

September 8, 1980

T-1-232

FOOD PRODUCTION AND
INSPECTION BRANCH

DIRECTION GENERALE,
PRODUCTION ET INSPECTION
DES ALIMENTS

SECTION
PESTICIDES

TRADE MEMORANDUM

Re: Product Specific Registration (PSR) Policy - Pesticides

In accordance with new Departmental Policy established by the Deputy Minister, pesticide registration procedures are now being implemented that are more product specific, rather than generic in nature. These changes will focus initially on the active ingredient or basic chemical, as well as on a more detailed consideration of the formulated product, per se. This initiative is an important first step towards tightening pesticide regulation controls and operational procedures in the interest of greater assurance of the safety and effectiveness of every product registered under the Pest Control Products Act.

The following paragraphs outline initial operational procedures that have been put in place to implement this new policy:

1. Status of products already on the market and properly documented new active ingredients will not be directly affected.
2. Most applications, with the major exception of compounds supported by Industrial Biotest (IBT) data and those under re-evaluation, received prior to September 8, 1980 will be handled via the previous generic registration policy. Applications received prior to September 8 that involve new sources of a previously registered active ingredient require special consideration; we are currently developing a proper procedure to accommodate these situations.
3. For applications received after September 8, 1980, product specific registration (PSR) will at least involve "tying" each individual submission to a basic producer via a manufacturing specification (T-1-223), a data base index (T-1-212) and written confirmation from the basic manufacturer that his specific product and process is the ultimate source of the

active ingredient. In many situations, particularly those involving older compounds and certain antimicrobial products, this basic requirement will not suffice since there is no complete data base on file that can be cited as directly associated with the individual manufacturer or basic supplier. In these cases, a full data submission will be required. Subsequent applications will not be granted registration unless they can provide or cite a comparable, adequate data package.

In summary, applications made after September 8, 1980 will fall into four categories:

- I A complete and current data package will be required for new products or label expansions that cannot be directly associated by the applicant, or on his behalf by the basic supplier, with an adequate data base already on file that relates specifically to the basic supplier's technical ingredient and manufacturing process.
- II In situations where IBT is not implicated and a more modern and adequate data package exists the PSR requirement may be met by a minimum of:
 - 1. "Tying" the specific submission to a basic producer via a manufacturing specification (T-1-223) and data base index (T-1-212) provided either by the formulator or his basic supplier.
 - 2. Written confirmation from the basic manufacturer which verifies his specific product and process as the ultimate source of the active ingredient.
- III No new products or label expansions will be accepted for IBT chemicals or compounds under re-evaluation without written agreement from Health and Welfare Canada.
- IV Temporary registrations will not be extended or advanced to full registration status for any situations covered by category I and compounds supported by IBT data without written agreement from Health and Welfare Canada.

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Distribution: PPD-2, PCP-1,2,3,4,5,6,8,10,12