Pesticide Toxicology
and International Regulation
Current Toxicology Series

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Pesticide Toxicology and International Regulation

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Preface

Pesticides are used daily and internationally on a massive scale. They have conferred immense benefits to mankind by contributing significantly to improving health and nutrition, and to the economy in the form of cheaper food. This is mainly as a consequence of their use in crop protection, food preservation, and the control of insect vectors. However, this has sometimes been at a cost since improper and/or inappropriate usage has led to small- and large-scale poisoning incidents in humans, domestic animals, and wildlife, and resulted in significant adverse phytotoxic, ecotoxic, and general environmental adverse effects. Pesticides fall into numerous chemical classes, which have widely differing biological activities and thus differing potential to produce adverse effects in living organisms, including humans. These considerations, coupled with the fact that, in addition to their use by highly trained agricultural and horticultural professionals, they are also generally available for use by less well trained or even untrained individuals, stresses the need for the control (regulation) of their release, use, and sale. This is further emphasized by the fact the pesticide industry is large, lucrative, and highly competitive. Regulation of availability, control on use and sale, and restrictions on use is carried out by competent national government (federal) authorities through their own individual pesticides safety precautions schemes, and often with due regard given to advice originating from credible international bodies such as the World Health Organization (WHO). In most scientifically and technically advanced communities the regulations and guidelines of the competent authorities now offer a considerable degree of, although not necessarily total, protection for the community. Whilst informed discussions between industry and government may be necessary and helpful, these editors believe that ultimate conclusions and decisions on clearance of pesticides should be a function of the relevant national competent authority and its independent advisory structure. It is thus important that government has available independent scientific advice from individuals of appropriate integrity.

There is a need for continual review of pesticides once they have been authorized for release (with varying degrees of restrictions) on to the market. This oversight function is required for, amongst other issues, the recognition of adverse effects not predictable or predicted, abuses and misuses, and other factors that may pose hazards to public health and the environment. This watchdog activity is sometimes, at least in some cases and in part, a function of follow-up schemes by the competent regulatory authorities who arrange for periodic reviews of pesticides following their clearance for use. In other cases, this function may be delegated to other
governmental departments, e.g. public health. In yet other cases this function may result from the activities of private (non-governmental) organizations supported by public contributions. In respect of the latter organizations, it is relevant to recall the comment of Mellanby (Biologist, vol. 21, p. 131, 1974), who emphasized the harm that can be done to the credibility of scientists by the pronouncements of others who are not scientists, but who use the jargon of science to promote their own objectives. Although many private organizations conduct good work and draw attention to some problems, a few others have interests more of a sociopolitical basis than genuinely humane reasons for their existence. For pesticides, an informed and balanced opinion on their benefits, and their relative safety-in-use is necessary for discussion about recommendations on the control of pesticides. In this respect, the competent authority should have credible professional advisers and advisory committees who have no vested interests in the economy (profits) of the pesticide industry but who have national and international respect for professional integrity.

There have been major changes in the regulation of pesticides (including biocides) in both the European Union and the United States of America. In the European Union the main change has been the harmonization of pesticide regulation under Directives 91/414 for agricultural and horticultural pesticides (‘plant protection products’) and 98/8 for biocides. Meanwhile in the United States, the Food Quality Protection Act (1996) demanded consideration of all pathways of pesticide exposure (aggregate risk assessment) and the consideration of exposure to multiple pesticides (cumulative risk assessment). Furthermore, in the United States there is progressive harmonization between the three countries (America, Canada and Mexico) of the North American Free Trade Area (NAFTA). The needs of aggregate and cumulative risk assessment has led to the questioning of current procedures for deterministic risk assessment and the consideration of probabilistic exposure assessment. So far probabilistic methodology has not been applied to the toxicology side of risk assessment, but logically it could be. Another change in pesticide regulation is the Sanitary and Phytosanitary (SPS) agreement under the Uruguay round of the General Agreement on Tariffs and Trade (GATT). The Uruguay round of GATT not only established the World Trade Organization but it was also decided that, except in certain circumstances, Codex Alimentarius Commission food standards should be used in international trade. The expert advisory committee in respect of pesticides in such circumstances is the Joint Expert Meeting on Pesticide Residues (JMPR), which is convened jointly by the World Health Organization and the Food and Agricultural Organization of the United Nations. The activity of the Organization for Economic Cooperation and Development (OECD) in developing internationally acceptable test guidelines should also not be forgotten.

Despite the moves towards harmonization, which would be expected to lead to less duplication and easier registration of active ingredients, this has not always transpired and the process has, in some ways, become more bureaucratic. Thus,
committees have proliferated like the hydra. For example, whereas there was formerly one committee in the United Kingdom dealing with pesticides, namely the Advisory Committee on Pesticides (ACP), there are now three, the ACP, the Pesticides Residues Committee (PRC), and the Biocides Consultative Committee (BCC). Also, and in the widest sense of harmonization, some countries appear to choose to ignore or apparently refuse to adopt sensible suggestions, such as harmonization of units; thus, harmonization of scientific and medical units by the United States seems to be the exception rather than the rule at both a national (federal) and a state level, although some organizations will give harmonized units in parentheses. On other scientific concepts, some agencies seem to accept without question, and without medical or scientific discussion or comment, what are to be regarded as, at the least, suspect unscientific definitions, criteria, or arguments for certain concepts. One of the most notable of these was introduced by the European Union (Council of Europe) in regard to immunologically mediated biological reactions, and notably on the definition and thus classification of substances having a sensitizing potential for the respiratory tract. The criteria for a respiratory sensitiser includes one stating (unequivocally) that for the purposes of definition and classification it does not have to be demonstrated that the material produces its sensitizing effect through an immune mechanism. This criterion was apparently the result of pseudoscientific political pressure from the representative one EEC country, and was amazingly adopted from the European Union by the OECD without question or comment. This activity, which goes contrary to current credible science, and is to be reprimanded, has several disturbing repercussions. First, it calls into question the medical and scientific credibility and membership of the appropriate EU expert committee, which flagrantly ignored internationally agreed concepts, research, and clinical findings with respiratory sensitizers. Secondly, and against widely held opinion and knowledge, the reason(s) for this pseudoscientific and unbelievable decision and action must be regarded as suspect. Finally, one practical implication is that many irritant (inflammatory-inducing) materials, without effects on the immune system, will be wrongly classified.

This book aims to bring together the regulation of pesticides with the more important aspects of their toxicology. The regulatory chapters deal with regulation in the EU, NAFTA, and Japan, respectively. Several toxicology chapters deal with insecticides, chapters being devoted to the major groups of insecticides, with one on miscellaneous insecticides. There are also chapters on fungicides, herbicides, and biocides; inevitably because of the chemically disparate nature of these compounds (particularly fungicides) compared with insecticides, these have been dealt with differently, in small groups or by individual active ingredient. Other chapters discuss biological pesticides, occupational exposure, and treatment of pesticide poisoning. It is hoped that bringing together regulation and toxicology in this way may help to stimulate more intelligent and integrated approaches to pesticide regulation and the related needs for toxicology (in all its subdisciplines) and information from other relevant disciplines. Although most regulatory authorities issue what purport