ABSTRACT. Today there is considerable disagreement between the US and the EU with respect to food safety standards. Issues include GMOs, beef hormones, unpasteurized cheese, etc. In general, it is usually asserted that Europeans argue for the precautionary principle (with exceptions such as the Sanitary and Phytosanitary Agreement where "substantial equivalence," a form of familiarity, is used) while Americans defend risk analysis or what is sometimes described as the familiarity principle. This is not to suggest that EU member countries agree on how the precautionary principle should be applied; considerable differences exist among nations as will be noted below.

In this paper I review both positions arguing that they are best understood as variants of the homiletics of risk rather than as differing scientific positions. I conclude that while science must necessarily enter into the formulation of food and agricultural standards, state policy, private economic interests, and the interface between the two (e.g., when democratic states are successfully lobbied to support particular private interests), play important roles in determining how particular risks will be treated. Moreover, I argue that the role of science must necessarily be limited if its credibility is to be preserved.

KEY WORDS: food safety, genetically modified organisms, policy, regulation, risk, standards

All that happens is as usual and familiar as the rose in spring and the crop in summer.

– Marcus Aurelius

They say miracles are past; and we have our philosophical persons, to make modern and familiar, things supernatural and causeless. Hence is it that we make trifles of terrors, ensconcing ourselves into seeming knowledge, when we should submit ourselves to an unknown fear.

– William Shakespeare, All's Well that Ends Well

This paper was originally presented at the annual meetings of the European Society for Agriculture and Food Ethics in Copenhagen, August 2000. It is based upon work supported by the National Science Foundation under Grant No. SBR 9810149. Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author and do not necessarily reflect the views of the National Science Foundation. The author would like to thank Craig Harris and the anonymous reviewer for their helpful comments.
They rode, as the Spanish proverb expresses it, “with the beard on the shoulder,” looking round from time to time, and using every precaution . . . against pursuit.

— Sir Walter Scott, Peveril of the Peak

What a curious world we live in. People pay good money to ski down mountains at breathtaking speed. Others play rough and tumble games like (American) football. Still others go out of their way to find restaurants that serve exotic foods of uncertain origin. Japanese consumers seek out sugu, a type of blowfish that can be deadly if not prepared carefully. And, at the same time, these very same people often avoid certain activities because they see them as far too risky. Away with smoking, genetically modified foods, etc.

Are these people merely irrational? Are they oblivious to scientific findings that document the statistical probability of harm associated with various activities? Are they ignorant? Scientifically illiterate?

Bruno Latour (1987) has suggested that irrationality is always an accusation. What is rational to one person is quite irrational to another. But does this mean that we are lost in a sea of irrationality? Of relativism?

In this paper I shall argue that the current debates between the European Union and the United States over the Precautionary Principle and Risk Analysis (or what is sometimes referred to as the familiarity principle), respectively, are far less about what constitutes sound science than they are about what interests are at stake and what values are taken to be paramount in particular historical situations.

THINKING ABOUT HOMILETICS

In Protestant theology – about which I claim absolutely no expertise – it is common to refer to homiletics, the art of explaining particular sayings, often of biblical origin, and of using them to exhort the congregation to do good things, to engage in good works. Thus, a sermon might be easily drawn out of any given line of text in the Bible. But homiletics is hardly confined to theology. We commonly use homilies as explanations of everyday events or as warnings to others to engage or not to engage in particular behaviors. Thus, in the English language we note that “an apple a day keeps the doctor away,” and “a stitch in time saves nine,” but also “don’t drink and drive,” “eat from all the major food groups,” “get plenty of sleep,” and so on. Moreover, advertisers have added to the collection of homilies in an attempt to increase sales of their products. Thus, Burger
King “does it your way.” When Ronald Reagan was still an actor, he used to tell Americans every Sunday night that at General Electric, “progress is our most important product.” Smokey the Bear tells us that “only you can prevent forest fires.”

Francis Bacon (1994 [1620]) warned us against such “old wives’ tales” and René Descartes (1956 [1637]) urged us to abandon our prejudices but, in point of fact, science, too, has its homilies. These include: A result is significant if $p < 0.05$. Type I error (a false positive) is more important than Type II error (a false negative). Break complex problems down into small parts. Try to quantify the phenomenon. Be as precise as possible. Make sure that measures are valid. Always use the scientific method. Of course, for some scientists other homilies apply: For them Type II error is more important. Problems should be treated holistically, etc. In short, science – like all other everyday practices – has its share of homilies as well.

One peculiar aspect of homilies is that they are often contradictory when posed in isolation to each other. However, as I shall argue further below, this contradictoriness is only problematic when the homilies are viewed outside their normal context of use. This is particularly clear in the case of the debate between the EU and the US.

We might well consider the Precautionary and Familiarity Principles as consisting of two pairs of homilies in binary opposition as noted in the fourfold table below:

<table>
<thead>
<tr>
<th>Precaution</th>
<th>Familiarity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>There is no place like home</td>
</tr>
<tr>
<td>Look before you leap</td>
<td>Familiarity breeds contempt</td>
</tr>
<tr>
<td>Negative</td>
<td>He who hesitates is lost</td>
</tr>
</tbody>
</table>

What is evident from the table is that both principles can be viewed either positively or negatively. There are times when precaution is essential and other times when it can and should be thrown to the wind. Similarly, there are times when familiarity provides comfort and security and other times when it undermines those states. The only way that we can successfully use the homilies is by knowing which one is appropriate to a given situation. That ability comes not from blindly following a rule but from experience in applying it in a variety of situations.1

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1 A reviewer notes that in doing a risk assessment of GMOs, one could first employ the concept of familiarity and, based on the level of scientific uncertainty revealed, invoke the precautionary principle in decision-making. Indeed, this seems quite plausible. However, it merely reaffirms the claim made here: Like all homilies, familiarity and precaution only make sense when situated in a set of social relationships. However, at the same time it
THREE EXAMPLES

Let us consider three situations in the domain of food and agriculture: (1) GM foods that are permitted if not actively encouraged in the US while they are de facto prohibited in the EU, (2) the European and US positions on unpasteurized cheeses, and (3) the EU and US positions on scrapie in sheep. The case of GM food is relatively well-known, and illustrates the EU and US positions with respect to precaution and familiarity, respectively. I shall argue that the latter two cases, however, represent precisely the opposite positions.

It should be noted what is not claimed here: Neither the citizens of the US nor those of the EU are monolithic in their views. However, what I shall consider below are the majority positions taken, not the range of views held by various groups within the US or the EU. Let us begin with GM foods.

GM Foods

The US regulatory apparatus for food is divided into three parts, each with distinct, although somewhat overlapping jurisdiction. In brief, the Food and Drug Administration (FDA) is responsible for ruling on most food safety questions related to GM foods. The United States Department of Agriculture (USDA) is responsible for animal health and phytosanitary inspections associated with GM foods as well as the safety of GM meats. The Environmental Protection Agency is responsible for monitoring environmental impacts of GM crops and animals. Both the FDA and USDA have adopted the familiarity principle with respect to GM food, crops, and animals. Until recently, when it bowed to public pressure, FDA did not require any approval for GM foods unless the manufacturer was concerned about possible harm. USDA has generally granted permission to seed companies to test and to market GM crops on the grounds that they are not significantly different from (or "substantially equivalent" to) non-GM crops. And, EPA has not blocked planting of GM crops on environmental grounds, although it has imposed certain requirements on seed producers and farmers (see Levidow, 1999). In short, the US position on GM crops has been staunchly behind the familiarity principle. Indeed, Cathy Wotecki, the Undersecretary for Food Safety and Inspection at USDA, was recently quoted as saying that the precautionary principle “left me completely mystified” (Hagstrom, 2000). As a result, most Americans now eat a significant number of GM foods (especially products with

should be noted that regulatory agencies in the US and EU do not usually employ the concepts in this manner.
cor or soybeans as an ingredient). However, they do not know which products are GM, as – in keeping with the familiarity principle (and usually employing the concept of “substantial equivalence”) – there is no labeling requirement.

In contrast to the US position, European regulators and especially retailers have been far more circumspect with respect to GM foods. Currently, with few exceptions, European farmers are prohibited from planting GM crops. Furthermore, although processed GM foods may be freely imported, there is a \textit{de facto} moratorium on the importation of GM foods, as most retailers refuse to stock them. In addition, some member states have imposed special conditions on GM foods (see Levidow et al., 2000). Indeed, unlike the US situation, where organized resistance to GM foods is relatively ineffective, public opinion in much of Europe is strongly opposed to GM foods.\footnote{In part, the differences between the US and the EU can be explained by differences in both the policy process and the media. The US winner-take-all presidential system tends to stifle minority opinion on both the right and left in favor of the “mainstream.” In contrast, EU parliamentary systems tend to give greater voice to minority opinion, even to the election of minor party members of parliament. Similarly, the US media tends to be geographically based, while the EU media is often associated with particular political parties. Thus, the US media tend to stay in the mainstream, while EU media reflect a broader range of concerns.}

\textit{Scrapie}

Scrapie is a disease of sheep not unlike Bovine Spongiform Encephalopathy (BSE), or Mad Cow Disease. Indeed, scrapie is so similar to BSE that it is difficult, if not impossible, to tell the diseases apart using common laboratory tests.\footnote{Recent research in Switzerland shows promise for developing a simple test, but this is still several years from development (Fischer et al., 2000).} However, unlike BSE, scrapie has long been known. It is endemic in parts of Europe and occasionally appears in the US. In addition, while BSE appears linked to a form of Creutzfeldt-Jakob disease in humans, it is unclear whether scrapie has any effects on humans who eat lamb. Effects on persons who eat sheep cheese are even less clear. While scrapie has long been a problem in Europe, it is relatively rare in the US. Since 1952, USDA has attempted to eradicate the disease in the United States. Since 1992, USDA has maintained a “Voluntary Scrapie Flock Certification Program” to certify that flocks are free of the disease.
In addition, the department buys infected flocks of sheep from farmers so as to keep scrapie under control (United States Department of Agriculture, 2000).

In 1996, several Vermont farmers purchased milk sheep from suppliers in Belgium and the Netherlands. The Dutch and Belgian suppliers guaranteed that the sheep had not been fed any of the mechanically recovered meat that would cause scrapie or BSE to appear. They also passed all the necessary US animal health regulations as administered by the Animal and Plant Health Inspection Service (APHIS) of USDA. The farmers then established a cheese factory and began selling the cheese. However, from the beginning USDA inspectors complained about the imported sheep. The farmers were urged to sell their sheep to USDA which, in turn, would destroy them. As APHIS inspector, Linda Detwiler, put it in a radio interview, “Especially with BSE or mad cow there are so many unknowns that it is our mission to take every step to prevent the entry of BSE mad cow disease into the United States. We are being overly cautious for fear that the agent would be introduced into the United States as a massive endemic disease . . .” (National Public Radio, 1999).

More recently, US officials quarantined and initiated court proceedings to destroy three flocks containing a total of 376 sheep based on four slaughtered sheep from one flock of 21 found to have carcasses with characteristics that in some ways resembled BSE and scrapie (Animal and Plant Health Inspection Service, 2000). In justifying the proposed “euthanizing” of the animals, the USDA argued that,

the test that was positive – Western-blot – cannot differentiate between scrapie and BSE. The only known method to differentiate between these two diseases requires a series of mouse bioassay systems, which take at least 2–3 years for completion. These sheep could possibly have been exposed to BSE in Europe. If they were actually infected with BSE, this would present a significant animal and human health risk. This possibility warrants the conservative actions USDA has taken to minimize any potential risks (Animal and Plant Health Inspection Service, 2000, p. 2).

Furthermore, it was noted that failure to destroy the animals could devastate the US livestock industry.

After some prolonged litigation, the courts supported USDA’s regulatory decision and the animals were all destroyed (New York Times, 2001). Clearly, the US scrapie case illustrates a use of the precautionary principle.

In contrast, the EU position on scrapie was developed much later, only requiring notification of authorities in January of 1993 (Council of the

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4 According to the USDA report, four tests were performed. Two were negative, one was positive, and one was inconclusive.
European Communities, 1991). More recently, individual nations such as Britain have instituted compulsory slaughter programs with compensation to sheep farmers. In addition, the use of certain parts of the animal carcasses (e.g., brains) in the human food chain has been prohibited. The EU position may be described as one of familiarity moving toward precaution as a result of the BSE problem.

**Unpasteurized Cheese**

Finally, consider the fact that the French and Italians (and to a lesser extent several other southern European nations) produce and consume large quantities of unpasteurized cheeses. (In contrast, their northern neighbors pasteurize all their cheeses, much like the US.) Such cheeses have been made for centuries following traditional recipes and are an important ingredient in the diet and cuisine of these nations. The US prohibits importation and sale of unpasteurized cheeses unless they are at least 60 days old on the grounds that they may harbor *Listeria monocytogenes* and other dangerous bacteria. Moreover, the FDA is considering extending the ban to all unpasteurized cheese (Anderson, 2000), spurred on by an American trade group representing industrial cheese producers. In fact, recently some unpasteurized Epoisses cheese produced in France resulted in the deaths of two people (Sicakyuz, 1999).5

Like their American regulatory agency counterparts, European regulators are quite aware of the dangers of eating unpasteurized cheeses. However, they believe that, given the long tradition of preparing these cheeses in small quantities under careful control, the likelihood of becoming seriously ill or dying from eating them is quite remote. Proponents of unpasteurized cheese note that Listeria is often present in a wide variety of fresh and processed foods, including many fresh fruits and vegetables. Indeed, a number of US consumers recently died from *Listeria* found in hot dogs produced in a large facility. Adults who are in good health rarely contract listeriosis, regardless of the source. In fact, one of the two persons to die in France was an infant (Lichfield, 1999). Regardless of which side of the argument one takes, it is clear that this is a use of the familiarity principle; southern Europeans argue that they know this technology well and that it is unlikely to be unduly hazardous to the general population. They also argue that the risks are well-known and worth taking.6

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5 It is not entirely clear if the cheese in question was unpasteurized or not. See Barrett (1999). Moreover, it appears that the factory in question was known for taking shortcuts with respect to safety (Lichfield, 1999).

6 For a strong defense of unpasteurized cheeses, see Anderson (2000).
The cases described above illustrate that both the precautionary and the familiarity principles are used on both sides of the Atlantic. Like all good homilies, they are rhetorical devices used to justify particular actions (or inactions). And, when there is opposition, the opposition uses an equal and opposite homily to make its case. However, it would be an error to assume that there is always disagreement across the Atlantic on issues of risk. In fact, I suspect that there is usually more agreement than disagreement. A more accurate and graphic representation would look as follows:

<table>
<thead>
<tr>
<th>United States</th>
<th>Europe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarity</td>
<td>Familiarity A. Green beans</td>
</tr>
<tr>
<td>Precaution</td>
<td>B. Unpasteurized cheese, scrapie</td>
</tr>
<tr>
<td></td>
<td>Precaution C. GM foods</td>
</tr>
<tr>
<td></td>
<td>D. Laboratory biosafety regulations</td>
</tr>
</tbody>
</table>

As the reader will immediately note, in the cases in boxes A and D, not discussed above, there is widespread agreement. Neither Americans nor Europeans are much concerned about the safety of green beans (although they might be concerned about the use of certain agrochemicals on them). The same would apply to thousands of other fresh and processed food products. As long as conventional production and processing practices are applied, they are handled as things about which we are quite familiar. In contrast, both Europeans and Americans agree on the framework for laboratory biosafety, and they further agree that it is one where precaution should prevail. Indeed, US and EU regulations on laboratory experimentation with GMOs employ several categories of risk, from high risk pathogens that are placed under strict containment to those which would die if released into the environment, thus requiring only minimal precaution. But to understand why agreement or disagreement occurs, we need to inquire into the special place occupied by regulatory or mandated science.

Conventional scientific inquiry may well be directed toward application. Indeed, as early as 1932, Thorstein Veblen acerbically remarked that a scientist’s “inquiry is as ‘idle’ as that of the Pueblo myth-maker. But the canons of validity under whose guidance he works are those imposed by the modern technology, through habituation to its requirements; and therefore his results are available for the technological purpose” (Veblen, 1932, p. 17). Nevertheless, even the most applied scientists, e.g., plant breeders, are not asked to develop a new variety in six
months. They do and are expected to work at whatever pace the field can progress, but they are almost never under a short-term deadline to produce results.

Furthermore, in “normal” settings, scientists move toward their individual and collective goals by amassing evidence, usually through experiment, although sometimes through observation as well. A scientist who wrote a paper that contained only a literature review and no new findings would be hard pressed to find a journal that would accept it.\textsuperscript{7} In contrast, this is rarely if ever the case for regulatory science (see Salter, 1988). Regulatory science differs from conventional science in several ways:

1. **Most importantly, regulatory science is charged with developing recommendations that will inform public policy.** For example, a food safety agency may be asked to determine if a given type of food is safe for human consumption. This involves, (a) determining the level of potentially harmful substances “normally” found in the product, (b) determining if that level is below some threshold value that is deemed “safe,” and (c) making policy recommendations based on the available data.

2. **Regulatory science is often accomplished without reference to any of the usual apparatus used in scientific research.** Often it only entails an analysis of extant literature (often compiled for other reasons) by a group of experts. For example, the Codex Alimentarius operates this way in determining the safety guidelines for food products. No experiments are conducted. No measurements are taken. Instead, existing studies are pieced together as best as possible in an attempt to derive a “best answer” to questions perhaps not even asked in the studies that are reviewed.

3. **Most regulatory science is not peer reviewed.** This is the case for several reasons including (a) the immediacy of the results required of the participants, which would be difficult or impossible to achieve were peer review to be introduced, and (b) the new questions that would be introduced into the process were peer review to be used. For example, peer reviews often request that additional information be provided – information that might well be lacking without additional research.

4. **The data of regulatory science are often proprietary.** While conventional science relies, in principle, on public access to raw data, for many analyses regulatory science relies on reports of findings and on

\textsuperscript{7} Certain journals publish reviews of the literature to aid scientists in a given discipline. However, no one knowledgeable in the field would consider this to be original research.
confidential data and reports of findings that private companies are requested to submit.  

5. The legal framework is central to regulatory science and only marginally relevant to other scientific endeavors. Regulatory scientists usually work according to precise legal guidelines that specify how committees will function, what bodies will review what materials, how particular problems are to be defined, and what shall count as evidence.

6. Strong emphasis is placed on reaching closure. In conventional scientific settings, closure is neither emphasized nor even desired (Meyer, 1999). The call for more research at the end of scientific articles is legendary. But such ambivalence is undesirable to policy makers, who desire to use the authority of science to legitimate decisions and who are pressed to act with all deliberate speed.

7. Scientists are often required to give or evaluate evidence that is outside their area of expertise. In more conventional settings, scientists tend to stay close to their particular areas of expertise, while in regulatory settings, scientists may be forced to evaluate, for example, conflicting data from subfields of ecology and molecular biology. Although many if not most regulatory panels are selected with careful inclusion of scientists from a range of relevant disciplines, few scientists are familiar with the whole of their individual disciplines. For example, few phytopathologists are familiar with the behavior of the full range of fungal, viral, and bacterial diseases affecting plants.

8. Regulatory scientists must be responsive to various publics as they are not merely doing science, but also making policy. Scientists (and politicians) who err on the side of caution risk “crying wolf too often,” such that no one listens. Scientists who are incautious risk creating calamities that undermine their credibility as well – witness the debacle with BSE in the United Kingdom.

9. Regulatory science has, and is designed to have, impacts on economic, political and social actors. For example, the enactment and enforcement of the US food and drug laws in 1906 resulted in a restructuring of the processed food industry – a restructuring welcomed by larger processors and forcing out of business smaller ones that could not afford the new equipment needed to obey the law (Levenstein, 1988). Similarly, the US ban on milk cans and their replacement with on-farm tanks, ostensibly for safety reasons, forced many small dairy farmers out of business (Young, 1991). As Salter (1988, p. 68) notes with respect to the Codex: “The decisions made by Codex and its commit-

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8 The reviewer notes that in the Netherlands, company data relating to GMOs are rarely treated as confidential. This is not the case in the US.
tees... have a direct effect upon the profit levels of major corporations. The trade relations created by Codex standards are likely to benefit some countries, and some interest groups more than others."

Consider, for example, the networks aligned around unpasteurized cheeses in Europe. They include milk producers, thousands of small cheese makers, wholesalers, retailers, and most importantly, the consuming public. In contrast, on the other side of the Atlantic, such networks are weak or even non-existent. Instead, there are strong anti-networks consisting of large dairies and even larger cheese manufacturers strongly arguing for exclusion of unpasteurized cheeses so as to protect the public health. The differential EU and US positions on scrapie and GM foods can be similarly contextualized.

In sum, regulatory science is not only quite different from conventional science; it is also fundamentally intertwined at every step with political and economic interests that have a stake in its findings. It is for this reason that we find the US and the EU adopting apparently inconsistent and even contradictory positions with respect to the safety of food products. But when the cases above are examined by asking who wins and who loses, the positions become far more coherent. If one asks what is at stake for each side, then the positions become painfully obvious.

But this is not to suggest that it is all a matter of competing interests, and that there is no science involved (cf. Jukes, 2000). It is to argue that the mixing of scientific and political/economic issues serves to delegitimate science by making claims for science that cannot possibly be defended (Thompson and Dean, 1996). It is one thing to weigh the scientific evidence that has accumulated for the safety or lack of it for some food product, however limited, incomplete, inaccurate or biased that evidence might be. It is quite another to say that the evidence is inadequate to make a judgment. It is still something else to assert that the product in question is sufficiently (or insufficiently) safe. Ironically, the position of value neutrality taken by some regulatory scientists as well as the use of science to justify political decisions, undermines the legitimacy of that science by presuming that expert knowledge can be used to make what are essentially political, economic and cultural decisions.

The core of the problem lies in the differential valuation of risks. Even in cases where there is widespread agreement on the nature of the risk, there may be quite different valuations of the importance of that risk based on other economic and cultural values. Furthermore, these values, as articulated in governmental policies, may well stem from the different constellations of stakeholder groups that form around particular issues and the political clout of those stakeholders. They may well be summarized in
the form of homilies which, when applied outside a particular situation, appear absurd and even contradictory. Hence, the US and EU may apply opposite homilies to the same issue not because they are guilty of duplicity, but because different things are at stake, different groups are implicated, and different groups have political clout in different situations. And, in cases where the US and EU agree, such as those of green beans and biosafety, similar values, stakeholders, and political clout are likely to be found. Failure to recognize the limits to science and the necessary inclusion of values in risk decisions fails to serve the public and delegitimizes science.

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