



Working Out the Bugs in Pesticide Regulation: A Survey of the Joint Efforts of the EPA and FDA

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Working Out the Bugs in Pesticide Regulation: A Survey of the Joint Efforts of the EPA and FDA

By: Jonathan Lindsay

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Professor Peter Barton Hutt

Food and Drug Law

Harvard Law School

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I. Introduction

The history of pesticide regulation has been nothing short of a roller coaster ride. Just when it seemed as if all the glitches had been worked out, a new inconsistency or complexity arose. Given the prevalence and hence importance of pesticide usage in the United States, there has been no shortage of interested parties, poking and prodding at every new legislative provision or agency rule. The result has been a no-stone-unturned attitude towards pesticide regulation. This has led to a significant slowdown in the governmental machinery responsible for protecting us on the one hand, and for not sabotaging an otherwise adequate and reasonably priced food supply on the other hand. This daunting task is arguably too great for any one agency. Hence, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) have joined forces to meet the task at hand. Therein lies the problem, however. Coordination between the agencies has been elusive at best. Plowing through a field of inconsistency and ambiguity, the dual-agency attack has provided us with a story worth telling. Section II of this paper provides the reader with a brief history

of pesticide regulation as it existed before the Food Quality Protection Act of 1996 (FQPA). A substantial discussion is included on the Delaney Clause, the thorn of all thorns in the agencies' sides for many years. Section III discusses the major provisions of the FQPA, as applied to pesticide regulation. Section IV is devoted to a comprehensive discussion of the winding road that followed the Act. In particular, the problems created by the FQPA, most notably a jurisdictional nightmare that would take two years to sort out utilizing the combined efforts of the FDA and EPA. Even then, jurisdictional issues remain unresolved as "fixes" are still in the works.

II. Pesticide Regulation Before the

Food Quality Protection Act of 1996

A. A Brief History of Pesticide Regulation

Although pesticide regulation dates back to The Federal Insecticide Act of 1910, regulation was narrowly focused on labeling requirements until 1972.¹ By amending the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1947,² Congress created a registration requirement for all pesticides to be enforced by the newly created Environmental Protection Agency (EPA).³ Thus, under FIFRA, a pesticide must be registered before it can be sold or distributed. In reviewing a registration application, the statute directs the EPA to engage in what amounts to a risk-benefit analysis by weighing "the economic, social, and environmental

¹See Marina M. Lolley, *Carcinogen Roulette: The Game Played Under FIFRA*, 49 Md. L. Rev. 975, 977 (1990).

²Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80104, 61 Stat. 163 (1947) (codified at 7 U.S.C. §§ 136 et seq. (Supp. 1997)).

³See Scott Douglas Bauer, *The Food Quality Protection Act of 1996: Replacing Old Impracticalities with New Uncertainties in Pesticide Regulation*, 75 N.C. L. Rev. 1369, 1372 (1997).

costs and benefits” of the pesticide’s use.⁴

The other major piece of legislation on point is the Federal Food, Drug, & Cosmetic Act (FD&C Act) of 1938. Pesticide regulation was brought under its umbrella with the passage of the Miller Pesticide Amendment of 1954, now section 408 of the FD&C Act.⁵ Pursuant to section 408, the EPA must set tolerances, or maximum allowable levels, for pesticide residues on raw agricultural commodities.⁶ If these tolerances are exceeded, the residue-containing food will be considered “adulterated” and, hence, prohibited by the Act.⁷ In keeping with the spirit of FIFRA, this section also embraces a riskbenefit approach by instructing the Administrator to consider, when setting tolerances, “the necessity for the production of an adequate, wholesome, and economical food supply”.⁸

However, the philosophy of regulating pesticides under the rubric of a risk-benefit inquiry would soon be undermined with the passage of the Food Additive Amendment of 1958,⁹ now section 409 of the FD&C Act. In particular, the FD&C Act defined pesticide residues in processed food as food additives where “they are either concentrated during food processing or are not reduced to the extent of good manufacturing practice during such processing.”¹⁰ The erosion of the traditional risk-benefit approach was provided courtesy of the now infamous Delaney Clause, contained in the 1958 Amendment. In particular, the Delaney Clause sets a zero-level tolerance for all carcinogenic additives.¹¹ Thus, if a pesticide was considered to be a food additive

⁴7 U.S.C. § 136(bb), amended by Food Quality Protection Act § 230(a).

⁵Pesticide Chemical Act, Pub. L. No. 83518, 68 Stat. 511 (1954).

⁶See Peter Hutt & Richard Merrill, FOOD AND DRUG LAW 306-07 (2d ed. 1991).

⁷See 21 U.S.C. § 342(a), amended by Food Quality Protection Act § 404.

⁸21 U.S.C. § 346a(b) (2) (B) (iii) (II), amended by Food Quality Protection Act § 405.

⁹Pub. L. No. 85929, 72 Stat. 1785 (1958)

¹⁰James Smart, *All the Stars in the Heavens were in the Right Places: The Passage of the Food Quality Protection Act of 1996*, 17 Stan. Envtl. L.J. 273, 279 (1998); FD&C Act § 402(a)(2)(C), 21 U.S.C. § 342(a)(2)(C) (1994).

¹¹See FD&C Act § 409(c)(3)(A), 21 U.S.C. § 348(c)(3)(A) (1994). See also *Les v. Reilly*, 968 F.2d 985, 989 (9th Cir. 1992) (stating that the Delaney clause has been interpreted as “an absolute bar to all carcinogenic food additives”).

under the definition given above, and it exhibited carcinogenic properties, then it would be banned without the benefit of a risk-benefit examination.

Therefore, pesticide regulation turned on the question of whether or not the pesticide could be considered a food additive under section 409. The answer to this question lied in the fact that section 409 applied only to certain processed foods. In particular, it applied only when the pesticides concentrated in the food during processing, as well as to those whose residues had not been adequately removed.¹² Further, raw agricultural products were always exempt from the section 409, and hence the Delaney Clause, since pesticide residues on unprocessed foods automatically failed the “food additive” definition.

Adoption of the Delaney Clause and EPA’s subsequent interpretations created what has been dubbed the “Delaney Paradox”.¹³ In the first instance, pesticides that were used in unprocessed foods or which did not concentrate during processing would avoid Delaney, requiring only a section 408 tolerance.¹⁴ Further, for these types of pesticides, tolerance levels were based on a risk-benefit analysis. Alternatively, a pesticide used on foods to be processed that did not concentrate during processing, required both section 408 and section 409 tolerances.¹⁵ Moreover, a concentrating non-carcinogenic pesticide would be dealt with under the riskbenefit rubric discussed above. However, if the same pesticide were carcinogenic, the Delaney Clause would prohibit the EPA from setting a tolerance level for it, regardless of the level of risks or benefits.¹⁶

¹²See *supra* note 10 and accompanying text.

¹³See Dominic P. Madigan, Setting an Anti-Cancer Policy: Risk, Politics, and the Food Quality Protection Act of 1996, 17 Va. Env’tl. L.J. 187, 196 (1998) (describing the inconsistency which has come to be known as the “Delaney Paradox”).

¹⁴See Bauer, *supra* note 3, at 1377.

¹⁵See *id.*

¹⁶See *id.*

B. The Expansion of Delaney

Whether by accident or not, two EPA policies would serve to dramatically expand the reach of the Delaney Clause, and with it a swirl of controversy. Adoption of the first policy, dubbed the “coordination” policy, was purported to be part of an effort to limit the effects of the “Delaney Paradox” discussed above.¹⁷ In particular, interpreting the statute strictly, a carcinogenic pesticide could be registered under FIFRA and receive a tolerance level under section 408 if a risk-benefit analysis supported it. However, the same pesticide would be barred from receiving a tolerance level under section 409 if it could ultimately be used on processed foods. To avoid this dichotomous treatment, the EPA essentially read the Delaney Clause into section 408 by adopting a coordination policy. Under this policy tolerances would not be assigned for pesticides that were to be used on raw products if the same pesticide would fail to qualify for a tolerance under section 409 if used on processed foods.¹⁸ EPA rationalized this policy by asserting that, without it, the marketplace would suffer since farmers would be unable to know ahead of time if in fact their crops would be processed.¹⁹ The second policy which served to expand rather than contract the effects of Delaney was EPA’s “concentration in fact” policy. Here the idea was that a pesticide residue would be regulated under section 409 (and hence Delaney if it were oncogenic) if the pesticide concentrated at all, regardless of the degree of concentration.²⁰ The alternative policy, which would have limited Delaney’s reach, would have been one where a pesticide would be deemed a “concentrating pesticide” only where it concentrated to a point above its tolerance level. By rejecting this approach in favor of a “concentration in fact” approach, the EPA seemed

¹⁷See Smart, *supra* note 10, at 282-83.

¹⁸See The Pesticide Coordination Policy: Response to Petitions, 61 Fed. Reg. 2378, 2379 (1996).

¹⁹See Section 409 Tolerances; Response to Petition Requesting Revocation of Food Additive Regulations, 55 Fed. Reg. 17,560, 17,562 (1990).

²⁰See Madigan, *supra* note 13, at 197-98.

to be undermining its self-professed efforts to restrict the negative impact of the Delaney Clause.

Whether there was in fact an effort to limit Delaney’s reach or not, two things seem obvious in retrospect. First, these ruling dramatically expanded the reach of the Delaney Clause. In the case of the “coordination policy”, unprocessed foods were to be subjected to the same scrutiny as that of processed commodities. In the case of the “concentration” policy, the EPA adopted the most expansive definition it possible could. And second, the traditional risk-benefit spirit of pesticide regulation was slowly being whittled away.

C. Getting around Delaney

Following the passage of the Delaney Clause and EPA’s subsequent policy adoptions, EPA found itself facing intense criticism. For example, the clause made it difficult to replace older, more dangerous pesticides.²¹ Such pesticides had tolerances based on outdated, less sensitive tests. New and potentially safer pesticides, on the other hand, faced state-of-the-art testing procedures which made them more likely to fail Delaney.²² Thus, it was argued that, in its present state, the Delaney Clause was actually increasing risk due to pesticide residues.

EPA received yet another blow with a 1987 National Research Council (“NRC”) report asserting that the

²¹See Board on Agriculture, Nat’l Research Council, *Regulating Pesticides in Food: The Delaney Paradox* 41 (1987) (hereinafter NRC Report).

²²Instead of being able to detect residues up to the parts per million level, as was the case when the Clause was initially passed, modern technology was making it possible to detect carcinogenic pesticide residues up to the parts per trillion level.

Delaney Clause was not the most effective way of reducing cancer risk. The report estimated that up to 90% of diet-based cancer risk was the result of “uses sanctioned by tolerances granted before” the more rigorous testing requirements adopted in 1978.²³ Further, the report found that approximately one half of the cancer risks posed by pesticides were from foods unprocessed foods, which, due to their raw form, were beyond the scope of the Delaney Clause.²⁴ The report recommended that “[a] negligible risk standard for carcinogens in food, applied consistently to all pesticides and to all forms of food, could dramatically reduce total dietary exposure to oncogenic pesticides with modest reduction of benefits.”²⁵

The NRC report placed the irrationality of the Delaney Clause squarely before the EPA. By highlighting the ineffectiveness of the Clause, the report made public that which EPA had been struggling with for some time. Mainly, the fact that Delaney was, at best, ineffective in the pesticide context, or more likely, a counterproductive rule.²⁶ Immediately after the report was published, the EPA began to engage in what can only be described as an anti-Delaney campaign. Although there was evidence before the report suggesting that the EPA was resistant to applying the Delaney Clause,²⁷ it was not a position taken publicly until the announcement of its “de minimis” exception to Delaney in October 1988.²⁸ The “de minimis” policy was essentially a “gutting” of the Delaney Clause. Under the exception, the EPA would apply a negligible risk standard set at one-in-one-million lifetime risk.²⁹ Any pesticide which presented less than a negligible risk of cancer would be approved under section 409.³⁰

What is so interesting about the adoption of the “de minimis” exception to Delaney was the overwhelm-

²³Id. at 11

²⁴See Smart, *supra* note 10, at 290 (stating the Committee’s findings and recommendations).

²⁵Id. at 290 (quoting NRC Report, *supra* note 21, at 12).

²⁶See *generally* id. (discussing the NRC Report’s findings which point to the ineffectiveness of the Delaney Clause).

²⁷See id. at 283-86 (stating that the EPA, in following the FDA’s lead, avoided application of the Delaney Clause by adopting FDA policies which limited the applicability of Delaney).

²⁸See Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement, 53 Fed. Reg. 41,104 (1988).

²⁹See id. at 41,104.

³⁰See id. at 41,112.

ing sentiment that the policy was against the law. Some have tried to explain EPA's seemingly irrational behavior by suggesting that it was the only way to get the other branches of government involved.³¹ By inviting a challenge to the new rule, EPA would force the courts to strike it down, which would ultimately force Congress to respond. Although it is possible that this may have been the case, it is unclear to this author why the EPA could not have achieved the same result by simply applying the Delaney Clause in its rigid form. Presumably an equally dramatic effect could have been achieved with an EPA proposal to ban all carcinogenic pesticides. Surely this would have evoked a Congressional response.

Commentators have also suggested that the rule appears to be nothing more than a pretense particularly in light of the fact that the issue had been all but decided in the DC Circuit, in *Public Citizen v. Young*.³² In that case, the court held that the FDA incarnation of the de minimis exception to Delaney for color additives violated the statute.³³ However, careful reading of the opinion shows that the court deliberately limited its holding to the color additives provision.³⁴ The court went on to state in a footnote that "the operation of the food additive Delaney Clause raises complex issues...."³⁵ Thus, in light of the courts careful exclusion of the food additives issue, it may have been the case that the reverse was actually true. Namely, that it was the DC Circuit inviting the EPA to promulgate an exception to Delaney, not the EPA "baiting" the courts into striking down such an exception.

³¹See Smart at 294 (stating that the policy's clear conflict with the Delaney Clause "suggests that the agency strategically released the de minimis policy statement in order to effect a change in the law through a showdown with the other branches of government").

³²See id. (stating that this "almost certainly dictated a similar ruling on a challenge to the de minimis application to section 409).

³³See *Public Citizen v. Young*, 831 F.2d 1108, at 1113 (D.C. Cir. 1987).

³⁴See id. at 1120 (stating that although the provisions for color additives and food additives are almost identically worded, their context is clearly different).

³⁵Id. at 1118 n.13.

D. Revenge of Delaney

If in fact the DC Circuit had sent the EPA a message in 1987 with its *Public Citizen v. Young* decision, it fell on deaf ears in 1992 in the Ninth Circuit. In *Les v. Reilly*,³⁶ the Ninth Circuit overturned the EPA's de minimis policy holding that both the language of the statute and the legislative history indicate that Congress intended that it be applied in rigid fashion.³⁷ The court further noted that it was not for the EPA or the courts to decide on the wisdom of the Delaney Clause.³⁸

The apparent inconsistency between the DC Circuit holdings and the Ninth Circuit's may stem from two important factors. First, and most obvious, is the fact that we have different courts deciding cases at different times. Second, there had been a noticeable change in public sentiment in the interim. In particular, there seemed to have been a growing concern with the safety of children. This shift appears to coincide with the 1989 study from the Natural Resources Defense Council (NRDC) focusing on the cancer risks to children by pesticide residue.³⁹ In particular, the pesticide known as Alar became almost a household name thanks to the NRDC's effective use of the media. Despite efforts by both the EPA and FDA, public reaction to the scare forced the EPA to ban Alar.⁴⁰

³⁶*Les v. Reilly*, 968 F.2d 985 (9th Cir. 1992).

³⁷*See id.* at 98889.

³⁸*See id.* at 990.

³⁹*See generally* Natural Resources Defense Council, *Intolerable Risk: Pesticides in Our Children's Food* (1989).

⁴⁰*See* Hutt & Merrill, *supra* note 6, at 318.

E. The Time Was Right

With EPA's de minimis policy overturned and public sentiment shifting, the pressure was squarely on the shoulders of Congress. In what appeared to have been an effort to turn the heat up even more for Congress, the EPA quickly announced that it would have to "revoke tolerances for numerous widely used pesticides".⁴¹ Although efforts to amend the much-maligned Delaney Clause were being made as far back as the 100th Congress in 1987,⁴² it would not be until 1991 that Representatives Terry Bruce (DIL) and Thomas Bliley (RVA) would introduce H.R. 3216 —the bill which would eventually be passed as the Food Quality Protection Act (FQPA) of 1996. However, it would take key judicial decisions like *Les v. Reilly* and numerous debates over several subsequently introduced bills before Congress would be able to make headway on the issue.⁴³ In addition, the EPA had begun to react to the *Les* decision and environmentalists' pleas by revoking 23 different pesticide tolerances between 1993 and 1996.⁴⁴ Given the potential financial impact such revocations could have, it was no surprise that these revocations were met with intense criticism and legal challenge from industry.⁴⁵ This fact was not lost on the House Commerce Committee during the FQPA hearings. It found that such disruption "could have serious dietary and cost consequences for consumers and serious adverse impacts on the economies of the nation's major agricultural States."⁴⁶

⁴¹Bauer, *supra* note 3, at 1382.

⁴²See Smart, *supra* note 10, at 290-92 (describing how three newly introduced bills contained language aimed at eliminating the disparity created by the Delaney Clause).

⁴³See *generally* id. at 318-28 (asserting that many factors contributed to the passage of the FQPA in 1996 including Republican efforts to improve their environmental record, judicial establishment of a schedule to revoke old pesticide tolerances, industry rhetoric, and changing public opinion about the effectiveness of the Delaney Clause).

⁴⁴See Madigan, *supra* note 13, at 217.

⁴⁵See *Section 409 Tolerance Revocation Proposals Criticized*, *Pesticide & Toxic Chemical News*, Vol. 23, No. 34 (June 21, 1995) (describing several criticisms and challenges levied by industry against EPA section 409 tolerance revocation proposals).

⁴⁶Madigan at 218 (quoting H.R. Rep. No. 104669, pt. 2, at 32 (1996), reprinted in 1996 U.S.C.C.A.N. 1268, 1271).

Amidst intense pressure from all angles —industry, environmentalists, and even the EPA itself— the House passed the bill on July 23 with a vote of 417 to 0. The next day, the Senate approved it by voice vote with no debate.⁴⁷ Considering the intense debates that had preceded it, the passage of the FQPA was actually sudden and almost anti-climatic.

III. Second Generation Pesticide Regulation: The Food Quality Protection Act of 1996.

A. Setting a Single Standard for Pesticide Tolerances

In place of the now-defunct zero-level tolerance for carcinogenic pesticides, the FQPA establishes a single safety standard for pesticide residues for all foods. This is accomplished by redefining the terms “food additive” and “pesticide chemical residue” such that all food borne pesticide residues are covered by section 408 of the FD & C Act.⁴⁸ This was then followed by the amendment of section 408’s safety standard to one of “reasonable certainty” such that “no harm will result from aggregate exposure to the pesticide chemical residue.”⁴⁹ This standard is applied in a quasi-risk-benefit fashion. It falls short of a true risk-benefit approach in the sense that it severely limits the circumstances under which a pesticides benefit may be

⁴⁷See Bauer, *supra* note 3, at 1385-86.

⁴⁸See Food Quality Protection Act of 1996 § 402(a), 21 U.S.C.A. § 321(q)(2) (West Supp. 1996).

⁴⁹Food Quality Protection Act of 1996 § 405(b)(2)(A)(ii), 21 U.S.C.A. § 346a(b)(2)(A)(ii) (West Supp. 1996).

considered. The FQPA allows the EPA to consider benefits, but to a much less extent than it previously did under its now overruled de minimis exception. Under the EPA's de minimis policy the "EPA's tolerance-setting practice for carcinogenic residues was to create a range of risk between 1/1,000,000 and 1/10,000 in which the EPA would consider a pesticide's benefits."⁵⁰ Under the FQPA, the EPA must first determine what level of exposure is "safe". Once that is done, the EPA may adjust a pesticide's tolerance level to account for its benefits, but only to the point that the pesticides residue poses no more than "two times the safe exposure level over a lifetime of exposure."⁵¹ Indications are the EPA will define "safe" as any risk greater than 1/1,000,000 lifetime risk.⁵² That being the case, the EPA would only be allowed to adjust tolerances to account for benefits when the risks posed are between 1/1,000,000 and 1/500,000 for lifetime exposure to the risk. Any risk greater than 1/500,000 for lifetime exposure would bar any consideration of benefits.

Nevertheless, the shift away from a Delaney-type approach to the current version of a risk-benefit approach represents a fundamental shift in how we, as a society, view risk. In 1958, the Delaney Clause was written to reflect the fundamental belief that carcinogenic risks could not be adequately managed, but rather should be eliminated whenever detected. This unbending sentiment, however, has seen its gradual erosion through episodes like the saccharin incident, for example. Perhaps the phenomena of risk-saturation⁵³ has also played a part in the emerging public acceptance of informed risk management.

⁵⁰Bauer at 1398-99.

⁵¹Id. at 1399.

⁵²See id.; Section 408(b)(2)(A)(ii) of the FQPA defines "safe" to mean "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."; "[A] 'reasonable certainty of no harm' is generally interpreted to mean that there be no more than a [1/1,000,000] chance that the residue would cause cancer." Id. at note 240 (quoting David Hosansky, Pesticide Bill Highlights, 54 Cong. Q. Wkly. Rep. 2104, 2104 (1996)).

⁵³Risk-saturation is the phenomena that results from a bombardment of information concerning the pervasiveness of daily carcinogen exposure. The effect of this bombardment is the general acceptance of risk as a way of life and is best exemplified in the increasing popular slogan of "everything causes cancer".

B. Other Provision

Stemming from the new found public awareness of children’s safety, the FQPA requires the EPA to consider the special susceptibility of children and infants to pesticides.⁵⁴ The Act also creates a timeline for the EPA to follow in reevaluating existing tolerances,⁵⁵ preempts states from setting their own tolerances,⁵⁶ and limits the number of remedies available to the FDA.⁵⁷

IV. Pesticide Regulation: Post-Delaney

A. Increased demand on EPA resources

The FQPA, although alleviating some of the constraints the EPA felt as a result of the Delaney Clause, imposes new and difficult responsibilities on the EPA. For example, as mentioned above, the Act requires the EPA to assess pesticide residue risks to infants and children based on available information. Further,

⁵⁴See FQPA § 405(b)(2)(C)(i)(II), 21 U.S.C.A. § 346a(b)(2)(C)(i)(II) (West Supp. 1996). EPA must also publish a special determination of safety for infants and children. See *id.*

⁵⁵See *id.* § 405(q), 21 U.S.C.A. § 346a(q) (West Supp. 1996)

⁵⁶See *id.* § 405(n)(4), 21 U.S.C.A. § 346a(n)(4) (West Supp. 1996).

⁵⁷“The Act limits civil penalties to \$50,000 per individual and \$250,000 per entity, up to a maximum of \$500,000 for all violations adjudicated in a single proceeding... [and the] FDA must opt either for civil penalties or for criminal penalties, but cannot pursue both.” Allison D. Carpenter, *Impact of the Food Quality Protection Act of 1996*, 3 *Env’tl. Law.* 479, 490 (1997).; “Assessment of a civil penalty also prohibits use of the seizure authorities provided in FFDCA § 304, 21 U.S.C. § 334 (1994) and the injunction authorities of FFDCA § 302, 21 U.S.C. § 332 (1994).” *Id.* at note 107.

“[T]he FQPA now requires EPA to consider aggregate exposure (i.e., exposure not only from dietary sources, but also from other sources such as drinking water and residential uses of the given pesticide). Also, in establishing tolerances, EPA must consider the cumulative effects from multiple compounds with a common mechanism of toxicity. These provisions are among the most technically challenging mandates imposed by the FQPA, in large part because of the lack of information and experience in assessing aggregate exposure and cumulative risk.”⁵⁸

In addition, the FQPA directs the EPA to reassess all existing tolerances within 10 years,⁵⁹ and must apply the new safety standard to existing tolerances, in order of priority, to those tolerances that appear to pose the greatest risk to public health.⁶⁰ According to EPA estimates, there are more than 9,000 tolerances that have been established for pesticides.⁶¹ Thus, meeting this statutory schedule would require the EPA to average over 3 tolerance reassessments per working day. This would be a monumental task in itself, however the task is compounded by the fact that EPA must give priority to those pesticides posing the greatest risks —pesticides which represent some of the “most widely used and difficult to assess.”⁶² To make matters worse, more than two years have passed and the Agency has yet to issue a tolerance reassessment for any existing tolerance under the FQPA.⁶³

B. The Next Thorn Bush: Jurisdiction

⁵⁹ See 21 U.S.C. s346a(q)(1)(c).

⁶⁰ See Weinstein (stating that “the Agency will not have much time to develop its new policies and procedures before having to tackle some of the toughest issues”).

⁶¹ See Office of Prevention, Pesticides, and Toxic Substances, U.S. EPA, 1996 Food Quality Protection Act Implementation Plan 4 (1997).

⁶² Id.

⁶³ See id.

1. Historical Account of Jurisdiction for Pesticide Regulation (Pre-FQPA)

Although there is little question that the EPA has jurisdiction over the sale, distribution, and use of “pesticides”,⁶⁴ the issue has been somewhat more muddled when it comes to pesticide residues. The complications begin with the fact that the EPA has interpreted the terms “pesticide”⁶⁵ and “pest”, as defined in FIFRA, quite broadly. This has led to the extension of EPA jurisdiction to chemicals “used to control weeds and fungi on crops, and microorganisms that may be present on permanent or semi-permanent surfaces, such as counter tops and food processing equipment that may come in contact with food.”⁶⁶ Moreover, the EPA utilizes the registration provisions of FIFRA to regulate everything from the composition of the pesticide, to its labeling.⁶⁷

Since its inception in 1970, the EPA assumed jurisdiction for “pesticide chemicals” as defined under the FD&C Act. Under the original wording, this meant that the EPA would regulate the residues of FIFRA pesticides when they appeared “in or on raw agricultural commodities.”⁶⁸ However, the scope of the term “pesticide chemical” was narrower under the FD&C Act than was the term “pesticide” in FIFRA.⁶⁹ This caused EPA’s residue jurisdiction to fall short of its pesticide jurisdiction, as defined under FIFRA. By default, the FDA would assume jurisdiction for pesticide residues that were not in raw agricultural commodities, and hence not considered “pesticide chemicals”.⁷⁰ Such residues would instead be treated as “food

⁶⁴See FIFRA, 7 U.S.C. 136 et seq.

⁶⁵“The term ‘pesticide’ means... any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest....” FIFRA §2(u).

⁶⁶63 Fed. Reg. 54532 (October 9, 1998).

⁶⁷See *generally* FIFRA §12(a).

⁶⁸63 Fed. Reg. 54532, 54533 (October 9, 1998).

⁶⁹FD&C Act limited the definition of a “pesticide chemical” by requiring that it be a FIFRA pesticide “which is used in the production, storage, or transportation of raw agricultural commodities” FD&C Act, §201(q), 21 U.S.C. 321(q) (1994) (amended 1996).

⁷⁰See 63 Fed. Reg. 54532, 54533 (October 9, 1998).

additives” and regulated by the FDA accordingly.⁷¹ Pragmatically speaking, the only pesticides that fell into FDA’s lap under the food additives guise were pesticides used for antimicrobial purposes. Examples of such included residues found in disinfectants used on food-contact surfaces, residues on food packaging material, and slimicides used in the manufacture of paper and paperboard.⁷²

The result of this erroneous distinction between raw agricultural commodities and processed foods is that two given pesticides, having identical chemical structures, may be subject to different safety standards depending on whether they resided in processed or unprocessed foods.

2. Effects of the FQPA

In an attempt to eliminate the differing treatment for processed and unprocessed foods, the FQPA made significant changes to the FD&C Act’s language regarding pesticides. These changes, however, raised serious jurisdictional. In particular, the FQPA eliminates the restriction that a “pesticide chemical” exist only where the pesticide is used in conjunction with a raw agricultural product.⁷³ Further, the Act modifies the term “food additive” such that it now excludes pesticide residues “on a raw agricultural commodity or processed food”.⁷⁴ The intended effect of these changes was to give the EPA sole jurisdiction over all pesticide residues on food, regardless of whether the food was processed or not.⁷⁵ However, this was not entirely the case as

⁷¹The FD&C Act provides an exclusion for “pesticide chemicals” from the definition of “food additive”. See § 201(s). Thus, as soon as a substance falls within the definition of a “pesticide chemical”, it is automatically removed from the definition of “food additive”, and hence removed from FDA jurisdiction.

⁷²See *id.* at 54534.

⁷³See FD&C Act §201(q)(1).

⁷⁴*Id.* at §201(s)(1)

⁷⁵The FQPA creates a single, health-based standard, eliminating “longstanding problems posed by multiple standards for pesticides in raw and processed foods.” USEPA, Office of Pesticide Programs, *Highlights of the Food Quality Protection Act of 1996*, (visited Jan. 28, 1999) <<http://www.epa.gov/oppppsl/fqpa/fqpahigh.htm>>; See also John Dubeck, Antimicrobial Regulatory Technical Corrections Act Becomes Law; Jurisdictional Chaos Created by FQPA Also Addressed in a Joint FDA/EPA Policy Statement, (visited Jan. 28, 1999) <<http://www.khlaw.com/artca.html>> (hereinafter ARTCA Becomes Law).

will be discussed in the following section —section IV(B)(2)(a)(i). Furthermore, these changes have led to significant shifts in the jurisdictional boundaries between the FDA and EPA in the area of antimicrobials.

a. Jurisdictional Implications of the FQPA for Antimicrobials

i. Antimicrobial Substances Directed Against Microbes in or on Edible Food, Animal Drinking Water, and Process Water t

Both the FDA and EPA claim, and it does not appear, that the FQPA amendments have altered the jurisdictional boundaries for this category of antimicrobials. Both pre- and post-FQPA jurisdiction for this category is shared between the EPA and FDA, with the boundary often being located along the difficult to draw and often baseless line of processed food/raw agricultural commodity.

The dichotomy between processed and unprocessed foods, although eliminated by the FQPA in the definition of “pesticide chemical”, persists in the definition of the term “pests”. Under a long-standing rule, the EPA excludes all microorganisms in processed foods from the definition of “pests.”⁷⁶ Accordingly, antimicrobial chemicals used on such organisms are not considered “pesticides” under FIFRA, and hence are not “pesticide chemicals” under the FD&C Act.⁷⁷ As mentioned above, if such residues can not be classified as “pesticide chemicals”, they are, by default, FDA regulated “food additives”.⁷⁸ Hence, pesticide residue in or on “processed foods” are subject to FDA regulation, while residue on raw agricultural commodities are subject to EPA jurisdiction. Although this oversight creates no new jurisdictional issues, it continues the historically inconsistent treatment for antimicrobial pesticides.

The EPA has admitted that a distinction between processed and unprocessed foods is ambiguous at best.⁷⁹ This is due to the fact that it is virtually impossible to ascertain whether a given activity is “processing” or simply post-harvest treatment. This distinction is particularly strained when the antimicrobials are used

⁷⁶See 40 CFR 152.5(d).

⁷⁷Even after the 1996 amendments, the FD&C Act requires that “pesticide chemicals” be “pesticides” as defined under FIFRA. See FD&C Act §201(q)(1). See also 63 Fed. Reg. 54532, at 54536.

⁷⁸See *supra* note 71 and accompanying text.

⁷⁹See 63 Fed. Reg. 54532, at 54537.

inside a food processing facility, where some commodities leave the facility with no processing and others undergo further processing.⁸⁰ Accordingly, in an attempt to counter this baseless distinction the EPA has recently announced its intention to change the definition of “pest”.⁸¹

ii. Antimicrobial Substances Used to Sanitize or Disinfect Food-Contact Surfaces:⁸² Prior to the FQPA, this category of antimicrobials was not regulated as “pesticide chemicals” since they did not satisfy the requirement that they be “used in the production, storage, or transportation of raw agricultural commodities.”⁸³ Instead, they fell within FDA’s jurisdiction as a “food additive”. However, with the elimination of the restrictive language, such antimicrobials satisfy the definition of “pesticide chemical” under the FD&C Act. Accordingly, jurisdiction over this category has been effectively transferred to the EPA.

iii. Antimicrobial Substances Used in the Production of Food Packaging Materials & Food-Contact Articles:⁸⁴

As with the preceding category of antimicrobials, jurisdiction over this category is considered to have been transferred from the FDA to the EPA with the elimination of the language in the FD&C Act requiring that a pesticide be “used in the production, storage, or transportation of raw agricultural commodities”.⁸⁵ Without this language, such substances are “pesticide chemicals” and hence not “food additives”, as they were previously considered.

Some commentators have suggested, however, that the jurisdictional shift for this category of antimicrobials is unnecessary under the law and has occurred only as a direct result of the adoption of a narrow definition

⁸⁰See *id.*

⁸¹See *infra* Section IV.E.

⁸²“This category includes antimicrobial substances that are used in or on equipment in food production facilities such as farm bulk tanks and milking machines; in manufacturing facilities such as meat saws/grinders, shellfish skimmers...; in retail food facilities such as bulk tankers used for liquid eggs or dairy products.” 63 Fed. Reg. 54532, at 54538.

⁸³*Id.*

⁸⁴“This category of products includes slimicides used in the manufacture of food-contact paper and paperboard, and preservatives added to... adhesives or coatings...[,] and sanitizers applied to food containers such as aseptic packaging.” Further included in this category are “pesticide products such as: preservatives used in... adhesives and coatings intended for use in food-contact articles, and antimicrobial substances used in the manufacture of conveyor belts, cutting boards, plastic tubing, and other articles that come in contact with food....” *Id.* at 54539.

⁸⁵*Id.*

of “food”.⁸⁶ In particular, the EPA has chosen to define food as that which is edible and intended to be consumed.⁸⁷ This definition excludes food-contact items from the definition of “processed food”, which in turn negates the EPA jurisdiction exception for pesticides used for microorganisms in processed foods. If, however, food-contact items were defined as a type of “food”, then they would be considered “processed food”, since they are clearly not raw agricultural commodities. That being the case, pesticide residues would not be subject to EPA jurisdiction since, as mentioned previously, the working definition of “pesticide chemical” excludes microorganisms used on processed foods.⁸⁸

John Dubeck, the apparent originator of the premise outlined above, presented it to EPA and FDA officials on February 18, 1997 at a meeting on “Jurisdictional Issues for Antimicrobials Used in Food Applications.”⁸⁹ However, neither agency has accepted Dubeck’s interpretation.⁹⁰

C. Fixing the Fix: Efforts to undo the unintended effects of the FQPA

⁸⁶See John B. Dubeck, Regulatory Jurisdiction Over Antimicrobials Used in Contact With Processed Food (visited Jan. 28, 1999)<<http://www.khlaw.com/archives.fdamicro.htm>> (hereinafter Jurisdiction Over Antimicrobials) (outlining the premise upon which the conclusion is ultimately drawn that no jurisdictional changes resulted from the FQPA).

⁸⁷See 63 Fed. Reg. 54532, at 54533.

⁸⁸This broad interpretation of “food” could follow from its equally broad definition in the FD&C Act, namely that “food” is any article used as food by man or animal, including components of such articles. See FD&C Act § 201(f). Furthermore, such an interpretation is not without judicial precedent. In *Natick Paperboard Corp. V. Weinberger*, 525 F.2d 1103 (1st Cir. 1975), *cert. denied*, 429 U.S. 810 (1976), the court found paperboard intended for packaging food without an intervening barrier to be covered by the definition. Further, in *United States v. Technical Egg Products, Inc.*, 171 F. Supp. 326 (N.D. Ga. 1959) the court allowed incubator reject eggs intended for non-food use to be seized as food.

⁸⁹See Jurisdiction Over Antimicrobials, *supra* note 86.; See also John B. Dubeck, Summary of February 18, 1997 Meeting with EPA and FDA on Jurisdictional Issues for Antimicrobials Used in Food Applications (visited Jan. 28, 1999)<<http://www.khlaw.com/articles.htm>> (hereinafter Meeting With EPA & FDA).

⁹⁰From Dubeck’s report of the meeting he notes that “it seemed clear that at least some FDA staff were not comfortable with EPA’s interpretation of the Act”. *Id.*

As early as December 4, 1996, the EPA and the FDA believed that they had the jurisdictional issue under hand.⁹¹ They even were purported to have had an agreement “in principle” on the affected products, and further claimed to have “found their views to be in sync....”⁹² However, it would take almost two years before any agreement would be finalized.

The first announcement of a firm agreement came on May 8, 1997.⁹³ Although technically referred to as “an agreement in principle”, the announcement included a very detailed explanation of where the line would be drawn. The agreement as announced called for antimicrobials used in food packaging to remain at FDA and be regulated as food additives under Section 409 of the FD & C Act. In turn, antimicrobials used in or on articles other than food packaging will be dealt with as follows:

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⁹¹See *FQPA Jurisdiction Issues Being Sorted Out by FDA and EPA*, Food Chemical News, Vol. 38, No. 44 (Dec. 23, 1996).

⁹²*Id.*

⁹³See *EPA, FDA Reach Tentative Decision on FQPA Jurisdiction Issue*, Pesticide & Toxic Chemical News, Vol. 25, No. 29 (May 14, 1997).

This agreement was slated to be solidified via a memorandum of understanding (MOU) between the Agencies. However, such an MOU would never be drafted.

Apparently, the problem with the May 8th agreement was that it was still based on making a distinction between processed foods and raw agricultural commodities. Unable to work out the logistics of drawing such a line, the agencies went back to the proverbial drawing board. A few months later they announced that a new approach to the jurisdictional problem would be tried.⁹⁵ At a Sept. 17 meeting, the two agencies agreed that it was fruitless to try to define jurisdiction in terms of whether food was processed or not. Instead, the agencies agreed that an amicable result could be achieved by redefining the term pest under FIFRA.⁹⁶ The intended effect of altering the definition of “pest” would be to restrict the term such that more uses of antimicrobial substances will be deemed food additives instead of pesticides.⁹⁷ This would return jurisdiction to the FDA for those types of antimicrobials that were accidentally transferred to EPA’s jurisdiction.

A month after their decision to redefine “pest” through regulatory avenues, the agencies decided to employ a two-pronged attack by pursuing both a regulatory and legislative approach.⁹⁸ Presumably, the primary advantage of a legislative fix is timing. A regulatory approach would tend to take longer, given the notice and comment requirements. Curiously, however, while the proposed rule focused on amending the term “pest”, the legislative solution was aimed at the term “pesticide chemical”. Although the intended effect was to be the same in either case, the result may turn out to be different.⁹⁹

⁹⁵See *EPA and FDA find creative solution to FQPA jurisdiction question*, Pesticide & Toxic Chemical News, Vol. 25, No. 50 (Oct. 8, 1997).

⁹⁶See *id.* (stating that George Pauli, director of the Division of Product Policy in FDA’s Office of Premarket Approval stated publicly that the agencies do in fact have an agreement to implement the new approach).

⁹⁷See *id.*

⁹⁸See *Legislative solution to FQPA jurisdiction questions pursued*, Pesticide & Toxic Chemical News, Vol. 26, No. 2 (Nov. 5, 1997).

⁹⁹See *infra* discussion Section IV.D through IV.E.

On October 9, after two years of agency efforts, Congress passed the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA).¹⁰⁰ ARTCA amends the definition of “pesticide chemical” such that regulatory jurisdiction reverts back to FDA in the following situations:

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Ironically, on the same day that ARTCA passed, the EPA and FDA jointly issued a notice of policy interpretation, announcing their final proposal for solution to the jurisdictional debate.¹⁰² With one notable exception, passage of the Act makes the proposed rules largely unnecessary.

¹⁰⁰The Antimicrobial Regulation Technical Corrections Act (ARTCA) of 1998 (P.L. 105-324, 112 Stat. 3035).

¹⁰²*See generally* 63 Fed. Reg. 54532 (Oct. 9, 1998).

D. The Persistent Dual Standard

The one notable exception mentioned above involves the complication posed by food processing facilities. In particular, after ARTCA, antimicrobials on raw agricultural commodities in food processing facilities and in or on food contact materials are still considered “pesticides”, subject to FIFRA registration requirements under section 408. However, under the new definition of “pesticide chemical”, such residues may no longer be covered.¹⁰³ Given the broad definition of “food additive”, such residues would then be classified as such under section 409 of the FD&C Act, subject to FDA jurisdiction. The end result is that there are still situations, although definitely fewer than before FQPA, where a pesticide is judged under two separate standards. For example, it is possible for a pesticide to not be registrable because it fails the new section 408 safety standard, yet have foods treated with it considered unadulterated as long as such residues pass any food additive standards.¹⁰⁴

The FQPA did in fact create a brighter line by relegating all section 408 duties to the EPA and all section 409 duties to the FDA.¹⁰⁵ Post-ARTCA, however, the jurisdictional crossover is not dual-agency jurisdiction as it was previously, but rather it is dual-chemical jurisdiction, with the double standard coming by way of the differences between section 408 and section 409.¹⁰⁶

E. The Final Fix?

¹⁰³ See ARTCA Becomes Law, *supra* note 75.

¹⁰⁴ See *id.*

¹⁰⁵ “EPA issued food additive regulations for residues of pesticide chemicals that were expected to concentrate beyond the tolerance for the raw agricultural commodity when foods were processed.” Jurisdiction Over Antimicrobials, *supra* note 86.

¹⁰⁶ See Appendix A (outlining the differences between section 408 and section 409).

Recognizing the persistent dual jurisdictional problem, the EPA and FDA proposed a solution in the same October 9, 1998 notice discussed above. The solution comes by way of redefining the term “pest”, as they had previously proposed to do. The new definition would exclude “microbes that are in or on raw agricultural commodities or in process water used on such commodities in a food processing facility.”¹⁰⁷ Thus, this troublesome category of pesticides would not fall under the FIFRA section 408 definition, nor the FD&C Act “pesticide chemical” definition, but would instead be regulated as solely a “food additive” under section 409.

That is not the end of the story, however. This proposal is not unanimously acceptable due to the fact that it removes requirements that some antimicrobial manufacturers register their products with the EPA. Industry claims that this would be unfair to those companies who have already had to register their products.¹⁰⁸ According to Paul Wright, attorney for Dow Chemical Co., the proposal would create marketplace confusion since some companies will have to maintain two sets of labels for the same product, depending on the intended use.¹⁰⁹ Further, The Biocides Panel, part of the Chemical Manufacturers Association, plans to oppose the rule.¹¹⁰ Thus, it does not appear that we’ve heard the last on this issue.

¹⁰⁷63 Fed. Reg. 54532, at 54537.

¹⁰⁸See Bert McMeen, *Pesticides: Anti-microbial Bill Passed in House Would Restore Some FDA Jurisdiction*, BNA Chemical Regulation Daily News (Oct. 13, 1998).

¹⁰⁹See *id.* (noting that, up to this point, chemicals registered under FIFRA cannot be used for non-FIFRA application under the law, and that changing this premise would create the need to have a two-label system, one for FIFRA application and one for non-FIFRA uses).

¹¹⁰See *id.*

V. Conclusion

Despite consistent criticism from both industry and environmental groups, the FDA and EPA have managed to clear two large hurdles. First, and most formidable, was the “Delaney Paradox”. Second, the jurisdictional surprise that followed from the Delaney fix. Much has been said about the inability of the system to correct that which is obviously in need of repair, but if one keeps in mind how many hands are on the controls, it is almost remarkable that this was ever accomplished. With the loud voices of industry and environmentalists, Congress is sure to hear two very different sides on this inherently ambiguous issue, and anything less than a perfect scientific answer is sure to seed the process with the personal biases and convictions of the decision-makers. In addition, although allowed wide discretion, agencies often stand helpless to correct a legislative mistake. As was seen with the Delaney Clause, an attempt to undo some of the unintended side effects of a legislative mandate can be met with a court order, courtesy of one side of a cause or the other. To make matters worse, these issues often have more than two sides, with the majority of the debate taking place somewhere in between.

Although the twisted road that has been pesticide regulation appears to be straightening out, one wonders if a “final fix” will ever be possible, given the constant creation of new types of pesticides and new applications for them.

APPENDIX A: Comparison of Sections 409 and 408

SECTION 408	SECTION 409
Safety standard specifically prohibits approval of substances that cause cancer by ingestion (Delaney Clause); otherwise, discretion is left to the agency to determine safety. Constituents policy allows substances to be approved that have carcinogenic impurities as long as the food additive, per se, is not carcinogenic.	Safety standard specifically mandates consideration of several factors, e.g., cumulative exposure from the same and related substances, special safety factors to account for increased risks to children, and consideration of endocrine effects.
No statutory reevaluation is mandated.	Within ten years all existing tolerances must be reevaluated under the new safety criteria noted above
Safety data become public.	Safety and efficacy data become public but with limitations intended to prevent use of the data for foreign approvals and data compensation applies to subsequent applicants that have not generated their own data.
De minimis levels (assuming they are not already exempt by virtue of general recognition of safety) may be exempted from regulation; a codified threshold of regulation policy applies to applications that result in dietary exposures of less than 0.5 ppb in the daily diet.	Exemptions from tolerance may be issued where residues are safe at all expected levels or are expected to be trivial. This is not an exemption from the need for a regulation, just an exemption from the need for a specific quantity limitation on specific foods.
Regulations applicable to antimicrobials generally define conditions for use that will not create unsafe residues based upon conservative assumptions defined in the petition seeking approval.	Traditionally, tolerances have focused on the need to quantify residues and develop validated analytical methods to detect the residues. Enforcement of tolerances is independent of whether the pesticide was properly used in accordance with its directions.

Food cannot be adulterated as a result of use of an additive in accordance with a food additive regulation.	Food is automatically adulterated, notwithstanding use of a pesticide in accordance with its labeling, unless an applicable tolerance or exemption from tolerance has been promulgated.
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Reprinted from John Dubeck, “Jurisdiction Over Antimicrobials”, *supra* note 86.