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## REACH Could Require European Registrations For U.S. Inerts Exporters

***REACH applies the precautionary principle to chemicals used in Europe. While active ingredients for agricultural pesticides are exempted, the situation at this point for inerts is unclear. As things now stand, REACH could impose substantial data burdens on inerts producers or require the substitution of less-toxic chemicals in pesticide formulations.***

Companies marketing inert, agricultural pesticide ingredients in Europe may face some major financial burdens under a sweeping regulatory program slated for adoption by the second quarter of 2007.

Europe's Registration, Evaluation and Authorization of Chemicals (REACH) legislation wending its way through a web of governmental chambers will affect an estimated 30,000 chemicals – although the active ingredients used in agricultural pesticides would remain regulated under Council Directive 91/414/EEC.

The Directive is in the midst of a major overhaul, but chemical producers around the world are currently focused on REACH, which will apply the precautionary principle to the most toxic and persistent substances in commerce – and generally tighten European regulation of chemicals.

Last month, a European Parliament panel adopted controversial language which – assuming it's adopted by Parliament – will require, among other things, the substitution of less-toxic chemicals in products with safer alternatives if alternative ingredients are available.

The amendments adopted by the Environment Committee of Parliament probably won't have much, if any, impact on the inerts – or, in European parlance, co-formulants – in pesticide products because it's believed that they wouldn't meet the toxicity thresholds triggering the substitution mandate.

However, while active ingredients are exempted from the major REACH titles, the situation for inerts is unclear, at this point. The most recent (June) draft of the massive proposal includes language which appears to limit inerts regulation. But, the Brussels-based European Crop Protection Association (ECPA) argues, if the authors of that language intended to limit inerts regulation, then the language needs revision.

Without it, ECPA warns, REACH could impose substantial data burdens on inerts producers, which, in turn, would increase the costs of agricultural pesticides.

### REACH

Currently, REACH is comprised of six separate volumes – with the flow chart describing the prescribed, regulatory processes running 17 pages. According to the European Commission (EC), the data on 99% of the



 

chemicals (by volume) in EU commerce is "sketchy," but REACH will set up a registration process under which producers will be required to fill the data gaps – with the toughest requirements and mitigation measures reserved for chemicals classified as those posing "very high concerns."

Those chemicals include persistent bioaccumulative toxics (PBTs); carcinogenic, mutagenic or reproductive toxics (CMRs); and very persistent and very bioaccumulative substances (vPvBs).

REACH advocates, like the Corporate Europe Observatory, accuse industry of attempting to derail the regulatory program with "scare mongering, flawed impact studies and delay tactics."

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REACH opponents, like the Competitive Enterprise Institute (CEI), view the regulation as "inherently unreasonable" and "suicidal" for European commerce.

Once the program is adopted, an intense, fast-track implementation process will ensue. The effort will be shared by many European governments, but, ultimately, the regulations will be administered by a body to be known as the European Chemical Agency (ECA), which will be established in Helsinki.

## THE REACH TITLES

REACH is comprised of numerous legislative titles, with the three main pieces being Registration, Evaluation and Authorization – each of which delegates regulatory oversight to the ECA or individual EU nations, depending on the title.

The Registration Title, which applies to companies producing or importing more than one metric ton of chemical products, will require the submission of a dossier of environmental and public health data, and may require additional testing if the ECA determines that the dossier data doesn't support safety claims for the product.

**REACH opponents, like the Competitive Enterprise Institute (CEI), view the regulation as "inherently unreasonable" and "suicidal" for European commerce.**

Companies producing or importing chemicals in volumes exceeding 10 metric tons must also submit "chemical safety reports" on the carcinogenicity, persistence, and bioaccumulative potential of the chemicals – along with exposure data reflecting all of their known uses.

Under the Evaluation Title, EU nations will take turns deciding if there are data gaps in the dossiers for substances exceeding the 10-ton threshold, or posing specific risks, or both – with the final decision on a data call-in (although REACH doesn't use that term) requiring full concurrence from the other EU nations. Absent full concurrence, the decision will be up to the EC.

Under the Authorization Title, CMRs, PBTs and vPvBs will be banned from EU markets unless their manufacturers demonstrate that mitigation measures would reduce their risks – or that their economic and

 

sociological benefits exceed their risks. EU nations would submit proposals for restrictions, if any, on chemicals proposed for Authorization – with the EC making the final decisions on bans.

Those decisions could go against chemicals of "very high concern" if the EC – applying the precautionary principle – determines that the chemicals are too risky for Authorization, and the data supporting its Authorization wouldn't be available for a long period of time.

## PESTICIDE EXEMPTION

Under Article 15 of the June REACH draft, ECPA points out, plant protection products (including the active and inert ingredients in agricultural pesticides) are exempted from the Registration Title. ECPA says the exemption is sensible because pesticides are already regulated under Directive 91/414/EEC.

Quoting the draft, ECPA notes that Article 15 of that draft encompasses "active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to [Directive 91/414/EEC] or in [other European regulations]."

Those pesticide compounds would be regarded as registered, and their registrations complete, once there's an EC decision on the sufficiency of a registration dossier. ECPA argues, however, that Article 15, as worded, fails to "achieve the intention" of exempting co-formulants.

Therefore, ECPA wants the inerts reference in the first sentence deleted, such that Article 15 would open by saying, "Active substances to the extent that they are manufactured or imported for use in plant protection products…."

In addition, ECPA wants to add the word "co-formulants" to the Article 15 statement saying that any substance included in Annex 1 to Directive 91/414/EEC "shall be regarded as being registered and the registration completed" if the EC has reached a completeness decision.

Pointing out that the compounds used as inerts are also used in other types of products – ranging from paints and detergents to biocides and veterinary products – ECPA argues that "it is *the uses* of such substances covered by Directive 91/414/EEC that should be preserved from double regulation, not the substances themselves.

"The proposed [ECPA] wording," the Association continues, "clarifies that substances are only regarded as being registered for their uses in plant protection products. For other uses they have to be registered under REACH."

## ECPA COMMENT

*Insider* asked Stephan Schraff, Governmental Affairs Manager for ECPA, to comment on the inerts issues raised by REACH – as well as the pending revisions to the European pesticides directive.

Additional information on the REACH initiative is available at http://ecb.jrc.it/REACH/

 

*Insider*: What is the pesticide exemption in REACH?

*Schraff*: We, at ECPA, are looking primarily at the implications of REACH specifically on plant protection products, and the first very important statement is that we are excluded from the Authorization Title of REACH. If you look at Article 55, which expresses the current wording of the Council's Common Position, there's an exemption for all substances used in plant protection from the Authorization Title – and this is understandable because, in the EU, plant protection products and their active substances are already authorized under Directive 91/414.

*Insider*: What does REACH say about co-formulants?

*Schraff*: Article 15 [in the June draft of REACH] deals with active ingredients and co-formulants specifically for plant protection products, and, when the [Council of Ministers] drafted this article they had in mind to exempt the active substances and the co-formulants from the Registration and Authorization Titles, and the wording that they used for this exemption is that only the active substances and co-formulants used in plant protection products shall be regarded as registered under REACH. The big problem that we have with this [phrasing], especially for co-formulants, is that these products are not only used in plant protection products, so this exemption wouldn't work for the co-formulants. It might work for the active substances, because most of the actives are very specific to plant protection products, but there are some that are used in biocides, for example, or in veterinary products, so, even for some of the active substances, this exemption wouldn't work because they're not only used in plant protection products but also in other end-use products.

There was a good intention by the Council to have an exemption from derogation for substances used in plant protection products, but the actual drafting of this article has been inadequate, and [a revision of the phrasing] is something we have advocated for the second reading. There were two amendments on this issue tabled [meaning voted upon] in the Environmental Committee [of Parliament], but both of these amendments were not accepted. That was due to a split in the conservative group in the parliament.

*Insider*: Are co-formulants used in agricultural products exempted from the Authorization Title?

*Schraff*: No. If they meet the Authorization criteria, the co-formulants are not exempted. But, I would not expect the co-formulants to fall under the Authorization process because, of the 30,000 substances that REACH is dealing with, only a small number, about 1,500, will probably go to Authorization; by far, the largest number of them will only be registered, and most co-formulants will only be registered, as well.

"We, at ECPA, are looking primarily at the implications of REACH specifically on plant protection products, and the first very important statement is that we are excluded from the Authorization Title of REACH." *Stephan Schraff, Governmental Affairs Manager, European Crop Protection Association*

"The big problem that we have with this [phrasing], especially for co-formulants, is that these products are not only used in plant protection products, so this exemption wouldn't work for the co-formulants." *Stephan Schraff, Governmental Affairs Manager, European Crop Protection Association*

 

*Insider*: How will registration requirements for co-formulants affect industry?

*Schraff*: This will have a major impact on our industry because we will have to create a lot of new registration data, which is not available at this moment. So, for co-formulants, we really see a problem – not so much for the active substances, because most of them will fall under the derogation from registration, and are exempt from authorization, but, for the co-formulants, this really could cause problems for the pesticide industry.

We are still discussing this with Members of European Parliament, here, and also with representatives of the Council Working Group, to convince them that this wording should be changed in the final text, and while I couldn't tell you if we will succeed, we are still heavily involved in the work on this and we'll try to get a change in the wording on this in the final text. If we do not succeed with this advocacy, we will try to find a way to do so in the REACH implementation programs [RIPs], because you will have a lot of guidelines going with the regulation, which will be necessary because there will be a wide scope for interpretation. The Commission is currently preparing the RIPs, and we have nominated representatives to the working groups that are working on those RIPs, and we will certainly try to make our views known during the work process.

"[F]or co-formulants, we really see a problem – not so much for the active substances, ... but, for the co-formulants, this really could cause problems for the pesticide industry." *Stephan Schraff, Governmental Affairs Manager, European Crop Protection Association*

*Insider*: Would the substitution amendments have any impact on co-formulants?

*Schraff*: I don't think the co-formulants would meet any of those criteria. If you create data showing that you meet one of the criteria which triggers substitution, then you could end up losing co-formulants. But, as I say, it's not probable that this would happen. For the co-formulants, we see the problem more in registration rather than authorization.

*Insider*: Turning to the European pesticides directive, what is the status of the pending revisions?

*Schraff*: There is a proposal on the table from the Commission. It was transmitted in June by the Commission to Council and Parliament. The Council has already started working on it; the Agricultural Working Group of the Council had some meetings in September and, I think, in October. In Parliament, the committees involved – the Environmental Committee, the Agriculture Committee and the Internal Market Committee – have been nominated. All three of those committees will provide opinions.

This specific legislation concerning the placing on the market of plant protection products in the EU is actually going to be a regulation in the future. They changed that from a directive to a regulation; the difference is that the regulation would be binding, directly – not to be transposed by the member states in national law: it will be directly legally binding in the member states.

 

*Insider*: What will the revisions seek to do?

*Schraff*: The Commission is claiming a simplification of the system. We wouldn't agree completely on this. There will be a change in data protection rules; there will no longer be a national, provisional authorization, which is in the current Directive. There also were some major changes concerning cutoff criteria, which means, if you meet these criteria, there will not be a risk assessment.

There will only be these hazard-based criteria, so, if you [exceed] hazard-based criteria, there won't be a risk assessment – and you're out of the game. This is one of the major points where we see a real problem for plant protection products.

They will also introduce comparative assessment, so this discussion which we have avoided in REACH by being exempt from the Authorization Title will now be on the table during the revision process of the Directive.

Concerning data protection, what they are proposing now is that data protection time will run for 10 years for first authorization, and there will be no data protection for re-authorizations of existing products. If you change the formulation, they will consider the product to be new – and you could ask for data protection. But, if you keep the same formulation, even after the 10-year period and enter re-authorization, you don't have any data protection for any new data that you would have to provide for the re-authorization.

"This specific legislation concerning the placing on the market of plant protection products in the EU is actually going to be a regulation in the future." *Stephan Schraff, Governmental Affairs Manager, European Crop Protection Association*

*Insider*: How will the cut-offs work?

*Schraff*: What they are proposing is that CMR [category] 1 & 2 substances, the PBT's and vPvB's, are some of the substances which will fall under these cutoff provisions. For example, if a substance is considered to be a CMR 1, there will not be a risk assessment. The difference between having this substance meeting this hazard criterion and the risk assessment is, of course, that you have to see both together. If you wish to use a substance which is potentially hazardous, and you put in place risk mitigation tools, then you will not have a risk in the end. But, this second part would not be done, anymore. Only hazard would be looked at, and this is one of our major advocacy issues.

*Insider*: Turning back to REACH, what is the expected timeline for adoption?

*Schraff*: Right now, there are informal meetings between Council and Parliament going on, where they are trying to agree on a common approach, and we will then have the second-reading plenary vote in Parliament either at the end of this month, or, as it's becoming more likely, in the second week of December. And, then the Council has to agree to the amendments adopted in Parliament in the second reading, so you're probably looking at adoption of the REACH text in the first quarter of 2007.

 

*Insider*: At what point after that does the Helsinki environmental agency become established?

*Schraff*: They want to set up the agency within one year after the text has been adopted.

*Insider*: At this point, besides the potential impacts on co-formulants, what is your principle concern with REACH, if you were to single out one concern?

*Schraff*: We have the feeling that it is going in the wrong direction because it's moving away from risk assessment, and we will do all we can to talk to key decision makers to let them know that this is the wrong way.

## Off Limits: Label References To Liability Waivers Requiring Grower Signatures

***Special local need registrations carry the risk that untested pesticides may damage specialty crops. To protect themselves, registrants have required farmers to sign strong indemnification agreements before using a SLN pesticide. States generally have opposed such agreements, and EPA now concurs, while also tightening pesticide warranty statements in general.***

Companies seeking to shield themselves against crop damage lawsuits should not attempt to link their product labels to signed agreements related to product uses authorized under special local needs (SLN) registrations, EPA's Office of Pesticide Programs says in newly issued guidance.

The guidance, which was issued on Oct. 20 by OPP's Labeling Committee, clarifies existing policy, and advises the addition of some label wording to ensure that warranty statements and disclaimers on all pesticide labels are consistent with FIFRA.

SLN registrations are granted by state lead agencies under Section 24(c) of FIFRA (after a review by OPP's Registration Division). The registrations enable growers to apply pesticides for specialty crop uses which don't have Section 3 registrations.

Because registrants haven't necessarily tested their pesticides on the crops identified in a 24(c) label, there's a risk that the pesticide could injure the crop and expose the registrants to liability claims – which, for specialty crops, could be enormous.

Consequently, registrants have tried to protect themselves with signed agreements in which growers acknowledge the risks they're taking with 24(c) pesticide uses and, in some cases, promise not to sue if crop damage results from those uses.

However, a number of SLAs were concerned that, by approving 24(c) labels which reference these agreements, they could be exposed to

 

liability claims, themselves. All SLAs, moreover, oppose any implied responsibility to enforce agreements referenced on labels.

In fact, one state has banned 24(c) indemnification agreements altogether (see *Insider*, Vol. 1, No. 5, "Liability Disclaimers On Pesticide Labels Banned By California," March 16, 2004). And, the State FIFRA Issues Research and Evaluation Group included liability waivers in a "Top 10" list of controversies submitted to the OPP Labeling Committee for attention.

Now, however, SLAs receiving 24(c) labels with references to mandatory, liability-waiver agreements – or labels with liability-waiver agreements attached to them – can point to the OPP guidance and escape contentious debates over any label statements indicating a requirement for signed, liability waivers.

"I see this guidance as a good example that issues can move through the SFRIEG [and on to OPP], even fairly quickly, and we can get results." Dave Fredrickson, President, SFIREG

## A 'PLEASANT SURPRISE'

Dave Fredrickson, who is now the SFIREG President, is gratified that the Committee has addressed the issue.

It was the SFIREG Pesticide Operations and Management, or POM Committee, that "sort of started this issue," Fredrickson told *Insider*, "and I'm pleased to see how well it turned out – and really pleasantly surprised that they didn't only deal with 24(c) labels but also the Section 3 issues.

"I see this guidance," Fredrickson added, "as a good example that issues can move through the SFRIEG [and on to OPP], even fairly quickly, and we can get results."

## THE SFRIEG STATEMENT

In its "Top 10" list (see *Insider*, Vol. 2, No. 24, "States Pushing To Impose New Pesticide Label Requirements," Dec. 20, 2005), the SFIREG pointed out that, besides their inappropriate language, the waiver statements were frequently dominating the rest of the 24(c) labels.

Although 1997 policy guidance on liability waiver statements included a template for approved language, "it seems that, recently," the SFIREG "Top Ten" listing says, "some twists to this old plot have arisen. Some SLNs included the liability statement first and have added significant amounts of additional language. Some liability statements take up more than a whole page in the label."

Despite the 1997 policy guidance, which was hammered out by the Office of General Counsel (OGC), OPP, and registrants, labels with references to signed liability waivers kept turning up in 24(c) label submissions.

Thus, as Fredrickson pointed out, the latest guidance document is "only a change in the sense that we got OGC to tell the Registration Division, 'Hey, knock it off! We already answered that issue' – which is exactly what we were looking for."

 

## THE GUIDANCE

The clarified guidance reiterates that, in 1997, "OPP, in coordination with OGC and the regulated community, developed general guidance on language acceptable in waiver of liability statements…." The original guidance said that then, as now, it is unacceptable "to have label language that requires (or appears to represent that EPA will enforce) a user to sign an agreement before purchasing [a pesticide] or using it."

Under the newly issued guidance, OPP will not disallow statements which "merely reference the existence of private liability agreements" as long as they don't "provide false or misleading information about the legal remedies available to growers."

Otherwise, the guidance points out, "EPA believes that products bearing labeling that requires growers to waive their rights to bring suit as a condition of lawful use of a product are not consistent with FIFRA and should not, therefore, be registered by states pursuant to Section 24(c)."

"EPA believes that products bearing labeling that requires growers to waive their rights to bring suit as a condition of lawful use of a product are not consistent with FIFRA and should not, therefore, be registered by states pursuant to Section 24(c)." *EPA Guidance Document*

The guidance includes examples of unacceptable label statements which have been corrected for conformity with OPP policy. The corrections apply to Section 3 as well as Section 24(c) language, and include:

- The insertion of the phrase, "**To the extent consistent with applicable law**" in "Disclaimer of Warranty" statements limiting warranties to those on product labels and in Limitation of Liability Statements which limit damage awards to the price paid for products.
- Changing "should" to "**must**" in the statement, "The directions for use of this product are believed to be adequate and must be followed carefully."

The "applicable laws" insertions refer to state and local laws which, the guidance points out, "may not allow the manufacturer to limit its liability by offering its product 'as is.' In addition, the same laws may not allow certain limitations of liability or remedy."

Fredrickson observed, "I think [the 'applicable law' insertions] are long overdue. They reflect the current state of the product liability suits that have been heard in the last several years, so we think that language makes sense."

Fredrickson also suspects that signed warranty waivers wouldn't necessarily hold up in court because, "Saying that the product could kill a crop implies the registrant knows something they're not telling. I made that argument to the companies during our SFIREG discussions, as well. When you put that statement on the table, you've actually opened the door wider to potential lawsuits. A judge is going to look at that and say,

 

'If you made them sign this before they could have it, you're kind of tipping your hand that this might not be the best thing to do.' I'm pretty sure that's the way judges in this state would look at it."

Regarding the replacement of "should" with "must" in statements advising growers to read the directions carefully, Fredrickson said, "Anytime we can get 'shoulds' off the label is a good thing."

## ACCESS DENIED?

Despite the firm position taken by OPP in the guidance, growers, Fredrickson said, should not worry that they will be denied access to special pesticide uses they need to mitigate local pest problems.

> "Saying that the product could kill a crop implies the registrant knows something they're not telling." *Dave Fredrickson, President, SFIREG*

"Some of the registrants who were reluctant to give [the signed agreements] up," he pointed out, "have actually been in here meeting with [Wisconsin registration officials] who are responsible for special registrations, saying, 'Okay, we're going to adopt the language from EPA,' so I think we're okay."

Fredrickson also pointed out that grower requests for the use of a product under a 24(c) label don't originate from, and aren't approved in, a vacuum.

"Normally, before we are going to consider a 24(c)," Fredrickson said, "there is going to be some data from somebody else. It may not be from the registrants, but there's going to be some university work that helps guide us in that regard, and we do partner very closely with our scholars at UW-Madison, or in the UW system. In fact, our staff had that meeting [recently]. They sat down with the whole UW group, which we try to do once a year, and brainstorm on what's ahead – what [requests] may be coming in, what's on the horizon for requests, then say out front, 'We've got data on this, we don't have data on that.' And that's really helpful."

> "My position has been, and remains, that these agreements are really a relationship between registrants and their customers." *Jim Gray, Registration Specialist, North Dakota Department of Agriculture*

## CONCERN LINGERS

Jim Gray, Registration Specialist for the North Dakota Department of Agriculture, says he has a lingering concern about the impacts of the OPP guidance.

"If we disallow those types of agreements entirely," he told *Insider*, "I am concerned that some registrants, especially with products used for high-value crops, will simply no longer support the use of their products in certain situations. And, that's something that does concern me because we do have those types of crops in North Dakota."

## 'NON-ISSUE'?

Gray stresses that, "I respect state regulators who want to formally disallow this type of language.

 

"But," Gray adds, "I've always looked at this as sort of a non-issue. My position has been, and remains, that these agreements are really a relationship between registrants and their customers. And, as long as the Department isn't charged with enforcing anything, we really don't have a dog in that fight, and I wouldn't have any problem with those types of statements as long as there's nothing on the label that forces me to go out and enforce and check for signed agreements.

"There are some statements found on the labels," Gray continued, "that say something along the lines of, 'The registrant intends that the customer sign an indemnification statement.' That's a lot different than saying the customer *must* sign an indemnification form waiving all liability because, then, that's a requirement

"Otherwise," Gray added, referring to agreements which states don't need to enforce, "it's really something between the registrant and grower. It would be no different than me walking into an electronics store and buying a DVD player without a warranty and the store saying, 'You realize you're on your own here. You realize that if you take this thing home and it doesn't work you're accepting all responsibility for that,' and if I say, 'Yes,' then, that's the way it is."

## Biotech Field Trials Raise Thorny Confidentiality Issues

***State regulators want access confidential EPA information on local field trials for genetically engineered crops, while companies are concerned that state sunshine laws may result in disclosure to vandals bent on destroying biotech plantings or competitors.***

The National Association of State Departments of Agriculture (NASDA) and the Pew Initiative on Food and Biotechnology are nearing the end of a joint effort to develop options for states seeking confidential information about field trials of crops engineered to express plant incorporated protectants (PIPs).

NASDA, which has an affiliation with 22 national associations representing state agricultural programs, advocates on behalf of policies "which support and promote the American agricultural industry, while protecting consumers and the environment."

The Pew Initiative, a non-advocacy group supported by a grant from the Pew Charitable Trusts, "was established in 2001 to be an independent and objective source of credible information on agricultural biotechnology" while "encouraging debate and dialogue."

Pew and NASDA have jointly sponsored several workshops addressing a wide range of issues raised by testing and growing genetically engineered (GE) crops. Additionally, the Pew Initiative has published special reports on the issues; one of them, "Tending the Fields: State & Federal Roles In

The PEW Biotech reports, and the proceedings of the PEW/NASDA workshops published to date, are available at: http://pewagbiotech.org.

 

The Oversight Of Genetically Modified Crops" addresses, among other things, the conflicts that arise over regulatory access to confidential business information related to experimental, GE crop plantings.

Testing the efficacy of PIPs expressed by genetically modified organisms (GMOs) requires an experimental use permit (EUP) from the Biopesticides and Pollution Prevention Division of EPA's Office of Pesticide Programs.

On Sept. 29, BPPD issued for public comment a draft Pesticide Registration Notice laying out its process to review EUP applications, its guidelines to ensure that the tests are safe, and the conditions under which a tolerance, or exemption from tolerance, would be required for small-scale field tests (involving less than 10 acres) for biotech food and feed-crop plants expressing PIPs.

The draft PR Notice is not intended to address any of the thorny issues which arise when states lacking the statutory authority to protect CBI would like to inspect, or are asked by EPA to inspect, an experimental planting.

The Agency is well aware of these issues, and has been following the PEW/NASDA effort to address them. *Insider* asked an EPA official to discuss the PR Notice, and asked officials at Pew and NASDA to provide background, and updates, on their joint effort to find potential solutions to the CBI debate.

## THE PR NOTICE

BPPD Director Janet Andersen told *Insider* that the PR Notice fulfills the Aug. 2, 2002 mandate (67 *Federal Register* 50578) from the White House Office of Science and Technology Policy for all federal agencies [USDA, FDA and EPA] with regulatory authority over GE crops to issue policies "to describe the potential for the intermittent presence of trace amounts of biotech products in food or feed – and how we would handle those.

"FDA has their policy out, and it's now final guidance," Andersen continued. "[The Animal Plant and Plant Health Inspection Service of] USDA has put some guidance out, but they are also planning to change their regulations [and issue a programmatic Environmental Impact Statement, or EIS, on the release of GE organisms]."

The publication of the draft PR Notice, Andersen pointed out, "doesn't mean we have changed our mind in any way about the safety of these field tests. As we went through this process, we tightened things up to make sure companies understood that they're not supposed to allow any [PIP or GE plant] residues into the food or feed supply unless it's already approved [with a tolerance decision] – which would be true for any pesticide."

Asked why the draft PR Notice says "EPA urges" – instead of requires – "potential registrants to consult early with the EPA to ensure that appropriate physical and/or biological controls are in place to restrict the

 

flow of genetic material, including seeds, from field tests," Andersen said those consultations, while desirable, aren't necessarily indicated for all registrants.

"The big guys, if they're going to do an experiment, they know how to isolate the plants and don't need guidance from us," Andersen said. "But, if you are, say, an academic just starting out in this work, you probably ought to talk to us. Biopesticide registrants are typically small companies, and we encourage them to come in and talk to us about what they're doing so we can give them advice, so that they don't do tests that they don't need to do, so they understand the risk questions we're asking, and so they do the tests in a manner that's useful to us. Frankly, the [major registrants] come in and talk to us, too."

**"As we went through this process, we tightened things up to make sure companies understood that they're not supposed to allow any [PIP or GE plant] residues into the food or feed supply unless it's already approved [with a tolerance decision] – which would be true for any pesticide."** ***Janet Andersen, Director, BPPD***

## CBI ISSUES

Although PIPs are intended to mitigate pests, they are not viewed by EPA as pesticides, which has caused some states to question whether they have the authority, as the Agency's regulatory partner, to oversee GMO field tests. However, states which believe they have this authority don't necessarily know when, or if, field trials referenced in *FR* notices announcing EUPs have been initiated. That information is CBI-protected by EPA, which will not release it to states whose sunshine laws could allow its disclosure.

Companies are sensitive about the details of their field trials because "there are business practices involved and they don't necessarily want their competition knowing what they're doing," Andersen said. "Additionally, the companies don't want vandals coming in and destroying [a planting] because it's a biotech crop, and that does happen, occasionally."

Obviously, states with strong sunshine laws don't want to be blamed for vandalism if it occurs after they divulge test locations to the public, which means they may refuse to perform field-trial inspections requested by EPA.

At the same time, the states want to ensure that growers exporting conventional crops to markets which have banned GE crops are not at risk from potential GMO releases from nearby field trials.

"It's a tricky problem," Andersen said, "but the Pew is working with state representatives, and some states, to work out ways to resolve this problem and give the state regulators the information they need without causing CBI problems."

## POSSIBLE OPTION

Keith Pitts, Director of Public Policy for the Pew Biotech Initiative, told *Insider* that a number of options for resolving CBI issues are enumerated in the published proceedings of a Pew/NASDA workshop. The report on

 

the workshop and related meetings, "Agricultural Biotechnology Information Disclosure: Accommodating Conflicting Interests Within Public Access Norms," provides summaries of CBI disclosure laws and issues in 21 states. It also provides ten detailed options to facilitate the release of data submitted to federal agencies to state regulatory officials.

Pitts said EPA and APHIS "have both committed to work with their sister agencies in state government to resolve these [CBI] issues, with an intent to move forward with [Option 1]."

Option 1 is titled, "Restricted Access Webfiles." Under that option, says the report, "state officials could access federal electronic databases after state officials are trained and certified and are aware of the confidentiality constraints on access to the private proprietary data. EPA would have one database subfile that was specifically designed for access by authorized state officials [and] would contain only [the] number of elements that fit the needs of the state personnel who now receive notice of permits – with the number X signifying the data elements that reflect informational needs. These needs would be identified in a formal report to the relevant federal agencies by the committees of the National Plant Board and the American Association of Pest Control Officials. They might include specific crop location, cooperator identity, and so forth."

> "[T]he companies don't want vandals coming in and destroying [a planting] because it's a biotech crop, and that does happen, occasionally." *Janet Andersen, Director, BPPD*

## THE ISSUES

"States," said Pitts, who was formerly Special Assistant to the Deputy Secretary of USDA, "may not necessarily want to replicate what the feds are doing, but there are sets of issues and concerns that may be unique to a state, especially relating to these field trials, and those fall into the basket of market-related issues. The second basket of issues includes compliance and enforcement – and the lack of some key data which is considered CBI. It's very difficult for state regulators to learn the 'when,' 'if's,' and 'how's' of field trials in their states.

"While some states may be perfectly comfortable allowing the feds to handle the issues entirely," Pitts continued, "I think they've become the minority over the years. There are some states that certainly want to have a beefed up relationship and some oversight over how these field trials are being conducted, and I think one big driver with this has been the pharmaceutical applications in [GE] food crops, so there are a set of potential safety issues that states want to feel assured are being adequately addressed.

"But," Pitts added, "the coordinated framework and regulatory authorities they tap at the federal level prohibit the feds from making any decisions about biotech crops, other than safety assessments; they don't really look at any of the marketing impacts from any of their decisions, and I think that states are increasingly finding that they've got to deal with those issues on their own – assuring export markets that a certain [genetically

 

modified, or GM] crop isn't being grown in a state at all, or it's being confined in a way that's adequate to ensure that it's not going into channels where it's not approved.

"That leads to the issue of peaceful coexistence among GM, non-GM, conventional, and organic growers, so all those sets of issues fundamentally tie into the question of how aware are you – the state regulator – of what's going on in your state? So that's kind of the key piece for the states, and even for the other workshops that flowed from that. The other workshop we held was on 'peaceful coexistence,' looking exclusively at market-related issues, and we published the proceedings of that workshop in August. In 2005, we held a workshop in Dallas, where we looked at the mechanics of sharing and maintaining CBI, and those proceedings are under final review, and I'm expecting them to be published this month.

"At the Dallas workshop," Pitts explained, "we had subgroups meeting to settle on some options to manage CBI concerns, but we didn't get into what should, or shouldn't be, declared CBI. Option 1 looks like it's the most promising. What's still under discussion is: will it solve the problem for all states? It may not. I think some states have pretty expansive sunshine laws that may make that an issue as far as whether or not they feel comfortable receiving CBI and keeping it protected."

**"While some states may be perfectly comfortable allowing the feds to handle the issues entirely, I think they've become the minority over the years." *Keith Pitts, Director of Public Policy, Pew Biotech Initiative***

One state aggressively addressing CBI issues, said Pitts, is Oregon, which "is planning to become co-regulators with the feds on biopharming applications and have a state-run permitting program in which they collect fees, and, according to a report from their biopharming panel, they will pass some legislation to protect CBI relative to these crops."

EPA, Pitts observed, "has a clear prohibition against sharing CBI data with anyone, so I think they've got a couple of steps that they need to take. But, most of the EPA information is already accessible to the public, so what we're talking about here is site, location, and time of planting. I think EPA is going to have to go back to individual registrants and get an okay from them to post this data [under the Option 1 proposal]."

Pitts says the collaboration with NASDA started in 2003, when "we asked them to look at our report on biotech oversight and opened a discussion with them. It became clear that they were trying to address the tensions between state and federal government and trying to figure out where they fit in with this whole regulatory scheme, so I had some discussions with [NASDA's Animal and Plant Health Safeguarding Coordinator] Bob Ehart around the idea of some workshops, and the first issue that came up was CBI-related concerns."

## NASDA WEIGHS IN

Ehart, who was formerly an Executive Assistant engaged in technical issues at the Wisconsin Department of Agriculture, told *Insider* that the

 

CBI issues may be viewed most simply as "lots of 'round pegs and square holes.' There are a lot of pieces of information considered CBI at the federal level that states do not need, and the states don't want to duplicate federal efforts to assess the science associated with the organism; but you may need to know the construct of the organism, so, in some instances, you may want to have some more information on some types of projects – and not need it for others.

"Now," Ehart added, "from what I hear from state personnel, if they know what the organism is and how it's been engineered, they have a pretty good idea of the risks to existing crops in the state, and the regulatory oversight that may be needed, and, so, while they may not need to know everything, they need to have some idea about the intended benefit of the crop that people are trying to determine from the field trials – and the location of the trial."

**The CBI issues may be viewed most simply as "lots of 'round pegs and square holes.'" *Bob Ehart, Animal and Plant Health Safeguarding Coordinator, NASDA***

But, "location" is tricky, Ehart observed.

"If EPA publishes a *Federal Register* notice saying they've granted an EUP for a company to test a GMO," he pointed out, "they will list the states where they might grow it. If the EUP has been granted in February, the company may plant in the South; if it's granted in April, they may list some states in the North and Midwest, so what gets published in an *FR* notice may indicate that they're planning to plant all over the place and yet they may plant in only one location. So, if the Missouri people say, 'Where are you planting it?' The company could just say, 'We're not planting it here.'

"Some things are considered to be protected under FIFRA, [and] some things are not," Ehart continued. "Sometimes, companies list things that are, maybe, questionable, but if it's listed as [protected] there has to be a [transparent] process by which that determination is made.

"If EPA wants a state do an investigation under FIFRA," Ehart added, "then they have to provide certain information to the state. However, if a state can't keep it protected, the state actually doesn't want it provided to them. So, it gets into a situation where there's no assurance that the procedures under the existing federal process will mirror those of the state, so it's all case-by-case as to whether these things can be done – whether a state can actually do the EUP inspection."

Consequently, Ehart said, the states need procedures for obtaining and protecting CBI – possibly by performing EUP inspections under a memorandum of understanding with EPA.

"An MOU to do the inspections with a federal credential could work," Ehart said. "But, it could raise a question: if the inspection isn't done under state authority, is it really being done correctly or not? And, that's something we have to figure out if, procedurally, there's some way to possibly do it."

 

Ehart notes that, "In December of 2003, about a year after I had joined NASDA, I had an opportunity to meet with most of our members, and we decided by the fall of 2004 to reconstitute our Biotech Task Force, which had been dormant for some time. So, all of these things are kind of converging, and when that [Pew Biotech Oversight] report came out, Keith and I started talking about the similarities between what they'd found and what our members were identifying as issues. Keith said the Initiative was definitely working on exploring the state biotech issues, and we started with CBI because, frankly, if we have these confidentiality issues, it doesn't matter how much cooperation there is between the states and the feds."

**NEXT STEPS**

The NASDA Biotech Task Force, Ehart said, is actively considering the options available to address CBI issues, and "they're working on a CBI piece for our Farm Bill language.

"Legislation is one of the longer-term fixes we're considering," Ehart said, "although there hasn't been a strong push to fix these things through legislation – for example, through revisions to the Plant Protection Act. But, I should mention that, the way NASDA has looked at our cooperation with Pew – it's a huge opportunity to have the kinds of discussions we don't normally have so thoroughly. It's providing us with well-reasoned options to consider, but anything that's going to happen in terms of policy changes at the state or federal level will still have to go through the normal, public hearing processes for additional input."

## Coumaphos Rescues Beleaguered Beekeepers, But For How Long?

***Bayer seeks a permanent registration for the organophosphate pesticide coumaphos to protect honeybees, following the emergence of pest resistance to older products. Although sales to beekeepers are miniscule, the economic impact to agriculture as a whole would be enormous without pollinating bees. Unfortunately, however, pest resistance to coumaphos is now emerging also.***

A recent tolerance request for coumaphos residues in honey and honeycomb is good news for beekeepers struggling to control a parasite threatening the U.S. apiary industry.

EPA's Office of Pesticide Programs published a Notice of Filing announcing the request, which was submitted by the IR-4, in the Oct. 18 *Federal Register* (71 *FR* 61465). The request is supported by residue work performed by the Bayer HealthCare Animal Health Division in Shawnee Mission, Kansas.

Bayer sells the only conventional insecticide product (CheckMite) for use

 

against varroa mite, which rapidly became a major, and widespread, bee pest since its establishment in the late 1980s.

The coumpahos strips are available in 46 states under a FIFRA Section 18 emergency exemption from permanent tolerance requirements. The Section 18, which was issued on Aug. 16, 2000, represents the only new, organophosphate pesticide use approved by OPP since the 1996 enactment of the Food Quality Protection Act.

Prior to CheckMite, beekeepers relied on a pyrethroid-based product, Apistan, which became ineffective as the mites developed resistance to its active ingredient – fluvalinate. In fact, this resistance was a key factor in the OPP decision to grant the Section 18 (65 *FR* 49927) – but resistance to coumpahos is now emerging, as well.

Consequently, beekeepers have started using a thyme-derived biopesticide in conjunction with CheckMite, but that doesn't mean they could give up the coumaphos product – particularly when coumaphos is also effective at controlling the African small hive beetle, which invaded the United States in 1998.

At the same time, OPP – under increasing pressure from environmental groups – has become tougher on Section 18s that repeat year after year.

So, while it's unlikely that OPP would have pulled the Section 18 for coumpahos, the Bayer decision to proceed with a Section 3 registration means that beekeepers will continue to have access to CheckMite. A Bayer scientist says it was the company's intention to seek a permanent registration all along – even though the contribution of the product to company sales is miniscule.

The October 18 *Federal Register* announcing the request for coumaphos residues in honey and honeycomb is located at: www.pesticide.net/x/fedreg/2006/EPA-20061018A.

## THE MITE

A single, U.S. varroa mite detection occurred in 1979 in Maryland; by 1987, it was found in Florida and Wisconsin. The mites feed on developing bee larva as well as adults and pupa, and reproduce in brood combs. The adult mites deposit their eggs in bee larvae, with the result that young bees emerge severely deformed.

## PROGRESSION OF THE 18

Bob Arther, Manager of Entomology and Parasitology for Bayer Animal Health, discussed the coumpahos Section 18 with *Insider*.

"The whole process as been a very cooperative effort between USDA and ourselves," Arther said. "It's our understanding that USDA took the lead as far as the tolerance issues were concerned because, as a government agency, I think they probably could justify the necessity for the product better than Bayer could from a commercial standpoint."

Arther explains that, in January of 1999, Section 18s allowing the use of 10% coumpahos CheckMite strips for varroa mite and small-hive beetle

 

control were first granted to a number of states. The label limited hive treatments during non-honey-flow periods to ensure that coumaphos residues wouldn't enter the honey and wax. Because this use was considered a non-food use, tolerances weren't necessary.

As an additional effort to ensure that residues from this use wouldn't occur, label directions for the Section 18s in the year 2000 were modified to require that the strips were removed at least 14 days prior to honey flow, after which the strips could not be placed in hives intended for comb honey production.

The Section 18's for 1999 and 2000 reflected EPA's conclusions that, based on the use directions for coumaphos strips, there were no reasonable expectations for coumaphos residues to occur in honey and wax, and considered the strips to be a non-food use.

**The Section 18's for 1999 and 2000 reflected EPA's conclusions that, based on the use directions for coumaphos strips, there were no reasonable expectations for coumaphos residues to occur in honey and wax, and considered the strips to be a non-food use.**

However, even with the modified label directions, low levels of coumaphos residues were detected in some honey and wax samples. Thus, in August of 2000, temporary coumaphos tolerances for honey and wax were established and published in the *Federal Register*. The temporary tolerances are slated to expire in December of 2007, but, with the tolerances in place, the use of the strips remained available in states which were granted Section 18 exemptions.

In August of 2002, Bayer completed residue studies with coumaphos strips – with its intention being to obtain a Section 3 registration so that the strips could be used by beekeepers at any time. The residue studies were conducted to provide data as to what the highest levels of residue might be.

"At the time this work was completed," Arther recalled, "EPA was reviewing new pesticide applications and tolerance petitions submitted by industry based on a priority-list system. EPA allowed each company a limited number of priority actions, and EPA considered Bayer, including the Animal Health, Crop Protection and Specialty Products Divisions, to be one company.

"There were only a few priorities available to Bayer," Arther continued, "and these were designated as major actions, such as the registrations of new herbicides. If Bayer Animal Health had submitted the tolerance petition and application for registration without a priority listing, EPA would have given these actions a very low priority.

"Alternatively," Arther continued, "because bees are extremely important to American agriculture, the IR-4 program agreed to submit the tolerance petition to establish the appropriate tolerances. IR-4 submitted the petition in August 2002, and EPA did not require a priority listing for the submission. Subsequently, Bayer applied for the Section 3 registration of the bee strips in October 2002.

 

"EPA," Arther added, "was required to resolve issues with all of the organophosphate pesticides by August 2006, as per the [Food Quality Protection Act]. EPA has resolved most of the organophosphate issues, and now is scheduled to review and act upon the IR-4 petition to establish permanent tolerances. Only after the tolerances are established can EPA grant any subsequent registration, such as the coumaphos bee strip which requires the existence of the tolerances.

"It has been a long process," Arther observes, "but we always had the intent of pursuing a Section 3 registration."

## BUSINESS CONSIDERATIONS

Considering the size of Bayer sales in the animal health industry – nearly $1 billion annually – the contribution of CheckMite sales to the overall revenue picture is negligible. Consequently, Arther says, there were some internal questions regarding the investment in coumaphos residue work in relation to potential return on investment.

"There have been a number of times when there was some curiosity, internally, about the time and money we were spending on the field trials," Arther said, "although that might have reflected a lack of understanding of the critical importance of this coumaphos product to agriculture. We still feel it's critical to agriculture, so a handful of us have been staying after it."

> **"EPA has resolved most of the organophosphate issues, and now is scheduled to review and act upon the IR-4 petition to establish permanent tolerances."** ***Bob Arther, Manager of Entomology and Parasitology, Bayer Animal Health***

Arther pointed out that, according to the American Bee Federation, "one-third of the U.S. diet is derived from fruits and vegetables pollinated by honeybees. Now, we're talking about a small industry – 2,000 professional beekeepers and 100,000 hobbyists – so, as far as any financial contribution to Bayer, the amount is insignificant. But, the contribution of the product to protecting pollinating bees is very, very significant."

## GOING FORWARD

By 1997, Arther said, varroa mite resistance to fluvalinate was becoming "serious."

So, he recalled, "In 1998, we and a number of beekeepers had a productive meeting at EPA and, as a result of explaining the emerging resistance problem, we were able to start a program, in cooperation with USDA, to pursue coumaphos as an alternative to Apistan.

"By happenstance," Arther continued, "that was the time when the first issues with the African small hive beetle were emerging for the beekeepers, and it just so happened that, while we were doing testing on the mites, USDA started testing the product against the hive beetle and discovered that it worked quite well, so, while we were developing coumaphos for the mite we were able to establish that using the product in a slightly different manner made it effective against the hive beetle, as well.

 

"There are some other products available for the hive beetle," Arther added, "but those products, I believe, are applied on the ground around the hives. As far as I know, [CheckMite] is the only small-hive beetle product which can be used directly in the hive. So, our label has claims for both varroa mites and small hive beetles."

## FORMULATION SELECTION

"We had another product that was sold in Europe, a liquid coumpahos formulation, for varroa mite control, but that particular formulation was really not very well suited for beekeepers in the United States," Arther said. "But, we had expertise in plastic matrix technology to incorporate coumaphos in a plastic resin as a slow-release delivery system based on the work we'd done with insecticidal ear tags for cattle, so that's why we went that route to develop that formulation as a strip: U.S. beekeepers were used to using Apistan, which was a strip, so we wanted to do the same thing with coumpahos."

"It has been a long process, but we always had the intent of pursuing a Section 3 registration." *Bob Arther, Manager of Entomology and Parasitology, Bayer Animal Health*

## FINDINGS

"The testing and evaluation," Arther continued, "were done in cooperation with USDA and one of the beekeepers in Umatilla, Fla,, who provided hives and facilities for setting up studies for residue work there.

"EPA determined," Arther continued, "that any residues in honey and wax, based on our recommended use of the product – that is, using the product when there isn't any honey flow, leaving strips in place no longer than 42 to 45 days, and not treating more than twice a year – would be negligible. Based on the data we provided to them, they set temporary tolerances of 0.1 parts per million in honey and 100 ppm in wax.

"But, our field work," Arther added, "indicates that the residues are actually well below those limits."

## COUMAPHOS RESISTANCE

Arther acknowledges that mite resistance to coumaphos has emerged. However, the problem, he says, isn't arising from the product, itself.

"We are aware that the strips are not performing, at this time, as they were when they first became available in 1999," Arther said. "Our opinion is that the reason for the resistance is that the strips are not always used as labeled. They've been left in hives longer than the 42-to-45 day period. Some beekeepers may become a little lazy, or they're inclined to leave them in longer [for additional protection], or, in some cases, they're not taking them out of the hives, at all.

"Our opinion is that the reason for the resistance is that the strips are not always used as labeled." *Bob Arther, Manager of Entomology and Parasitology, Bayer Animal Health*

"The problem that results," Arther continued, "is that, once the active level of coumpahos has been depleted from those strips, there's still a residual

 

which won't kill the mites but will allow for genetic selection of resistant mites, and we feel that has been the problem leading to resistance."

Arther points out that "adult mites live on the outside of bees, and, when bees interact with other hives, those adult mites can be transferred to other colonies. So, because so many of the U.S. colonies are mobile, and are moved around, it makes it very easy for infested bees to transport the mites to uninfested hives. In February, for example, over a million colonies were transported into California for almond pollination. Colonies are also transported to the Northeast, for blueberry pollination, down to Florida, for melon pollination – basically all over the United States."

Because the hive transport is spreading resistant mites all over the United States, beekeepers are using thyme-derived, or thymol, products, as well, and "it's become clear that they need to use both to keep their mite management systems going," Dan Kunkel, Associate Director of the IR-4, told *Insider*. "So, when the USDA asked us to submit the request for the [permanent] tolerance, [IR-4 Biopesticide Director] Michael Braverman, who was already involved with thymol, worked on [the tolerance request] as well."

**"All those problematic OPs have gone by the wayside, for the most part, but there are still a couple of areas where they're still important in that we really don't have alternatives for them at this time."** ***Bob Arther, Manager of Entomology and Parasitology, Bayer Animal Health***

## COUMAPHOS TICK USE

Besides the niche uses of coumaphos for varroa mite and small hive beetle, "the other, sort of remarkable niche for coumaphos involves the tick that spreads cattle tick fever, which is a serious disease that was introduced along the Texas/Mexico border," Arther pointed out.

"The disease," he continued, "was eradicated back in the '60s by treating the cattle with an arsenical in dip vats. In 1968, coumpahos was developed as the alternative to that arsenic use, and it has remained the only product in that control program. It's been used by USDA and APHIS since 1968, and it's the only thing that really works for them. There are other things that could be used but they're happy with how well it's worked over the years.

"We've had other coumpahos uses for livestock that have been weeded out over the years, because it's an OP," Arther added, "but this other, remaining niche use is very valuable in preventing those ticks from crossing the Mexican border, so that's the other use we're supporting even though, again, it doesn't provide much of an economic benefit to Bayer.

"So," Arther observed, "all those problematic OPs have gone by the wayside, for the most part, but there are still a couple of areas where they're still important in that we really don't have alternatives for them at this time."

 

PESTICIDE.NET Insider eJournal

# A PESTICIDE.NET Profile Of The North American Pollinator Protection Campaign

***Honeybees in southern China have been wiped out and farmers now must pollinate fruit trees by hand. The North American Pollinator Protection Campaign hopes to avoid a similar fate in the U.S.***

Apple orchards in southern China provide the most vivid – if grim – illustration of a land without honeybees.

According to a paper posted by a British web site (www.beesfordevelopment.org), there are areas of China where the disappearance of honeybees has forced apple growers to pollinate apple flowers by hand – typically using a small brush or the filter-side of a cigarette.

Could that happen in the United States?

Most Americans who remember seeing bees in their gardens and back yards are aware that there aren't many, if any, feral bees to be seen where they used to be plentiful.

**Most Americans who remember seeing bees in their gardens and back yards are aware that there aren't many, if any, feral bees to be seen where they used to be plentiful.**

The reasons ascribed to their decline are plentiful, although there is often controversy when blame is assigned – especially when it comes to pesticide drift.

However, for those with a focus on efforts to preserve U.S. pollinators, there is major clearinghouse of data sources and links to relevant programs (both public and private) at www.nappc.org – the Internet home of the North American Pollinator Protection Campaign.

The mission of the group is simply "encouraging the health of resident and migratory pollinating animals in North America."

Given the complexity of its mission, NAPPC has established associations or partnerships with a vast array of entities – 120 in all – including apiaries, the California Department of Pesticide Regulation, museums, commodity groups, the United Nations Food and Agricultural Organization, universities, EPA's Pesticide Environmental Stewardship Program, the National Wildlife Federation, Canada's Pest Management Regulatory Agency, the USDA Agricultural Research Service, Syngenta Crop Protection, among many other partners.

Kimberly Winter, International Coordinator for NAPPC, told *Insider* that "we pride ourselves on the diversity of our stakeholders and our ability to bring that diversity to the table for discussions on the issues that affect pollinator conservation.

"I think," she added, "that we're able to have those discussions without being contentious, which is part of the reason we've been able to pull together symposia and even persuade the U.S. Postal Service to issue a

 

pollinator stamp series [to be issued in June]. We're not a group that bangs on the door demanding immediate action and threatening to leave if our demands aren't met. We bring people to the table and discuss things diplomatically."

Winter says it's difficult to identify the top NAPPC priorities because "we have a million different projects happening simultaneously. But, I would say one of our priorities would be applying the results and indications from the National Academy of Sciences pollinator studies that just came out.

"What we hope to do," Winter continued, "is use the results of that study to garner further research and investment by foundations and the government in pollinator conservation research, which would include things like studies on the ground of the economic importance of pollinators to agricultural crops. It would include monitoring and assessment of different pollinator species in the field and crops in the United States in different eco-regions. It would include increasing the level of research on different pollinator groups – you know that honeybees have been studied quite a bit. We'd like to get more research dollars invested in some of the rarer species or the species that have not yet really been studied in terms of life history traits and in terms our their population. Some of them are declining without us even knowing what they are.

**"We pride ourselves on the diversity of our stakeholders and our ability to bring that diversity to the table for discussions on the issues that affect pollinator conservation."** ***Kimberly Winter, International Coordinator, NAPPC***

"So many people don't know how important the pollinators are to agriculture," Winter added, "and the Academy findings alone will be a great wake-up call for the general public. They don't realize the importance of these little guys."

"Another priority," Winter noted, "was having June 24-30 declared National Pollinator Week, which came out in a USDA proclamation during our October meeting. We are really hoping for a media bonanza that week to get the word out to the public."

Winter said that, also during the October symposium, Gabriella Chavarria, Vice President of Science and International Conservation at Defenders of Wildlife, shared some information about the hand-pollination in China. (A paper by Chavarria, "Potential Consequences of Non-Native Bee Importation into North America," is available at the NAPPC web site.)

"She didn't really want to emphasize what was the distinct cause of [pollinator disappearance in China]," Winter pointed out. "What she emphasized was that the pollinators were gone. The crux of her presentation was that there are a lot of exotics out there that should not be imported for the purpose of pollination because, why introduce an exotic when you've got, for example, in North America, 4,000 species of native bees, why would we need to bring in more? What we need is research on our native bees to find out which ones are good. So, she

 

didn't really go into the cause and effect of it, she just said, here is an example of a system where it has completely shut down, the pollinators are not there, and people are having to hand-pollinate."

Among the many NAPPC efforts associated with EPA, the Association has started "reviewing some questions that they had devised in past years for pesticide applicator training material. It's a list of 10 or 12 questions for the pesticide applicator exam, so what we did is we create some questions that were pollinator-specific, just to draw some attention to the fact that some of the beneficial insects such as pollinators are out there and pesticide applicators should be aware of them, and, hopefully implement some behavioral changes to prevent over-spraying or spraying pollinators to death. We worked directly with EPA on that."

NAPPC, Winter notes, is not open to general public membership.

"When we started," she said, "we were a hand-selected group of experts in pollination. Then, as we watched the decline of pollinators, we decided we had to join forces with other stakeholders. We still want to contain our membership, but we need to reach out to the public, and we decided to go forward with that effort last year. We need the public supporting our mission."

## An *Insider* Look At Varroa Mite Research

***Jeff Pettis, Research Leader of the Agricultural Research Service's Bee Research Laboratory, discusses efforts to stop the deadly bee pest.***

Not only are varroa mites a deadly bee pest, they've become resistant to a pyrethroid pesticide and, now, they're starting to exhibit resistance to an organophosphate – coumpahos – which is the most effective tool currently available to control the mite.

The Agricultural Research Service's Bee Research Laboratory in Beltsville, Md., has been investigating, among other apiary issues, the biology and control of honey bee parasites, diseases and pests.

*Insider* asked Jeff Pettis, Research Leader at the ARS lab, to update recent developments in varroa mite research and control.

*Insider*: Where does varroa mite rank among the threats to honeybees?

*Pettis*: I feel it's the number one stressor. Pesticide drift does weaken colonies at certain times of the year, as do diseases and cool weather – all of that comes into play. It's a real battle to keep honeybees healthy, these days. But, varroa is the most significant stressor.

*Insider*: How significant is the level of varroa mite resistance to coumaphos?

*Pettis*: That is hard to say. I developed a field assay that beekeepers and

 

state regulators can use to detect coumaphos-resistant varroa, and it's been used in certain states, and by certain bee inspectors, to document the presence of resistant mites. But, I haven't done any kind of survey work, because my focus was just getting the assay out there, and I honestly don't have a good idea. What I do know is that the level of resistance is probably higher in commercial hives than in hobby hives.

"It's a real battle to keep honeybees healthy, these days. But, varroa is the most significant threat." *Jeff Pettis, Research Leader, Agricultural Research Service Bee Research Laboratory*

*Insider*: How does thymol complement coumaphos – and what is its mechanism of action?

*Pettis*: No one really knows the thymol mechanism other than it might be an irritant to the mites. But, if you get too much thymol into the colony it's disruptive to the bees as, well. There are a lot of things involved with balancing the toxicity of a substance to bees, versus its toxicity to mites.

*Insider*: Have honeybees developed any resistance to coumpahos?

*Pettis*: I don't think so. I think the dose in the strip has a sufficient safety margin built into it that the bees are not greatly affected, and the reason I doubt that bees are developing resistance to it is simply because they're not under as much selection pressure as the mites. The product is killing a lot of the mites, and those that survive have some mechanism to resist the coumpahos.

*Insider*: Is the Jacobson varroa species the primary mite of concern in the United States?

*Pettis*: Yes. There are other species, but we don't have any of those species in the United States. There are also different Jacobson biotypes, not even subspecies, but strains of varroa that seem to behave quite differently in terms of – to use a word which isn't really applicable to parasites – their virulence to bees. Some biotypes of varroa seem to do more damage to our European honeybees than do others.

*Insider*: Where are those other varroa species?

*Pettis*: Primarily Asia.

*Insider*: Do you feel that the varroa problem is worsening?

Pettis: For the past 10 years, it's been the number one problem for beekeepers, and I would have to say it's getting worse because varroa is now resistant to two of the control products, coumpahos being one and the other being fluvalinate – which controlled the mite worldwide pretty well. So, on the chemical control side, we're losing ground; the things we have coming along aren't as effective but, in some ways, that's not a bad thing.

In terms of selecting bee stocks that are somewhat tolerant or resistant to the mite, we're making great strides. But, we have to get beekeepers to use those stocks for them to work across a wide geographic area because

 

what happens is that beekeepers have preferences for bees that they know and that work well in their regions of the country. There are a lot of beekeeper biases.

But, they don't have a lot of alternatives, so their hand is being forced. There are a number of thymol products on the market, and they all work, but they tend to be temperature-dependent, so application timing becomes very important.

*Insider*: Are there any other biopesticides in use or on the horizon?

*Pettis*: There's an organic acid, formic acid, which is in a commercial product out of Canada. We actually developed a formic acid gel out of this lab, but we had packaging problems and it never made it to the market. Formic acid is a strong acid, so it raises safety issues for the beekeepers, although it's been used in Europe for years.

Another product, and we're working on making it legal, here, is oxalic acid. It's a milder acid to some degree, and it has worked well in Europe as a cleanup product – when there aren't any young bees in the colony and the bees are getting ready for winter.

*Insider*: Where did the mite come from?

*Pettis*: It came out of Asia on another species of honeybee, which is very similar to the European honeybee. It arrived in South America, first, and it was moving around with the Africanized honeybees. Actually, the European honeybee is exotic to all the Americas, as well. It was only found in Europe, and it was brought here by the Colonists. The Native Americans called it the "white man's fly."

Prior to the honeybees, flowering plants were pollinated by solitary bees, like the bumblebee. As U.S. agriculture became larger, you needed a mobile pollinator for these huge acreages – something with a large number of individuals to get out across the fields.

*Insider*: Why isn't the mite a federally listed exotic pest?

*Pettis*: The mite moved around the beekeeping community so quickly that APHIS just decided there was no way to regulate it, due to the mobile nature of beekeeping operations. About a third of all our managed colonies go to California to pollinate almonds, so we have this nice, large mixing bowl, there. Then, they're moved out to apples, then cranberries, then blueberries, and so forth. There's a great pot out there for mixing the bees and introducing the mite to colonies that aren't infested.

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