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## **An Agricultural Law Research Article**

### **Setting an Anti-Cancer Policy: Risk, Politics, and the Food Quality Protection Act of 1996**

#### **Part 2**

by

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announced its pesticide residue de minimis policy, a group including environmentalists and the State of California filed a petition seeking cancellation of tolerances for four carcinogenic pesticides under the Delaney Clause.<sup>137</sup> The EPA denied the petition, in accordance with its new policy.<sup>138</sup> In subsequent litigation, a panel of the Ninth Circuit unanimously held that the pesticide de minimis policy was legally impermissible.

Like the court in *Young*, the Ninth Circuit in *Les v. Reilly* stressed the “clear and mandatory” nature of the Delaney Clause.<sup>139</sup> The court explained that once scientists determine that a food additive is a carcinogen, “the clause affords no flexibility.”<sup>140</sup> Furthermore, the *Les* panel found that the legislative history of the food additive Clause, with its emphasis on scientific uncertainty and public concern over cancer, “reflects that Congress intended the very rigidity that the language it chose commands.”<sup>141</sup> Finally, the court noted that the Clause had been strictly interpreted for thirty years, and that Congress had ratified this construction “by reenacting all three FDCA provisions which contain Delaney clauses without changing the Agency’s [strict] interpretation.”<sup>142</sup> The court aired the EPA’s argument that a de minimis exception was necessary “in order to bring about a more sensible application of the regulatory scheme,”<sup>143</sup> but declined on institutional grounds to revise the statutory scheme. “If there is to be a change, it is for Congress to direct.”<sup>144</sup> Four years later, Congress accepted the court’s invitation.

#### d. *The Impact of Les*

Central to any understanding of the FQPA is the impact of the *Les* decision. Strictly speaking, *Les* only applied to food additive regulations for four pesticides that were used on a handful of

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<sup>137</sup> See *Les v. Reilly*, 968 F.2d 985, 988 (9th Cir. 1992).

<sup>138</sup> See *id.*

<sup>139</sup> *Id.*

<sup>140</sup> *Id.* (citing PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 78 (1st ed. 1980)).

<sup>141</sup> *Les*, 968 F.2d at 989. The Court quoted remarks by Representative Delaney in a 1958 hearing, referring to an FDA decision to permit small amounts of a carcinogenic additive in food: “The precedent established by the Aramite decision has opened the door, even if only a little, to the use of carcinogens in our foods. That door should be slammed shut and locked. That is the purpose of my anti-carcinogen provision.” *Id.* (citation omitted).

<sup>142</sup> *Id.* at 990.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

foods.<sup>145</sup> But the Ninth Circuit's strict reading of the Delaney Clause implicated a much greater universe of pesticide residues; in 1994, the EPA estimated that *Les* potentially affected thirty-four pesticides, representing one hundred chemical/crop combinations.<sup>146</sup> The EPA was forced to consider this broader universe under a consent decree entered into as a result of litigation subsequent to *Les*. In the *California v. Browner*<sup>147</sup> settlement agreement, the EPA eventually agreed to a timetable under which it would "propose to revoke any section 409 food additive regulation, i.e. tolerances, which violates the Delaney [c]ause."<sup>148</sup>

Prodded into action by *Les* and the *California v. Browner* settlement, the EPA began the process of revoking tolerances for Delaney-violating pesticide residues.<sup>149</sup> Between 1993 and 1996, the agency acted in several waves: (i) revoking six food additive regulations for six pesticides, including those under litigation in *Les*;<sup>150</sup> (ii) revoking tolerances for thirteen food additive regulations for five pesticides;<sup>151</sup> and (iii) revoking six tolerances for four pesticides.<sup>152</sup> Even as it issued these proposed revocations, however, the EPA sounded almost apologetic: "The strict application of the Delaney clause requires us to take these revocation actions . . . . [U]ntil the law is changed, EPA must comply with it as it stands, including the Delaney clause."<sup>153</sup>

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<sup>145</sup> See *id.* at 987.

<sup>146</sup> See Updated List of Pesticides and Uses Potentially Affected by the Delaney Clause of the Federal Food, Drug and Cosmetic Act, 59 Fed. Reg. 14,980, 14,980 (1994).

<sup>147</sup> No. CIVS-89-0752 (E.D. Cal. filed Feb. 9, 1995).

<sup>148</sup> *Id.* at 3. In *Browner*, the state had alleged that the EPA "failed to take certain actions to prevent residues of pesticides that 'induce cancer' from being present in processed foods as food additives contrary to the Delaney Clause." *Id.* at 1.

<sup>149</sup> Because revocations were subject to administrative requirements, such as hearings, no pesticide uses were actually stopped. Less than two months after the passage of the FQPA, the EPA withdrew the revocation for seventeen of the tolerances. See Withdrawal of Pesticide Tolerance Revocations, 61 Fed. Reg. 50,684 (1996). These revocations had been stayed by court orders, thereby preventing the finalization of the revocation. See *id.*

<sup>150</sup> See Revocation of Food Additive Regulations for Benomyl, Mancozeb, Phosmet, and Trifluralin, 58 Fed. Reg. 37,862 (1993); Dichlorvos; Revocation of Food Additive Tolerance, 58 Fed. Reg. 59,663 (1993); Dicofol; Revocation of Food Additive Tolerance, 59 Fed. Reg. 10,993 (1994).

<sup>151</sup> See Revocation of Pesticide Food Additive Regulations, 61 Fed. Reg. 11,994, 11,999 (1996). The EPA revoked thirteen other tolerances in the same action, but these revocations resulted from new evidence suggesting that the residue did not concentrate in processed food. See *id.* at 11,996.

<sup>152</sup> See Revocation of Pesticide Food Additive Regulations, 61 Fed. Reg. 39,528 (1996). The EPA revoked two other tolerances because it determined that they were not needed. See *id.*

<sup>153</sup> EPA, PRESS RELEASE, IN DELANEY ACTION, EPA REVOKES TOLERANCES FOR FIVE PESTICIDES (Mar. 18, 1996).

Opponents of the Delaney Clause realized that these (and expected future) revocations would have a considerable economic impact upon the food and agriculture industries. Supporters of early versions of the FQPA embraced a study suggesting that implementation of *Les* would cost the industries and consumers over \$400 million.<sup>154</sup> Affected interests brought this message to Congress in hearings on the FQPA.<sup>155</sup> Ultimately, the House Commerce Committee noted that up to one-hundred crops might have been affected by the Delaney-mandated revocation of pesticide tolerances.<sup>156</sup> The Committee concluded, “[d]isruption in the production of these crops could have serious dietary and cost consequences for consumers and serious adverse impacts on the economies of the nation’s major agricultural States.”<sup>157</sup>

### 3. Conclusion

This discussion suggests that given policymakers’ views of the benefits offered by pesticides, the Delaney Clause was, at best, a historical anomaly, and at worst, a project destined for failure. As its early history indicated, the Clause was viewed as a superfluity. On those occasions when the Delaney Clause exerted a regulatory impact upon economically important food additives, policymakers began to search for ways to escape the flat ban. In 1977, policymakers were willing to reject Delaney’s flat ban to enable the public to receive an apparent benefit from saccharin. In 1996, Congress made the same move for pesticides, replacing Delaney with a negligible-risk standard. In short, the history of the Delaney Clause indicates that decisions over acceptable levels of risk are intimately tied, to no great surprise, to the benefit at stake.

#### B. The Rise of Scientific Ability & Risk Assessment

Although these policy concerns drove reconsideration of the Delaney Clause over the last decade, Congress did not enact the FQPA simply because the Delaney Clause had begun to impact pesticide tolerances. This political story must be supplemented by

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<sup>154</sup> The study was discussed in a congressional hearing over a precursor to the FQPA. *See 1995 FQPA Hearings, supra* note 10, at 37-41, 47-48.

<sup>155</sup> Seeking to localize the impact of the Ninth Circuit decision, for instance, the American Farm Bureau provided representatives with a state-by-state and crop-by-crop breakdown of the impact of a strict interpretation of Delaney. *See id.* at 63-66.

<sup>156</sup> *See* H.R. REP. NO. 104-669, pt. 2, at 32 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1271.

<sup>157</sup> *Id.*

a scientific one, because Delaney's narrowing reflects important changes in policymakers' understanding both of cancer and of broader scientific issues.

The drafters of the FQPA explicitly described their purpose as the scientific modernization of pesticide regulation. The House Commerce Committee declared its intent to "modernize the regulation of pesticides" and to "replace[] the outdated Delaney Clause."<sup>158</sup> President Clinton echoed this sentiment when signing the bill into law.<sup>159</sup> The modernization arguments, in part, reflected a kind of "original intent" theory of risk regulation: if members of Congress in 1958 could have foreseen the scientific advances that expanded the scope of the Delaney Clause less than thirty years later, Congress never would have enacted such a sweeping ban.<sup>160</sup>

The modernization argument thus reflected a new confidence in scientific ability, a greater acceptance of scientific uncertainty, and new ways of thinking about how regulators assess and manage risks to public health. The FQPA reflects an increased willingness by Congress to grant administrative agencies discretion in managing public-health risk. To give greater meaning to these assertions, it is necessary to examine the background to the passage of the Delaney Clause in 1958.

## 1. *The Delaney Approach*

### a. *The Significance of Uncertainty*

The Delaney Clause is an unsurprising reflection of its time. For the purposes of this note, several features of 1958 thought concerning science and carcinogenesis stand out. The first is scien-

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<sup>158</sup> *Id.* at 29 (emphasis in original).

<sup>159</sup> The President told his radio audience, "The old safeguards that protected our foods from pesticides were written with the best intentions, but they're simply no longer up to the job. Bad pesticides have stayed on the market too long, good alternatives have been kept out. There are strong protections against cancer but not against other health dangers." President's Radio Address, *supra* note 1, at 1. See also Goldman, *supra* note 77 ("The new law replaces outdated provisions with modern, health-based regulatory tools.").

<sup>160</sup> See, e.g., Food and Drug Administration, Listing of D&C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28,331, 28,343 (1986) ("There is no indication that in 1958 Congress foresaw the likelihood that, within less than 30 years after the Delaney Clause was enacted, science would have progressed so far as to be able to document the widespread presence of trace amounts of proven carcinogens in food."); Merrill, *Repudiation*, *supra* note 15, at 15 ("Proponents of the Delaney Clause did not expect that significant numbers of food ingredients would prove to be carcinogenic.").

tific uncertainty surrounding carcinogens, grounded in scientists' inability to determine conclusively whether exposure to a chemical was safe. In 1949, Arnold Lehman, the head of the FDA's Division of Pharmacology, wrote, "[w]hile it is not especially difficult to evaluate a set of pharmacological data which lead to the conclusion that the substance being investigated is a poison, it is extremely difficult to conclude that any chemical is safe for human consumption."<sup>161</sup>

This concern for scientific uncertainty was reflected in a 1952 congressional report<sup>162</sup> that sparked the passage of legislation codified as sections 408 and 409 of the FFDCFA.<sup>163</sup> While acknowledging the "genuine need for the use of many chemicals in connection with our food supply,"<sup>164</sup> the drafters expressed repeated concern about the uncertain safety of many food additives. The report found that of the 704 chemicals used in foods at the time, only 428 were known to be safe.<sup>165</sup>

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<sup>161</sup> Arnold J. Lehman et al., *Procedures for the Appraisal of the Toxicity of Chemicals in Foods*, 4 FOOD DRUG COSM. L.Q. 412, 432 (1949).

<sup>162</sup> SELECT COMM. TO INVESTIGATE THE USE OF CHEMICALS IN FOODS AND COSMETICS, INVESTIGATION OF THE USE OF CHEMICALS IN FOODS AND COSMETICS, H.R. REP. NO. 82-2356, (1952), *reprinted in* 12 LEGISLATIVE HISTORY OF THE FOOD, DRUG & COSMETIC ACT 499-537 (1979) [hereinafter DELANEY REPORT].

<sup>163</sup> The legislation included the 1954 Miller Pesticide Amendments and the 1958 Food Additive Amendments. See PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 321 (2d ed. 1991); Dunkelberger & Merrill, *supra* note 29, at 421. The former legislation was codified as section 408 of the FFDCFA, the latter as section 409. The Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, headed by New York Representative James J. Delaney, examined the presence of synthetic food additives, such as preservatives, animal hormones, and pesticides. The Committee concluded that then-existing legislation, which placed the burden of proving unsafety on the FDA, was inadequate to protect public health. See DELANEY REPORT, *supra* note 162, at 518. See also Roger D. Middlekauff, *The 1950s: The Delaney Clause is Enacted*, 45 FOOD DRUG COSM. L.J. 31, 39-40 (1990). At the time of the Delaney Report, it was believed that 100 pesticide chemicals were in use, with more than 30,000 products being registered for use. See DELANEY REPORT, *supra* note 162, at 510. Today, that number is over 330 pesticide chemicals. See *infra* text accompanying note 209.

<sup>164</sup> DELANEY REPORT, *supra* note 162, at 501. The FDA was more dramatic in its assessment: "[U]nless the necessary insecticides and fungicides for food crops are used, the insect army will take over our food supply." Middlekauff, *supra* note 163, at 39, (citing U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, FOOD AND DRUG ADMINISTRATION, 1959 ANNUAL REPORT 8 (1959)).

<sup>165</sup> See DELANEY REPORT, *supra* note 162, at 502. "Thus, there are approximately 276 chemicals being used in food today, the safety of which has not been established to the satisfaction of many groups concerned with the health and safety of the public." *Id.* (citation omitted).

Reflecting a growing public unease about cancer,<sup>166</sup> the report expressed a particular concern about uncertainty regarding carcinogenic chemicals:

One problem which is causing scientists increasing concern is the possible effect of various synthetic substances in the production or acceleration of cancerous growths. The testimony proffered was not that certain chemicals presently in use as additives and insecticides do cause cancer, but rather that there is a definite lack of knowledge on the subject. The head of the Nutrition Unit in the Biochemistry Section of the National Cancer Institute set forth the situation in the following language:

In summary, I have pointed out: (1) That a large number of chemical compounds induce cancer in animals. (2) That there is no way of predicting their cancer-inducing properties without a biological test. (3) That the careful testing of chemicals for cancer-producing properties in animals is exceedingly difficult to evaluate. (Citations omitted.)<sup>167</sup>

Scientific uncertainty continued to be a driving force in the Delaney context well beyond the 1950s. In the midst of the debate over saccharin in 1977, Acting FDA Commissioner Sherwin Gardner discussed the possibility that the Delaney Clause might be repealed. Expressing concern over this possibility, he remarked that repeal “would pose a basic dilemma for FDA because present scientific knowledge does not permit us to conclude with any confidence that any given level of exposure to a carcinogenic additive will be safe, in the sense of posing no risk to human health.”<sup>168</sup>

Closely linked to the importance of scientific uncertainty at the time of Delaney’s passage was the era’s conception of chemical carcinogenesis. When Congress enacted the Delaney Clause in 1958, the non-threshold model of carcinogenesis—positing that no level of exposure to a carcinogen is risk-free—dominated scientific thought.<sup>169</sup> In hearings considering the application of the Delaney

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<sup>166</sup> See, e.g., HUTT & MERRILL, *supra* note 163, at 868 (“[a]s the number of people dying from cancer increased in the 1930s and 1940s, public concern about the disease grew. Inevitably, this concern stimulated congressional consideration of measures to reduce potential cancer risks”).

<sup>167</sup> DELANEY REPORT, *supra* note 162, at 503.

<sup>168</sup> *Proposed Saccharin Moratorium Ban—Oversight, Hearings Before the Subcomm. on Health and the Env’t of the House Comm. on Interstate and Foreign Commerce, 95th Cong. 42-43 (1977).*

<sup>169</sup> See, e.g., WILSON, *supra* note 86, at 2 (“[I]ate in that decade [the 1950s], regulatory

Clause to color additives in 1960, HEW Secretary Arthur Fleming testified that “no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance. Unless and until cancer research makes a breakthrough at this point, the principle in the [Delaney] anticancer clause is sound.”<sup>170</sup> Under this state of knowledge, the Delaney Clause seemed to its supporters a prudent approach.<sup>171</sup> Since there was no way to determine whether there was a safe exposure level to a carcinogen, the best option was to ban the presence of the substance in food.

Another driving force behind Delaney was the notion that when considering public-health risks, “cancer is different.”<sup>172</sup> This apparently was the view of both Representative James Delaney,<sup>173</sup> sponsor of the Clause that bears his name, and the post-War FDA prior to the enactment of the Delaney Clause. For instance, the FDA used 100-fold safety factors (similar to those suggested in the legislative history of the FQPA) to set exposure levels for non-carcinogenic chemicals. No such safety factors were used for car-

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scientists proclaimed that for carcinogens, ‘no safe dose exists’”) (citations omitted).

<sup>170</sup> *Color Additives, Hearings Before the House Comm. on Interstate and Foreign Commerce*, 86th Cong. 62 (1960), reprinted in 16 LEGISLATIVE HISTORY OF THE FOOD, DRUG & COSMETIC ACT 67 (1979). A study prepared by the National Cancer Institute for the HEW concluded, “[n]o one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop.” *Id.* at 49.

<sup>171</sup> See, e.g., WILSON, *supra* note 86, at 3 (“At the time the ‘no threshold’ policy was established, scientific theory could provide little guidance to policy makers.”).

<sup>172</sup> That “cancer is different” is illustrated by the difference in treatment between carcinogens and noncarcinogens under the 1958 Act. A widely-quoted Senate report passage (which provides a historical antecedent to the FQPA’s notion of safety) defined safety in negligible-risk terms for noncarcinogens:

Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance . . . . [T]he safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.

FOOD ADDITIVES AMENDMENT ACT OF 1958, H.R. REP. NO. 85-2284, at 4 (1958), reprinted in 14 LEGISLATIVE HISTORY OF THE FOOD, DRUG & COSMETIC ACT 825-26 (1979). Since the Delaney Clause is a zero-tolerance proviso to the FFDCA’s requirement of safety, it has been interpreted to be impliedly separate from this de minimis approach.

<sup>173</sup> In a 1958 hearing, referring to an FDA decision to permit small amounts of a carcinogenic pesticide in raw food, Delaney stated: “The precedent established by the Aramite decision has opened the door, even if only a little, to the use of carcinogens in our foods. That door should be slammed shut and locked. That is the purpose of my anticarcinogen provision.” *Food Additives: Hearings Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 85th Cong. 498 (1958), reprinted in 14 LEGISLATIVE HISTORY OF THE FOOD, DRUG & COSMETIC ACT 660 (1979). See also *Les v. Reilly*, 968 F.2d 985, 989 (9th Cir. 1992).



cinogens, however: “The agency’s goal was to prevent the use of carcinogens in human foods or drugs.”<sup>174</sup> The legislative history of the 1958 legislation indicates that the relevant House Committee sought to enact a more flexible standard for the regulation of non-carcinogens than the flat ban of the Delaney Clause: “[Safety] does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance . . . . Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.”<sup>175</sup>

*b. Risk Analysis: Assessment and Management*

The Delaney Clause, like the negligible-risk standard of the FQPA, represents a Congressional attempt to regulate carcinogens in the face of scientific uncertainty. Accordingly, the Clause can be seen as a legislative determination of the acceptable level of carcinogenic risk in the food supply. Legislators in 1958 determined that a zero-risk approach—the flat ban of the Delaney Clause—was most appropriate for certain substances. This response to a public-health risk differs markedly from the negligible-risk standard enacted in 1996, and indicates several changes in the policymakers’ approach to risk.

Before diving into the particulars of the 1958 and 1996 legislation, it is necessary to provide general background on policymakers’ and scientists’ responses to public-health risks. Risk analysis issues are commonly divided into i) risk assessment and ii) risk-management concerns.<sup>176</sup> Risk-assessment concerns include those issues surrounding modern quantitative risk-assessment tech-

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<sup>174</sup> HUTT & MERRILL, *see supra* note 163, at 866. *See also* Lehman et. al., *supra* note 161, at 432 (“[T]here are some compounds which produce effects so alarming in animals that one has no hesitation in excluding such compounds from further consideration. For example, if a chemical has been shown to possess carcinogenic properties, there would be no question in applying animal data to man.”).

<sup>175</sup> FOOD ADDITIVES AMENDMENT OF 1958, S. REP. NO. 85-2422, at 6 (1958), *reprinted in* 14 LEGISLATIVE HISTORY OF THE FOOD, DRUG & COSMETIC ACT 918 (1979).

<sup>176</sup> For discussions of risk assessment and risk management, *see generally* ASSESSMENT AND MANAGEMENT OF CHEMICAL RISKS (Joseph V. Rodricks & Robert G. Tardiff eds., 1984); WORST THINGS FIRST? THE DEBATE OVER RISK-BASED NATIONAL ENVIRONMENTAL PRIORITIES (Adam M. Finkel & Dominic Golding eds., 1994). For debate concerning the appropriateness of risk assessment and management, *see generally* Donald T. Hornstein, *Reclaiming Environmental Law: A Normative Critique of Comparative Risk Assessment*, 92 COLUM. L. REV. 562 (1992); William D. Ruckelshaus, *Risk in a Risk Free Society*, 14 ENVTL. L. REP. (Envtl. L. Inst.) 10,190 (1984); David Doniger, *The Gospel of Risk Management: Should We be Converted?*, 14 ENVTL. L. REP. (Envtl. L. Inst.) 10,222 (1984).

niques: through what methodologies do scientists discover the health risks and public benefits of pesticide exposure and use?<sup>177</sup> Risk-assessment issues are mostly scientific ones, although, as will be discussed, the policymaker's role is significant in the quantitative risk-analysis field. In the field of pesticide regulation, risk-assessment issues include the plotting of dose response curves, establishing a "no observable effect level," or examining threshold and non-threshold effects. Since risk assessment relies upon scientific methodologies, advances in analytical chemistry, for instance, will most directly affect the risk-assessment component of risk analysis.

Risk management represents a second-order decision. Once scientists have identified a risk through the risk-assessment process, the risk-management decision is whether the identified risk—from a carcinogenic pesticide residue, for instance—is acceptable on policy grounds. Risk management thus encompasses the heart of the debate between a Delaney zero-tolerance stance versus the FQPA de minimis-risk approach. In the case of the Delaney Clause and the FQPA, the risk-management debate distills down to whether a zero-risk or negligible-risk standard is a more appropriate response to regulating carcinogens in food.<sup>178</sup> Under the negligible-risk approach, scientists (risk assessors) seek to determine what level, if any, of the pesticide residue is safe for human consumption. Regulators implementing a risk-management policy would then prohibit growers or food processors from distributing food containing pesticide residues exceeding this permitted level. The Delaney approach acknowledges uncertainty in the science of risk assessment, and bans the presence of the pesticide in the food supply. Scientists need only determine that the pesticide is a carcinogen. Regulators then ensure that no carcinogenic pesticides are used on food crops.

*c. Delaney's Reflection of Risk Management and Assessment*

Understood in these terms, there are two threads to the Delaney approach. The first is the risk-management decision based upon the scientific uncertainty described above. Any distrust of scientific ability is manifested as a risk-management decision. The sec-

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<sup>177</sup> See Bauer, *supra* note 15, at 1391-99 (describing the EPA's risk-analysis process for pesticides).

<sup>178</sup> See generally RODRICKS, *supra* note 8, at xxiii-xxiv (discussing the rationale of zero- and negligible-risk standards).

ond, and related, thread is the limited role for risk assessment under the Delaney scheme.

In 1958, Congress was willing to accept uncertainty for non-carcinogenic public-health risks, although it was unwilling to make the same leap for some carcinogenic risks. Without exception, all additives falling under the purview of the Clause were deemed unsafe. At its heart, therefore, the Delaney Clause is a policy expression about the limits of science. Scientific risk assessment plays a key role under the Delaney approach, because it determines whether a chemical is carcinogenic. The role for scientists, however, is narrow. Once risk-assessment techniques suggest that a chemical is a carcinogen, the chemical is barred under the strict interpretation of the Delaney Clause in *Young and Les*. In other words, once agency scientists conclude that a chemical induces cancer, agency regulators are governed by the flat ban of the Delaney Clause. Accordingly, any discretion under the Delaney Clause comes in the administrative agency's assessment of the risks involved.

The Clause embodies the belief that any attempt to manage carcinogenic risks will fail to provide sufficient public health protection; the relationship between carcinogenesis and the environment is just too complex for policymakers to regulate. Under Delaney, Congress has already made the risk-management decision. Thus, the risk-management decision (zero tolerance) is distinct from the risk-assessment issues; an increased quantum of information about a chemical's risk potential is treated separately from the risk-management decision of how to treat that information.

Sound reasons exist for maintaining a Delaney-type approach to carcinogenic risks because many sources of uncertainty remain in modern risk analysis. For instance, the ability of scientists to identify a threshold level or to determine the actual risk posed by a carcinogen at low doses is problematic;<sup>179</sup> similarly, the competency of regulators to ensure that exposure levels remain beneath that threshold is questionable. Alternatively, one might be suspicious of risk assessment because of the number of policy choices involved in the scientific decision-making. A National Academy of Sciences panel in 1983 found roughly 50 points in the risk assessment process requiring a choice "among several scientifically

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<sup>179</sup> See, e.g., Catherine A. Picut & George A. Parker, *Use of Biological Thresholds to Reinterpret the Delaney Clause: A Proposal for Minimizing Cancer Risk*, 47 FOOD & DRUG L.J. 107, 124 (1992) ("[T]here is scientific uncertainty associated with proving a carcinogen's mechanism of action or biological threshold.").

plausible options.”<sup>180</sup> The Natural Resources Defense Council (NRDC), an environmental organization at the center of the Delaney debate, catalogued sources of this modern uncertainty in risk assessment:

Uncertainties derive from a broad array of problems, including gaps or uncertainties in toxicological data, our failure to understand the differences between the effects of a chemical on laboratory animals versus humans, problems in determining what subpopulations such as children are at special risk, difficulties in translating from high dose to low dose exposures, the lack of hard data on actual exposure to the chemical from multiple sources, and many other problems.<sup>181</sup>

Under this acknowledgment of scientific uncertainty, a Delaney-type standard would be perfectly sensible. Despite advances in our understanding of chemistry, toxicology, and the mechanisms of carcinogenesis, much uncertainty remains in this field.

## 2. *The FQPA's Approach*

The FQPA's regulatory scheme reflects a different response to risk in the food supply. The new legislation manifests an increased comfort with scientific uncertainty, and gives the EPA greater flexibility in making risk-management determinations. At the same time, the FQPA increases policymakers' reliance upon risk-assessment techniques.

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<sup>180</sup> COMMITTEE ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUBLIC HEALTH, NATIONAL RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 28-33 (1983).

<sup>181</sup> NATURAL RESOURCES DEFENSE COUNCIL, WHITE PAPER: THE NEED FOR A PHASE-OUT OF CARCINOGENIC PESTICIDE RESIDUES, *reprinted in 1995 FQPA Hearings*, *supra* note 10, at 86-87 [hereinafter WHITE PAPER]. Similar sentiments were voiced widely among other environmental organizations. *See, e.g., 1995 FQPA Hearings*, *supra* note 10, at 95-96 (statement of Jay Feldman, National Coalition Against the Misuse of Pesticides). These uncertainties remain even if a carcinogen is assessed under the threshold model. The no observable effect level (NOEL), *see supra* note 60, associated with a threshold effect does not provide assurance that a particular dose is risk-free, rather, it only means that scientists have not yet identified effects at lower doses. *See RODRICKS*, *supra* note 8, at 167. Factors contributing to uncertainty under this model are animal tests with a limited number of subjects, an inability to perform toxicity tests in all species, and the question of whether a tested species exhibits sensitivity to the effects of a toxicant. *See id.* (“[T]he problem of proving that a threshold dose exists is something like the problem of proving a negative proposition.”). For further discussions of potential problems with the FQPA's standard, *see Bauer*, *supra* note 15, at 1399-1408.

a. *An Increased Reliance Upon Risk Assessment*

The FQPA rejects the uncertainty-driven view that regulators should strictly prohibit the presence of carcinogens in the food supply. By replacing the Delaney Clause with a negligible risk standard, the FQPA embodies a faith that scientists and regulators can both quantify and manage carcinogenic risks. One might think of the FQPA as beginning with the proposition that “[e]very day we take risks and avoid others.”<sup>182</sup> The FQPA’s acceptance of risk is, ultimately, an acceptance of scientific uncertainty.<sup>183</sup> This is a very different approach to carcinogen regulation than that embodied in the 1958 Act.

Coupled with the FQPA’s increased comfort with scientific uncertainty is a greater role for risk-assessment techniques. The standard that there be a reasonable certainty of no harm from a chemical<sup>184</sup> implicitly relies upon risk assessment. This is manifested in the legislative history of the FQPA, which explicitly recognizes disparate regulatory treatments of threshold and non-threshold chemicals.<sup>185</sup> This approach is a very different conclusion than that taken by a congressional subcommittee two decades earlier: “Efforts to precisely measure risk posed by individual cancer-causing agents currently involve so many obstacles that they are an essentially useless exercise . . . .”<sup>186</sup>

When viewed in light of the sources of remaining uncertainty, it should thus be apparent that the 104th Congress manifested a comfort level with scientific uncertainty that was not present in 1958, at least with regard to carcinogenic pesticides. There is a significant conceptual gap between a legislature explicitly expressing concern about uncertainty, and a legislature implicitly accepting the notion that “every day we take risks and avoid others.” Congress has committed itself to a view that pesticides offer bene-

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<sup>182</sup> Richard Wilson & E.A.C. Crouch, *Risk Assessment and Comparisons: An Introduction*, 236 *SCIENCE* 267, 267 (1987). The 16th century “enigmatic alchemist” Paracelsus is reputed to have articulated the premise underlying modern risk assessment: “Poison is in everything, and nothing is without poison. The dosage makes it either a poison or a remedy.” HUTT & MERRILL, *supra* note 163, at 864.

<sup>183</sup> See, e.g., Wilson & Crouch, *supra* note 182, at 267 (“The concept of risk and the notion of uncertainty are closely related.”).

<sup>184</sup> See FQPA § 405(b)(2)(A)(ii), FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii) (Supp. II 1996).

<sup>185</sup> See H.R. REP. NO. 104-669, pt. 2, at 40-41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1279-80.

<sup>186</sup> SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 94TH CONG., REPORT ON FEDERAL REGULATION AND REGULATORY REFORM 511 (Comm. Print 1976).

fits to society. When this premise is coupled with an understanding that carcinogenic risks are easily discovered, and may well be unavoidable,<sup>187</sup> a legislative outcome accepting some de minimis level of carcinogenic risk is understandable, and even likely.

*b. Changing Roles in Risk Management and Assessment*

By lessening the strictness of the risk-management decision governing carcinogenic pesticides, the FQPA represents a congressional willingness to allow greater room for modern risk analysis, particularly the assessment aspect of that analysis. But what Congress has given the EPA with one hand, it has taken away with the other. Although Congress has granted the EPA discretion to decide what constitutes reasonable certainty of no harm, Congress has reduced the EPA's discretion to assess that risk in the first place.

The lawmakers negotiating the language of the FQPA in 1996 consciously rejected a proposal to define a "safe" level of exposure in numerical terms.<sup>188</sup> By defining safety as a "reasonable certainty of no harm,"<sup>189</sup> Congress has given the EPA responsibility for defining what is meant by safe. Although the House Commerce Committee report suggests that the EPA define an acceptable carcinogenic risk as one in a million, it notes that the EPA has flexibility to adopt a new interpretation of "reasonable certainty of no harm."<sup>190</sup> Accordingly, risk-management decisions are left largely in the hands of regulators.

What the EPA gains in discretion over risk-management issues, however, the FQPA takes away in risk assessment. As discussed in Part II of this Note, Congress directed the FDA to consider a number of factors when performing risk assessments for pesticide residues. Significantly, this included consideration of infants and children when setting tolerances. In requiring the EPA to look at the special vulnerabilities and exposures of infants and children to pesticides, Congress stepped directly into the process of evaluating the risks pesticide residues pose to humans. Under the Delaney approach, this evaluation was left in the hands of the EPA.<sup>191</sup> An-

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<sup>187</sup> See *infra* section III.B.2.c.

<sup>188</sup> See *infra* note 251 and accompanying text.

<sup>189</sup> See FQPA § 405(b)(2)(A)(ii), FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii) (Supp. II 1996).

<sup>190</sup> H.R. REP. NO. 104-669, pt. 2, at 41 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1268, 1280.

<sup>191</sup> The new legislation also establishes some limits on the EPA's control over risk management discretion by confining lifetime and annual risks from those tolerances estab-

other example of legislative intrusion into risk assessment is a congressional requirement that the EPA set tolerances using data from the actual residue levels on food crops, instead of the EPA's prior practice of assuming that farmers apply the maximum permitted amount of pesticide.<sup>192</sup> This final illustration represents a fairly high degree of micro-managing of the risk-assessment process; deciding what level of pesticide exposure to consider might typically be thought of as the kind of decision made by an expert agency.

If the Delaney Clause represents distrust of scientists' ability to safely manage risk in the food supply, the FQPA represents distrust of agency procedure in assessing the risk. Under this conceptualization, the FQPA represents not only a shift of the zero risk-de minimis debate (i.e., a changing notion of the acceptability of a certain level of risk), but also a statement about the appropriate means of ensuring the safety of pesticide-bearing foods. This view thus requires refinement of the earlier observation that the FQPA represents a Congress more confident in the ability of scientists and regulators. In the FQPA, Congress expresses confidence in the risk-management aspect of food safety, but also expresses an increased level of distrust in administrators' control over risk assessment. As such, the FQPA suggests a growing confidence among lawmakers in their public health and food safety expertise.

To the extent that the FQPA represents a degree of role reversal, this switch is unsurprising. The Delaney Clause came to be viewed in some quarters as an illustration of the perils of over-specificity in lawmaking.<sup>193</sup> The "modernization" arguments for Delaney reflected this in suggesting that Delaney had locked regulators into a 1958 scientific world by dictating a risk-management policy that Delaney "reformers" believed was no longer appropriate.<sup>194</sup> In establishing its "reasonable certainty of no harm" standard,<sup>195</sup> the FQPA establishes sufficient agency flexibility to prevent a recurrence of such criticism. By adding

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lished with an eye toward benefits.

<sup>192</sup> See FQPA § 405(b)(2)(E)(i), FFDCFA § 408(b)(2)(E)(i), 21 U.S.C. § 346a(b)(2)(E)(i).

<sup>193</sup> See MASHAW ET AL., *supra* note 93, at 122-23 (using the Delaney Clause as an example of statutory precision and its consequences).

<sup>194</sup> See, e.g., Sunstein, *supra* note 103, at 497 ("The factual background against which the Delaney Clause was written was so different from the present circumstances that the statutory terms 'induce cancer' must be treated as ambiguous.").

<sup>195</sup> See FQPA § 405(b)(2)(A)(ii), FFDCFA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii).

specificity to the risk-assessment determination, however, Congress has maintained a key role in the regulation of pesticides without ceding vast amounts of discretion to the implementing agency. The policy decisions surrounding the risk-assessment process<sup>196</sup> potentially give the EPA a great deal of discretion over the regulation of carcinogenic risks.<sup>197</sup> In the FQPA, Congress responded to scientific uncertainty by providing some guidance as to the acceptability of risk (reasonable certainty of no harm), and by seizing greater control over the assessment of that risk.

*c. An Increased Scientific Confidence*

Accounting in part for increased congressional confidence are scientific advances in a number of fields, which shall be discussed below. Understood in these terms, the Delaney modernization argument suggests that, because our basic understanding of chemistry and carcinogenesis has improved dramatically since 1958, a flat ban on carcinogens is inappropriate. In other words, scientific advancements have reduced the amount of uncertainty regulators perceived in 1958. When unpacked, this version of the modernization argument appears to reflect three broad changes in the relationship between science and regulatory policy between the mid-1950s and 1990s: (i) improvements in analytical chemistry; (ii) improvements in scientists' understandings of cancer and carcinogenesis; and (iii) a growing awareness of the multiple sources of risk from the food supply.

*i. Improved Analytical Abilities*

Dramatic improvements in analytical chemistry further drove reconsideration of the Delaney Clause. As chemists refined their ability to discover increasingly minute quantities of substances, they were able to determine in food the presence of chemicals previously undetected. In the 1950s, chemists were generally unable to measure pesticide residues at less than 0.05 parts per million.<sup>198</sup> By the 1990s however, some laboratories were able to detect chemicals in the parts per quintillion ( $1 \times 10^{-18}$ ).<sup>199</sup> This scientific

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<sup>196</sup> See *supra* text accompanying notes 176-77.

<sup>197</sup> See, e.g., Alon Rosenthal et al., *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 *ECOL. L.Q.* 269, 276 (1992) ("In the face of profound scientific uncertainty about cancer risk, agency risk assessors can make numerous quasi-policy judgments in deciding how chemical risks are calculated.").

<sup>198</sup> See Merrill, *Repudiation*, *supra* note 15, at 13-14. This article presents a discussion of improvements in analytical chemistry and toxicology in greater detail than provided here.

<sup>199</sup> See Christine Gorman, *Getting Practical About Pesticides*, *TIME*, Feb. 15, 1993, at 52.



advancement was not lost on those seeking to roll back the Delaney Clause. In his opening statement during hearings over the FQPA in 1995, Representative Michael Bilirakis, Chairman of the House Subcommittee on Health and Environment stressed:

Since the passage of the Delaney clause, science has developed sophisticated methods to detect smaller and smaller residues. For example, today we routinely measure in parts per trillion, so we can find some of these carcinogens in foods even though they are present in such minuscule levels that they pose no hazard whatsoever.<sup>200</sup>

ii. *Increased Number of Carcinogenic Chemicals*

In addition to their ability to detect ever-smaller sizes of chemical particles, scientists developed an increased awareness that more chemicals could be properly classified as carcinogenic than they had previously realized.<sup>201</sup> The 1952 Delaney Committee counted (noncarcinogenic) suspect chemicals in foods only in the hundreds, concluding that of the 704 chemicals used in foods at the time, 276 had not been shown to be safe.<sup>202</sup> There were only four known human carcinogens in 1958.<sup>203</sup> Even in the late-1970s, FDA officials stated that carcinogens were rare.<sup>204</sup>

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<sup>200</sup> 1995 FQPA Hearings, *supra* note 10, at 1 (statement of Rep. Michael Bilirakis). Chairman Bilirakis' point was widely echoed by supporters of the 1995 legislation. *See, e.g., id.* at 2, 4-5 (statements of Reps. Waxman, Towns and Ganske). A high-ranking EPA official made a similar point. *See id.* at 8-10 (statement of Lynn R. Goldman, Assistant Administrator, Office of Pesticides and Toxic Substances). During the same hearing that Representative Bilirakis spoke, EPA officials were reminded of similar comments made by EPA head Carol Browner in 1993 to *Time* magazine ("There are scientific anachronisms that get created any time you have a 30-plus-year-old environmental regulation. It is time to revisit Delaney with the knowledge we have now."). *Id.* at 28. *See also*, Gorman, *supra* note 199.

<sup>201</sup> *See, e.g.,* WILSON, *supra* note 86, at 33 ("[In 1958], there existed a widespread sentiment that carcinogens 'just should not be part of the food supply.' This sentiment presupposed that carcinogens were rare; now we know that they are common.").

<sup>202</sup> *See* DELANEY REPORT, *supra* note 162, at 502.

<sup>203</sup> *See* Food and Drug Administration, Listing of D&C Orange No. 17 for Use in Externally Applied Drugs and Cosmetics, 51 Fed. Reg. 28,331, 28,343 (1986). A 1957 study by the National Cancer Institute suspected only a dozen food or color additives and three classes of chemical contaminants as being carcinogenic. *See* Merrill, *Repudiation*, *supra* note 15, at 15-16.

<sup>204</sup> *See*, for example, the statements of FDA Commissioner Donald Kennedy, who wrote that "[t]he potential for causing cancer is not widespread among chemicals, and not an effect readily revealed upon heroic exposure. Instead it is a rare property . . ." *What Animal Research Says About Cancer*, HUMAN NATURE, May 1978, *quoted in* MASHAW, ET AL., *supra* note 93, at 126.

It is correct that carcinogens are rare among the universe of chemicals. By the end of 1990, scientists had identified more than ten million chemical compounds.<sup>205</sup> Relative to the universe of potential carcinogens in the 1950s, however, there has been a dramatic increase in the number of suspected carcinogens.<sup>206</sup> For example, twenty years after passage of the Delaney Clause, scientists suspected that about 1,000 chemicals were potentially carcinogenic.<sup>207</sup> This estimation may represent the tip of the iceberg, since few food additives are tested for carcinogenicity.<sup>208</sup> A recent NAS committee found that, of a sample of roughly 330 known or suspected carcinogens identified by the International Agency for Research on Cancer and the National Toxicology Program, almost 160 may be encountered in U.S. diets.<sup>209</sup>

If the universe of animal carcinogens has increased in the past forty years, this is especially true of pesticides. In 1987, an NAS panel studying the Delaney Clause noted that nearly twenty percent (53 out of 289) of the pesticides then used on foods had been identified as oncogens by the EPA.<sup>210</sup> The EPA reported a year later that it was aware of "limited evidence" of carcinogenicity . . . for 66 or more of the approximately 350 food-use pesticides al-

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<sup>205</sup> See PERCIVAL ET AL., ENVIRONMENTAL REGULATION, LAW, SCIENCE, AND POLICY 461 (2d ed. 1996).

<sup>206</sup> Some researchers contend that the methodology for testing potential carcinogens may be responsible for the increase in the number of suspected carcinogens. See Bruce N. Ames and Lois Swirsky Gold, *Too Many Rodent Carcinogens: Mitogenesis Increases Mutagenesis*, 249 SCIENCE 970, 970 (1990). Chemicals are commonly tested by exposing rodents at near-toxic levels, called the maximum tolerated dose (MTD), over an extended period of time. See RODERICKS, *supra* note 8, at 140-41. Risks of carcinogenesis in rodents from these high-dose experiments are then extrapolated to develop risk estimates in humans exposed at low levels. See *id.* Bruce Ames and Lois Swirsky Gold have suggested that the MTD approach is equivalent to "chronic wounding," whereby the chronic exposure to high doses of toxic chemicals stimulates cell division (mitogenesis). An increased rate of cell division is associated with an increased opportunity for genetic mutation, and thus cancer-formation. See Ames & Gold, *supra*, at 970; see also Jean Marx, *Animal Carcinogen Testing Challenged*, 250 SCIENCE 743, 744 (1990).

<sup>207</sup> See Merrill, *Repudiation*, *supra* note 15, at 17

<sup>208</sup> A 1984 National Academy of Sciences Committee found that there was "no toxicity information available" for 46 percent of the 8,627 chemicals regulated or classified by the FDA. See *id.* at 16-17.

<sup>209</sup> See COMMITTEE ON COMPARATIVE TOXICITY OF NATURALLY OCCURRING CARCINOGENS, NATIONAL RESEARCH COUNCIL, CARCINOGENS AND ANTICARCINOGENS IN THE HUMAN DIET, app. B at 381 (1996) [hereinafter NATURALLY OCCURRING CARCINOGENS]. This number was computed by the author by counting the chemicals listed in the appendix. The list of carcinogens included those chemicals found from synthetic and natural sources. See *id.*

<sup>210</sup> See DELANEY PARADOX, *supra* note 15, at 36.

ready approved for use.”<sup>211</sup> The agency reported that it expected this number to rise as it evaluated more studies on food-use pesticides.<sup>212</sup>

As scientists grew more sophisticated in their abilities to detect small amounts of carcinogens, and as they came to realize that more chemicals were actually carcinogenic, the Delaney Clause grew in importance. The Clause no longer applied to a handful of substances, but to many pesticides important for farming. As with saccharin in the 1970s, the Delaney Clause in the 1980s and 1990s attracted more attention as it grew in scope.

### iii. Comparative Risk Assessment

Another factor contributing to the narrowing of the Delaney Clause was a sense among policymakers that some risks may truly be understood as negligible or de minimis. For instance, a 1987 National Academy of Sciences committee pointed out that on average, we face a 25 percent risk of developing cancer in our lifetimes.<sup>213</sup> This comparative risk assessment gained judicial notice in *Public Citizen v. Young*.<sup>214</sup> In *Young*, the plaintiffs challenged the FDA attempt to establish a de minimis exception to the Delaney Clause for color additives.<sup>215</sup> Although he rejected the agency’s arguments for reasons of statutory construction, Judge Williams concluded that the risk posed by the color additives seemed trivial.<sup>216</sup> The Court noted that activities posing similar risks included consuming one peanut containing the maximum permitted level of the liver carcinogen aflatoxin once every 250 days, or spending 1,000 minutes a year in a high altitude city, such as Denver.<sup>217</sup> The Court added that “[m]ost of us would not regard these as high-risk

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<sup>211</sup> Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104, 41,108, 41,119 (1988).

<sup>212</sup> See *id.* at 41,108.

<sup>213</sup> See DELANEY PARADOX, *supra* note 15, at 3. It continued: “For perspective, it is worth noting that an additional dietary oncogenic risk of 1 in 1 million or  $1 \times 10^{-6}$  would raise this background risk of 0.25 to 0.250001.” *Id.*

<sup>214</sup> 831 F.2d 1108, 1111 (D.C. Cir. 1987).

<sup>215</sup> See *id.* at 1109.

<sup>216</sup> See *id.* at 1111.

<sup>217</sup> See *id.* Aflatoxin is an extremely potent liver carcinogen. See, e.g., RODRICKS, *supra* note 8, at xviii-xxv. Living at high altitudes poses an increased risk of cancer because of higher levels of cosmic radiation. See *Young*, 831 F.2d at 1111. There is a one in a million risk of being hit and killed by an asteroid. See Kathy Sawyer, *The Sky is Falling But Most Pieces Miss*, WASHINGTON POST, Feb. 16, 1997, at A1, A27.

activities. Those who indulge in them can hardly be thought of as living dangerously.”<sup>218</sup>

*iv. New Understandings of Cancer*

Another changing scientific factor that undercut the Delaney Clause’s legitimacy among policymakers was the realization that there may in fact be safe levels of exposure for some carcinogens. Accordingly, the Delaney Clause’s notion that there are no safe levels of exposure may be incorrect for some carcinogens. Under this biological “threshold” model of carcinogenesis, a sufficiently low level of exposure is biologically equivalent to no exposure.<sup>219</sup> Thus if a pesticide residue exhibited only a threshold carcinogenic effect, and a threshold could be determined, regulators could set a tolerance level at a point sufficient to ensure that human exposure to the residue would not exceed the no observable adverse effect level (plus a safety factor). It is noteworthy that the legislative history of the FQPA distinguishes between threshold and non-threshold chemicals,<sup>220</sup> rather than carcinogens and non-carcinogens, as under the Delaney Clause. The EPA is also well aware of threshold carcinogenicity; for example, the agency’s 1996 Proposed Guidelines for Carcinogen Risk Assessment discusses threshold effects that may be “a secondary effect of toxicity or of an induced physiological change.”<sup>221</sup>

This example leads to another development in our understanding of carcinogenesis: secondary mechanisms. Under this mechanism of action, “the carcinogen causes an intervening pathological change and this pathological change is the direct cause of cancer.”<sup>222</sup> For instance, a chemical may induce bladder stones that themselves are the causative element in carcinogenesis.<sup>223</sup> Unless the test subject is exposed to sufficiently high levels of the chemi-

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<sup>218</sup> *Young*, 831 F.2d at 1111.

<sup>219</sup> See *WILSON*, *supra* note 86, at 5 (“[A]t some nonzero exposure the response not only passes below the limit of detection, and not only approaches zero as a limit, but becomes exactly, identically, zero.”).

<sup>220</sup> See *supra* text accompanying notes 58-65.

<sup>221</sup> Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. 17,960, 17,993 (1996). EPA Assistant Administrator Lynn Goldman discussed carcinogenic threshold limitations when testifying before a House subcommittee in 1995: “For some—it used to be all, but now it is still most—carcinogens, we assume there is no such thing as a threshold, and therefore we can’t guarantee a no effect level.” *1995 FQPA Hearings*, *supra* note 10, at 19.

<sup>222</sup> *Picut & Parker*, *supra* note 179, at 117.

<sup>223</sup> See Proposed Guidelines for Carcinogen Risk Assessment, 61 Fed. Reg. at 17,989.

cal, no cancer will result.<sup>224</sup> Understandings of threshold effects or secondary mechanisms thus assume that there are safe levels of exposure to a chemical. Under this assumption,<sup>225</sup> policymakers could argue against Delaney's zero-risk standard: if there is a safe exposure level, then a zero-risk ban is inapposite.

v. *Naturally-Occurring Carcinogens*

Furthermore, it has not escaped the notice of policymakers that many chemicals in the food supply that pose carcinogenic risks occur naturally. In an important, albeit controversial, series of papers, biochemist Bruce Ames has argued that much dietary carcinogenic risk is inevitable. Ames and his colleagues reported in 1987, that "[t]here is increasing evidence that our normal diet contains many rodent carcinogens, all perfectly natural or traditional (for example, from the cooking of food), and that no human diet can be entirely free of mutagens or agents that can be carcinogenic in rodent systems."<sup>226</sup> In the area of pesticides, Ames has suggested that 99.99 percent of human exposure to pesticides, by weight, occurs from naturally-occurring toxic substances.<sup>227</sup> Other researchers have supported this argument. For instance, one study suggests that traditional foods contribute 1,000 milligrams of carcinogens a day to the human diet, while pesticides and other carcinogenic contaminants constitute only 0.1 milligrams daily.<sup>228</sup>

A National Academy of Sciences panel recently credited this body of work, cautiously concluding that "it is plausible that naturally occurring chemicals present in food pose a greater cancer risk

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<sup>224</sup> The FDA relied on a secondary carcinogen theory when it approved selenium as an animal feed supplement in the early 1970s. See *Selenium in Animal Feed*, Proposed Additive Regulation, 38 Fed. Reg. 10,458 (1973). Selenium is linked with liver tumors, but only at high levels causing non-carcinogenic liver damage. See Picut & Parker, *supra* note 179, at 117-18. The FDA approved selenium on the theory that the mineral did not "induce cancer" within the meaning of the Delaney Clause. See *id.* at 118 n.58. ("[T]he FDA opted not to characterize selenium as what would appropriately be regarded today as a secondary carcinogen, but rather to characterize it as a noncarcinogen.").

<sup>225</sup> But see WILSON, *supra* note 86, at 5.

<sup>226</sup> Bruce N. Ames et al., *Ranking Possible Carcinogenic Hazards*, 236 SCIENCE 271, 273 (1987). Using a scale comparing human exposure to a carcinogen with a measure of carcinogenic potency in rodents (the HERP index), Ames and his colleagues have suggested, for instance, that a gram of dried basil leaves (containing the possible carcinogen estragole) may pose a greater carcinogenic risk than a can of diet soda (saccharin). See *id.*

<sup>227</sup> See Bruce N. Ames et al., *Dietary Pesticides (99.99% All Natural)*, 87 PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES 7777 (1990), cited in NATURALLY OCCURRING CARCINOGENS, *supra* note 209, at 20.

<sup>228</sup> See NATURALLY OCCURRING CARCINOGENS, *supra* note 209, at 289.

than synthetic chemicals.”<sup>229</sup> In short, the panel agreed with Ames that natural carcinogens are more prevalent in food than synthetic carcinogens,<sup>230</sup> and the committee found little evidence to suggest that there was any difference between the carcinogenic potency of natural versus synthetic chemicals.<sup>231</sup> The committee determined that when calories and fat intake are taken into account, natural substances pose a greater carcinogenic risk than synthetic ones, but it stressed that a lack of information about naturally-occurring carcinogens precluded a definitive conclusion about the relative risks posed by natural versus synthetic chemicals.<sup>232</sup>

### 3. Conclusion

In some sense, the forces that drove passage of the Delaney Clause—most notably, a concern over scientific uncertainty—are still with us. Scientists remain unable to identify with complete certainty the level at which a chemical poses a carcinogenic threat. The FQPA, however, manifests an increased willingness among policymakers to accept that risk. In part, this is the result of lawmakers’ awareness of developments in scientific techniques; improved analytical abilities meant that the Delaney Clause would directly begin to impact the rapidly expanding universe of detectable carcinogens. Furthermore, the past four decades have witnessed changing conceptions of risk. An implicit assumption underlying the increased acceptance of comparative risk assessment is that some risks are inevitable—as demonstrated by researchers’ growing interest in naturally-occurring carcinogens. These factors provided the framework supporting the “reasonable certainty” standard that the FQPA embodies.

## IV. THE POLITICS OF PESTICIDES: WHAT WAS UNIQUE ABOUT 1996?

### A. Pre-1996 Political History

In early 1996, most observers on Capitol Hill thought that the Delaney Clause would remain in place for pesticides.<sup>233</sup> Indeed, in

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<sup>229</sup> *Id.* at 309.

<sup>230</sup> *See id.* at 303.

<sup>231</sup> *See id.* at 306.

<sup>232</sup> *See id.* Ames and Gold have suggested that four-fifths of the chemicals adequately tested for carcinogenic potential in rodents are synthetic chemicals. *See Ames & Gold, supra* note 206, at 970.

<sup>233</sup> *See* Howard Cohen, Majority Counsel, House Commerce Committee, Speech at a

March, 1996, Senator Nancy Kassebaum, Chair of the powerful Senate Committee on Labor and Human Resources, deleted reference to the Delaney Clause from an FDA reform bill, reportedly believing that Delaney was sufficiently controversial to delay passage of the broader FDA legislation.<sup>234</sup> Most environmental advocates—a constituency that gained increased importance as Democrats sought to portray the GOP of the 104th Congress as defenders of corporate polluters—still publicly supported Delaney.<sup>235</sup>

Despite this support for the Delaney Clause, there was also considerable opposition to the Clause.<sup>236</sup> The food industry had supported revision of Delaney for two decades.<sup>237</sup> Members of Congress had floated bills proposing to replace Delaney for pesticides as early as 1977; these proposals, however, mustered greater attention in the 1990s.<sup>238</sup> As President Clinton signed the FQPA into law, he remarked that the Vice President had held hearings on the issue fifteen years previously.<sup>239</sup>

In 1993, the Clinton Administration, which at that time shared power with a Democratic majority in Congress, proposed eliminating Delaney's coverage for pesticide residues.<sup>240</sup> Combined with the political momentum created by *Les*, and subsequently by *Browner*, the Administration's proposal to move toward a negligible-risk standard shifted the debate. By breaking with the pro-Delaney position traditionally held by a number of prominent Democratic lawmakers, the Clinton proposal blurred the political

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Conference Presented by the American Crop Protection Association and McKenna & Cuneo, L.L.P. on Food Safety and the FIFRA Amendments of 1996 (Sep. 10, 1996).

<sup>234</sup> See *Senate Panel Shelves Debate on "Delaney Clause" in FDA Markup*, INSIDE WASHINGTON'S FDA WEEK, March 29, 1996, at 4. Ironically, although Congress revised the Delaney Clause's scope, the FDA reform bill died in the 104th Congress.

<sup>235</sup> See, e.g., WHITE PAPER, *supra* note 181.

<sup>236</sup> As one commentator has suggested, "[a]ll parties involved—the present administration, congressional representatives, the Environmental Protection Agency (EPA), public interest groups, and the affected industries—agree that the zero-tolerance standard for food additives is, in the context of its present use, a flawed standard." Gillan, *supra* note 9, at 14. While this summary exaggerates the consensus (see, e.g., environmentalists' support for the Delaney Clause; see *infra*, note 261), there was little doubt that there existed a clearly-defined opposition to Delaney by the mid-1990s.

<sup>237</sup> See *1995 FQPA Hearings*, *supra* note 10, at 68 (statement of Dr. Stephen Ziller, Vice President for Science and Technical Affairs, Grocery Manufacturers of America).

<sup>238</sup> See Merrill, *Repudiation*, *supra* note 15, at 31 n.169.

<sup>239</sup> See *Remarks by President Clinton At Signing of Food Quality Protection Act*, FEDERAL NEWS SERVICE, Aug. 5, 1996, available in LEXIS, News Library, Curnws File.

<sup>240</sup> Bills were introduced in May, 1994: S. 2084, 103d Cong. (1994); H.R. 4362, 103d Cong. (1994).

boundaries surrounding Delaney and depoliticized the Clause.<sup>241</sup> The Administration's proposal thus simultaneously opened the door to the kind of consensus-building that eventually resulted in overwhelming support for the FQPA and continued the strong anti-Delaney momentum initiated by the Reagan and Bush Administrations. That momentum grew stronger with the Republican takeover of Congress in 1994.

Several factors explain the change in political momentum leading to the decision to displace the Delaney Clause. First, policy-makers had become relatively well-versed in the risk, science, and policy issues, as discussed above. They were also made well aware of the impact of the *Les* decision, and its potential economic impact on the production, agriculture, and food industries. And finally, the FQPA reflected a grand political compromise at a time when Members of Congress—about to enter the post-Labor Day stretch of their reelection campaigns—most needed to demonstrate their ability to negotiate with each other.

#### B. *The FQPA Represented a Compromise*

Critical to passage of the FQPA was whether the committees with jurisdiction over pesticides could craft a congressionally-acceptable and veto-proof compromise to the residue regulation. Six weeks after the enactment of the FQPA, congressional staffers speaking before a meeting of the American Crop Protection Association (ACPA) described a political endgame that intentionally searched for compromise.<sup>242</sup> Congressional staff prepared “a creative approach” to pesticide regulation, presented this approach to the Clinton Administration, and received the EPA's feedback and technical expertise.<sup>243</sup> For part of the critical discussions, representatives of environmental groups and the food industry participated in the negotiations.<sup>244</sup> Kay Holcombe, Minority Counsel to the House Commerce Committee, described these overtures to the

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<sup>241</sup> In 1995, for instance, the chief sponsors of an early version of the FQPA were Representatives Thomas Bliley, a Virginia Republican, and Edolphus Towns, a New York Democrat. The Food Quality Protection Act of 1995, H.R. 1627, 104th Cong. (1995). Leading Committee Democrats opposed this bill, however.

<sup>242</sup> The ACPA is the chief association of the pesticide industry.

<sup>243</sup> See Kay Holcombe, Speech at a Conference Presented by the American Crop Protection Association and McKenna & Cuneo, L.L.P. on Food Safety and FIFRA Amendments of 1996 (Sep. 10, 1996).

<sup>244</sup> See *id.* These outside representatives were Mark Childress of the Environmental Working Group and Edward Dunkelberger, outside counsel to the National Food Processors Association. See *id.*



Administration and targeted constituents' groups as an attempt to create a bill that could be implemented in practice.<sup>245</sup> The move also had the political advantage of ensuring that affected parties felt as if they had something to gain by participating, thereby minimizing criticism from stakeholders.

In the end, the FQPA was made possible because, in the words of Commerce Committee Majority Counsel Howard Cohen, "everyone was willing to make compromises."<sup>246</sup> This willingness ultimately translated into a final bill that was passed quickly. Committee staff did not seek extensive feedback from a vast number of affected interests, in part out of fear that the legislation would be undone by an attempt to reopen the bill.<sup>247</sup> Staffers described a process of careful legislative craftsmanship, with parts of the final bill coming from several previous proposals, and a fair degree of horsetrading.<sup>248</sup> For instance, Gary Dotson, a legislative assistant to Representative Henry Waxman, described Democrats' agreement on language in the FQPA limiting states' abilities to enact stricter standards as a compromise to ensure the enactment of stiffer civil penalties for violating the pesticide requirements of the FFDCA.<sup>249</sup> Ultimately, the bill contained something for everyone.

### 1. *Republicans' Goals*

Republican members of Congress had several critical goals for reforming pesticide residue regulation, according to Committee staffers.<sup>250</sup> Key for Republicans was the elimination of Delaney's absolute ban on carcinogenic pesticides. GOP members also sought to include language permitting the consideration of benefits in tolerance-setting, the pre-emption of state and local residue standards, and the inclusion of a narrative, non-numerical safety standard.<sup>251</sup>

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<sup>245</sup> *See id.*

<sup>246</sup> Cohen, *supra* note 233.

<sup>247</sup> *See* Holcombe, *supra* note 243. Holcombe noted that staffers felt they had contacted a broad spectrum of stakeholders. *See id.*

<sup>248</sup> *See* Gary Dotson, Legislative Assistant to Rep. Henry Waxman, Speech at a Conference Presented by the American Crop Protection Association and McKenna & Cuneo, L.L.P. on Food Safety and FIFRA Amendments of 1996 (Sep. 10, 1996).

<sup>249</sup> *See id.*

<sup>250</sup> *See* Cohen, *supra* note 233.

<sup>251</sup> *See* Dotson, *supra* note 248. This final goal was a response to the position of Representative Waxman, perhaps the leading House Democrat on pesticide issues, who had taken the position that if Delaney was to be eliminated, Congress ought to write a "one-in-a-million" risk standard into the legislation. *See id.*

The FQPA represented a step back from a version of the bill that had been introduced in 1995.<sup>252</sup> An examination of the 1995 bill suggests the degree of compromise embodied in the final legislation. In place of what is now the “reasonable certainty of no harm” language, the 1995 bill would have deemed a tolerance “adequate to protect public health if the dietary risk posed to food consumers by such level of the pesticide chemical residue is negligible.”<sup>253</sup> EPA officials expressed confusion over the applicability of a negligible-risk standard to noncancer, threshold effects because negligible risk is a concept associated with the way carcinogenic, non-threshold effects are assessed.<sup>254</sup>

The 1995 bill also would have provided great latitude in considering benefits of pesticides. In place of the highly circumscribed regime of benefit consideration now in place, the previous legislation would have permitted a “not unreasonable” level of risk in situations where a new pesticide would be safer than an older one or where the availability of the pesticide would enable the maintenance of “an adequate, wholesome, and economical food supply for consumers.”<sup>255</sup> Notably, the preemption language codified in the current FQPA was broader in the previous version of the legislation.<sup>256</sup> Instead of the enacted FQPA requirement that the EPA consider the effects of pesticides on infants and children when setting tolerances, the 1995 bill merely mandated the collection of information on the subject.<sup>257</sup>

## 2. Democrats' Goals

For pro-Delaney advocates, the critical question was what they could extract in return for agreeing to narrow the applicability of the Clause. Although the 1995 legislation was co-sponsored by members of both parties, senior Democrats and environmentalists had opposed the legislation. For many, including several key Democrats on the House Commerce Committee, a major return came in the form of the FQPA's statutory mandate that the EPA consider the special susceptibilities that infants and children have to pesticide residues.<sup>258</sup>

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<sup>252</sup> H.R. 1627, 104th Cong. (1995).

<sup>253</sup> *Id.* § 405.

<sup>254</sup> See 1995 FQPA Hearings, *supra* note 10, at 9 (testimony of Lynn Goldman, Assistant Administrator, EPA).

<sup>255</sup> H.R. 1627, 104th Cong. § 405 (1995).

<sup>256</sup> See *id.*

<sup>257</sup> See *id.* § 301.

<sup>258</sup> See 1995 FQPA Hearings, *supra* note 10, at 2-3 (statement of Rep. Waxman).

The primacy of this issue was apparent from the opening statements during a 1995 subcommittee hearing on the FQPA, where spokespersons for both sides agreed on the need for reform, but differed on the nature of that change. Republican Subcommittee Chair Michael Bilirakis spoke of the need to “modernize” the Delaney Clause by enabling the EPA to adopt a *de minimis* approach.<sup>259</sup> Democratic Representative Henry Waxman immediately countered with another approach to modernization: “Our pesticide laws do need reform. The National Academy of Sciences told us that two years ago when it released its report on pesticides in the diets of infants and children.”<sup>260</sup> Environmentalists echoed Waxman’s sentiments.<sup>261</sup> Representative Waxman’s staffer, Gary Dotson, told the ACPA conference that the addition of the children and pesticide language was the crucial factor enabling the new—non-Delaney—safety standard to go ahead.<sup>262</sup>

In addition to the infants and children provisions, Democrats and their environmental allies sought other revisions.<sup>263</sup> These included a change in the terminology of the section 408 safety standard,<sup>264</sup> limits on the broad benefits provisions in the 1995 bill,<sup>265</sup> consideration of the cumulative effects of pesticides, and language concerning the effects of estrogenic pesticides.<sup>266</sup> The final draft of the FQPA reflected these changes.

### 3. Congressional Need for Compromise

The ultimate compromise served members of Congress from both sides of the aisle. When Republicans recaptured control of both chambers of Congress in the 1994 elections, the newly-dominant GOP, especially the freshman members of the House, exhibited an aggressive style of political activism. Challenging long-held assumptions about what was legislatively achievable, they brought a bold agenda to Washington, promising to revolu-

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<sup>259</sup> See *id.* at 1.

<sup>260</sup> *Id.* at 2.

<sup>261</sup> See *id.* at 78 (testimony of Erik Olson, Natural Resources Defense Council); *id.* at 91 (testimony of Jay Feldman, National Coalition Against the Misuse of Pesticides); *id.* at 104 (testimony of Carolyn Brickey, National Campaign for Pesticide Policy Reform).

<sup>262</sup> See Dotson, *supra* note 248.

<sup>263</sup> See, e.g., 1995 FQPA Hearings, *supra* note 10, at 84-85 (prepared statement of Erik Olson, Natural Resources Defense Council); Holcombe, *supra* note 243.

<sup>264</sup> See FQPA § 405(b)(2)(A)(ii), FFDCA § 408(b)(2)(A)(ii), 21 U.S.C. § 346a(b)(2)(A)(ii) (Supp. II 1996).

<sup>265</sup> See FQPA § 405(b)(2)(B), FFDCA § 408(b)(2)(B), 21 U.S.C. § 346a(b)(2)(B).

<sup>266</sup> See FQPA § 405(p), FFDCA § 408(p), 21 U.S.C. § 346a(p).

tionize the role of the federal government by drastically reducing regulatory burdens. The 104th Congress was a contentious affair, highlighted by the shut-down of the federal government in the winter of 1995-96. By the summer of 1996, leaders of both major political parties realized it was in their interests to demonstrate to their constituents that Republicans and Democrats knew how to legislate together. As such, the debate's occurrence in the final weeks of the 104th Congress proved to be a political fortuity.

## V. CONCLUSION

The replacement of the Delaney Clause is a story of the interwoven relationship between science and policy. The nature of regulators' response to carcinogenic pesticides in food grew increasingly important as scientists detected greater numbers of carcinogens, in ever-smaller amounts. By the 1980s, the Delaney Clause was hardly the legislative superfluity envisioned by key policymakers thirty years previously. Understood in this light, the *Les* court's strict reading of the Clause became critical; by denying the EPA a de minimis exception to the language of the Clause, the decision forced lawmakers to define the acceptable level of carcinogenic risk from pesticide residues.

This is not to say, however, that the FQPA was inevitable as a policy matter, let alone as a political one. Despite the advances in scientific ability, much uncertainty remains regarding the application of risk-assessment methodologies, and thus many of the concerns driving passage of the Delaney Clause are still relevant. Accordingly, much of the FQPA's significance lies in demonstrating how these scientific advances have engendered increased comfort among lawmakers with methods of quantitative risk assessment. In turn, this acceptance of risk assessment indicates how lawmakers have changed their notion of what constitutes acceptable risk over the past forty years. Furthermore, the FQPA illustrates how Congress, while ceding scientific power to an administrative agency, can place legislative controls on the agency to maintain congressional oversight of risk regulation.

The full implications of the FQPA, of course, remain to be seen. One significant open question is whether Congress will be moved by similar considerations to reevaluate the Delaney Clause for food additives, color additives, and animal drugs. It may be sufficient to note that most of the controversy surrounding Delaney over the past decade has focused on pesticides. With the Food

Quality Protection Act, most of that controversy has been laid to rest, at least for the moment.