusive evidence as to the degree of risk. Instead the court requires that "risk must be adequately backed up by available scientific evidence."89 This is dramatically different from the US system requiring the agency to show direct causation is more likely by a substantial basis. Under the US system it appears as if the EPA cannot act based on the best available scientific evidence, but must wait for scientific consensus or compelling direct evidence using generally accepted methods. Because of these differences it is easier to see why the EU is able to err on the side of precaution by banning Atrazine, while the US chooses to wait for certain evidence.

# E. Political Actors and Policy Instruments like Green Party, Changing Global Politics

Part of the differences in the way the U.S. and the EU have treated Atrazine may have a great deal to do with the different political actors and policy instruments. In the EU countries green parties have been highly influential as in Denmark, Sweden, and Germany. Moreover, the EU has continually moved towards integration, while the US has moved toward fragmentation. Environmental regulations in the US fall under a variety of statutes like TSCA, FIFRA, CAA, CWA, SDWA, ESA, etc. Most of the environmental regulations fall under the EPA, but parts also fall under other agencies like BLM, Army Core of Engineers, etc. However, the EU's environmental regulations are focused on centralizing environmental regulations amongst all of the member countries by combining regulation under one agency under the Commission for the Environment and integrating policies across different media. The EU has gone so far as setting the integration of different environmental concerns, like air, water and health as a specific goal as part of the EU's Fifth Environmental Action Plan. Both of these factors: political actors and policy instruments, influence the

 $^{90}\,$  PRESS Release, Natural Res. Def. Council, supra note 60, at 245.

<sup>&</sup>lt;sup>87</sup> Pfizer Animal Health SA v. Council of the European Union, 2002 E.C.R. II-3305, Case T-13/99 (Court of First Instance, European Union).

<sup>&</sup>lt;sup>88</sup> *Id.* at ¶ 139.

<sup>&</sup>lt;sup>89</sup> *Id*.

<sup>91</sup> Wossink, supra note 18, at 234.

See European Comm'n, Environmental Integration, http://ec.europa.eu/envrionment/integration/integration.htm (last visited Sept. 7, 2006) (explaining that environmental integration became a priority in the European Union's Fifth Environmental Action Programme (1993-2002) in response to issues raised at the Earth Summit in Rio in 1992).

degree of enforcement. With less political backing and a high degree of fragmentation an agency like the EPA has a lot less flexibility and must choose its battles carefully creating an incentive to wait for more scientific certainty.

It is also true that since the EU is a sort of supra-national organization it is somewhat protected from the political climates of individual countries. Here in the U.S., the EPA and environmental regulations at the federal level are directly under the President. Therefore, if the President does not prioritize the environment an already resource scarce EPA may be reluctant to take political risks by challenging industry and powerful lobbies like the agricultural lobbies in the US. The current Bush administration has definitely placed the environment as a low priority in comparison to national security and other issues like social security, taxes and education.

### F. Syngenta's Stakes- Industry

Part of the difference between EU and US regulations of Atrazine might be answered by the difference in the incentives of stakeholders, like Syngenta. The US market for herbicides is over 40% of Syngenta's market, while the EU only compromises less then 25%. Orn or maize is the single crop that accounts for the largest share of herbicide use, so it is not surprising that Atrazine is an herbicide used primarily on maize. Herbicides are restrictions Atrazine was a \$400 million global market used in 69% of US maize crops and 53% in European countries like the EU. The US is the largest producer of maize (corn), therefore, it is easy to see why Syngenta spent a lot of time, money and effort engaged in the EPA's FIFRA reregistration process in the U.S.

Given this information it seems highly likely that Syngenta was more motivated to participate actively to push Atrazine through the US re-registration process because of its financial stakes than it was to the fight the EU legislative ban. This effect was probably increased by the fact that in the larger Atrazine consumption countries within the EU Syngenta was already offering and selling Atrazine alternatives. When combined with the greener political opposition within the EU discussed in section E, it seems that there is compelling evidence to argue that

<sup>93</sup> See Syngenta Global, Products & Services: Herbicides, http://www.syngenta.com/en/products\_services/herbicides.aspx (last visited September 18, 2006) (noting U.S. market for herbicides is stronger than European market).

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<sup>94</sup>Id.; see PRESS RELEASE, SYNGENTA GLOBAL, E.U. RE-REGISTRATION OF ATRAZINE NOT GRANTED DESPITE FAVORABLE SCIENCE REVIEW, http://www.syngenta.com/en/media/article.aspx?pr=100403&Lang=en (Oct. 4, 2003) (stating Atrazine primarily used for maize crops and that Syngenta already offering Atrazine alternatives in Italian and German markets).

<sup>&</sup>lt;sup>95</sup> Atrazine Fact Sheet, 56 PESTICIDE NEWS 20, 20-21 (June 2002), available at http://www.pan-uk.org/pestnews/Actives/Atrazine.htm.

<sup>&</sup>lt;sup>96</sup> See Frederic J. Frommer, Syngenta's Massive Lobbying Keeps Carcinogenic Corn Pesticide on the Market, http://thereitis.orgdisplayarticle853.html (last visited Sept. 18, 2006) (indicating that Syngenta, manufacturer of Atrazine, a pesticide linked to deformities in frogs, spent \$260,000 lobbying the Environmental Protection Agency and other government officials).

<sup>97</sup> See PRESS RELEASE, SYNGENTA GLOBAL, E.U. RE-REGISTRATION OF ATRAZINE NOT GRANTED DESPITE FAVORABLE SCIENCE REVIEW, http://www.syngenta.com/en/media/article/aspx?pr=100403&Lang=en (Oct. 4, 2003) (stating Atrazine is primarily used for maize crops and in major European markets, like Germany and Italy, the company markets alternatives to Atrazine).

industry incentives may have been a critical factor in explaining the results of Atrazine regulation in the EU and US.

### V. CONCLUSION

On their official website Syngenta has stated that they have agreed to follow EPA advice and carry out appropriate testing to determine the possible effects of Atrazine. <sup>98</sup> The EPA's official policy is not to comment on pending litigation, therefore, their stance on the NRDCs ESA claim is unclear.

The EU system may be superior for dealing with issues like EDCs where the science is plagued with great uncertainty, but the potential risks to human health and the environment are catastrophic. In these situations industry may use uncertainty in science to block regulation by agencies; however the principles upon which EU regulations are often founded, like the precautionary principle and free trade seem to be able to circumvent scientific evidentiary problems associated with highly complicated EDCs.

In contrast, the U.S. system seems overly dependent upon industry cooperation and scientific certainty due to different policy instruments, different political actors, different evidentiary standards for enforcement, different levels of agency deference, the lack of specific legislation of principles, and the inability to use free trade arguments. Designed to regulate carcinogen type chemical pollutants and prevent premature actions against industry, the current US regulatory system may not be prepared to deal with these types of complex toxics in the future. Given the complexity of newly discovered toxins like EDCs, this type of system, which grants agencies such little discretion in the fact of slightest uncertainty, may be outdated.

<sup>&</sup>lt;sup>98</sup> See Syngenta Crop Protection, Science Panel Supports EPA Views on Atrazine/Amphibian Research, http://www.syngentacropprotection-us.com/prod/herbicide/Atrazine/index.asp?nav=epa\_research (last visited Sept. 18, 2006) (stating Syngenta is currently developing a research proposal based in large on the recommendations of the EPA and the SAP).