

Food Quality Protection Act of 1996: Background reading for slide set

1 Title slide

Food Quality Protection Act (FQPA) was passed in July 1996, signed into law on August 3, 1996.

2 FQPA was passed unanimously by Congress

FQPA was passed with broad based support from industry, ag commodity, environmental and health interests. FQPA featured “something for everyone”.

3 FQPA was intended to ...

For industry, agriculture, and commodity groups, FQPA was supposed to *fix the Delaney Clause*. The Delaney Clause was passed in 1958 - it mandated a zero tolerance for potential carcinogens in processed food. Delaney attempted to address the possible link between some pesticides and human cancer. However, it soon produced problems. It did not hold raw foods to the same standard as processed foods. Hence, the Delaney Paradox - a pesticide that could not legally be found in processed foods under Delaney could still be used on the raw commodity. Another problem was that detection of pesticides improved greatly since 1958, making a “zero tolerance” difficult to meet. EPA historically did not enforce Delaney, but in the 1990s was sued by environmental groups. EPA lost, and began enforcement action against pesticides which violated Delaney. Examples of pesticides affected by Delaney were acephate (Orthene), atrazine, benomyl (Benlate), carbaryl (Sevin), mancozeb (Dithane), metolachlor (Dual), and permethrin (Ambush, Pounce). Thus, when FQPA was written to include a “Delaney fix”, many commodity groups, farm organizations, and chemical manufacturers supported the proposed law.

The other major goal of FQPA is to *protect infants and children from pesticides*. A 1993 report by the National Academy of Science examined pesticides in the diets of infants and children, and pointed out that children are not small versions of adults; they are growing and developing, and therefore have different physiology than adults. The study speculated that some pesticides might have a greater impact on children. It concluded that food tolerances for pesticides should be lowered to account for potential differences in sensitivity of children, and that exposure through means other than food should be considered.

Finally, FQPA addresses *endocrine disruption*. In 1996, the book “*Our Stolen Future*” was published. This book dealt with endocrine disruptors, compounds which mimic or block hormones, or affect hormone producing tissues. It chronicled human health problems linked to endocrine disruption, as well as alleged developmental and reproductive effects on wild and domestic animals. It also listed actions that could be taken to protect humans from endocrine disrupting compounds, including making testing for endocrine disruption part of the pesticide registration process.

4 FQPA amends the two most important laws regulating pesticides in the U.S.

1) the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which sets guidelines for pesticide registration, classification (general versus restricted), and use, as well as applicator certification and 2) the Federal Food, Drug, and Cosmetic Act (FFDCA), which regulates the setting of tolerances for pesticides used on food crops. The Environmental Protection Agency is responsible for interpreting and implementing FQPA.

5 Amendments to FIFRA

FQPA makes several changes to FIFRA. Some of the more important changes are:

Periodic reregistration of pesticides: Under FIFRA, all pesticides must be registered with EPA. In the past, pesticides remained registered “forever”, without any reexamination of safety or efficacy data. In 1988, Congress amended FIFRA so that EPA would review all pesticide registrations over a 10 year period. Now under FQPA, periodic reregistration of pesticides will continue on an cycle to routinely examine new health, safety, or efficacy data.

Reduced risk pesticides: The EPA has developed a category of reduced risk pesticides. Pesticides which are considered safer will fall into the category and will be reviewed at a faster pace by EPA.

6 Change in minor use definition:

In the past, a *minor use pesticide* was one used on a crop grown on less than 300,000 acres. That definition is now expanded. A pesticide used on a major crop can be considered a minor use if it is not being supported by a company, but

- i. is the only effective alternative,
- ii. is safer than other alternatives, or
- iii. is important for an IPM program or for resistance management.

Under this new definition, even major crops like corn or soybean could support minor uses if the appropriate criteria are met. Also, FQPA contains incentives for companies to develop and maintain registrations on minor crops.

7 EPA has classified 28 U.S. crops as major.

EPA recently classified 28 U.S. crops as MAJOR, based on acreage. Twenty of these are grown in Michigan. It is not clear if crop classified as “major” would be eligible for the minor crop incentives mentioned above.

8 Changes to FFDCA: FQPA “fixes” the zero tolerance standard

The changes to FFDCA are more complicated. Delaney is Dead, i.e., FQPA repeals the Delaney Clause for pesticides. Instead, the zero tolerance standard for Delaney pesticides is replaced with a new uniform standard that fundamentally changes the way pesticide tolerances are set in raw and processed foods.

9 New standard

The new standard for setting residue tolerances is a that tolerances must be “safe”, i.e., tolerances must “provide a reasonable certainty that no harm will result from aggregate exposure”. ALL tolerances for pesticides on food crops must to be reviewed using this new standard over the next 10 years. This means EPA must reexamine approximately 9,700 individual tolerances (for example, Guthion on apples, Dithane on potatoes, atrazine on corn) by 2006.

10 Schedule for reviewing tolerances

EPA’s assessment schedule for tolerances calls for examining 33% within 3 years, 66% within 6 years, and 100% within 10 years. EPA will take a “Worst First” approach, that is within the first 3 years (by August 1999), it will review the tolerances of pesticides it considers to be of greatest risk, particularly to children. The pesticides EPA will review first are:

- *organophosphates (OPs)* - OPs are structurally related to nerve gas; they are neurotoxins which inhibit the enzyme cholinesterase in the nervous system of animals, including humans. OPs include such insecticides as Diazinon, Dursban, Guthion, Lorsban, malathion, and Orthene.
- *carbamates* - Many carbamates (although not all) have a similar mode of action as OPs. Hence they may also quite toxic to humans. Carbamates include insecticides like carbofuran (Furadan) and carbaryl (Sevin), plus fungicides like benomyl (Benlate) and herbicides such as desmedipham and phenmedipham (Betamix) [the later are apparently not cholinesterase inhibitors].
- *B2 (“probable human”) carcinogens* - The EPA has a classification system for carcinogens. A type A carcinogen, like asbestos, has been conclusively linked to cancer in humans. B2 carcinogens are those which cause cancer in lab animals (usually at very high dose levels), but human evidence is lacking. EBDC fungicides like Bravo and Dithane, plus several herbicides, are classified as B2s.

The Risk Cup

11 EPA’s method to explain tolerance setting: the Risk Cup

EPA has used the analogy of a “Risk Cup” to explain the new way of setting tolerance under FQPA. The *Risk Cup* is filled with the acceptable daily exposure to a given pesticide. In other words, it contains the amount of pesticide you could be safely exposed to every day, for 70 years, without a significant health risk. This includes acute (short term - for example neurotoxicity) and chronic (long term, for example organ damage or immune suppression) risks.

12 Individual risk cups

In the past, when setting a residue tolerance, EPA considered each pesticide/crop combination separately. In other words, there were many risk cups, one for each individual pesticide/ crop combination. (for example, a tolerance for Guthion on apples, Counter on corn, and Lorsban on peppers)

13 Common mechanism of toxicity

Under FQPA, EPA must now consider together compounds with a *common mechanism of toxicity*, that is, pesticides with the same mode of action in your body. In other words, there is a single risk cup for pesticides that have the same effect on people.

14 Common mechanism example, OPs

For example, organophosphate insecticides inhibit the enzyme “cholinesterase” in the human nervous system. A scientific panel advising EPA recently made the decision that all OPs indeed work the same way in the human body and thus have a “common mechanism of toxicity”. Under FQPA, all 39 OPs will be considered together for purposes of setting a residue tolerance - they will all effectively be in the same risk cup. There will be other common risk cups for other groups of pesticides.

15 Dietary exposure

In the past, when setting a residue tolerance, EPA considered only exposure to pesticides in your diet. In other words, the risk cup contained only the residues on food.

16 Aggregate exposure

Under FQPA, EPA must now consider *aggregate exposure* to pesticides from dietary and non-dietary sources. In other words, the risk cup contains residues from all sources - food, water, pets, turf, garden, household uses, and more. This means that although tolerances apply only to pesticides used on food crops, pesticides that have non-food uses will count for purposes of setting the food tolerance and will compete with food uses for space in the mythical risk cup! In fact, non-food pesticides will also have to provide additional data on aggregate exposure when they come up for registration, especially if they have a high risk of exposure to children. Although EPA has not made a final decision on how to partition the risk cup, it has said room in the cup will be allotted roughly by thirds:

- 1/3 dietary exposure (food)
- 1/3 environmental exposure (air, water)
- 1/3 non-dietary exposure (residential, ornamental, pet, etc.)

17 Aggregate exposure example, chlorpyrifos

Chlorpyrifos is a commonly used organophosphate. It is sold under the trade name Lorsban for field and vegetable crops, and Dursban for pet, household, and ornamental uses. Under FQPA, all uses and possible exposures to chlorpyrifos - food, water, air, turf, household, ornamental, pet, - must go into the risk cup.

18 Original safety factors

In the past, when EPA set a residue tolerance, it added safety factors to make sure the tolerance was safe. The safety factors, usually ten-fold, were used to account for testing of pesticides in lab animals, not people, and to account for potential differences in susceptibility among individuals. This meant that the tolerance was set at a level at least 100 (10-fold times 10-fold) to 1,000 times lower than the level found to be safe in animal tests.

19 Now, EPA must consider infants and children

When setting a tolerance, EPA must now consider infants, children, and even other sensitive population subgroups (for example, pregnant women). In order to ensure these groups are protected, EPA can require up to an additional 10-fold safety factor on existing tolerances. This is sometimes referred to as “10x”. The additional safety factor is applied in cases where there is little or no data on the potential impact of a pesticide on infants and children. The result is that tolerances may now be set at a level 1,000 to 10,000 times lower than the level found to be safe in animal tests.

20 List of priority crops:

EPA has released a list of the top 20 crops in the diets of infants and children. It includes both major and minor crops, plus meats. Pesticides used on these 20 commodities will be particularly vulnerable to FQPA actions, for example, application of the additional safety factor.

21 Pre and Post FQPA

In summary, FQPA will fundamentally change the way EPA sets tolerances for pesticide residues in food. Before FQPA, there was a single risk cup for each pesticide/ crop combination. That cup included only dietary exposure. After FQPA, multiple products that have a common mechanism of toxicity go into the same risk cup. The cup gets crowded, and tolerances for the individual pesticides in the group get smaller. The provision for considering aggregate exposure means that all uses of products with a common mechanism, dietary as well as non-dietary, go into the same risk cup. The cup gets even more crowded, and room for food uses gets smaller. Finally, if an additional safety factor for children is added, this reduces the size of the risk cup, potentially by a factor of 10.

Other provisions of FQPA

22 Endocrine disrupters

An endocrine disrupter is a compound that mimics or blocks a hormone, affects hormone producing tissues, or disturbs a hormone target site. Endocrine disrupters therefore can impact normal hormone functioning and body processes, and result in developmental and reproductive problems. Famous examples include DDT, which impacted bird reproduction (i.e. thin egg shells in birds like eagles and falcons), and thalidomide, an anti-morning sickness drug given to pregnant European women in the 1950s and 1960s that caused terrible birth defects.

23 Endocrine system

The endocrine system is a group of organs in the body, for example the thyroid, pituitary, thymus, ovaries, and testes, that secrete hormones directly into the blood stream. The hormones move to target cells in the body and influence development, reproduction, and metabolism at incredibly low concentrations.

24 List of hormones

Some better-known human hormones are listed here.

25 Screening for endocrine disrupters

Under FQPA, EPA must develop a program to screen **all** pesticides (food or non-food use) and inert ingredients for endocrine disrupting effects. A blueprint for the screening program must be developed by August 1998, and the program itself must start by August 1999. No standard laboratory protocol is currently available for detecting and evaluating compounds for endocrine disruption. It is expected that the emphasis will be on estrogenic effects, and that the testing programs will use both cell culture and lab animals.

26 Pesticides with endocrine effects

Some currently registered pesticides with known endocrine effects are the following:

- endosulfan, an organochlorine insecticide, related to DDT, that mimics estrogen (the female hormone);
- vinclozolin, a fungicide which may be an anti-androgen (i.e. interfere with steroid hormones that effect male development);
- atrazine, a commonly used herbicide, that may disrupt reproductive cycles.

27 Consumer right-to-know

Under FQPA, EPA must develop a brochure that informs consumers about pesticide risks and benefits. The brochure must also explain ways to reduce exposure to pesticide residues in food, for example, by peeling and washing produce. The current draft version of the brochure also gives information on government efforts to protect consumers and on organic standards. The brochure is targeted for distribution in large retail grocery stores, and must be completed by August 1998. FQPA does not, however, mandate where or even if the brochures are displayed once they reach the grocery store.

Impacts

28 Potential Impacts of FQPA: Section 18s

Section 18s, emergency exemptions granted by EPA to use a pesticide on a crop for which it is not registered, have been changed under FQPA. A tolerance (usually time-limited) is now required for the proposed Section 18 pesticide on the crop of interest. Registrants and states must gather additional data to support the time-limited tolerance. This means Section 18s may be more difficult, or take longer, to obtain. At the same time, FQPA may generate more Section 18 applications. If products or uses are removed from the market (see below), there will be fewer registered options for growers, especially in minor crops. This could increase the number of Section 18 requests for these commodities. This scenario is already happening. In Michigan, the number of Section 18 requests in 1998 is 17 - seven more Section 18s than in any previous year.

29 Potential Impacts of FQPA: label changes

In order to mitigate the risk of its pesticide, a company could make changes in product labeling or use patterns to reduce residues. These changes might include reducing the use rate or number of sprays, reducing the amount of active ingredient, increasing preharvest interval, or changing the formulation or application method. The end goal is to reduce the overall residue level at harvest, in turn reducing dietary exposure to the pesticide.

30 Make room in the cup by making label changes:

Using the risk cup analogy, label changes could reduce the size of each use in the cup, creating room for more uses. However, only so much risk can be mitigated through label changes - significant reduction in the contents of a risk cup still will probably require elimination of uses and registrations.

31 Potential Impacts of FQPA: minor and specialty uses

Michigan economically depends on major crops like corn, as well as dozens of minor crops. One of the major concerns of FQPA is that registrants will be forced to choose between major and minor crops as FQPA is implemented, and that registrations on minor and specialty crops will be dropped. This would have the effect of eliminating OP, carbamate, or B2 residues from certain minor crops, especially fruits and vegetables.

32 Make room in the cup for registrations with greater return

Using the risk cup analogy, when a cup is full and overflows, products or uses must be removed. Uses with greater economic return for a pesticide manufacturer (such as corn, cotton, soybean)

would be retained. Specialty uses would be dropped to create the necessary room in the cup to keep the more profitable registrations. Food and non-food specialty uses would both be affected.

33 Potential Impacts of FQPA: eliminate certain classes

The most serious potential impact of FQPA could be the loss of entire classes of pesticides. The most likely classes to lose many registrations in the next several years are - organophosphates and/or carbamates due to toxicity concerns, EBDC fungicides, which are targeted as B2 carcinogens.

This would have the effect of eliminating residue of these pesticides from food produced in the U.S.

Slides listing the pesticides of concern (OPs, carbamates, and B2 carcinogens) for a variety of crops:

34 Pesticides of concern: corn

- many of the OPs listed are important for corn rootworm control, necessary in most continuous corn production, and in some first-year corn (in areas where rotation-resistant western corn rootworm is present).

35 Pesticides of concern: dry beans, sugar beets

- OP and carbamate use in sugar beet in Michigan is generally low, but necessary in certain years to deal with problem insects. Dry bean producers in Michigan rely on dimethoate (Cygon) for potato leafhopper control.

- not included on the slide are the carbamate herbicides desmedipham and phenmedipham (combination = Betamix) commonly used in sugar beet production. They are apparently not cholinesterase inhibitors, but are on EPA's list for tolerance reassessment by August 1999.

36 Pesticides of concern: vegetables

- OPs and carbamates are often needed, especially before harvest, to kill insects. Growers must usually meet high standards of processors and grocery stores, and consumers who want vegetables free of insects and insect damage. The fungicides listed as B2s are not only important during the field season, but make it possible to store produce for long periods post-harvest.

37 Pesticides of concern: fruit

- similar to vegetables, OPs and carbamates are sometimes needed late season for maggot control, and to meet high standards of processors and grocery stores. Consumers again demand perfect fruit and no insects. Fungicides are very important pre- and post-harvest.

38 Pesticides of concern: blueberries

- Michigan is the top producer of blueberries in the U.S.. Blueberry maggot is of great concern to growers, and there are few options (all OPs) for maggot control.

39 Pesticides of concern: Christmas trees

- Michigan is one of the top states for Christmas tree production. A number of OPs and carbamates are used for insect control, particularly to meet federal quarantine guidelines before the trees can be shipped out of the state (for example, gypsy moth and pine shoot beetle).

40 Pesticides of concern: mosquito control

- There a number of non-OP, non-carbamate options for mosquito control, including Bt and IGRs (insect growth regulators). Under FQPA, however, public health considerations are allowed, meaning that under threat of mosquito-borne illness, uses of certain OPs or carbamates might be retained. However, the concern is that if all other uses are canceled, manufacturers cannot or will not bother to retain production lines for a small public health market.

41 Pesticides of concern: turf

42 What does EPA need?

EPA needs accurate data on pesticide use to make sound decisions about pesticide registrations and tolerances. Data needs include crops treated, acreage treated, products used, rates, number of applications, efficacy of the product, predicted crop loss without each pesticide, and availability of alternative control measures. When EPA has little or no data about the use of a pesticide in a crop, it will use worst-case default assumptions to make decisions, i.e., it will assume the pesticide is used on all acreage at the highest rate, with greatest number of applications, and shortest preharvest interval.

43 Default vs. actual OP use

An example of the use of default assumptions was developed by Phil Korson of the Michigan Cherry Marketing Institute. White bars on the graph show the pounds of OP active ingredient predicted by default assumptions of maximum use in tart cherries. The pink bars show actual OP use by Michigan tart cherry growers, based on pesticide use survey data. Obviously OPs are occasionally necessary to control certain pests in certain years. But if EPA default assumptions are used, tart cherries would take up an unreasonable amount of room in the OP risk cup.

44 Political Considerations

Some things to consider when responding to FQPA:

- *EPA is under tremendous pressure.* Remember, Congress wrote and passed FQPA, then gave it to EPA to interpret and implement. FQPA includes a tight timeline for implementation - August 1999 is the first important deadline. There has been the threat of legal action from both environmental groups (EPA is moving too slow) and commodity/ chemical manufacturers (EPA is moving too fast).
- *GPRA*, the new Government Performance and Reporting Act, requires federal agencies to show concrete results. This means that EPA has an additional burden to make measurable decisions and report impacts of these decisions back to Congress.
- *Public perception.* Most people have no background in farming, and have little idea of what farming involves. The result is that the public expects plentiful, cheap, pest/damage-free food, and zero chance of pesticide residues.
- *kids kids kids.* The bottom line for FQPA is that it was passed with the goal to protect infants and children from pesticides. Obviously this is a very emotional issue that cannot be argued against.

45 What can pesticide users do?

Don't misuse or overuse pesticides; use them only when necessary and follow label directions. Keep accurate records of actual pesticides use, and assist your commodity group or state extension personnel in filling out surveys about pesticide use. This is your chance to give EPA accurate data. Stay informed about the progress of FQPA through your state extension service, commodity groups, or farm organizations.

46 Take Home messages:

- *Support the original intent of FQPA*, which is to protect infants and children, and make our food supply safer. It is impossible to argue with such goals.
- *Open the FQPA process* - EPA must allow everyone who may be affected by FQPA to participate in the process. Growers especially must be given a chance to explain why and how they really use pesticides.
- *Base decisions on good science*. Collect the best pesticide use and residue data possible, and use this information to make decisions, instead of default assumptions.
- *Provide time* - in order to collect use and residue data, states and commodity groups need time and assistance.
- *Alternatives* need to be in place before many OPs, carbamates, and B2s are withdrawn from the market. In many minor crops, there are few viable alternatives available. Canceling OPs and carbamates without alternatives could lead on reliance on a single chemical group, for example, pyrethroids, which could in turn lead to problems like resistance. Or, if no viable alternatives are available, many growers may go out of business. This could lead to concentration of production in a single region (look at the lesson of El Nino in California) or increased reliance on imported food that may actually have residues of the same products we wanted to keep out of U.S.-grown produce. It takes time and money to develop such alternatives, so there must be emphasis at the federal level in funding for research.

For more information

- Complete FQPA text: www.pestlaw.com/law/HR1627.htm
- EPA's FQPA web page: www.epa.gov/oppppspl/fqpa/
- MSU web site: whalon.prc.msu.edu

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