

PR Notice 87-7. Notice to Producers, Formulators and Registrants of Pesticides

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

## PR Notice 87-7

## NOTICE TO PRODUCERS, FORMULATORS AND REGISTRANTS OF PESTICIDES

ATTENTION: Persons Responsible for Contracting for Pesticide Formulation

SUBJECT: PESTICIDE CONTRACT MANUFACTURING

The Environmental Protection Agency is revising its policy with respect to the required registration of pesticides supplied under contract. Generally, pesticides supplied under contract (even to a single formulator) must be registered with the Agency before being transferred. A 60-day grace period for applying for registration is provided for producers having existing contracts as of July 31, 1987.

As of August 1, 1987, any pesticide transferred between establishments not operated by the same producer will be considered to be in violation of FIFRA sec. 12 unless it is:

1. Registered with the Agency;
2. The subject of a pending application for registration;
3. Transferred under a contract entered into before August 1, 1987; or
4. Eligible for an exemption from registration because:
  - a. Its pesticide constituents are derived from registered products; or
  - b. Its producer is also the registrant of the final product for which the transfer is accomplished, in accordance with 40 CFR 162.5(b)(1).

As of October 1, 1987, a pesticide transferred under 3. above will be considered to be in violation of FIFRA sec. 12 unless it is registered or the subject of a pending application for registration.

No response to this notice is required. However, producers of pesticides who contemplate shipping under contract in the future should apply for registration as soon as possible to avoid being in violation of the Act. Registrants who enter into long-term contracts for supply of pesticides should ensure that such contracts take into account the Agency's requirements to avoid disruption of production because of failure of their supplier(s) to obtain registration.

## II. WHY THE POLICY IS BEING CHANGED

The result of these policies has been to encourage the use of contractual arrangements to produce and distribute pesticides that are never registered, particularly technical grade pesticides. The Agency has found that the contract manufacture exemption increasingly is proving an impediment to an effective and efficient regulatory program, resulting in less than adequate regulation and environmental protection.

Accordingly, the Agency has decided that it can no longer sanction the distribution of unregistered pesticides under these contractual arrangements. The practice of contract manufacturing to produce unregistered pesticides permits a large volume of pesticides to be transferred without the regulatory oversight contemplated by FIFRA. EPA has encountered a number of difficulties with the contract manufacturing exemption scheme:

1. A producer under contract has the opportunity to evade the "sole source" limitation. A producer is not limited in the number or type of contracts it may accept to produce a pesticide. A company may undertake a number of contracts to produce what is essentially the same pesticide for a number of different companies. Although each contract may provide for production only for a single registrant, the producer is engaging in multiple "sole source" contracts. The Agency believes that this practice is widespread, and, even if not intentional, the practical result is the distribution of an unregistered pesticide.

2. Implicit in contract manufacturing is a distancing of the registrant from direct oversight of the production process. The contract manufacturing exemption permits a registrant to contract out the entire production of his registered product. In the most extreme situation, but one which EPA believes is not uncommon, a registrant may not produce, formulate, package, label, or even distribute the registered product for which he is responsible in an establishment under his ownership or management. Potentially, there is a diminution of control and monitoring of production and distribution by the registrant in such a contract operation.

If the pesticide being used in a contract operation is registered, the Agency exerts direct control over the product through its registrant. If the pesticide is unregistered, EPA has no means of assessing or regulating the process or the product. EPA must rely on the registrant of the final product to ensure that the pesticide is produced and distributed in compliance with FIFRA. The fact that he is operating at a distance from his production processes magnifies any problem that might arise.

3. The establishment under contract is required to report its production of the pesticide. However, because the pesticide is not registered, retrieval of production data for active ingredients is difficult. EPA's section 7 production data system relies on EPA registration numbers to record production amounts. The Agency has insufficient information concerning the volume and types of pesticides being produced. Section 7 production reports are replete with examples of pesticides having a large production of formulated product with no apparent production of

technical pesticide. EPA must assume that this is due to the fact that all technical material is being produced under the contract manufacturing exemption.

4. Non-registration of pesticides undermines the efforts of producers who register their products to comply with the Act, and creates inequities that translate into economic advantages. For example, producers who register their pesticides are subject to requirements for developing data or compensating for the use of data developed by others. These registration costs are absorbed into and recouped in the sales price of the pesticide. The producer of a pesticide who is not compelled to register his product because of the contract manufacturing exemption escapes these costs, and may produce the pesticide more cheaply for contracting formulators.

5. EPA can regulate such products only indirectly by regulation of the final products containing the pesticide, an inefficient and time-consuming process that affords less assurance of environmental protection.

### III. REVISIONS TO POLICY

A. As an immediate step, EPA has revoked its Compliance Policy 3.6 permitting "sole source" transfer of pesticides. The effect will be that, in accordance with the definition in § 162.3(dd), transfer of pesticides under contract will be permitted without registration only if the transferor possesses a registration for the final product.

B. In a final rule concerning registration procedures, EPA will provide an exemption permitting the transfer of constituents or intermediate forms of a registered pesticide if all source pesticides are also registered. The Agency is providing this exemption in this notice, and expects to promulgate its final rule by the end of August, 1987, with an effective date in April or May of 1988.

### IV. EFFECT OF POLICY CHANGE AND ENFORCEMENT DATES

The effect of this policy change is to require the registration of pesticides now being produced and transferred under the contract manufacturing exemption. In the future, existence of a contract will no longer be considered sufficient to permit legal transfer of unregistered pesticides except as described below.

A. Transfer of registered pesticide products under contract is not affected by this notice. All such transfers are legal and may continue.

B. Transfer of unregistered pesticide products under contracts in existence as of July 31, 1987. Unregistered pesticides transferred under such contracts may continue to be transferred provided that the producer/transferor obtains or applies for registration by September 30, 1987. Producers who transfer unregistered pesticides will be expected

to demonstrate that a contract was entered into before August 1, 1987, and that it has not been renewed in the interim.

C. Transfer of unregistered pesticide under contracts entered into after July 31, 1987. Transfer of unregistered pesticides under such contracts will be acceptable only if the transferred pesticide is registered, or the producer of the transferred pesticide is the registrant of the final product that is registered. Transfer of unregistered pesticides under such contracts will be considered to be in violation of FIFRA sec. 12(a)(1)(A). Such pesticides may be subject to Stop Sale, Use or Removal Orders under FIFRA sec. 13.

#### V. EXAMPLES

Some examples of acceptable and unacceptable transfers of pesticides as of October 1, 1987, are given below.

1. Company A is the producer of a pesticide, which is used solely for further formulation into its own registered end use product by an integrated system in its own establishment. Company A is not required to register its pesticide, since no transfer of unregistered pesticide occurs.

2. Company A is the producer of a pesticide. Company A may legally transfer the unregistered pesticide to another establishment owned by A, or to Company B under contract to produce A's registered end use product. Company A is the transferor of the pesticide, and possesses a registration for the end use product. Company B is therefore considered to be "operated by the same producer" as Company A, and Company A is not required to register the pesticide before transfer.

3. Company A is the registrant of an end use product. Company A may contract with Company B to produce an unregistered pesticide, formulate that pesticide into Company A's registered end use product, package and label the material for Company A, all at Company B's establishment. Company B may not legally transfer the pesticide to any other Company, including Company A, at any stage of production except in its final registered end use form, which includes packaging and labeling.

4. Company A is the registrant of an end use product. Company A contracts with Company B to acquire a pesticide and formulate its end use product. Company B may purchase registered pesticide from Company C for this purpose. If Company C's product is unregistered, however, Company C may not legally transfer the unregistered pesticide to Company B.

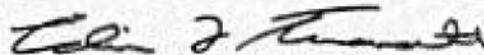
5. Company A is the registrant of an end use product. Company A contracts with Company B to acquire a pesticide and formulate its end use product. As long as Company B purchases a registered pesticide for this purpose, all intermediate transfers between Company B and Companies D, E, and F for formulation, packaging or labeling are legal. In this case, all pesticide constituents are acquired from registered sources, and the end use product is registered.

6. Company A is the producer of an unregistered pesticide. Company A may not transfer that pesticide to Company B for formulation into Company B's registered end use product. Likewise, Company A may not transfer the pesticide to Company C which is under contract to Company B.

VI. FOR FURTHER INFORMATION

Information on the general requirements of this notice may be obtained from Jean M. Frane, Registration Division, at 703-557-0944, or John J. Neylan III, Office of Compliance Monitoring, at 202-382-7825.

Information on procedures for registration of currently unregistered pesticides may be obtained from Product Managers in the Registration Division, EPA.



Edwin F. Tinsworth  
Director, Registration Division  
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