

**"KEEPING CHEMICAL TOOLS  
IN THE PIPELINE"**

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**Visual #1: Keeping Chemical Tools in the Pipeline**

Thank you and good morning. I sincerely appreciate the opportunity to address the concerns and challenges cotton producers and crop protection companies mutually face today with the shifting regulatory scene in Washington. Central to this theme is the threat of implementation going awry with the 1996 Food Quality Protection Act -- or FQPA, as it has become popularly known.

Fortunately, we stand together and with many other production ag allies in facing the challenges posed by FQPA. These alliance relationships are not new; they are time tested through working closely for over 8 years to reform the Delaney Clause; and over 10 years of work together on agricultural water quality policy. By continuing to hang together, and with hard work, I am confident that our food and ag coalition interests will persevere.

Nowhere is there better evidence of the strength and internal trust of our food and ag alliance than in the relationship between ACPA and the Cotton Council. Your Washington staff and my team at ACPA are in constant contact. John Maguire and Carla West are respected partners throughout the Washington Ag Community. We work closely with Phil Burnett and Andy Jordan in Memphis.

Of course! Cotton is important to my industry. You are a \$1 billion business for us in the USA, our largest insecticide market, and in 1996 were 13.7 percent of our total sales. Not only do you produce a great product in the course of using our technology, you are leaders in environmental Stewardship, IPM use, and resistance management innovation. Our partnership and trust history runs long and deep.

I'd like to touch on some issues in addition to FQPA, but will devote most of my time on this preeminent issue.

What is the nature of the FQPA challenge? Perhaps it is put into perspective by the 1997 story of Terry Downs of Twin Falls, Idaho, and his now infamous school science fair project.

Terry won first place when he showed how conditioned we have become to alarmists practicing junk science and spreading fear of everything in our environment.

His project urged people to sign a petition demanding strict control or total elimination of the chemical "Dihydrogen monoxide." The student gave plenty of good reasons, since:

1. It can cause excessive sweating and vomiting;
2. It is a major component of acid rain;
3. It can cause severe burns in its gaseous state;
4. Accidental inhalation can kill you;
5. It contributes to erosion;
6. It decreases effectiveness of automobile brakes; &
7. It has been found in tumors of terminal cancer patients.

Of the 50 people the student asked to support the ban of the chemical, 43 said yes, six were undecided ... and only one knew the chemical was water.

Appropriately, the title of the prize winning project was "How Gullible Are We?"

EPA's implementation of the new food quality law has already tested the limits of ...how gullible we are.. yet the really BIG decisions under the new law are still to come. This law directly affects the crop production tools which you and your fellow growers will have available for years to come. The decisions to be made, whether based on sound science or not, will determine the number and types of pesticides you will be able to use.

**Visual #2: Requirements**

This sweeping law (the most comprehensive pesticide law since the early 1970s) substantially changes the way pesticides are evaluated for health effects. For example, rather than meeting the earlier standard "adequate to protect public health," the new law sets a standard which assures that a pesticide tolerance will pose a "reasonable certainty of no harm." As you likely know, a tolerance sets the amount of a pesticide normally measured in parts per million--that can legally be present on or in a harvested crop.

When evaluating and setting tolerances, new requirements for extended safety of infants and children are included in the Act. In certain instances, an added, ten-fold uncertainty factor may be set in computing the safe level of exposure for children.

Those working in the food and fiber ag coalition, saw long-term benefits in the broad-reaching legislation, such as removal of the unworkable and outmoded Delaney Clause. Under Delaney, pesticide residues in processed foods were considered "food additives" and subject to outdated food

and drug laws related to any detectable residue of an animal carcinogen. Strictly applied, Delaney threatened the registration of more than 30 essential crop protection products. Under the new Act, pesticides are excluded from The Delaney Clause.

### **Visual #3: Other Major Requirements**

In exchange, EPA must now consider aggregate exposure to a pesticide, including both dietary and non-dietary exposures, such as drinking water, household, and lawn and garden uses. The non-dietary exposures must be allotted a share of the maximum allowable exposure level.

Historically, when setting a tolerance, EPA examined each pesticide individually, one crop or use at a time, allowing additional uses to a label until reaching a maximum allowable exposure. Under the new Act, EPA must examine groups of pesticides based on whether such groups share a common mechanism of toxicity. In other words, groups which act in a similar way in the human body, must now share a single, collective maximum allowable exposure limit. It is widely suggested, for instance, that many organophosphate insecticides could end up sharing one "risk cup" and thus many crop uses could be threatened.

Also, EPA must develop new toxicology testing and screening for potential endocrine system effects.

To be sure, virtually all the new requirements of FQPA were evolving in regulatory practice, and reflected emerging scientific knowledge. But FQPA has placed a whole new spin on things.

### **Visual #4: Impact**

Although our coalition appreciates the benefits of the Food Quality Protection Act, we also are keenly aware of the massive undertaking involved in EPA implementation, given the extremely complicated science and short time frames. Since the law did not provide a transition period for phasing in these major regulatory changes, its impact is both simultaneous and immediate: the full force of law is brought to bear on what had been a steady and sure scientific and regulatory process.

Actually, there is precious little that is new in the Act, or which had not been proposed. But the fact that so much is required of EPA and industry, virtually overnight, places valid science and regulation at risk and opens up many opportunities for "political mischief." Add to this the extraordinary expectations of many in the environmental activist community, and you have a political time bomb that is ticking towards a very real disaster for production agriculture.

We have a choice: Do we want a Delaney "deja vu" where EPA and agriculture are saddled with unworkable

regulation, or do we want to make sure that the best science and most up-to-date information is used to stay on a straight track?

### **Visual #5: Pre-Food Quality Protection Act**

To help understand the changes brought about by FQPA, think of the exposure that can be safely allowed for a particular pesticide as filling a cup, what we have come to call in FQPA parlance, the "risk cup." The risk cup holds the total amount of daily pesticide risk that will not affect a person's health over a lifetime. Each tolerance for residues of a pesticide on a food crop adds a certain amount to the risk cup for dietary exposure. Before the Food Quality Protection Act was passed, each pesticide had its own risk cup which held the risk only from use on food crops - in this case, shown on the accompanying slide, from corn and apples. (By the way, cotton is affected by pesticide food tolerance decision making because of cotton seed oil in the human diet plus residue potential from some cotton crop by product livestock feed uses.)

### **Visual #6: Aggregate Risk Assessment**

Under FQPA, the risk cup must make room not only for residues in food, but also for any residues that may occur in drinking water, and from pesticide uses in and around the home. This is the concept of "aggregate exposure" to residues from different sources.

This new requirement creates an urgent need to generate timely and accurate dietary and non-dietary exposure data to demonstrate the safety of pesticides as part of the regulatory decision process. In the absence of such data, so-called "default" assumptions may be used to assign risk values for non-food exposures. As you can easily guess, these assumptions don't come close to reflecting real-world scenarios.

### **Visual #7: Residential Use Patterns**

For example, this graph for a major cotton insecticide compares residential exposure based on actual scientific data with theoretical EPA estimates for broadcast, crack and crevice, liquid turf and granular turf pesticide use. Look at the difference. It's huge! If residential assumptions grossly overestimate actual exposure, there won't be much room in the risk cup for food and other agricultural uses.

### **Visual #8: Cumulative Risk Assessment**

Furthermore, the FQPA requires that, if different pesticides act on human health by the same mechanism of toxicity, they must share the same risk cup. Trouble is, the ways to evaluate such common mechanisms and apportion the risk cup allowance among pesticides have yet to be worked out.

What's more, if data regarding health effects or exposure involving infants and children are not yet complete, EPA may use an additional safety factor in risk assessment, further reducing the amount of "risk" in the cup.

All these factors tend to reduce the amount of "risk" that is available for use of the pesticide on crops. This is why it is so important that we have accurate data and information with which to estimate exposure. We can ill afford to lose important pesticide uses because of unreasonable, unrealistic exposure estimates.

You might ask: if the new requirements in the law are fair and can be scientifically applied, AND the pesticides were safe under former requirements, why wouldn't the new standards apply? We agree that they should but contend that more time and information is needed to fairly comply with the new provisions. Safety testing and exposure data previously assembled to gain registrations and tolerances do not always or completely fit the new law's requirements.

A lot to absorb? You bet it is! The law's mandates fell on an EPA Office of Pesticide Programs woefully short of professional staff to handle such an influx on such short deadlines. Additional staff was a must, and the Agency has been scrambling to add competent professionals. Also necessary are new science and testing methodology, whose development and validation are required from both government and industry. This is a process normally measured in years, rather than months.

#### **Visual #9: Rush-to Judgement Effects**

Unfortunately, in the absence of current data and actual farm use information, EPA's decisions on pesticide use are being based on overly conservative assumptions even though there is specific new authority for the collection and use of accurate data in FQPA.

If FQPA continues to be implemented in this hasty manner, it is likely that there will be an unnecessary decrease in the number of effective, efficient pesticides available for farmers. Crop yields and farmer income will be in jeopardy. This is a very real concern for my industry, as well as for the National Cotton Council and other food, agriculture and commodity groups. That is why we are working together in a grand coalition to see that EPA does the right thing.

#### **Visual #10: Other Rush-to-Judgement Effects**

The potential loss of critical pesticides may prevent many farmers from fully practicing Integrated Pest Management and other conservation efforts, to the detriment of the overall environment. Bad FQPA decisions threaten to dramatically increase pest resistance management challenges.

It also could discourage development of future, more effective and more environmentally friendly crop protection products. Major new, innovative pesticide registration decisions have already suffered a serious slow down from FQPA direct and indirect effects. We surveyed ACPA members in January of '97 and discovered 37 new products and 131 new uses in limbo due, in part, to FQPA slow downs. That's 2 to 3 billion dollars of U.S. agriculture assets idling!

And, foreign farmers--who could choose from an array of crop protection products no longer available to U.S. producers--even though full science review would prove them safe--would enjoy a decided, competitive edge over American farmers. You see, use of the vast majority of pesticides in production agriculture results in no detectable residues in the commodities that are harvested -- so farmers elsewhere would technically comply with import restrictions while producing commodities using pesticides U.S. farmers could no longer employ! Surely this is not what Congress intended with the Food Quality Protection Act! Our efforts should enhance, not limit, U.S. crop production and encourage our agriculture exports to assure the number one competitive position American farmers have earned through their "blood, sweat and tears" in world markets.

#### **Visual #11: Status**

PA is deciding now which pesticides and pesticide uses will remain available, and which will not. Meanwhile, requests to EPA for emergency or alternate pesticide crop uses are being delayed or turned down, even when severe pest outbreaks occur. Just witness the experience of California cotton growers in the past two summers, when faced with severe aphid infestations.

A note on the issue of Section 18 requests: During a recent meeting of EPA's Pesticide Program Dialogue Committee--an advisory group on which I serve, along with others in agriculture and other stakeholders--Jean Marie Peltier of California's Department of Pesticide Regulation presented a common-sense solution involving a legitimate, scientific default mechanism to handle such matters. Instead of EPA taking immediate action on the proposal, the well-developed idea was shelved, postponing any relief for at least another growing season.

#### **Visual #12: Some Cotton OPs May Be Affected**

In a recent paper, Leonard Gianessi, widely respected economist at the National Center for Food and Agricultural Policy and a consultant to EPA, outlines a very real problem for EPA, farmers and industry. He notes that the task Congress handed to EPA under the Food Quality Protection Act, is practically impossible: To reassess all of the U.S. pesticide tolerances "more than 9,000" within 10 years, with

just one third--that's more than 3,000--by August 1999. That's less than 20 months from now!

EPA has announced that it will look at the riskiest chemicals first, for which there are about 1,500 tolerances. This group includes the organophosphate insecticides, used widely to control cotton pests, as well as many insects that attack fruit, vegetables and other essential crops. There are few or no effective alternatives to these insecticides, many of which you depend on to protect your cotton. Gianessi notes that perhaps 50 percent of the uses, or tolerances, for the organophosphate insecticides could be dropped by EPA if current "real world" data are not considered in the risk assessment process. Carbamate insecticides follow the OPs on the EPA's timetable, and face many serious challenges if, again, newly assembled and formatted data cannot be presented before final decisions by EPA are rendered.

### **Visual #13: Requirements strict, but workable if:**

As mentioned, under FQPA and its expanded requirements, all pesticides-- including those for home and garden and for public health protection--must be reevaluated for safety.

The requirements are strict, but workable:

- IF EPA and industry are allowed to develop needed scientific methodology and data;
- \* IF decisions are based on actual pesticide use and exposure, rather than on "defaults" and "worst case" assumptions; and,
- IF EPA sets scientifically practical policies and time lines for consistent implementation.

Congressional backing is needed to convince EPA that this is the road to follow; that accurate exposure data must be developed to support sound, science-based decisions regarding pesticide tolerances and uses. These decisions, and the approach EPA takes to making them, are critical to you and to the crop protection industry.

### **Visual #14: What is Being Done**

Currently, EPA and individual chemical companies are conducting risk assessments for organophosphate insecticides. Use patterns are being determined and available exposure data are being examined.

Our food and fiber agriculture coalition is hard at work telling Members of Congress and their staffs of the problems inherent in EPA's haste to meet FQPA's deadlines for tolerance reassessment. The allies are striving to achieve a common--and common-sense goal: To assure that EPA uses the best scientific data based on actual pesticide use and current cropping information.

Is this self interest for my industry? Certainly! But also for your interests and the interests of all producers and growers

who rely on effective, efficient, dependable crop protection technology. And, ultimately, it is in the best interest of the American food consumer.

FQPA is 16 months old. My industry accepted it when it was passed. We accept it now. The fundamentals aren't new--human health and safety, aggregate risk, common mechanism, endocrine assessment and extra margins of safety to protect children. Those are fundamentals we have supported. And, we firmly back making the best science better, but believe strongly that we must do so deliberately, using the best, most realistic data possible.

### **Other Issues**

In addition to FQPA there are two other major and connected issues I want to mention.

First is the exciting new development we know as biotechnology. These innovations offer some of the most useful and profitable opportunities for enhancing production agriculture we've seen in a generation or more. Not every biotech innovation will work perfectly, and none will work in isolation. My industry needs to stop promoting biotech at the expense of convention pesticides. You need both in your tool kit. Growth in crop biotech is astounding. In the U.S. we saw biotech planted acres go from under 8 million in 1996 to about 30 million in 1997. Experts think sales will grow 50 percent per year globally -- from \$235 million in '96 to over \$1.8 billion in 2001. Yet at 1.8 billion in 4 years, biotech sales might only be about 5 percent of my industry's total sales. So, perspective is VITAL!

Biotech also presents us with new and profound public policy and public relations challenges. ACPA and the Cotton Council are working closely on those fronts -- both here in the U.S. and globally. Examples include work together on the EPA's on again-off again erratic approach to the cotton/bromoxynil tolerance -- an FQPA symptom... and outreach to USTR on European approval of safe, bioengineered commodities.

Second, a word on real economics. I'm keenly aware that the economics of cotton production are facing tougher times right now -- and all of you are seeking ways to cut costs. Some biotechnology solutions may appear to cost more, others may offer attractive financial rewards. Certainly, biotechnology in the soybean arena appears to be putting tens of millions back in the "farmers's pocket."

But remember that economic benefits occur when healthy competition exists. FQPA arbitrary decisions that do not reflect sound science can serve to reduce competition and drive up your input costs while reducing your crop protection choices. Growers falling in love with just one alternative, and abandoning other useful tools, can have similar effects. Balance and perspective in our business,

regulatory, and political relationships is almost always a good and healthy phenomenon.

#### **Visual #15: What You Can Do**

Along with your association and our other agricultural allies, we want to assure that needed crop protection products remain available to you. And my industry's ability to develop newer, safer crop protection products must also be preserved.

This is a challenging time, but it is an exciting time for all of us in agriculture as we near the new century. Let me assure you that I don't believe the sky is falling. There are solutions to our concerns over implementation of the Food Quality Protection Act, and they can be accomplished. But the coalition needs your help to do it! We need you to get involved in the political process. Make your voices heard, let Washington know about your concerns. The first step

to success is to work through your grower groups, like the Cotton Council. Remember there is strength in numbers!

Let's take a lesson from Terry Downs' science project. We don't have to allow the proponents of junk science, those who would scare us with stories of dihydrogen monoxide, killer water, to trump our sound science and our commitment to modern agriculture.

We can continue to provide abundance for American consumers and others throughout the world by working together to sustain the tools we must have for a profitable, highly productive agriculture. Thank you for your help.

#### **Visual #16: Keeping Chemical Tools in the Pipeline**

Now, if we have time for questions, or your comments, I would be more than happy to hear them.