



**US Environmental Protection Agency
Office of Pesticide Programs**

**EPA Response to Petition
for S-metholachlor**

September 15, 2009



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

SEP 15 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

John Abbott
Syngenta Crop Protection, Inc.
410 Swing Road
Greensboro, NC 27419

Re: Petition for Extension of the Exclusive Use Period for Data Protection for
Data Submitted for S-Metolachlor Technical (EPA Reg. 100-815)

Dear Dr. Watson:

This is in response to your request dated February 15, 2005¹ that data associated with the original registration of the active ingredient s-metolachlor receive an extension of their exclusive use protection period. You cited FIFRA section 3(c)(1)(F)(ii) as the authority for the Agency to make such a determination. The initial registration date for s-metolachlor was on March 14, 1997 for the product named s-metolachlor Technical. The Agency **denies** your petition for extension of exclusive use data protection for reasons described below.

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 currently have exclusive use protection. FIFRA section 3(c)(1)(F)(i) and its implementing regulations carefully circumscribe the

¹ The Agency sent Syngenta an interim request for more information on May 18, 2007. This response incorporates the new information Syngenta submitted to the Agency in response to the interim request. The novel issues in this petition were finally resolved on June 23, 2009, when EPA issued its Qs & As addressing the exclusive use statutory provisions.

set of data that is eligible for exclusive-use protection. A study entitled to exclusive use protection is defined in 40 C.F.R. 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);

Provided that, a study is an exclusive use study only during the 10-year period following the date of the first registration.

The following is our analysis for determining whether the data associated with the registration you have cited contains exclusive use data. First, there are data associated with this registration that 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.² The registration you cited was granted on March 14, 1997 and was the first registration for s-metolachlor with the product name S-Metolachlor Technical.

Please note, 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).

² 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 exclusive-use 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, or the remainder of the original 10-year exclusive-use period. See 49 FR 30884, 30889.

Now that the Agency has determined there are studies associated with this registration that are exclusive use studies³, we must determine whether you have met the criteria for extending the exclusive use protection period 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 years 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

(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.

Syngenta requested 3 years extension of exclusive use data protection for registration of 18 crops. Eleven of the minor uses Syngenta requested to be considered towards extension of exclusive use data protection are FIFRA section 24(c) registrations. FIFRA 24(c) uses are not eligible to be counted towards extensions. FIFRA section 3(c)(1)(F)(ii) contains the requirements that the minor uses be “registered by the Administrator.” Since 24(c) registrations are granted by a state and are not registered by

³ This response is general in nature. For purposes of this petition, EPA did not determine which data associated with this registration have/had exclusive use data protection.

the Administrator they do not count towards the number of minor uses necessary to extend the period of data exclusivity. Therefore, the 11 minor uses associated with 24(c) registrations; spinach, horseradish, asparagus, carrots, rhubarb, green onions, Swiss chard, radish, dry bulb onions, cabbage, and peppers, are not eligible to be counted towards an extension.

As for the uses that were not 24(c) registrations, EPA reviewed its files and found the following: The initial registration of s-metolachlor occurred on March 14, 1997. On April 3, 2003 a FIFRA section 3 registration was granted for tomatoes and on April 7, 2003, FIFRA section 3 registrations were granted for the following six grasses grown for seed; ryegrass, bentgrass, Kentucky bluegrass, orchardgrass, tall fescue and fine fescue. As required by statute, the aforementioned uses were all registered within the requisite seven-year period.

Syngenta requested that fresh tomatoes be considered as a minor crop for extension of the exclusive use data period for s-metolachlor. After reviewing the currently approved label for s-metolachlor the Agency determined that fresh market tomatoes are not labeled separately from processing tomatoes. The label permits the use of s-metolachlor on transplanted and direct-seeded tomatoes. The Agency does not have enough information to determine if direct-seeded and transplanted tomatoes fit the definition of a minor crop and therefore cannot conclude that Syngenta's tomato request is for a minor crop. Therefore, fresh tomatoes can not be counted towards the extension of exclusive use data protection for s-metolachlor. The six grasses grown for seed; ryegrass, bentgrass, Kentucky bluegrass, orchardgrass, tall fescue and fine fescue are considered minor crops and are eligible to be counted towards an extension.

Next, EPA analyzed whether these uses met any of the statutory criteria. The Agency reviewed the additional information submitted in support of the petition for extension of the exclusive use period for s-metolachlor. Syngenta's petition claims that s-metolachlor meets two of the criteria: (I) there are insufficient efficacious alternative registered pesticides available for the use and (III) the minor use pesticide plays or will play a significant part in managing pest resistance.

S-metolachlor is a chloroacetamide herbicide and is a WSSA Group 15 herbicide. It is applied preplant or preemergence to control grasses, yellow nutsedge, and certain broadleaf weeds. As BEAD described in its previous analysis (Zinn, 2007), the registrant claims that there are no documented resistant biotypes to chloroacetamides, such as s-metolachlor, in the United States. The Agency found only one case of resistance to this mode of action: flufenacet (oxyacetamide)-resistant Italian ryegrass in Idaho (Heap, 2007). Other herbicides with the same mode of action include dimethenamid-p and napropamide.

Criteria Analysis for Grasses Grown for Seed

S-metolachlor is registered for use on established stands of grasses grown for seed (ryegrass, bentgrass, Kentucky bluegrass, orchardgrass, tall fescue and fine fescue) in Idaho, Oregon and Washington. The label states that s-metolachlor will control or suppress volunteer seedlings of the following grasses: perennial ryegrass, fine fescue, tall fescue, orchardgrass, bentgrass, and Kentucky bluegrass. It will also control or suppress rattail fescue, annual bluegrass, Italian ryegrass, California brome, downy brome, and roughstalk bluegrass. These weeds are in addition to the grass, sedge, and broadleaf weeds described on the label. The majority of the alternatives are discussed below in the section "Ryegrass for Seed." Due to the similarities in alternatives, only differences in alternatives are discussed for the other grasses grown for seed.

The Agency reviewed the additional information supplied by the registrant and found that Syngenta did not make a compelling case to support the resistance management claim. For all the grasses grown for seed, other herbicides with the same mode of action (e.g., dimethenamid-p and/or flufenacet) are registered, which Syngenta acknowledges. We do not have usage data for grasses grown for seed so the extent to which these herbicides are used is unclear. The Agency is unable to conclude that s-metolachlor plays a significant role in resistance management.

Ryegrass for Seed

Syngenta describes 20 other herbicides registered for use on ryegrass grown for seed as not being an alternative, an unacceptable alternative, or a partial alternative.

The Agency agrees that as post-emergence broadleaf herbicides 2,4-D, MCPA, clopyralid, bromoxynil, dicamba, carfentrazone-ethyl, fluroxypyr, and tribenuron-methyl are not sufficient alternatives to s-metolachlor. In addition, paraquat, glyphosate, and glufosinate have a different use pattern and no residual control and thus are also not alternatives to s-metolachlor.

Diuron, ethofumesate, metribuzin, oxyfluorfen, and pronamide are described as unacceptable alternatives. Diuron and ethofumesate do not claim control of volunteer crop seedlings on the label. The diuron and ethofumesate labels were checked and the claim was confirmed. For metribuzin, oxyfluorfen, and pronamide, the registrant claims that the weeds spectrum controlled is limited. In addition, the registrant describes other limitations, including that metribuzin and oxyfluorfen have the potential to cause crop injury. According to the pronamide, metribuzin, and oxyfluorfen labels, a limited spectrum of weeds is described as controlled or suppressed by these herbicides. The Agency agrees that these herbicides are unlikely to be adequate alternatives to s-metolachlor.

Syngenta describes dimethenamid-p, flufenacet + metribuzin, pendimethalin, and quinclorac as partial alternatives. Pendimethalin, s-metolachlor, flufenacet+metribuzin, and dimethenamid are used preemergence and described as having their own strengths and weaknesses (Lies, no date). Therefore, although Syngenta states that none of the alternatives are complete alternatives, it is not clear that the alternatives are insufficient.

Both dimethenamid-p and flufenacet have the same mode of action as s-metolachlor. A comparison of the dimethenamid-p and s-metolachlor labels shows considerable overlap in the weeds controlled, although each label claims control of some weeds that the other does not. Efficacy ratings indicated that both s-metolachlor and s-dimethenamid provide control of similar weeds with similar efficacy (Colquhoun et al., 2001). There are some restrictions with use of dimethenamid-p, including the potential for crop injury if applied during cold temperatures. Syngenta claims that dimethenamid-p has less residual activity than s-metolachlor, but did not provide references or documentation to support this claim. Grazing and feeding treated grass or other plant parts to livestock is restricted for dimethenamid-p whereas s-metolachlor may be grazed after a certain period of time (varies depending on location). However, there are three methods of managing the grass stubble after harvest: thermal (e.g. burning), clean nonthermal (e.g. baling), and mowing and then leaving it on the field to compost (Lies, no date). The extent to which each method is used is not clear. It is unclear to us whether these restrictions are justification for the efficacy criteria. Also, because dimethenamid-p and flufenacet have the same mode of action, it is not clear how s-metolachlor plays a significant role in resistance management.

S-metolachlor and the other acetamide herbicides are described in the United States Department of Agriculture (USDA) Crop Profile for Ryegrass Seed in Oregon, 2002. However, they are not included in the description of the standard treatments that are used for most established grass seed acreage. Given the lack of usage data, it is difficult to determine the extent to which s-metolachlor is used in perennial ryegrass production.

Therefore, we are unable to conclude that s-metolachlor plays a significant role in resistance management or that there are insufficient efficacious alternatives.

Other Grasses Grown for Seed: Bentgrass, Kentucky Bluegrass, Orchardgrass, Tall Fescue, and Fine Fescue

The majority of the alternatives are the same as for perennial ryegrass. There are some herbicides that are registered for other grasses grown for seed and not for perennial grasses. Likewise, in some cases, an alternative registered for use on perennial ryegrass may not be available for another grass grown for seed. Bentgrass grown for seed has the fewest alternatives discussed of all the grasses grown for seed described in this document.

Terbacil is registered for use on Kentucky bluegrass grown for seed, tall fescue grown for seed, and fine fescue grown for seed. Syngenta claims that terbacil has the potential to cause crop injury and that it controls a limited spectrum of broadleaf and grass weeds. The Agency confirmed these claims with the crop label.

Primisulfuron is registered through SLN labels for use on Kentucky bluegrass grown for seed. This herbicide is described as not an alternative because it has rotational restrictions, must be applied post-emergence, and only controls a limited spectrum of broadleaf and grass weeds.

Fluazifop-P-butyl and sethoxydim are registered for use on fine fescue grown for seed. Syngenta describes fluazifop-P-butyl and sethoxydim as not being alternatives because they only control grass weeds, are applied post-emergence, and have no residual activity. The Agency confirmed that there are 24(c) labels for fluazifop-P-butyl and agree that these herbicides are post-emergence grass herbicides.

The Agency does not believe that these additional alternatives change the conclusion for grasses grown for seed.

After consulting with USDA, the Agency decided that Syngenta did not make a compelling case for the efficacy or resistance management criteria for grasses grown for seed. The Agency **denies** your request for an extension of the exclusive use period for s-metolachlor.

A handwritten signature in blue ink that reads "Lois Rossi". The signature is written in a cursive style and is positioned above a solid horizontal line.

Lois Rossi, Director
Registration Division
Office of Pesticide Programs

cc: Dan Kenny
Joanne Miller
Michele Knorr
Nicole Williams
Pat Cimino

REFERENCES

Colquhoun, J., B. Brewster, C. Mallory-Smith, and R. Burr, 2001, Weed Management in Grass Seed Production, EM 8788, Oregon State University

Crop Data Management System (CDMS) search, Web address:
<http://premier.cdms.net/webapls>

Crop Profile for Ryegrass Seed in Oregon (Annual and Perennial Ryegrass), 2002, Web address: <http://www.ipmcenters.org/cropprofiles/docs/ORryegrass.html>

Heap, I., 2007, The International Survey of Herbicide Resistant Weeds, Online, Internet, February 14, 2007, Web address: www.weedscience.com

Lies, M., ed., High Yield Grass Seed Production and Water Quality Protection Handbook, Oregon Seed Council.

Zinn, N., 2007, Review of Justification for Extension of Exclusive Use Period for S-metolachlor, Office of Pesticide Programs, U.S. Environmental Protection Agency.