

US EPA ARCHIVE DOCUMENT



US Environmental Protection Agency Office of Pesticide Programs

Memorandum of Agreement Between EPA and Agan Chemical Manufacturing, Ltd., and Makhteshim Agan of North America, Inc. Regarding Registration of Pesticide Products containing Dicofol

May 2011

Memorandum of Agreement Between the Environmental Protection Agency and Agan Chemical Manufacturing, Ltd., and Makhteshim Agan of North America, Inc., Regarding the Registration of Pesticide Products Containing Dicofof

This Memorandum, effective as of the 17th day of May, 2011, sets forth the terms of an agreement (“Agreement”) made and entered into by and between Agan Chemical Manufacturing, Ltd., an Israeli corporation (“ACM”), and Makhteshim Agan of North America, Inc., a Delaware Corporation (“MANA”) (each of the foregoing entities hereinafter being referred to as a “Registrant” or collectively as “Registrants”), and The Office of Pesticide Programs (“OPP”) of the United States Environmental Protection Agency (“EPA”) on behalf of EPA, regarding the registrations held by the Registrants under the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) of pesticide products containing dicofof (“dicofof products”). Provided that the terms of this Agreement are fully implemented as stated herein and according to the schedules set forth herein, EPA has no current intention, with respect to the issues addressed in this Agreement, to initiate cancellation or suspension proceedings under sections 6(b) or 6(c) of FIFRA, or to take any action to limit their sale and distribution not specified in this Agreement.

The specific terms of this Agreement are as follows:

1. By its signature below, each Registrant hereby requests, pursuant to section 6(f) of FIFRA, and as conditioned in this Agreement, voluntary cancellation of all Registrants’ dicofof FIFRA registrations. The Registrants request cancellation of their technical product EPA Reg. No. 11603-26 (dicofof technical registration) as of May 17, 2011. The Registrants request cancellations of their end-use products, EPA Reg. Nos. 66222-21, 66222-56, 66222-95, but not to be effective before October 31, 2013. The Registrants’ requests are irrevocable and

unconditional, except as provided in this paragraph. The requests are expressly conditioned upon the inclusion in any cancellation order of the terms set forth in this paragraph concerning the effective date of cancellation, in paragraph 3 of this Agreement governing the treatment of existing stocks of canceled products, and in paragraph 4 regarding labeling. The Registrants also request that the Administrator waive the 180-day public comment period under section 6(f)(1)(C)(ii).

2. EPA intends to publish a Federal Register Notice promptly upon execution of this Agreement announcing receipt of the Registrants' requests for voluntary cancellation of all the Registrants' dicofol registrations and announce a 30-day public comment period. EPA anticipates that, shortly after the close of the public comment period, EPA will issue a final order granting the request for cancellation described in Paragraph 1 of this Agreement, with an immediate effective date with respect to the dicofol technical registration and an effective date of October 31, 2013, for the dicofol end-use products.

3. The voluntary cancellation request in paragraph 1 is expressly conditioned upon the inclusion of the following existing stocks provisions. In any cancellation order issued in response to Registrants' requests for voluntary cancellation:

(A) Registrants of dicofol end-use products shall be allowed to sell and distribute existing stocks until October 31, 2013, and thereafter only for export consistent with the requirements of FIFRA section 17 or for purposes of proper disposal;

(B) Sale and distribution of existing stocks of any dicofol product by persons other than Registrants shall be allowed until December 31, 2013, and thereafter only for products intended for export consistent with the requirements of FIFRA section 17 or for purposes of proper disposal; and

(C) Use of existing stocks of any end-use product shall be allowed until October 31, 2016, and thereafter only for purposes of proper disposal.

4. By their signatures below, MANA hereby requests and EPA grants amendments to MANA's dicofol end-use product registrations to add a condition of registration that as of August 31, 2011, the Registrants will not sell or distribute dicofol end-use products that do not bear a prominent sticker prior to sale or distribution by the Registrants that declares: "It is unlawful to use this product after October 31, 2016."

5. Each Registrant agrees that its failure to comply with any of the conditions of registration set forth in this Agreement shall be grounds for cancellation of its affected registration(s) under FIFRA Section 6(e).

6. The cancellation orders issued pursuant to this Agreement shall be deemed to satisfy all Data Call-In Notices issued to the Registrants under FIFRA Section 3(c)(2)(B) and orders issued under Section 408(p) of the Federal Food, Drug, and Cosmetic Act ("FFDCA") requiring the submission of data to support registrations of dicofol products, and the Registrants execution of this Agreement shall be deemed "appropriate steps" toward the securing of the data in question,

for purposes of FIFRA Section 3(c)(2)(B)(iv) and to have complied with dicofol orders under FFDCA. Provided that the terms of this Agreement are fully implemented as stated herein and implemented according to the schedules as stated herein, EPA does not intend to issue any further such notices to the Registrants pertaining to Registrants' currently registered dicofol products. However, any entity wishing to establish a registration for a dicofol product will be required to submit or cite data necessary to make the applicable finding under section 3 of FIFRA or section 408 of the FFDCA. Further, nothing in this Agreement shall restrict EPA's rights at any time to issue an order under section 408 of the FFDCA requiring the submission by any person of information necessary for retention of dicofol pesticide tolerances or, in the event such an order is issued against a Registrant or Registrants, restrict the Registrant's(s) right(s) to dispute the lawfulness or appropriateness of such an order.

7. Nothing in this Agreement shall be construed as preventing EPA from initiating any regulatory action it deems appropriate under FIFRA or the FFDCA, nor shall it be construed as preventing any signatory Registrant from raising any otherwise appropriate defense or challenge to such action. Each signatory Registrant shall be responsible solely for its own individual compliance with the obligations set forth in this Agreement.

8. EPA does not intend at this time to grant any application for registration, or amendment to any existing registration, of any product containing dicofol unless the registration includes all applicable terms and conditions of this Agreement. If EPA does so with terms and conditions different than those set forth in this Agreement, any Registrant may request (through appropriate

applications for new registrations or amendments to existing registrations) registrations with similar conditions pursuant to FIFRA Section 3(c)(7)(A) and EPA shall act promptly upon such a requests consistent with the requirements and decision review periods of FIFRA Section 33.

9. The Registrants agree that they will not challenge or provide financial or technical assistance to anyone challenging in any judicial or administrative forum any of the provisions of this Agreement, any cancellation orders or section 6(f) notices or the pendency of such orders or notices putting the terms of this Agreement into effect. Notwithstanding the foregoing sentence, nothing in this paragraph shall limit a Registrant's right to: (1) provide information concerning dicofol to any other entity unless it can reasonably be anticipated that such information is intended to be used by that entity in litigation (or in other ways) against the Agency for the purposes of challenging any of the provisions of or implementation of this Agreement; (2) challenge (in any forum) the Agency's failure to apply to dicofol after the date of this Agreement any changes in, or adoption of, EPA policies of general applicability that would result in a material change in the limitations or obligations imposed on Registrants under this Agreement; (3) support or participate in any action (in any forum) that challenges any EPA policy or practice of general applicability that may affect the limitations or obligations of Registrants under this Agreement, including the support of or participation in the activities of any trade association or coalition that is involved in any such challenge; (4) defend any personal injury/toxic tort suit and raise any defense in such suit; or (5) submit applications for registration of dicofol products provided that no such application shall be subject to 40 C.F.R. Part 164, subpart D.

10. In the event that any person, acting independently of any Registrant, asserts in any judicial forum that this Agreement (or any provision hereof) is inconsistent with any obligation of EPA or otherwise files an action challenging the lawfulness of this Agreement, and obtains a Court Order finding unlawful any provision of this Agreement that limits a Registrant's ability to sell or distribute dicofol product for any use that is lawful as of the effective date of this Agreement, each Registrant shall be relieved of all obligations to comply with this Agreement and EPA shall act promptly on any application consistent with such Court Order from a Registrant to amend its registration(s) to delete any cancellation dates for uses still on the label at the time of the Court Order. Nothing in this Agreement shall limit the right of any registrant to intervene in any proceeding to support the legality and appropriateness of this Agreement.

11. If a Registrant believes that any judicial or administrative proceeding or decision not addressed in the foregoing paragraph may either directly or indirectly impact this Agreement, such Registrant shall notify EPA as promptly as possible of its belief. The Registrants and EPA agree to meet within a reasonable time of EPA's receipt of such notification to discuss in good faith whether any changes to this Agreement are appropriate and, if so, to negotiate in good faith to adopt appropriate changes.

12. This Agreement may be executed in any number of counterpart originals, each of which shall be deemed to constitute an original agreement, and all of which shall constitute one agreement. The execution of one counterpart by any party shall have the same force and effect as if that party had signed all other counterparts.

13. It is hereby expressly understood and agreed that this Agreement was jointly drafted by the Registrants and EPA. Accordingly, the parties hereby agree that any and all rules of construction to the effect that ambiguity is construed against the drafting party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Agreement.

14. This Agreement constitutes the complete Agreement reached by EPA and the Registrants. All prior conversations, meetings, discussions, drafts and writings of any kind are specifically superseded by this Agreement. This Agreement shall be effective as to each party on the date stated on the first page of this Agreement, upon its execution by both that part and EPA. There are no agreements, representations, or inducements made or exchanged between the parties beyond those set forth in this Agreement. The terms of this Agreement may only be amended by mutual consent of the parties in writing.

[Remainder of page intentionally left blank]

This Agreement has been executed by the Office of Pesticide Programs and by duly authorized representatives of the Registrants:

Bernard P. Keigwin, Jr.
Office of Pesticide Programs

Date: 5/20/2011

Kris Venterdeh
Authorized Agent, Agan Chemical Manufacturing, Ltd.

Date: 05/17/2011

Kris Venterdeh
Authorized Agent, Makhteshim Agan of North America, Inc.
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Date: 05/17/2011