

NATIONAL STANDARDS FOR REGISTRATION AND FOR
RESIDUES OF PESTICIDES IN RELATION TO
TRADE AND COMMERCE IN EUROPE

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When Dr. Turtle asked me to attempt a short survey of the European registration and residue scene in relation to trade and commerce, I had the feeling that to seek the friendship of one I would invoke the enmity of all. But, after reading Dr. Turtle's text for the paper he has just presented to you in which he has traced the steady build-up of international understanding through the channeling of pesticide data from industry and governments through the FAO/WHO Committee of Experts, of which Dr. Turtle is Joint Secretary, to the Codex Alimentarius, I felt that an attempt to give an objective picture of the diverse European national attitudes and practices would be a small contribution to the ideal of harmonization.

Historically, the present pesticide regulations current in Europe have evolved out of a large number of national pure food laws, aided by poison acts and laws, and these were frequently administered by local, even municipal, authorities. The standard of public acceptance of stored food rose steadily in the 1930's, and the control of universal--even accepted--pests such as codling moth of apple, cherry fruit fly, and grain weevil by the chemical processes of spraying and fumigation was shown to be possible. As a result of the scarcities provoked by World War II, the rapid development and use of pesticides (especially parathion and DDT) on growing and stored food crops necessitated the progressive intervention of governments to protect the public.

With this basis, we may now consider the present position in Europe with its broad corollaries in the developing countries. There are four discernible trends:

1. A well controlled but somewhat rigid system favored in those countries already having a strong plant protection administration (for example, Germany, Austria, the Netherlands, and Scandanavia). The registration procedures tend to be elaborate and somewhat time-consuming, with an ideal of residue tolerances at absolutely minimal levels. Testing of pesticides was commonly done by the state, and companies' data were only regarded as supplementary.
2. A pragmatic system based on the urgency of need for pest control and freedom from overt public health effects, with no legally fixed tolerances has been evolved in the

United Kingdom and has been accepted rather widely in the Commonwealth. Industrial producers of pesticides present data which are accepted as a basis for health approval ("Notification") and for use recommendation (Voluntary Approval Scheme). FDA tolerances have always been favored as a broad guideline in the U.K.

3. In countries where facilities for critical work on biological evaluation and residue determination have lagged behind the rapid developments and proliferation of pesticides, registration was granted on a consideration of FDA approvals and those from other countries, modified by local demands and usage. This system eliminated the necessity of setting up an elaborate bureaucracy and costly technical facilities.
4. With the interpolation of numerous and often conflicting environmental demands and with the replacement of the familiar FDA system by the wider ranging, but, if I may say so with respect, the less universally applicable EPA requirements, at least as far as Europe is concerned, these countries are rapidly evolving their own registration procedures aided by expanded scientific services. These procedures are often based on an eclectic of existing questionnaires with the addition of special items consonant with national agricultural, economic, and social traditions. This means always something added and never anything withdrawn. For example, Italy stresses the fate of pesticides in soil and run-off water, Spain the absolute level of toxicity of the pure pesticide as measured by the LD₅₀, France the absence of toxic metabolites, while Germany prescribes "good agricultural practice" and lays great stress on the purity of cereals used in making baby foods.

In the last few years the rapidly increasing influence of the recommendations of the FAO/WHO Committee of Experts, as adopted by the Codex Alimentarius, together with more frequent consultation between European bodies (EEC, EPPO, ILO, FAO, and many others) are helping to break down a rigid legalistic approach to pesticide registration. Great improvements have been made in the quality of the technical representation of pesticide manufacturers in both national and international councils; in fact, the very ability of registration authorities to make these increasing exacting demands is largely dependent on the manufacturers' own improvements in residue detection for their products.

When all this has been said, the fact must be faced that we are perhaps a decade away from complete harmonization in Europe and that a return to any great dependence on one existing standard (e.g., FDA), however good, is unlikely. For the moment, each case must be submitted and argued separately, and some compromise between, for example, residue levels in international trade and those actually permitted for international consumption seems to be inevitable. This is not an ideal state of affairs and gives much

scope for the use of pesticide regulation as a fiscal means of keeping out competitive or officially unwanted products from abroad. In the long term, also, a bidding up of the number of tests necessary to secure the registration of pesticides will result in a diminution of progress and inhibition of innovation. In a paper given by Blair of Dow Chemical at the recent IUPAC Conference at Helsinki, it was estimated that only one new pesticide emerges per 10,000 compounds tested, with a time from discovery to marketing of 8 to 10 years and a total cost to the launching of sales of over \$10 million. This position is quickly worsening in the present climate of safety and environmental demands. There is, in fact, already a demand for a fair proportion of these expenses to be met from the public purse.

The ideal of the safe use of pesticides with minimum hazards to man or the environment seems to be agreed by all; but, if, as in so many parts of the developing world, the environment itself is man's worst hazard, our notions and standards of safety will have to be adjusted and with them our registration procedures, with the necessary compromises which must be built in to meet the needs of developing countries.