



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

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mr. Jerry Wells  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419

MAY 11 2012

Re: Petition for Extension of the Exclusive Use Data Protection Period for  
Mesotrione (EPA Reg. No. 100-1140) to June 4, 2014, Under FIFRA section 3(c)(1)(F)(ii)

Dear Mr. Wells:

This is in response to your request, dated April 15, 2011, that data associated with the registration of the active ingredient mesotrione receive extensions for the exclusive use period protection. You cited FIFRA section 3(c)(1)(F)(ii) as the authority for the Agency to make such a determination.

The 1996 Food Quality Protection Act (FQPA) amendments to FIFRA incorporated this subsection under 3(c)(1)(F), the section that provides for protection of certain data submitted in support of pesticide registrations. FIFRA section 3(c)(1)(F)(ii) sets forth the criteria for extending the period of exclusive use protection. The period of exclusivity can be extended one year for every three minor uses registered within the first seven years of an original registration whose data retains exclusive use protection, with a maximum of an additional three years to the exclusivity period.

The first step in determining whether data qualifies for an extension of its exclusive use period is to ascertain which data have exclusive use protection. FIFRA section 3(c)(1)(F)(i) and its implementing regulations carefully circumscribe the set of data that is eligible for exclusive use protection. A study entitled to exclusive use protection is defined in 40 CFR §152.83(c).

Pursuant to 40 CFR §152.83(c), the following requirements must be met for a study to be considered an exclusive use study:

- (1) The study pertains to a new active ingredient (new chemical) or new combination of active ingredients (new combination) first registered after September 30, 1978;
- (2) The study was submitted in support of, or as a condition of approval of; the application resulting in the first registration of a product containing such new chemical or new combination (first registration), or an application to amend such registration to add a new use; and

- (3) The study was not submitted to satisfy a data requirement imposed under FIFRA section 3(c)(2)(B);

The following is our analysis for determining whether the data associated with the registration you have cited contains exclusive use data. First, the data associated with this registration do pertain to, or have been derived from testing on, a new active ingredient.

Second, the data must have been submitted in support of the first registration of the new chemical.<sup>1</sup> The registration you cited was granted on June 3, 2001, and was the first registration with the active ingredient mesotrione, under the product name Callisto Herbicide (EPA Reg. No. 100-1131).

Lastly, because exclusive use protection is not available for studies that the agency requires to maintain registration in effect under FIFRA section 3(c)(2)(B), any such data associated with this registration will not receive exclusive use protection under FIFRA section 3 (c)(1)(F)(ii).

Now that the Agency has determined that studies associated with this registration are exclusive use studies<sup>2</sup>, we must determine whether you have met the criteria for extending the exclusive use protection pursuant to FIFRA section 3(c)(1)(F)(ii), and if so, by how many years.

FIFRA section 3(c)(1)(F)(ii) states, in pertinent part:

The period of exclusive data use provided under clause (i) shall be extended 1 additional year for each 3 minor uses registered after the date of enactment of this clause and within 7 years of the commencement of the exclusive use period, up to a total of 3 additional uses for all minor uses registered by the Administrator if the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, that:

- (I) there are insufficient efficacious alternative registered pesticides available for the use;
- (II) the alternatives to the minor use pesticide pose greater risks to the environment or human health;
- (III) the minor use pesticide plays or will play a significant part in managing pest resistance; or

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<sup>1</sup> Data are not protected solely because they pertain to the new chemical, but because they are submitted in support of a particular product registration of a new chemical. Thus, data submitted to support an application for the second (and later) registrations, by whatever applicant, of a product containing the same new chemical acquire no exclusive use protection. Additionally, data submitted in support of subsequent amendments to add new uses to the first registration of a product containing the new chemical gain such protection, but the protection is limited to data that pertain solely to the new use. Thus, for example, if the new use is approved after eight years of registration, the data supporting that use would gain exclusive use protection for only two years. See 49 FR 30884, 30889.

<sup>2</sup> This response is general in nature. If the Agency receives a me-too application for this pesticide during the extension period citing Syngenta data, it will then address whether those data have the extension of protection.

(IV) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The registration of a pesticide for a minor use on a crop grouping established by the Administrator shall be considered, for purposes of this clause, 1 minor use for each representative crop for which data are provided in the crop grouping. Any additional exclusive use period under this clause shall be modified as appropriate or terminated if the registrant voluntarily cancels the product or deletes from the registration the minor uses which formed the basis for the extension of the additional exclusive use period, or if the Administrator determines that the registrant is not actually marketing the product for such minor uses.

After reviewing the Agency's files and Syngenta's letter dated April 15, 2011, we have confirmed the following: In January, 2009, Syngenta petitioned the Agency for a three-year extension of the exclusive-use period for data submitted in support of the mesotrione registration. This request was based on consideration of 14 minor uses which were added to the mesotrione technical label within seven years of the initial registration. Seven of these met at least one of the criteria for the extension of the exclusive use period. Therefore, in March, 2010, the Agency granted a two-year extension of the exclusive-use period for data submitted in support of the mesotrione registration (until June 4, 2013). Two more minor uses are needed for mesotrione to be qualified for an extension of the exclusive use period one more year, for a total of 3 years. In April, 2011, Syngenta submitted information on 4 more minor crops (blackberry, raspberry, okra, and lingonberry), and requested an extension of the exclusive data use period for an additional year. After reviewing the currently approved label for mesotrione technical, the Agency has determined that the following minor uses qualify toward the request for extension of exclusive use protection<sup>3</sup>: okra and blackberry. As required by statute, the aforementioned minor uses associated with the crop groupings were all registered within the requisite seven year period.

Table1. Events Described in the Summary and Background Sections

Event	Date and Description
Registration of mesotrione (as Callisto Herbicide)	June 4, 2001
Initial 10 yr exclusive data use period.	June 4, 2011
Syngenta submitted initial application for extension of exclusive data use period in January, 2009	In the initial application, information on 12 crops was included. In January 2010, EPA determined that of the 12 crops, 6 crops meet the criteria for extension of exclusive data use period: asparagus, blueberry, cranberry, Kentucky bluegrass grown for seed, rhubarb, and sweet sorghum
Syngenta submitted information on two more	On March 3 2010, EPA determined that of these 2

<sup>3</sup> Because the statute sets a maximum of a three year extension for exclusive use protection provided that 9 minor uses are added within the seven year period after registration, the Agency did not list more than nine eligible minor uses. There may be additional uses not listed in this document that also count toward exclusive use protection. The agency will evaluate those uses for eligibility should the registrant decide to voluntarily cancel or stop marketing any of the 9 uses currently forming the basis of the extension.

crops; perennial ryegrass and tall fescue for consideration	additional crops, only perennial ryegrass meets one criterion for extension of exclusive data use period
Seven crops met the criteria and in June 2010, the Agency granted 2 years of extension of exclusive data use period for mesotrione	The new expiration date of exclusive data use period for mesotrione is June 4, 2013
In April 2011, Syngenta submitted information on four more crops; blackberry, raspberry, okra, and lingonberry.	EPA determined that of these 4 crops okra and blackberry meet one criterion for extension of exclusive data use period for mesotrione. This fulfilled the requirement of 9 minor crops needed for extension of exclusive data use period for maximum of 3years

In addition to meeting the minor use requirements, as stated above FIFRA section 3(c)(1)(F)(ii) requires that one of the criteria I - IV be met.

Mesotrione belongs to the Herbicide Resistance Action Committee (HRAC) Group 27. Group 27 chemicals act by inhibition of 4-hydroxyphenyl-pyruvatedioxygenase (4-HPPD). The Callisto label contains “mode/target site of action grouping and identification symbol” graphics, as well as voluntary resistance management statements recommended by PR Notice 2001-5. The label states, “Callisto is a Group 27 Herbicide (contains the active ingredient mesotrione). Naturally occurring biotypes of certain broadleaf weed species with resistance to triazines, glyphosate, PRO, HPPD and ALS inhibiting herbicides are known to exist. Performance of Callisto is not affected by the presence of biotypes resistant to triazines, glyphosate, PPO or ALS inhibiting herbicides. To prevent the risk of weeds developing resistance to Callisto in corn, always use full labeled rates. If applying Callisto postemergence after a mesotrione-containing preemergence herbicide, always add atrazine as a tank mix partner. No more than 0.24 lb. of mesotrione active ingredient must be applied per acre of corn per year (equivalent of 7.7 fl. oz. per acre per year of Callisto). If additional herbicide must be applied, it is recommended that a different mode of action be used, i.e., other than an HPPD inhibitor (Group 27 Herbicide). Callisto must be applied at full label rates to help prevent selection for, or population shifts toward, marginally tolerant weed species and/or species biotypes.”

The Agency determined that mesotrione plays a role in managing resistant weed biotypes in okra and blackberry, meeting the requirements of criterion III, above. The justification for this is as follows (excerpted from the memorandum, “Review of Justification for the Extension of Exclusive Data Use Period for Mesotrione (DP #389857),” dated November 30, 2011:

**Table 2. Crops Included in 2011 Submission and Supporting Data Status**

Crop	Acreage	Date Registered	Residue Data Submitted
Okra	2,444	03/17/08	Yes
Blackberry	14,874	01/09/08	Yes
Raspberry	21,554	01/09/08	Yes
Lingonberry (under other berries)	828	01/09/08	Yes

Source: Census of Agriculture, 2007.

**Okra:** Based on the USDA 2007 Census of Agriculture, acreage of okra grown in the United State is estimated to be 2,444 acres (Table 1). Therefore, the production acreage of okra does not exceed the threshold level used for determination of minor crop status under the provisions of FIFRA § 3( c )(l)(F)(ii). Furthermore, Syngenta registered mesotrione for weed control in okra production in March, 2008, within the first 7-yr period after the initial registration of this herbicide (June 4, 2001). Mesotrione is registered for pre and post emergence control of broad spectrum of weeds in okra production. EPA's analysis indicates that glyphosate, carfentrazone, sethoxydim, and trifluralin are available for weed management in okra production (Jennings & Mitchem, 2008). However, of these herbicides, mesotrione is the only herbicide which provides both pre and post-emergence control of weeds in okra production. According to the publicly available information, the only pre-emergence herbicide registered for weed control in okra production is trifluralin (Batts et al., 2008). For a better weed control, trifluralin must be soil incorporated within 24 hours after the application. In addition, trifluralin is primarily used for the control of annual grass species and small seeded broadleafweeds whereas the weeds controlled by mesotrione are mainly broadleaf weeds. Furthermore, many broadleaf weeds exhibit multiple resistances to different mode of action of herbicide groups such as ALS, ACCase, PPO, and EPSP inhibitors (WSSA, 2011). Mesotrione belongs to the HPPD site of action group (Group 27) and only common waterhemp (*Amaranthus tuberculatus*) biotypes have been reported to exhibit resistance to mesotrione (WSSA, 2011). Therefore, mesotrione can play a significant role in preventing the development of herbicide resistant weeds in okra production. Therefore, EPA finds that the use of mesotrione in okra production meets criterion III considered for the extension of exclusive use of data under the provisions of FIFRA § 3( c )(l)(F)(ii).

**Blackberry:** Based on the USDA, 2007 Census of Agriculture, acreage of blackberry production in the United States estimated to be 14,874 acres (Table 1). Therefore, EPA finds that the production acreage of blackberry does not exceed the threshold level used for determination of minor crop status under the provisions of FIFRA § 3(c)(l)(F)(ii). The use of mesotrione on blackberry was approved in January 2008, within the 7-yr period after the initial registration of this herbicide (June 4, 2001).

Table 3. Herbicides Used for Weed Control in Blackberry Production

Herbicide	Application Type	Mode of Action
Bantazon (non-bearing only)	Post	Photosynthetic inhibitor
Clethodim (non-bearing only)	Post	Lipid biosynthesis inhibitor
Fluazifop (non-bearing only)	Post	Lipid biosynthesis inhibitor
Sethoxydim	Post	Lipid biosynthesis inhibitor
Carfentrazone	Non-selective/preplant/Post-shielded	Protoporphyrinogen oxidase (PPO) inhibitor

Glyphosate	Non-selective/preplant/Post-shielded	EPSPS inhibitor
Paraquat	Non-selective/preplant/Post-shielded	Cell membrane disruptor
Pelargonic acid	Post	HPPD inhibitor
Dichlobenil	Pre	Cell wall synthesis inhibitor
Isoxaben (non bearing only)	Pre	Cell wall biosynthesis inhibitor
Norflurazon	Pre	Carotenoid biosynthesis inhibitor
Oryzalin	Pre	Microtubule assembly inhibitor
Napropamide	Pre	Inhibition of cell division
Simazine	Pre	Photosynthesis inhibitor
Terbacil	Pre	Photosynthesis inhibitor
Diuron	Pre	Photosynthesis inhibitor
Mesotrione	Pre and Post	HPPD inhibitor

Sources: (HRAC, 2011); (PMSP, 2003);(Syngenta, 2011).

Herbicides used for weed control in blackberry production and mode of action of those herbicides are shown in Table 3 (HRAC, 2011; PMSP, 2003). There are 8 alternative postemergence herbicides available for weed control in blackberry production (Table 1). Of these post-emergence herbicides, bentazon, clethodim, and fluazifop can be applied only on nonbearing blackberries and berry harvest is not allowed within 12 month of applying these herbicides limiting their utility (Syngenta, 2011). In addition, paraquat, glyphosate, and carfentrazone are non-selective herbicides. These herbicides can be applied as pre-plant burndown treatments or shielded or hooded applications after emergence of the crop. Care must be taken not to damage the blackberry plants due to direct contact or drift of these herbicides. Compared to the pre-emergence herbicides available for weed control in blackberry production, only mesotrione provides both pre and post-emergence control of a broad spectrum of weeds and none of the other pre-emergence herbicides provide control of emerged weeds at the time of herbicide application. In addition, compared to the other pre-emergence herbicides used for weed control in blackberry production, mesotrione is the only herbicide which inhibits the hydroxyphenylpyruvate dioxygenase (HPPD), which disrupts the biosynthesis of carotenoids. Furthermore, it has been reported that common weed species such as pigweeds (*Amaranthus* spp.), common ragweed (*Ambrosia artemisiifolia*), and lambsquarters (*Chenopodium album*) have developed multiple resistance to several groups of herbicides such as ALS, ACCase, and Glycines (WSSA, 2011). EPA's review indicated that mesotrione can play a significant role as an additional tool on management of herbicide resistance in weeds found in blackberry production. Therefore, EPA determined that the use of mesotrione in blackberry production meets criterion III considered for the extension of exclusive data use period under the provisions of FIFRA § 3(c)(1)(F)(ii).

#### **Raspberry and Lingonberry**

EPA did not review the information on other crops submitted by the registrant (raspberry and lingonberry) as 9 minor crops met the criteria considered for the extension of exclusive data use period for maximum of 3 years.

**CONCLUSIONS:**

Okra and blackberry qualify as minor-use crops, and also fulfill Criterion III under FIFRA § 3(c)(1)(F)(ii). This fulfills the requirement for two additional crops necessary to extend the exclusive use period for an additional year. The Agency, therefore, **grants** your request for an extension of exclusive use data protection for mesotrione under EPA Registration No. 100-1140 for an additional one (1) year. Exclusive use protection for data submitted in support of this registration which complies with 40 CFR §152.83(c) will expire on **June 4, 2014**.

A handwritten signature in black ink that reads "Lois Rossi". The signature is written in a cursive, flowing style.

Lois Rossi, Director  
Registration Division  
Office of Pesticide Programs