

## INDUSTRY ATTITUDES TO REGISTRATION OF AGRICULTURAL CHEMICALS IN AUSTRALIA

I.P. Anderson  
Hoechst Australia Limited, Agrivet Division  
PO Box 4300 Melbourne Vic. 3004

*Summary.* Industry accepts the need for registration of Agricultural Chemicals, and the need for Government to act as an "umpire". It is essential however, that Industry is involved in consultations with Government in the formulation of regulations and requirements relating to registration. There is also a real need for uniformity and harmonisation in regulatory requirements so that excessive and unnecessary costs and delays can be minimised.

### INTRODUCTION

Agricultural and veterinary chemicals are used throughout the world as a raw material for the production of food and fibre so that we, the human race, may dine, wine and clothe ourselves in the manner to which we are accustomed. The use of herbicides, insecticides, fungicides, growth regulants, anthelmintics, rodenticides etc. is essential to produce goods of acceptable quality and in sufficient quantity to satisfy our requirements.

Because agrochemicals are used to control pests and disease, they are by their very nature, biologically active and designed to be so. Therefore, there is a need to understand the degrees and limits of this biological activity so that the consequences of deliberate release of these biologically active agents into the atmosphere and into the environment, are known.

Industry certainly accepts the need for registration of agricultural chemicals and looks to government as the referee or the linesman or the reviewer or the umpire. Government has the capability to call on experts, and industry endorses the system of expert government control - as a "peoples watch dog" - on the use of chemicals. On this basis, if industry is prepared to accept the umpires decision, then so must the public accept the decision of these umpires, these experts in their particular field.

### GOVERNMENT INVOLVEMENT

In the early days, most reputable companies were aware of their responsibilities and they carefully evaluated their products. However, as is often the case where the public is involved, government becomes involved, to protect them.

In Australia, this started with the introduction of the Stock Medicines Act in S.A. in 1939; others followed. N.S.W. introduced a Pest Destroyers Act 1945 which was "An Act to regulate the sale and prevent adulteration of pest destroyers; to provide for inspection and analysis; and for registration of pest destroyers and for purposes connected there with." A large part of this Act was involved with specifications for lime sulphur but it is noticeable that there were no requirements for health. Acts and regulations proliferated in all states, as did, in the 1950's and 60's, new products for pest, disease and weed control, until eventually in the mid 1960's, industry, as the Agricultural and Veterinary Chemicals Association of Australia (AVCA), made a move to get some uniformity into this whole regulatory business.

## INDUSTRY INVOLVEMENT

Industry considers it to be essential for free and open consultation between industry and government in the preparation of requirements for regulation of agricultural chemicals. This consultation is essential to ensure that there are workable, obtainable and realistic requirements. What is the use of legislation which cannot be met? Consultation is essential. Industry was the major initiative in the formation of TCAC and TCVD, and in the formulation of requirements for clearance. These have changed considerably over the years and will continue to change and revision of these is a constant process and Industry is involved and it is Industry's duty to continue to be involved and to comment. It should not be forgotten that in the late 60's or early 70's a group from industry sat down in Tasmania with the Tasmanian Health Authorities and drafted the Tasmanian Pesticide Act which is still in my opinion, the most practical and easily complied with set of Acts and Regulations that we have in Australia. It satisfies government, it satisfies industry and it satisfies the public.

Industry should not look at government as being infallible, as being the people who make the rules by themselves. They expect to be challenged, they expect some sort of argument, and it is our job to ensure that this occurs where necessary. This whole consultation is an ongoing process.

## INTERPRETATION

Because we are involved in a biological science which is dynamic, which changes, which is never the same, we must learn to be flexible, and we must be prepared to change. Similarly, the interpretation of regulations must be flexible. Acts and Regulations and other requirements must be put together in such a way as to allow a flexibility and a reasonable interpretation on the part of both industry and government, relevant to the situation. It is important that the people addressing applications for registration have an understanding of the processes not only in their own area but also in the industry area and in the farming area. Interpretation must be flexible, must be reasonable, and must be always used.

## DEFINITIONS

There is often confusion between Regulations, Guidelines and Codes of Practice. It is important to differentiate between these 3 factors, as all are necessary in the regulatory process. Let me define them using the Concise Oxford Dictionary. Firstly, regulation: "A prescribed rule, authoritative direction." Similarly, regulate means "control by rule, or subject to restrictions." Secondly, guidelines: "Directing principle." Thirdly, code of practice: A code is defined as "a set of rules on any subject." Thus, a code of practice is defined as a set of rules on a particular system. It is important to note the differences in so far that regulations are something which should be obeyed and there is limited chance for flexibility. Guidelines on the other hand, are something which it is desirable to follow, and it is important that regulatory authorities do not interpret these as regulations. Guidelines are not there to enforce, but to try and obtain a degree of uniformity, and most responsible organisations will respond to guidelines. Codes of practice on the other hand, are there for use in manufacturing, formulating, business, management etc. and so whilst not necessarily enforceable, they tend to be enforced by the industry, as a self regulatory system. Many organisations have rules and regulations within their own organisations which can help maintain codes of practice.

## PRESENT REQUIREMENTS

Industry strongly supports the idea of harmonisation or uniformity of pesticide registration requirements throughout the world. It is accepted that we have a problem in Australia with our six different states. However, a major overseas manufacturing company has more than six states of Australia to contend with. It has some hundreds of countries, many of which may have different requirements. It is therefore, of the utmost importance, that there are uniform requirements. In Rome, October 1982, there was a Government Consultation on International Harmonisation of Pesticide Registration requirements and Australia was represented at this meeting. Basically, the requirements developed at this meeting appear to be acceptable on a world wide basis to most companies and to most governments, and it is therefore important that these guidelines be adapted in the various countries, as the cost of meeting different requirements can be excessive and totally unnecessary.

The 3 major areas, that is health, environment and efficacy, are fully addressed, and are included in our local requirements. Assessing these areas will vary and perhaps some comments are necessary.

Firstly in health. It is virtually impossible to prove complete safety of any product and therefore, the risk and hazard assessment of these materials must be left to the judgement of these experts who have the expertise and impartiality in this area and who understand the problem. Most of us here in this room, do not understand the nuances of toxicology, and in fact, there are very few people that do. Secondly, environment. This is also an area where it is difficult to be accurate and therefore, some of the assessments must be based on probabilities. As understanding of the environment of the creatures and of the likelihood of a product being involved in a situation must be evaluated. Environmental problems must be looked at in a realistic way and industry accepts that some regulatory effort is required. Thirdly, efficacy and of course crop safety. Long gone are the days when a company would put a product on the market which did not work, or is likely to cause a problem. We are all aware of the advances in litigation and common law claims. If a product does not work, then it is the manufacturer who suffers. Whilst there may still be a reasonable requirement for some umpire to look at the claims, this appears from my point of view, to be a diminishing area of importance.

## CONCLUSION

In conclusion, industry will certainly accept that registration of agricultural chemicals is a necessity. It is in effect, a regulatory watchdog, and as such forms a very useful purpose. It serves as a basis for the protection of the public and the environment against misuse, and hopefully abuse of products. There is however, the potential for registration and regulation to get out of hand and this is where it is important that industry be closely associated and involved with the formation and implementation of regulatory requirements. And finally, it is absolutely essential if we are to have regulations, that there be a degree of uniformity and harmonisation not only within Australia, but throughout the world so that excessive time and costs involved in *ad hoc* tests do not have to be passed on to the consumer who is already suffering from the high cost of regulation.