Industry's attitude to product development and registration

J.C. Benstead
Shell Chemical (Australia) Pty. Ltd.
155 William Street, Melbourne 3000

INTRODUCTION

In the field of agricultural chemicals, product obsolescence is a fact of life. This largely arises from changing circumstances e.g. development of resistance to a product by one or more of the target organisms. Other factors are of course involved - necessity for improved product performance, new market opportunities, etc.

This situation necessitates heavy expenditure for research and development of new products. The development starts with the synthesis and initial screening of candidate compounds, followed by a number of increasingly demanding screens. These move from the laboratory into the field, and then into different environmental situations both locally and around the world. The discovery and subsequent development of even one pesticide is a most complex and demanding process, and requires enormous resources in terms of technically trained manpower and sophisticated equipment - both laboratory and field.

The field development phase is in turn followed by product registration. The product registration system has been devised to cover aspects such as efficacy, safety to non-target species and also environmental, toxicological, residue and safe handling aspects.

Industry accepts the principle of such control, and the obligation of the various regulatory authorities to discharge this responsibility. In Australia there is the system of pre-registration "Clearance" through the Department of Primary Industry's Technical Committee on Agricultural Chemicals or Technical Committee on Veterinary Drugs. After the issue of a Clearance Certificate, this is followed by a separate State Registration in each State where marketing is to take place. The constitutional situation leads to some difficulties in the administration of the system, and similar, as well as different difficulties are experienced in some countries overseas. A further problem is the diverse nature of requirements between countries. It is necessary to draw on what is essentially the one data bank, supplemented by local data, for registration.

It is clearly of mutual benefit to Government and Industry for all parties to work together to ensure the smooth and efficient operation of the very costly development/registration system. Industry believes that in the appropriate cases, the following factors are of paramount importance; uniformity, consultation and representation.

COST OF DEVELOPMENT

Costs of development of a pesticide are escalating rapidly. This is partly due to general escalation of cost, but more to the increasing variety of data required. The difficulty of discovering

a satisfactory product also contributes to a low ratio of successful developments when compared with the number of compounds screened. This is usually put at approximately 1 in 10,000. This high failure rate is testimony to the stringency of requirements of the screening and development process. The cost of development of a "typical" pesticide is put at a figure around $10 million, with recent estimates rising above this figure.

This high cost is a major problem for the industry, and in fact has led to the withdrawal of several pesticide developers from further involvement in product development.

A particular problem which is due to the high cost of development of a new compound, is that of so-called "minor use". This covers the situation where the market in a particular crop or crops is insufficient for the company owning the product to spend money on development in that crop i.e. obtaining efficacy and residue data and completing registration. Such crops can be key crops in particular areas, and the situation can arise where a section of the industry is severely handicapped by lack of suitable registered pesticides. This is a serious problem around the world, and is the subject of much discussion and many proposals for its solution. Whose responsibility it is to obtain the required data, and should a recommendation be made in the crop and by whom? A solution to this problem must be found.

The U.S.A. has attempted to find a solution by the "IR-4" program, where a group was established within the U.S.D.A. to carry out the required field work, and prosecute the required registration. In other countries various schemes have been discussed and proposed. It appears that in many cases the solution will lie in close co-operation between Government and Industry in "pooling" data and resources to achieve approval and registration of such minor uses.

UNIFORMITY

A concern to industry both internationally and locally is the question of uniformity of requirements for registration. Obviously a multitude of requirements are more difficult and costly to satisfy than one uniform set.

These requirements cover the range from different efficacy and toxicological data, through to legislation, regulations and administration.

This problem has been recognized locally by the establishment of the Technical Committee on Agricultural Chemicals (T.C.A.C.) which has achieved much in the move to uniformity. Much remains to be done, and The Agricultural and Veterinary Chemicals Association is currently in discussion with the Government with the objective of making further improvements in the area.

The subject of uniformity of legislation and regulation is also causing problems in the international sphere. An example of this is that where one country has a unique requirement in its regulatory system, there is frequently a problem in economically justifying the work for that one country, even though the requirement may have arisen from a unique local situation.

UNIFORMITY IN EFFICACY REQUIREMENTS

It is well recognized that it is necessary when field testing an agrochemical to consider the range of environmental conditions. The classic case here is probably Queensland and Victorian tobacco, where conditions are so different that it is difficult to extrapolate from one area to the other. However, in many cases, extrapolation from one area to another (of similar but not necessarily identical conditions) should be possible. In the case of herbicides, soil type is of course crucial, but here again extrapolation is possible bearing this in mind.

In this respect, industry believes strongly in the "portability" of appropriate data e.g. overseas efficacy data should be acceptable as prima facie evidence of efficacy, supported by confirmatory local field data.

In the case of laboratory data, there appears to be no reason why portability should not be complete i.e. laboratory data should be acceptable internationally.

A further point in the area of efficacy is the definition of work required. There are differences in opinion in some cases as to the work required in specific areas, and there has been considerable discussion as to the desirability of establishing a "protocal" of requirement. Some of those involved have expressed reservations on this approach, but others believe that the establishment of a flexible requirement would avoid a situation where, for example, different assessment methods are requested in an identical situation.

UNIFORMITY IN TOXICOLOGICAL/ENVIRONMENTAL REQUIREMENTS

Toxicological requirements by and large come under the heading of "laboratory data" of the type which should be "portable" internationally.

Unfortunately this is not so in all cases e.g. some countries require that feeding studies be carried out locally, and in other cases studies different from the standard are specified. This not only leads to increased cost, but actually causes a situation where it can be difficult to arrange the "different" studies, due to shortage of laboratory space.

The same applies to some degree to environmental data - much of this is laboratory type data, but this is of course allied to field requirements which are essentially "local".

UNIFORMITY - LEGISLATION

The problems of uniformity in efficacy and toxicological requirements are also applicable to uniformity of legislation, registration and administration. Obviously it is more difficult and costly to meet many varying requirements than one, and this situation has been recognized in Australia by the establishment of the T.C.A.C.

As mentioned above, industry has co-operated with this body in progressing local uniformity, and is currently discussing ways of achieving further improvements.

The magnitude of the problem is also recognized internationally - W.H.O./F.A.O. recently held a "Harmonization of Legislation" meeting in Rome. This was a very considerable event in the International scene, and had a large Australian input.

Firstly, the Pesticides Co-ordinator, J.T. Snelson, was retained by F.A.O. to act as consultant in respect of this meeting, and secondly, Australia was very well represented by Government and Industry.

Some have expressed concern that such harmonization could lead to an extension of requirements in some countries, and this is of course a possibility, but it does appear on balance that the advantage is with a logical uniform set of requirements.

CONSULTATION

It is of the utmost importance that there should be consultation between Industry and Government e.g. during the preparation of legislation and regulations. This ensures that Industry attitudes and problems in the area are known before the legislation is finalized, and in many cases Industry can make a very positive contribution. Such consultation on protocols, legislation etc. is now being quite widely accepted in Australia.

REPRESENTATION

In many cases it is both possible and valuable to have an Industry representative on a Government Committee. This concept also is increasingly being accepted around Australia, in some cases e.g. Poisons Advisory Committees, it has been a reality for quite some time. In some cases it may not be appropriate, for example, when data confidential to one company is to be discussed, but at times where general subjects, policies/guidelines are under discussion, representation can be most valuable.