Conn & Smith Inc.
Professionals in Pesticide Regulatory Services

October 26, 2017
VIA EMAIL: Lisa.Brines@ams.usda.gov

Lisa M. Brines, Ph.D.
National List Manager
USDA National Organic Program

Dear Dr. Brines:

RE: Polyoxin D Zinc Salt
Planned Limited Scope Technical Report

This letter is submitted on behalf of Kaken Pharmaceutical Co., Ltd. (Kaken) and is for public posting in support of the petition regarding Polyoxin D Zinc Salt that was submitted to NOP on May 31, 2016, *i.e.*, nearly 17 months ago.

Crops Subcommittee's Questions for the Technical Reviewer

Based upon your email message to me dated October 13, 2017, the Crops Subcommittee, via the National Organic Program, has asked the Technical Reviewer to respond to the following questions in the planned requested limited scope technical report for polyoxin D zinc salt petition that was submitted May 31, 2016.

Q1. Could Polyoxin D function without the zinc salt added to it to improve surface retention, or would there be a possible replacement that would be non-synthetic? What is the action and use of Polyoxin D complex by itself compared to with zinc added?

Q2. There are numerous studies referenced by the petitioner that the Subcommittee would like verification on to help with the validity of the claims of the petitioner. Some specific examples are studies referenced for: soil studies, beneficial insect impact studies, impact on beneficial soil fungi, mode of action, etc.

Q3. Update on global organic use or recognition and/or any changes since the previous technical report.

Below, Kaken offers clarifications for the benefit of the Technical Reviewer and the members of the National Organic Standards Board and National Organic Program.

Q1a: Could Polyoxin D function without the zinc salt added to it to improve surface retention?

A1a: Polyoxin D without the zinc salt is *not* an EPA registered pesticide. It would be *prohibitively costly* to pursue EPA registration of polyoxin D (without the zinc) as a new active ingredient. New efficacy studies would be required. Commercially viable efficacy is not anticipated. If commercially viable efficacy could be demonstrated, well over 1 million dollars in new EPA registration studies would be required.

Surface tension is not the issue. Water solubility is the issue. Polyoxin D is very water soluble and would wash off the plant surface. Contact with the plant surface is needed for efficacy.

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Q1b: Would there be a possible replacement that would be non-synthetic?

A1b: This will depend upon the *published* efficacy data for each crop/disease combination of any candidate non-synthetic replacement.

This question also misses an important point. Polyoxin D zinc salt provides a new mode of action for organic growers who already have a short list of available modes of action. A new mode of action provides a tool for resistance management. Pathogen resistance to some fungicide active ingredients has been observed. More information of fungicide resistance is available from the Fungicide Resistance Action Committee at http://www.frac.info/home.

Q1c: What is the action and use of Polyoxin D complex by itself compared to with zinc added?

A1c: "Polyoxin D complex" *does not exist*.

- Polyoxin D zinc salt is an EPA registered pesticide.
- Polyoxin complex is *not* an EPA registered pesticide. Polyoxin complex is produced by Kaken and registered by Kaken for use in Asia. Polyoxin complex is *chemically quite different* than polyoxin D and polyoxin D zinc salt.
- Polyoxin D zinc salt and polyoxin complex have *very different efficacy*.

World-wide, there is:

- *No* commercial *production* of polyoxin D without the conversion to the zinc salt; and
- *No* commercial *use* of polyoxin D without the conversion to the zinc salt.

The pending petition is limited to polyoxin D zinc salt and its 5SC (5% suspension concentrate) formulation.

Q2: There are numerous studies referenced by the petitioner that the Subcommittee would like verification on to help with the validity of the claims of the petitioner. Some specific examples are studies referenced for: soil studies, beneficial insect impact studies, impact on beneficial soil fungi, mode of action, etc.

A2: Kaken welcomes the comments of the technical reviewer. Kaken notes:

- The studies on soil, beneficial insects, and beneficial soil fungi are applied biology studies, whereas the mode of action studies are physical chemistry (kinetics) studies.
- To provide the requested technical evaluation, the technical reviewer will need technical expertise in *both* biology and physical chemistry (kinetics).

Q3a: Update on global organic use or recognition?

A3a: The polyoxin D zinc salt 5SC formulation is specifically designed for the US organic market. At this time, organic use has been requested for the US only. No applications have been approved or are pending in other parts of the world. Correction of the error-filled September 23, 2012 NOP technical report is effectively a necessary first step before Kaken can realistically consider requesting organic approval in any other part of the world.

Q3b: Any changes?

A3b: Yes, there have been many changes in the United States and internationally. An NOP petition supplement is planned.

Kaken has:

- Conducted additional US efficacy trials; and
- Expanded the US EPA label to include new uses that will be important for organic growers. The most recently accepted EPA label is available at: https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:8:10470908525581::NO::P8_PUID,P8_RINUM:508243,68173-4 .

Final reports for the 2017 efficacy trials are anticipated to be received by Kaken by mid-December, 2017. A further proposed EPA label expansion is anticipated to be submitted to EPA by early 2018. EPA acceptance of the proposed revised label is anticipated approximately 90 days after submission, *i.e.*, by early April 2018.

Kaken has been pursuing international regulatory approvals.

- Canada and New Zealand. Polyoxin D zinc salt and the 5SC formulation have been registered for use in Canada and New Zealand. Crops grown in the United States and treated with polyoxin D zinc salt per the EPA registered label may be imported into Canada and New Zealand.
- Other countries. Kaken has submitted or is planning to submit multiple applications for regulatory approval to regulatory authorities in various regions of the world for which export of US grown commodities is important to US growers. These include applications for registration (use) and import MRL "exemption" applications. The earliest new regulatory approvals (registration and MRL "exemption") are anticipated during November/December 2017.

Please feel free to contact me at 703-339-1117 or cindy@connsmith.com or Mr. K. Takei of Kaken at takei_ken-ichiro@kaken.co.jp if there are any questions regarding this letter.

Sincerely,

Cynthia Ann Smith

Cynthia Ann Smith
Agent for Kaken Pharmaceutical Co., Ltd.

cc: K. Takei, Kaken Pharmaceutical Co., Ltd.