EPA UPDATE

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FQPA - Pesticide Tolerance Reassessment and Reregistration

I'd like to start with a quick review of FQPA so that we're all familiar with some of the terms. I will make it brief. Then I will provide an update on three specific pesticides that we are still working on and then wrap up with what we are expecting in the near future.

Federal Pesticide Laws
EPA regulates pesticides under broad authority granted in two major statutes, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Food, Drug and Cosmetic Act (FFDCA).

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - requires all pesticides sold or distributed in the United States (including imported pesticides) to be registered by EPA. EPA can also authorize limited use of unregistered pesticides or pesticides registered for other uses to address emergencies (Section 18) and special local needs (Section 24c).

1. All label language must be approved by EPA before a pesticide can be sold or distributed in the United States. The overall intent of the label is to provide clear directions for effective product performance while minimizing risks to human health and the environment. It is a violation of federal law to use a pesticide in a manner inconsistent with its labeling. The courts consider a label to be a legal document.

Federal Food, Drug and Cosmetic Act (FFDCA) - Requires EPA to set pesticide tolerances for all pesticides used in or on food. A tolerance is the maximum permissible level for pesticide residues allowed in or on commodities for human food and animal feed.

The Food Quality Protection Act drastically amended both of these laws. FQPA was passed unanimously by both chambers of Congress in 1996.

Prior to FQPA, EPA only evaluated pesticide exposure through food. But, now, the Agency, under FFDCA, must consider several additional risk factors. These new risks are:

- Aggregate risk – is the sum of the exposures from food, drinking water, and residential uses;
- Cumulative risk is the sum of all exposures from classes of pesticides that produce similar effects in the human body;
- An additional 10X safety factor to account for increased susceptibility to infants and children, or other sensitive subpopulations. Prior to FQPA, EPA had used two 10X safety factors - one to account for the uncertainty of extrapolating animal toxicity studies to humans and the other factor for the variability among people in their reactions to exposure. So, if EPA determined that the safety threshold was say 3, they would divide by 100 and the tolerance level would be 0.03. With another safety factor for children that level would then drop to 0.003. Going from 3 to 0.003 is pretty significant and pretty conservative.
- The final consideration that FQPA added was whether the pesticide produces effects on the human or other animal hormone systems. This effect is called endocrine disruption.

FQPA also amended FIFRA and directed EPA to review the safety of all existing tolerances that were in effect as of August 1996 and to reregister all pesticides that were registered prior to November 1984.

FQPA mandated a timeline for EPA to complete the tolerance reassessments. Of the 9,721 existing tolerances, EPA was to reassess:

33% within 3 years (completed)
66% within 6 years (completed)
100% within 10 years (over 99% completed on schedule

In September 2007, EPA announced that it had completed the last of 9,721 required tolerance reassessment decisions. We came through this phase of FQPA fairly well. We had some products that required us to put up a good fight – like Def and malathion. But, we did not lose any critical products.
BUT, here's the rub …. Only in government can you complete a task and yet not be complete. There are still three compounds that we are still working on – carbofuran, MSMA, and endosulfan.

Carbofuran
Carbofuran is a systemic, broad spectrum carbamate insecticide. It is a restricted use pesticide. It is only registered for cotton use for in-furrow application for thrip control. It was not until 1992, after foliar applications were shown to effectively control aphids, that states began making Section 18 requests for carbofuran. The registrant, FMC, submitted a request for a Section 3 registration for foliar cotton use back in 1995 but EPA has never responded.
As you well know, the cotton aphid is a very prolific pest. Aphids can complete an entire generation growth cycle in as little as four days and a single female can over 130 aphids in less than 7 days. This rapid reproduction allows cotton aphids to develop resistance to pesticide treatments very quickly. The cotton aphid has developed resistance to all the primary pesticides – the organochlorines, organophosphates, and pyrethoids. Currently, the neonicotinoids are the primary treatment. But, 2006 field data indicate that aphids are building tolerances to these compounds as well.

Carbofuran is the only remaining efficacious treatment for aphid control. It is used by growers in limited circumstances when primary treatments fail to provide adequate control. This limited use pattern means that aphids do not have sufficient exposure to carbofuran to develop resistance.
On Aug. 30, 2006, EPA issued its Interim Reregistration Eligibility Decision –in which it proposed to cancel the majority of uses of carbofuran because of estimated risks in food and drinking water, to applicators, and to birds.
The Council has invested a lot of time and resources defending this product. We have worked closely with FMC, other ag groups, and USDA. On numerous occasions, we have met with EPA, provided data to them, and submitted comments.

In a very unusual move, Agriculture Secretary Ed Shafer sent a letter to EPA on behalf of Furadan. The National Association of State Departments of Agriculture also weighed in their support for this product.

On July 31, 2008, EPA proposed to revoke all food tolerances for carbofuran saying there is no safe level of exposure from any residue that may remains on foods, even though their own documents acknowledge there are uses that meet the standard for dietary risk. According to FMC, their conclusions are based upon conservative computer models.

This process by EPA is unprecedented. Normally, EPA will cancel both the tolerances and registrations at the same time. I believe that the agency is going this route because, under FFDCA, they do not have to address benefits to agriculture, only dietary risk. By using this procedure, they will leave farmers in a legal dilemma. The labels will still be intact. That means that legally a grower can still use Furadan. But, when he does, because there is no longer a tolerance, he adulterates his crop and it is illegal for him to market that crop.

EPA indicated in writing and in conference calls that it would be willing to consider subsets of uses for carbofuran that might fit into the risk cup. On Sept. 19th, NCC staff along with corn growers and the potato council met with EPA. It was apparent that the Agency was not going to make those considerations.

On September 29, 2008, FMC submitted a letter to EPA voluntarily cancelling uses on a number of crops including cotton. But the company also reiterated its intent to add cotton foliar applications to the label.
It looks like, at this point, that EPA will proceed to revoke the tolerances. FMC has said on numerous occasions that it will take that decision to court.

MSMA
MSMA is an organic arsenic herbicide that has been used for a long time in cotton production. MSMA is used as a

tank mix and has been shown to act synergistically to enhance the effectiveness of the mix on a wide spectrum of weeds including grasses, sedges, and morning glory. With the emergence of glyphosate resistant weeds, MSMA has become a critical tool for weed resistance management.

In the August 9, 2006 Federal Register, EPA published notice of its intention to cancel registrations for all organic arsenical herbicides including MSMA.

The manufacturers of these herbicides vigorously oppose cancellation and, if necessary, are prepared to file suit against EPA's proposal on the basis that:

- EPA has underestimated the organic arsenicals' unique benefits to agriculture.
- EPA has overestimated the toxicity of inorganic arsenic
- EPA has overestimated the contribution of MSMA to the levels of inorganic arsenic in the environment, specifically to water.
- The grounds for evaluating MSMA on the basis of characteristics of inorganic arsenic, which is a completely different form with a completely different toxicity, are scientifically inadequate, unjustified, and incorrect,

NCC has also invested considerable time in this product. We have gotten the help from Senate Ag Committee staff which is unusual. They tend to not get involved for individual chemicals and prefer to stick with policy issues. But, they have been willing to communicate with EPA on behalf of MSMA. NCC also helped to organize a field trip in July 2007 for EPA officials to go to GA to observe firsthand the problem of glyphosate resistance.

Our most recent communications with the manufacturers indicates that they have made some positive headway with EPA. I'll read from their document. "We are confident that MSMA will be available at least for the next several years, and our expectation is considerably longer. Current discussions with EPA are focused on what we define, for the lack of a better term, as a "time limited" registration, with the idea of a science review at the end of the negotiated period.

There is NO discussion of a phase out or cancellation of MSMA. However, EPA has invited discussion on several additional mitigation measures to further reduce the exposure to inorganic arsenic possibly resulting from the use of MSMA. The mitigation measures are targeted mainly at surface water."

The reason for EPA's apparent change of heart is the accumulation of data indicating that inorganic arsenic is a threshold carcinogen. Now that sounds really bad but it's actually good – for us. A threshold carcinogen means that exposure to low doses of arsenic should be of no health concern. A non-threshold carcinogen, on the other hand, means that *any* exposure might have the potential to cause cancer.

So, things are looking good for MSMA. At least we will have some time to find some effective alternatives for it if necessary.

Endosulfan

Endosulfan remains a critical tool for pest management by Arizona and California cotton growers despite introductions of major new chemistries over the last decade. It remains among growers' principal choices for whitefly and late season aphid outbreaks.

Endosulfan is also important for pest resistance management. Insect growth regulators (IGRs) are the preferred crop protectants against these pests. However, IGRs are limited in the number of applications per season and are typically restricted to early to mid-season use. To prevent the development of resistance, all options are necessary, particularly in heavily infested areas. Endosulfan provides the only non-organophosphate alternative.

The major issue for EPA now is worker exposure although there has been some speculation that endosulfan may be an endocrine disrupter. EPA has proposed cutting the rate in half and restricting applications to 600 acres/day. Dr. Peter C. Ellsworth, Director, Arizona Pest Management Center has been extremely helpful with this issue, providing EPA with tons of data and other mitigation proposals.

If nothing else, endosulfan may die by litigation. It has been targeted by environmental groups and it seems to me that endosulfan could die by litigation. Currently, there are three legal actions ongoing:

- a lawsuit that a coalition of labor and environmental groups, including NRDC, filed July 24 against EPA to force the agency to stop reregistration of endosulfan, pending further risk assessment
- In another action, EPA is being challenged for not assessing on endosulfan as an endocrine disrupter.
- NRDC has also petitioned EPA to revoke all tolerances for endosulfan over concern for exposure risks to mixers, loaders, and applicators of endosulfan as well as residues in the food of native Alaskans.

FQPA – Registration Review

What we've talked about so far could be called FQPA Phase 1. FQPA also amended FIFRA to mandate registration reviews every 15 years. So now, we're into FQPA Phase 2. Registration review will attempt to evaluate the registrations of 1,100 active ingredients and over 20,000 products within 15 years. EPA will begin with pesticides with non-food uses and then go on to food uses, grouping active ingredients with similar modes of action – e.g. the organophosphates and carbamates are both cholinesterase inhibitors.

EPA published its final rule for the registration review program in the Federal Register on August 9, 2006. The Agency has published a schedule for this review for the years 2008-2011.

It is my understanding that the registration review will not be as exhaustive as Phase 1. I believe that EPA will rely on previous assessment unless new data, testing methods, or other challenges arise. However, EPA has made it clear that two issues will play into this review – endangered species and endocrine disruptors.

Endangered Species

The Endangered Species Act has been called the pit bull of all the environmental laws. It has no provisions for cost-benefit analyses. ESA provides the authority to protect critters at any cost regardless of economic harm. We saw what happened to the timber industry in the Northwest over the spotted owl.

There are over 1,200 species listed as either endangered or threatened in the U.S. under ESA. The law is administered by the Fish and Wildlife Service (FWS), in the Department of the Interior, and the National Marine Fisheries Service, in the Department of Commerce. Fish & Wildlife is responsible for fresh water and terrestrial species and NMFS covers salt water species including those that spawn in fresh water. These two agencies are commonly known as the Services. These agencies list and delist species, designate critical habitat, and formulate recovery plans.

ESA requires all federal agencies to consult with the Services on all federal actions. Pesticide registration is considered a federal action. EPA had neglected this requirement because it has believed that its environmental risk analyses take into account endangered species.

However, the Washington Toxics case in 2004 found EPA to be out of compliance with ESA for not consulting with the services. Fifty-four active ingredients were listed in that suit. EPA sent consultation packages to NMFS between August 2002 and December 2004. In the face of NMFS inaction, another lawsuit was filed against NMFS in 2007 for failure to consult. The settlement includes 37 pesticides and establishes a schedule for issuance of Biological Opinions.

Just this summer, the Services came out with its Biological Opinion of four of the compounds – it took them over four years to do that!!

There have been many challenges to EPA and the Services working together effectively:

- ESA was designed for site specific or more local projects. It was not designed to handle a nationwide action like a pesticide registration.
- EPA and the Services operate under different legal authority. As I said earlier, ESA has no provision for cost-benefit analyses. FIFRA does.

- The Services works in a more precautionary approach. "We have no evidence that a species is there … but it could be!" Where EPA works under a more science-based risk assessment.
- The Services are limited in resources. For example, F&W has only two people who have the background to do pesticide issues. EPA has hundreds.

I tell you all of this to make a point. And, that is, the ESA may prove to be major impediment to pesticide registrations – taking more time and resources and increasing the costs to register a pesticide.

Endocrine Disruptors

Just a quick blurb on endocrine disruptors. FQPA directed EPA to develop a screening program to determine whether certain substances may have hormonal effects in humans. EPA has been working for twelve years on developing such tests. Although EPA has some data on endocrine-disrupting pesticides, insufficient scientific data are available for most of the chemicals produced today to allow for an evaluation of endocrine associated risks. The science related to measuring and demonstrating endocrine disruption is relatively new and validated testing methods are still being developed.

This testing may prove to be yet another obstacle to registering or reregistering products.