



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

EPA Response to Petition for Halosulfron

September 10, 2009



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

SEP 10 2009

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Julie M. Butcher
Agent for Canyon Group, LLC
Canyon Group, LLC
P.O. Box 5569
Yuma, AZ 85366-5569

Dear Julie Butcher:

I am writing in reply to your June 5, 2009 letter petitioning the U.S. Environmental Protection Agency (EPA) for exclusive use protection for certain data submitted to EPA that support the minor use tolerances for pea and beans/succulent shelled/crop subgroup 6B; pea and beans/dried shelled/crop subgroup 6C; tuberous and corm vegetables/crop subgroup 1C; rhubarb; bushberry/crop subgroup 13-07B; apples; and okra for halosulfuron. You indicate that the standard 10 year exclusive use period for halosulfuron expired in 2004. However, you cite Section 210 (b)(4)(vi)¹ provisions for exclusive use data protection for a minor use of a pesticide as being applicable to the above minor uses. For the reason provided below, EPA has determined that these data are not eligible for exclusive use protection.

You are correct that FIFRA Section 3(c)(1)(F)(vi) allows for establishing a new exclusive use period for the data developed to add a new minor use to an existing registration that does not have exclusive use protected data. The following is the text of FIFRA Section 3(c)(1)(F)(vi):

With respect to data submitted after the date of enactment of this clause by an applicant or registrant to support an amendment adding a new use to an existing registration that does not retain any period of exclusive use, if such data relates solely to a minor use of a pesticide, such data shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application for a minor use by another person during the period of 10 years following the date of submission of such data. The applicant or registrant **at the time the new minor use is requested** shall notify the Administrator that to the best of their knowledge the exclusive use period for the pesticide has expired and that the data pertaining solely to the minor use of a pesticide is eligible for the provisions of this paragraph. If the minor use registration which is supported by data submitted pursuant to this subsection is voluntarily canceled or if such data are subsequently used to support a nonminor use, the data shall no longer be subject

¹ For purposes of responding to your petition EPA presumes that the reference to 210(b)(4)(vi) is supposed to be a reference to FIFRA section 3(c)(1)(F)(vi).

to the exclusive use provisions of this clause but shall instead be considered by the Administrator in accordance with the provisions of clause (i), as appropriate.

The data that support the registration of the uses requested in your petition were generated by IR-4. The Agency can only provide a new exclusive use period for minor use data that satisfy the regulatory definition of exclusive use data. IR-4 data are government-generated and do not fit within the definition of exclusive use data. The exclusive use status of a government-generated study is defined in 40 C.F.R. Section 152.94 as follows:

(b) In no circumstances does submission of a public literature or government-generated study confer any rights on the data submitter to exclusive use of data or compensation under FIFRA Section 3(c)(1)(F).

Therefore, the Agency can not establish a new data exclusive use period for the IR-4 data associated with the request for registration of the above crops.

Additionally, please note that apples are not considered to be a minor crop by the Agency. The definition of a "minor use" as defined in FIFRA § 2(II), as follows, pertains to the extension of exclusive use for minor use registrations provisions.

2(II) MINOR USE.—The term "minor use" means the use of a pesticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

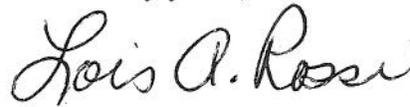
- (1) the total United States acreage for the crop is less than 300,000 acres, as determined by the Secretary of Agriculture; or
- (2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and
 - (A) there are insufficient efficacious alternative registered pesticides available for the use;
 - (B) the alternatives to the pesticide use pose greater risks to the environment or human health;
 - (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or
 - (D) the minor use pesticide plays or will play a significant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on existing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

The total United States acreage for apples is over 300,000 acres and the Administrator has not made a determination that halosulfuron use on apples meets the economic definition as stated above.

If you have any questions concerning EPA's determination that the data are not eligible for the exclusive use protection sought by the Canyon Group, LLC, please contact JimTompkins at (703) 305-5697.

Sincerely yours,

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

Lois A. Rossi, Director
Registration Division

cc: Dan Kenny
Michele Knorr
Barbara Madden
Nicole Williams
Jim Tompkins
Pat Cimino