

01 May 1997

Position Paper

Some Aspects of Benefit: Risk Evaluations in the Registration of Pesticides

INTRODUCTION

No field of human endeavour is entirely free of risk. All aspect of our daily life are surrounded by some degree of risk. Even to do nothing can incur a risk! In every case, we have to consider all risks of any activity in the light of all its benefits. This applies equally to the safe and effective use of pesticides.

Unfortunately, in certain countries, registration authorities are tending to concentrate increasingly on one parameter of possible risk, instead of total benefit: risk considerations. This trend is seen particularly when regulators think there are available safer alternatives - but which may not in fact be safer when all criteria of potential risk are considered. This paper advances reasons why the overall benefit: risk balance needs to be considered, and not just one criterion of risk in isolation. It also argues a case for registering several products for each use, whenever possible.

THE NEED OF PESTICIDES

Some 20-40% of the world's potential crop production is lost annually because of the effects of weeds, pests and diseases (FAO, 1981). A number of different means can, in theory, be used to protect crops. However, only one - the use of pesticides - has proved practical on a large scale, in terms of providing results which can be achieved with a fair degree of certainty. Crop losses would be doubled if existing pesticide uses were abandoned. Of the current world population (estimated at 4.5 billion), some 50% are still undernourished; the safe and effective use of pesticides can contribute significantly to tackling this problem.

Pesticides are of enormous benefit in public health programmes.

Examples include the eradication or control of rodents, insects, mites and snails which can carry debilitating - and sometimes lethal - diseases. The benefits of DDT in controlling anopheline mosquitoes, vectors of malaria well-know example.

The health aspects of pesticide usage also include the prevention of the production of highly toxic materials such as aflatoxins, from mould on peanuts, for example.

Economic factors also have a proper place in a consideration of the benefits of pesticides. Along with mechanisation and other changes in farming practice, pesticides have enabled production standards to be improved with fewer farm workers. A higher proportion of the working population has thus become available to work in manufacturing or service industries leading to economic diversity, growth and an improvement in living standards.

It needs to be recognised, therefore, that the benefits of pesticides can be medical, social and economic. All three factors have a proper place when considering benefit.

The acceptable balance of benefit over risk will inevitably be different under the vastly different circumstances which apply in different parts of the world.

OVERALL PRINCIPLES IN RISK EVALUATION

By definition, a benefit: risk evaluation requires a consideration of possible risks as well as benefits. Governments are familiar with these issues. In the regulatory process, the total risk has usually been judged in context of the overall benefits.

With the passage of time, the regulatory requirements of governments have increased - both in scope and complexity. In circumstances of increasing specialisation, there is a risk that any one reviewer will have an increasingly limited view of the overall data base and related issues. In the extreme case, this process can lead to an evaluation of a proposed use in the context of only one parameter of possible risk, independent of the benefit: risk balance overall.

Obviously, if the recommended use of an existing unique product involves a major threat, any use of that product can only be justified under clear circumstances of that product can only be justified under clear circumstances of special need, until an alternative product which is less hazardous becomes available.

However, this is not the situation with most pesticides.

Meanwhile, fashions in safety evaluations have tended to change with time. Topics which at one moment were thought to be particularly worrisome became less so as a greater technical understanding evolved. At the moment, soil persistence per se is a topical issue in parts of Western Europe. If the use of certain products is denied or curtailed solely on this basis, what will happen when the topical thrust of concern turns to another issue?

Moreover, it can actually be very misleading to consider one aspect of the safety data, such as chemical persistence in soil, in isolation. The point at issue is, or should be, whether or not the presence of residues in soil leads to any harmful consequences in practice. In fact, it then becomes necessary to consider the whole set of safety data in perspective.

Let us consider another example. In the developed world, most uses of the more persistent organochlorine insecticides have been phased out - often in favour of less persistent organophosphates. Viewed solely from an environmental perspective, this is supportable as a desirable move. We also need to remember, however, that some of the organophosphates are more acutely toxic than earlier organochlorines, which in practice had a good record of user safety. Thus, it would be imprudent to consider the environmental perspective in isolation.

Rather, the totality of the benefits and the whole package of safety data need to be considered, in perspective. Moreover, when this is done, the outcome may well be different under the vastly different circumstances which apply in different parts of the world.

USE OF THE AVAILABILITY OF PERCEIVED ALTERNATIVE PRODUCTS DURING REGULATORY DECISION-MAKING

Another trend has been for certain governments to cite the availability of perceived alternatives when judging whether or not to allow (continued) use of given products. Frequently, these have not been real alternatives at all.

Where several products meet existing standards for acceptable benefit versus risk overall, there are strong arguments for allowing all the products to be available for use. It is rare for two different products to do precisely the same job. There is a clear benefit in allowing the user the greatest possible flexibility in the choice of product whenever possible.

Let us consider some examples. In the effective control of certain weeds, the opportunity arises for weeds which had originally been of secondary importance to become more important. Thus, with the passage of time, a change to a product with a slightly different spectrum of weed control may become indicated. In selective weed control in cereal sin Western Europe, 2,4-D or MCPA alone once gave sufficient control individually. Now the spectrum of weeds which it is desirable to control requires a mixture of products which may vary according to local circumstances.

Among insecticides and fungicides, the different modes of pesticidal action shown by different classes of products are beneficial in minimising the development of resistance. Spectrum and type of activity are also very important. Even among products with the same mode of action and overall activity, good control of secondary pests can provide a benefit in removal of

the major pest allows secondary pests to grow in importance - e.g. in cereals where new varieties sometimes do not have resistance to minor pathogens.

While, therefore, there is a clear need to allow the grower the greatest possible flexibility in the choice of product to use, it must also be remembered that there is no such thing as absolute safety. While every reasonable effort should be made to evaluate the safety of products during their development, practical inability to demonstrate absolute safety is an argument for spreading whatever remaining risk there may be, no matter how small, between several products, wherever possible.

For all these reasons, it is inappropriate to undertake a comparative benefit: risk evaluation between two products in any one outlet when, considered individually, both products would meet acceptable standards for an approval.

SUMMING UP

- The issues surrounding benefit: risk assessments on pesticides are complex.
- The need for flexibility of choice to meet individual needs, from within a range of acceptable pest control measures, is essential.
- Meanwhile, it is inappropriate to undertake a comparative benefit: risk evaluation between two products in any one outlet when, considered individually, both products would meet acceptable standards for approval.
- It can be misleading to consider only one aspect of the safety data totally in isolation. It is necessary instead to consider the whole benefit and the whole package of safety data. Irrespective of the availability of perceived alternative products, benefit: risk evaluations should continue to be conducted on the basis of the total available data, on an individual product basis.
- These points are relevant to the concerns of agriculture, public health authorities, governmental regulatory agencies, the pesticide industry and the general public alike.
- Provided that each product can be used as recommended without unacceptable risk to the user, consumer and environment, the overwhelming balance of practical benefit favours each being made available for commercial use.

REFERENCE

FAO, 1981, "Agriculture: Toward 2000"

Dépôt legal : D 1987/2537/2