UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Benefits and Public Interest Findings for Flutianil (A New Fungicide) to Control Fungal Diseases on Apples, Cantaloupes, Cherries, Cucumbers, Grapes, Summer Squash and Strawberries (PC# 014018, DP# 437656)

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PRODUCT REVIEW PANEL: February 15, 2017

SUMMARY

Oat Agrio Co., Ltd., Tokyo (Japan) submitted an application for the registration of flutianil fungicide (a new active ingredient [a.i.] with a new mode of action on fungi) for controlling powdery mildews on apples, cantaloupes, cherries, cucumbers, grapes, summer squash and strawberries. The Biological and Economic Analysis Division (BEAD) is providing a benefits assessment and public interest finding for flutianil to the Registration Division (RD) for RD's consideration of whether to grant a conditional registration of a new active ingredient.

Based on information submitted by the registrant as well as publicly available information (as cited in the references section, below), BEAD concludes that flutianil has high benefits for the control of powdery mildews on various crops (apple, cantaloupe, cherry, grape, summer squash, and strawberry). Flutianil has a unique mode of action that inhibits haustoria formation in powdery mildew fungi and thus inhibits fungal infections and spread on plant hosts. This mode of action is different from the existing fungicides for controlling powdery mildews on different crops. It is classified as having an "unknown" mode of action (U13) by the Fungicide Resistance Action Committee (FRAC, 2017) and it does not have cross resistance with other fungicides. In efficacy trials, flutianil provided consistent and reliable control of powdery mildews on apple,

cantaloupe, cherry, grape, summer squash, and strawberry. Flutianil-treated crops showed a high degree of foliage protection allowing the crop to reach its full yield and quality potential. In addition to disease control, flutianil is likely to play an important role in fungicide resistance management because of its unique mode of action that is different than all registered fungicides.

BEAD finds that flutianil meets the presumption of public interest for a minor use on cantaloupes, cherries, cucumbers, summer squash and strawberries as each of these crop is grown on fewer than 300,000 acres. Additionally, BEAD has determined that the conditional registration of flutianil would be in the public interest because it also provides benefits in controlling powdery mildew disease on apple, cantaloupe, cherry, grape, summer squash, and strawberry.

BACKGROUND

EPA registers pesticides under section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). A registration is granted unconditionally under section 3(c)(5) of FIFRA or conditionally under 3(c)(7) of FIFRA if the appropriate criteria are met. Each authority available to EPA for registering a pesticide under section 3(c) involves a finding related to whether the pesticide poses unreasonable adverse effects on the environment. "Unreasonable adverse effects on the environment" is defined in section 2(bb) of FIFRA to include "any unreasonable risk to man or the environment taking into account the economic, social, and environmental costs and benefits of the use of the pesticide. Therefore, in cases where a pesticide presents meaningful risks, EPA assesses the benefits of the pesticide to determine whether those risks would lead to unreasonable adverse effects.

Under FIFRA 3(c)(7)(C), EPA can register a pesticide containing a new active through a conditional registration even though data are lacking because the registrant has not had sufficient time to generate all data required for registration.

A Federal Register (FR) notice (51FR 7632; March 5, 1986) describes criteria for conditional registration, including the requirement for the Environmental Protection Agency (EPA, or the Agency) to "determine that use of the new chemical during the period of the conditional registration will be in the public interest." According to the FR notice Part IV, Section A (Presumption of Public Interest), registration of a new pesticide is presumed to be in the public interest for 1) a minor use (e.g., less than 300,000 acres [FIFRA 2 (II) (2)]), 2) a replacement for another pesticide that is of continuing risk concern to the Agency, 3) a use for which an exemption under FIFRA Section 18 has been granted, and 4) a use against a pest of public health significance.

According to FR notice Part IV, Section B (Factors Affecting a Public Interest Finding), if a pesticide does not meet one of the four presumptive categories above, the EPA may determine that such a registration is in the public interest if: [1] there is a need for the new chemical that is not being met by other currently registered pesticides non-pesticidal alternatives; [2] the new pesticide is comparatively less risky to health or the environment than currently registered pesticides; or [3] the benefits (including economic benefits) from use of the new chemical exceed those of alternatives registered pesticides and other available non-chemical techniques.

INTRODUCTION AND REGISTRANT CLAIMS

Oat Agrio Co., Ltd., Tokyo (Japan) submitted an application for the registration of flutianil fungicide for controlling powdery mildews on apples, cantaloupes, cherries, cucumbers, grapes, summer squash and strawberries. It is claimed that flutianil has a unique mode of action, low toxicity profile, and it is highly effective in controlling various fungal diseases (powdery mildews) on different crops (apples, cantaloupes, cherries, cucumbers, grapes, summer squash and strawberries). Its use rate is significantly lower than the registered alternatives on all crops. It is likely to play a significant role in resistance management for controlling powdery mildews on different crops (major and minor) as its mode of action is new and no resistance has been reported in fungi against it. In addition, flutianil does not have cross resistance with other fungicides (Oat Agrios, 2016). This memorandum addresses BEAD's assessment for the registration of flutianil in regards to the public interest and a general discussion on benefits of using flutianil on different crops for controlling fungal pests.

BEAD ANALYSIS

BENEFITS:

BEAD reviewed the submitted data package by the registrant (Layton *et. al.,* 2016). The registrant claimed that flutianil belongs to Group U13 of fungicide grouping by Fungicide Resistance Action Committee (FRAC, 2016). BEAD verified that flutianil's mode of action is unknown and it belongs of Group U13. Flutianil has a unique mode and mechanism of action that inhibits haustoria formation in powdery mildew fungi that is essential to cause infections on plant hosts. Powdery mildews of cucurbits can cause yield losses up to 45 percent (O'Brien *et al.*, 1988). A review of submitted data showed that flutianil is effective against powdery mildew fungal pests (*Podosphaera leucotricha*, *Podosphaera xanthii*, *Podosphaera clandestina*, *Uncinula necator*, *Sphaerotheca macularis* f. sp. *fragariae*) at very low application rates (0.04lb ai/A per application) compared to registered alternatives (myclobutanil, quinoxyfen, triflumizole, pyroclostrobin, chlorothalonil, sulfur). A review of submitted comparative efficacy data showed that flutianil is very effective in controlling powdery mildews on different crops (apples, cantaloupes, cherries, cucumbers, grapes, summer squash and strawberries). The data also showed that flutianil's efficacy is generally superior or at par with commercial disease control standard achieved using registered alternatives (chlorothalonil, sulfur, triflumizole, quinoxyfen, myclobutanil, pyraclostrobin) on these crops.

According to the FRAC Code List 2017 (FRAC, 2017), most of the competitive active ingredients (except chlorothalonil and sulfur) have medium to high risk of resistance development in powdery mildews. On squash, powdery mildew has been reported to develop resistance against strobilurins (azoxystrobin) and triazole (myclobutanil, triflumizole) fungicides (McGrath, no date). Chlorothalonil and sulfur are protectant fungicides that have low risk of resistance development (FRAC, 2017) and are used in powdery mildew control programs (on different crops) with other fungicides (such as triflumizole, quinoxyfen) (McGrath, 2004; Koike, *et al.*, 2008; Schilder, 2013) for commercially acceptable disease control. There is no known resistance in powdery mildew fungi against flutianil. Flutianil is likely to play a significant role

in powdery mildew control on different crops and in resistance management because of its unique mode of action and high efficacy in controlling powdery mildews.

PUBLIC INTEREST FINDINGS:

BEAD's public interest finding review focused on two areas: FR notice Part IV, Sec. A [1]and information indicating performance of flutianil against target fungal diseases: efficacy against pests, its unique characteristics and resistance management (FR notice Part IV, Sec. B [3]). These areas are discussed as below.

Minor Use:
Flutianil is being considered for registration on many crops (cantaloupes, cherries, cucumbers, summer squash and strawberries). According to the 2012 Census of Agriculture (NASS, 2014), each of these crops is grown on fewer than 300,000 acres in the United States, which meets the definition of minor use.

Benefits in Comparison to Alternatives:

Flutianil is also being considered for registration on apples and grapes, which are not minor uses. Therefore, BEAD considered whether the benefits from use of the new chemical exceed those of alternatives registered pesticides and other available non-chemical techniques. These benefits of using flutianil on requested crops are discussed above.

CONCLUSIONS

BEAD concludes that flutianil has a unique mode of action and is highly effective in controlling powdery mildew diseases. Flutianil is likely to play a significant role in fungicide resistance management. Flutianil meets the presumption of public interest because of its proposed registration for minor uses (cantaloupes, cherries, cucumbers, summer squash and strawberries). Flutianil provides benefits since the benefits exceed those of the alternative control options as it has a new mode of action, no known resistance in any powdery mildew pathogen, has high efficacy in controlling the pests, and shall play a role in resistance management against powdery mildews on different crops. The main registered alternatives (such as triflumizole, myclobutanil, pyraclostrobin) have medium to high risk of resistance development in powdery mildews (FRAC, 2017).

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