SUCCESSFUL BEEKEEPING

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Successes and Failures: History of Formic Acid in the USA

When I designed Mitegone in 1994 it was a great success in Canada. By 2001 it was popular in the USA and even around the word. In 2013 we registered 65% formic acid in



Canada for use with MiteGone pads and method. Unfortunately, in the USA, it was a long and different story.

It started in 2001 during the National convention of the American Beekeeping Federation (ABF) in Kansas City. At this time, mites were becoming resistant to Apistan and there were no new pesticides on the horizon. The president of the association invited us to do a workshop on the use of formic acid. As there were some concerns about legalities of formic acid use, and us doing seminars on its use, the president obtained a ruling from the EPA allowing our presentation. To the best of my recollection, the ruling was read when our work shop was announced, and it said:

Formic acid is not registered as pesticide; it is an uncontrolled natural substance which has ability to control mites. As such, there is no US law that will prevent a beekeeper to use it in his own hives any way he wants. Advising someone on how to use formic acid is legal.

Also at this meeting, the ABF passed a resolution asking everyone including Bee research centers, government bodies, and the EPA to register formic acid for use with honey bees.

I have copies of EPA rulings sent to me by the EPA on my request clarifying the legality of MiteGone. These rulings say that MiteGone is dispenser and method and as such not regulated by the EPA and therefore it is permitted to be sold in the USA. However, it also says that advertizing and selling acid as a pesticide needs registration by the manufacturer or seller or be subject to regulatory actions.

The unfortunate result of this for US beekeepers is that chemical companies refused to sell formic acid to beekeepers because they do not want to register the product. Formic acid can be purchased by anyone and retailers do not ask a lot of questions, but beekeepers cannot show up in decaled honey farm trucks or leave paper trail by paying with honey farm cheque.

I was further invited to come speak at many state conventions and clubs meetings, to facilitate educational seminars, and help formulate resolutions to help with formic acid use in beehives. A resolution passed at the 2005 Tucson Arizona American Honey Producers annual meeting is the best at describing what the American beekeeper really wanted:

""Be it resolved that AHPA ask Congress and the Secretary of Agriculture to direct the EPA to release, register, or, exempt from registration: formic acid in liquid form, at 65% dilution of any US technical grade formic acid, for use in beehives." This letter was sent to the EPA but no official reply was received. A phone call was received by the secretary of AHPA asking him if the AHPA has a reliable dispensing method. He said he did and named me and MiteGone.

That was how I got Involved in the 2012 registration process when the AHPA sponsored the IR4 (agency to register minor pesticides) and named MiteGone as delivery method. I approached Univar USA (a major producer and retailer of formic acid) to join us and volunteer to act as the registrant on behalf of the American beekeeper. The IR4 suggested that we proceed first with the registration of formic acid as the active ingredient and then with a 65% dilution. In 2013, in the first pre-submission meeting with EPA, we got the go ahead from the EPA and were ordered to provide data required for pesticides.

It took another three years and many hours of searching: to find this data do not exist. No formic acid manufacturer in the USA was willing to provide TGAI data. Then, Univar agents found a company in China willing to generate the data for \$70,000. Even if someone finds the money and pays the Chinese for this data, under the EPA rules, the EPA will register that acid only and no other acid can be used.

Do we really want the health and existence of American bees to depend on one foreign producer of formic acid?

By 2016 we began the second pre-admission meet with the EPA and argued that:

In the USA, after twenty or more years of formic acid use to control mites, researchers have found no contamination or resistance due to formic acid's unique property as a natural substance having the ability to control pests. And whereas formic acid is made by half-a-dozen manufacturers in various concentrations and dilutions being most common, accessible and inexpensive, we ask the EPA to waive the data requirements and register 65% generic formic acid as a "pesticide for mites on bees" and allow its use, and sale of end-use products including locally filled MiteGone dispensers.

The focus was on generic formic acid so that beekeepers could buy it anywhere acid is available, at whatever concentration, and use it by whatever method they want. This is what beekeepers are currently doing so why not make it official?

The response of EPA was that this would be possible, but because there were previous and existing registrations of end-use products using formic acid, the previous registrants must have supplied the data, and therefore we must also.

By then, I knew from my contacts that what the EPA was saying was not true. Neither the original producers of formic acid (in Mother Nature known as ants) could not have provided the data nor have all six synthetic manufacturers of formic acid never generated such data because no one has needed them. A high ranking official of BASF told me in off-the- record that this data does not exist and their company is not interested in cooperating, as creating the required data is cost prohibitive.

The US Registrations dated in the mid or late 1990s (none on market today), in all likelihood, did not require the data or the data requirement was waived. For example, it was waived for Apicure for their tolerance level studies. The current products coming from Canada were registered through the Canada-US agreement and EPA accepted PMRA (Canadian) documentation.

Canadian registrants do not have to provide any technical data at all. They have to sign a declaration that they will use in their product, a dilution of 85% acid from Univar Canada, which was registered as the active ingredient. I'm one of those registrants, and the IR4 has and submitted to EPA a complete set of data UNIVAR Canada data submitted to the PMRA. Where there is no TGAI data that the EPA requires.

As a historical sidebar, the Canadian PMRA made a bit of a blunder when it cancelled the formic acid C94 EXCEMPTION from registration. To get out of this jam the PMRA sponsored UNIVAR CANADA to register the active ingredient 85% FA, and WAIVED the non-existent data requirements.

By the end of 2016, Oxalic Acid was registered and its TGAI data waived. President Obama released his directive to the EPA to speed up solutions and promote the health of pollinators. In September 2016 AHPA, on our request, and on behalf of American Beekeepers, sent a long letter to the Administrator of the EPA. The letter follows:

Environmental Protection Agency Att: Gina McCarthy, EPA Administrator

RE: Registration of 65% Formic Acid for use on Honey Bees

Dear Ms. McCarthy,

American beekeepers represented by our Association need your help. Since 2005 we have been trying to register 65% dilution of any US industrial grade formic acid for use on honey bees. It has been widely proven that 65% formic acid has the ability to control parasitic mites on bees. (See the attached letter sent to your agency in 2005).

Since our letter to your agency in 2005, your staff and scientists have been very helpful in this process. In 2012 we began the process with help of an IR-4 and have been following the rules for man made pesticides. For three years our agents have been looking for the TGAI data for formic acid required to complete this process. Unfortunately, all companies that make formic acid have declined our requests for data. Only one company from China was willing to generate the data but at a cost of \$70,000.

Since formic acid is an uncontrolled substance, the data normally generated for manmade pesticides does not exist. In fact, formic acid is not a man made pesticide but a natural substance that has the ability to control parasitic mites on bees. The original, natural producers of this substance are ants and they cannot provide the TGAI data.

We believe that it is part of your mandate and function to amend the existing EPA rules to accommodate natural substances like formic acid. You have done this previously for oxalic acid under President Obama's strategy to promote the health of honey bees and other pollinators.

What the American beekeeper wants is to register a 65% dilution of generic, US industrial grade, formic acid for use on honey bee regardless of the manufacturer or seller. Therefore we ask you to waive the requirement of TGAI for this natural substance.

Under the present EPA rules, any beekeeper can use formic acid in their own hives as there is no law against it. The attached ruling regarding MiteGone as a reliable, scientifically proven, and safe method of applying formic acid supports this rule.

However, if the manufacturer or retailer of formic acid advertizes or knows that beekeepers are using the product as a pesticide, then the chemical company must register the product as a pesticide, or be subject to regulatory actions. The unfortunate result of this for beekeepers is that chemical companies then refuse to sell formic acid to beekeepers because they do not want to register the product.

The only reply to our 2005 letter was that liquid formic acid registration will require a proven method of application. This method exists with MiteGone (<u>www.mitegone.com</u>). If a product like MiteGone, designed as dry dispenser to be filled by the beekeeper, is filled locally by local beekeeping stores for sale, the store must register product. This is clearly cost prohibitive.

Further, since liquid formic acid is not registered, and the use of formic acid on bees is claim for pesticidal intent, Florida and Hawaiian State Authorities have declared it illegal to use on honey bees. In North Dakota, beekeepers have been fined for using formic acid on their hives. There is no need or a practical way to register the Technical Grade Active Ingredient of generic formic acid as there are many manufacturers and retail sources. Unfortunately, a TGAI can be tied only to one specific source.

An argument has been made that there are existing registered products that contain formic acid. This statement is true but also false. USA made FOR-MITE EPA #6167-1 never made it to market. Apicure EPA #72839-1 after brief use was pulled off the shelves. Canadian made Mite Away products applied for a joint Canada/US registration using TGAI for Univar 85% acid for which the PMRA waived the requirements for most of the data

Lastly, 60 years of formic acid use in Europe and 30 in the Americas has proven that formic acid is a safe and effective treatment to control parasitic mites on bees. The American honey Producers Association as a public entity registrant will not sell formic acid or dispensers that are currently on the market. Therefore, we will not receive any income from this registration. We are asking for a "Minor Use Fee Waivers/Exemption".

The letter was accompanied by scores of attached documents ensuring that the EPA received the full story. Mrs. McCarthy's response from the EPA was very positive and we received a copy of an email directing her personnel to accommodate our request. Armed with this positive directive, we went into our third pre-submission meeting in 2017 with several goals including: <u>discussing new registration</u>, new use, first food use, and amendment of Registration process.

We discussed how, under President Obama's strategy to promote the health of honey bees and other pollinators, we could register (yet be exempt from the pesticide rules requiring product chemistry data) a 65% dilution of generic, US industrial grade formic acid, for use on honey bees to control mites regardless of the manufacturer or seller, and with any commonly known application method.

As the EPA suggested in the notes to our previous pre-submission meetings, we were asked to consider a submission under Rule #5 which is the submission of a request for the data requirements to be waived if the request is supported by a scientifically-sound rationale explaining why the data requirements do not apply. We felt that we had a compelling argument under this rule since science has proven that formic acid is not pesticide but a natural substance having the ability to control both Tracheal and Varroa mites.

We hoped that this registered exemption would standardize and legalize the current use of formic acid throughout the USA. We believed that it is part of the EPA's mandate and function to amend the existing EPA rules to accommodate natural substances like formic acid. The EPA has done this previously for Oxalic Acid.

The IR4 put together an excellent presentation in the meeting with EPA in the summer of 2017. This fall we received an answer from the EPA and unfortunately they are still requiring the generation of data to complete the registration.

I sent and email to the EPA issuer of the ruling and asked for a meaningful discussion on the subject but I did not receive an answer.

I'm sorry to inform you, the American Beekeeper, that I do not have \$70,000 dollars to pay the Chinese to generate data. Data that President Trump would probably not accept as it would tie the health of American bee's to Chinese acid. Further, I do not have 20 more years to continue this merry-go-round.

Therefore, I'm passing the torch to you, the American beekeeper, and both national associations. According to the information I have, since both the AHPA and the ABF are nonprofit associations and are not selling anything, they can sponsor the registration and as registrants and have no liability to do so. This leaves the use and liability risks to the beekeepers that are using it by their own choice.

Further, in a registered exemption, no registrant is required.

There must be someone in the EPA who has the authority to change or amend the rules

What you, the average American beekeeper, should do is exercise your personal political pressure. Write personally to your politicians and have your local associations write to President Obama that EPA is being negligent with his directive to protect pollinators. Also, write to President Trump and ask him to use his favorite sentence, "You are fired" and send it to the EPA official who is not willing to revise the rules and register or exempt formic acid.

Copy the head of EPA on all of your correspondence and tell all of them that you want:

Because Formic Acid is Natural Substance having ability to control mites, and not a man made pesticide: We, American Beekeepers, are asking the EPA to officially legalize, and exempt from registration the use of 65% dilution of Generic Liquid US industrial grade Formic acid regardless of origin for use against parasitic mites on bees, by any commonly known method of application.

I BELIVE YOU CAN SUCEED!

PS: When you do succeed, contact the IR4, they have all paperwork ready, and will gladly finish the job for you.