

Environmental Protection Agency

§ 154.27

concerning the risks and benefits associated with each use of the pesticide subject to the Special Review.

(5) A brief description of the Special Review process and a statement that registrants and applicants bear an affirmative burden of supporting registration of a pesticide product.

(6) A date by which information in response to the Agency's request for further information must be submitted.

(d) In his discretion, the Administrator may request that the Scientific Advisory Panel hold a public meeting to review the scientific issues related to the Special Review.

§ 154.26 Comment opportunity.

After issuance of a Notice of Special Review that applies to a use of a pesticide product (or category of products), any person may submit to the Agency any information, argument, or both, pertinent to:

(a) Whether the use of a pesticide product satisfies any of the §154.7 risk criteria, with respect to the composition, labeling, packaging, and restrictions on use of the product as currently registered.

(b) Whether the use of a pesticide product would satisfy any of the §154.7 risk criteria if its composition, labeling, packaging, and restrictions on use were approved in accordance with an application for registration or amended registration pending before the Agency. For further information see §154.27(b).

(c) Whether any risks posed by the use or proposed use of the product that satisfy the §154.7 risk criteria are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product.

(d) What regulatory action, if any, the Agency should take with respect to the use of the product.

§ 154.27 Meetings with interested persons.

(a) In the Special Review process, to assure openness and responsiveness, no person or party outside of government will be afforded special or preferential access to Agency Special Review decisionmakers or to the Agency's Special

Review process. At the same time, however, Agency personnel are free to meet and otherwise communicate with persons or parties outside of government, including registrants and manufacturers, users, trade unions, environmental groups and other interested persons, to obtain information, exchange views, explore factual and substantive positions, or discuss regulatory options concerning Special Review decisions.

(b) Meetings between EPA and any person or party outside of government will not result in undue delay in reaching Special Review decisions. During such meetings, the Agency will not commit to take any particular action concerning a pending decision. The Agency may receive and consider information and recommendations from persons or parties outside of government; however, the Agency will make the final administrative decision on a wholly independent basis and in accordance with law.

(c) Any interested person may ask to meet with Agency officials to discuss factual information available to the Agency, to present any factual information, to respond to presentations by other persons, or to discuss what regulatory actions should be taken regarding a pesticide which is or may be the subject of a Special Review. If, at its discretion, the Agency holds such meetings with any person outside of government concerning a use of a pesticide product, the Agency will prepare and file in the docket a memorandum of such meeting, meeting the requirements specified in §154.15(b)(7).

(d) Meetings described in this section may include meetings held after issuance of a Notice of Special Review with any registrant who proposes to change voluntarily the composition, packaging, and labeling, or other terms and conditions of registration of his pesticide product in a way which he believes would reduce the risks of use of the product so that it would no longer meet or exceed the risk criteria of §154.7. Meetings for this purpose will be most helpful and productive for both registrants and the Agency if they are requested by registrants shortly after the issuance of the Notice of Special Review.

(e) If the Agency meets with any person or party outside of government concerning a pending Special Review decision, the Agency will not issue a final Special Review decision until 30 days after inclusion of a memorandum concerning that meeting in the public docket. During those 30 days, any person or party may submit written comments to the Agency regarding the subject matter of the meeting in question. The Agency may issue a final Special Review decision without allowing this 30-day period if expedited action is necessary to protect public health or the environment, or if the Agency has invited other parties with potentially opposing viewpoints to the meeting in question (e.g., registrants, users, labor, and environmental groups).

(f) The Agency may decline to meet subsequently with any person or party who asserts unreasonable confidential business information claims pursuant to §154.15(c) for the purpose of circumventing the docketing procedures described in §154.15(b).

§ 154.29 Informal public hearings.

(a) *Timing.* At any time after issuance of a Notice of Special Review and prior to issuance of a Notice of Final Determination, the Administrator may conduct an informal public hearing to gather relevant information or otherwise assist Agency decisionmaking.

(b) FEDERAL REGISTER notice. The Administrator shall issue a notice for publication in the FEDERAL REGISTER of any informal public hearing to be held under this section. The notice shall contain the following information:

(1) The time, date, and place of the hearing.

(2) A brief description of the procedures governing participation in the hearing by interested persons.

(3) The issues to be considered at the hearing.

(c) *Transcript.* A verbatim transcript of the hearing shall be prepared and filed in the public docket.

§ 154.31 Notices of Preliminary Determination.

The Administrator shall prepare a Notice of Preliminary Determination

after the close of the comment period on a Notice of Special Review.

(a) *Contents of notice.* The Notice of Preliminary Determination shall respond to all significant comments submitted in response to the Notice of Special Review. For each use of a pesticide product that was the subject of the Notice of Special Review, the Notice of Preliminary Determination shall also include, as appropriate:

(1) A determination whether the use satisfies any of the risk criteria set forth in §154.7, and a discussion of the reasons for the determination.

(2) A determination of whether any changes in the composition, packaging, labeling, or restrictions on use of a pesticide product that were proposed in an application for new or amended registration submitted after issuance of the Notice of Special Review would reduce the risk so that the use no longer would satisfy any of the risk criteria in §154.7.

(3) If the use satisfies any of the risk criteria set forth in §154.7, a determination of whether the adverse effects posed by the use are unreasonable, taking into account the economic, social, and environmental costs and benefits of the use of the product, and a discussion of reasons for the determination.

(4) If the use is determined to pose an unreasonable adverse effect, a statement of the regulatory action, if any, which the Agency intends to initiate with respect to the use, and a discussion of the reasons for initiating that regulatory action.

(5) A statement that the Administrator is requesting comments from the Secretary of Agriculture and the Scientific Advisory Panel on the notices and analysis specified in paragraph (b) of this section, and that the notices and analysis are available on request.

(6) Instructions to interested persons on how to submit comments (including the deadline for submission of comments).

(7) The location of the docket under §154.15 and the times during which the docket will be available for inspection and copying.

(b) *Referral to Secretary of Agriculture and Scientific Advisory Panel.* If the Administrator proposes to cancel, deny,