

Pesticide Risk and Benefit Assessment

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ABSTRACT

The benefits of pesticides in improving the food quantity and quality requirements for an increasing world population are significant, and they can be described in agronomic, economic and social terms. The risks are assessed from the hazards which are likely to occur in practice ; the hazards are defined by the toxicity of the pesticide to non-target organisms at various exposure levels. There are ways of reducing the risks (mainly by reducing exposure in practice) and improving the benefits of pesticides ; these are known as risk management and benefit management respectively. The overall risk-benefit assessment is facilitated if each component can be expressed in financial terms, but it must be made nationally or locally on a sound technical basis against the prevailing agronomic, socio-economic and political circumstances.

Paraquat is used to illustrate the risk-benefit assessment process in general terms, and the conclusion is that the benefits greatly outweigh the risks.

It is important to keep the risks of pesticides in perspective with those associated with other naturally occurring chemicals in our diet and with other everyday aspects of life. In an overall context, the pesticide risk is small.

Key words : pesticide risk, benefit assessment, hazard assessment

Principles of Risk and Benefit Assessment

The principles of risk and benefit assessment of a pesticide involve a clear definition of the benefits ; the more obvious benefits are agronomic and economic, but there are often social benefits too which may be less evident. The assessment of the risk associated with a pesticide is more complex ; first it is necessary to define the hazard of the pesticide by observing the toxicity expressed in test organisms when they are exposed to different amounts of the pesticide. Then it is necessary to make further measurements and observations in relation to

the real-life situation so the risk can be assessed. The balancing of the risk and benefit scenarios is the risk-benefit assessment, the outcome of which can be influenced by management of either the risk and/or the benefit. Steps which can be taken to reduce the exposure usually lead to a reduction of the hazard and/or the risk ; this is risk management. Actions can also be taken to increase the number or impact of the benefits ; this is benefit management. These principles are illustrated diagrammatically as follows :

It is helpful to clearly define key certain words used in the context of this presentation.

Hazard. The existence, nature and extent of the toxic effects observed following the expo-

sure of an organism to a pesticide. This is the inherent toxicity of the pesticide.

Risk. The likelihood that the hazard can occur during or following the use of the pesticide in practice.

Benefit. Any consequence of pesticide use which enhances the well-being of individuals or groups.

Pesticides are designed to kill the target organisms to which they are directed, and therefore possess toxicological activity. During the synthesis programmes, chemists attempt to design out the toxicity of these molecules to non-target organisms but this selective toxicity is often only partially achieved. The key objective is to reduce the pesticide risk to non-target organisms to acceptable levels.

Benefits of Pesticides

The world population is expected to increase by about 50% in the next 33 years. Even with the current level of pesticide use, it is estimated that between 20% and 40% of the maximum potential crop yield in the agricultural production of food for human consumption is lost due to pests, disease and competition from weeds. A significant proportion of the world's population is under-nourished at the present time, a situation which must be rectified. The greatest increases in population are taking place in countries with weaker economies and less-developed

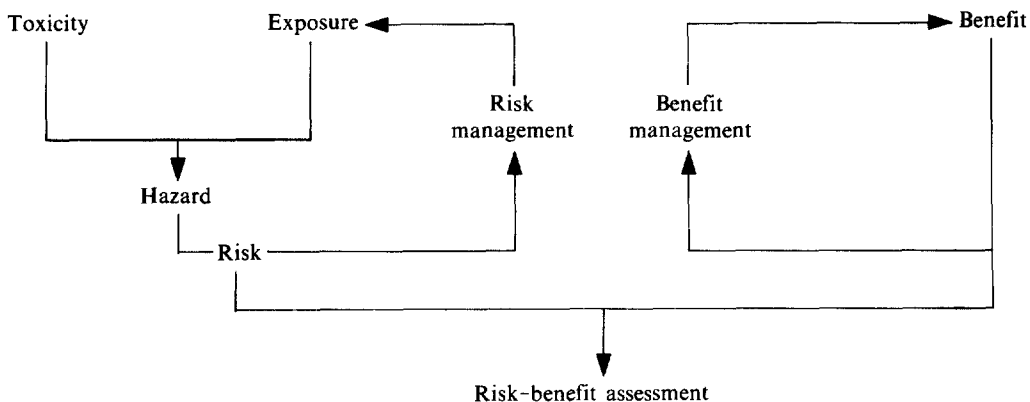
agricultural practices. Further, there is an increasing world-wide demand for better quality food. All these trends lead to the prediction that global food production needs to increase by 70% by the year 2025, with the greatest advances being needed in developing countries.

During this century, the technologies which have contributed to improved food production efficiency include mechanization, fertilizers, plant breeding, pesticides and integrated pest management. Pesticides have probably had the greatest impact, being cheap, very reliable and easy to use. Biotechnology offers the prospect of yet another step-change in the improvement of agricultural production efficiency, but it will be many years before the full impact is realized and it will not provide a total replacement for pesticides, especially in the developing countries.

1A. Man. Occupational situations.

Hazard assessment.

This is achieved by treating laboratory animals with technical and formulated product; increasingly, in vitro alternatives to laboratory animals are being used for some tests. Acute and sub-acute toxicity studies are conducted in which the product is administered by appropriate routes (oral, dermal, inhalation). The product is also assessed for irritancy, immunotoxicity, neurotoxicity, mutagenicity and teratogenicity. Human data from epidemiology studies and poisoning cases is invaluable.



1B. Man. Occupational situations.

Risk assessment and management.

Additional data needed for risk assessment can include human exposure measurement, dermal absorption in vitro, human volunteer studies which examine absorption, metabolism and excretion of a low dose of the pesticide, and identification of markers of human toxicity in clinical monitoring programmes. Actions to reduce human exposure (risk management) include the wearing of appropriate personal protection, good personal hygiene after work shifts finish, implementation of safety standards and preventative medicine practices. Manufacturing plant engineering specifications, procedures and maintenance should be of high quality, as should the maintenance of spray equipment for field use. Labels, pictograms and other pesticide literature should be legible, easy to understand and unambiguous.

2A. Man. Consumption of residues in food. Hazard assessment.

This is made by conducting studies in laboratory animals in which the technical material is administered daily by the oral route, usually in the diet. Sub-acute and chronic toxicity studies and teratogenicity studies are conducted in rodents and non-rodents whilst only rodents are used in carcinogenicity, reproductive toxicity and metabolism studies. In the event that metabolites of the pesticide occur in plants which are not also seen in the animal metabolism study, some toxicity studies on the plant-specific metabolites will be necessary.

2B. Man. Consumption of residues in food. Risk assessment and management.

Further information needed to assess the risk could include an understanding of the mechanism of the toxicity of the pesticide; to help decide its relevance to man, comparative studies in rodents, primates (in vivo and in vitro) and man (in vitro) may be performed to examine

absorption, pharmacokinetics, metabolism and toxicity. Risk management is achieved by applying an appropriate safety factor to the lowest no adverse effect level or benchmark dose level in the toxicity studies in animals. The safety factor is usually 100, which takes into account an assumed 10-fold increase in sensitivity to the toxic effects of the pesticide in man compared with animals and another factor of 10 to allow for hypersensitive individuals within the human population. The safety factor can be reduced or increased depending on the circumstances and the data available. After applying the safety factor, an acceptable daily intake (ADI) is established for the residues of that pesticide from all sources in the human diet. An ADI is established by national regulatory bodies, and also by the World Health Organization within the Joint Meeting on Pesticide Residues, as a safety standard for the pesticide.

In general terms, the benefits of pesticides include increased food production efficiency (time, cost, labour and yield), which can contribute to improved farmer wealth. Labour can be released from agricultural production and diverted to other industries which create greater national wealth; this can lead to greater social benefits for the population at large. Other economic benefits of pesticides will usually ensure more affordable food prices for the consumer, though improved quality and appearance of some produce can command a price premium. Pesticides reduce food losses during post-harvest storage due to fungal and insect infestation, and increase the opportunity for surplus food to be exported thus contributing positively to the national economy. Pesticides also have uses in the production of commodities such as cotton, rubber and palm-oil, public health, ectoparasite control in farm animals and pets and a variety of domestic applications (amateur gardening, wood treatment, rodent and insect control).

Techniques to improve the benefits of pesti-

cides (benefit management) include efficacy optimization through the use of safeners/enhancers where appropriate, formulation technology, selective targeting and mixture development. Treatment regimes involving more than one pesticide to manage resistance are often successful. The public perception of pesticides can be distorted by anti-pesticide lobby groups and irresponsible media reports; one way to counter this distortion is for the pesticide industry to promote the beneficial effects of its products, which can be achieved by a variety of means.

Hazard and Risk Assessment of Pesticides

Hazard assessment involves the determination of the intrinsic toxicological properties of a pesticide to non-target organisms. It forms the major part of government regulations which have to be satisfied in order to register a pesticide for sale and use. Of the £30-50 million spent by the industry to take a pesticide from synthesis to market, over one-third of this is used on safety evaluation to man and the environment. All hazard assessment studies should be conducted to high technical standards and many need to comply with Good Laboratory Practice requirements. For most studies, the key outputs include the determination, for each toxic effect, of a dose-response relationship and a no adverse effect dose level or benchmark dose level. A benchmark dose level is defined by the lower 95% confidence limit of the minimal discernible change in a parameter from the control level (usually 5%) caused by treatment with the pesticide.

There are several aspects of pesticide use which need to be considered separately when making hazard and risk assessments. First, with regard to man, there are the occupational situations which include the manufacture of technical and formulated product, the use of the

product in the field and, to a lesser extent, the transportation of the pesticide from manufacturer to the farmer; also, there is the consumption of residues in food treated with pesticides. Secondly, with regard to the environment, there is the nature and occurrence of pesticide residues in food, the behaviour of pesticide residues in other compartments of the environment and the effects which those residues have on the organisms which live in those compartments. Each of these aspects will be addressed in turn.

3A. Environment. Residues in food. Hazard assessment.

The first requirement is to understand the metabolic processes which the pesticide undergoes in the crop types to which it will be applied, and to identify the major metabolites. Then the residues of the parent pesticide and its major metabolites should be determined in each crop which will be treated by the pesticide. The standard of conduct of the residue trials is critical; they should be performed in relevant climatic conditions and to a replicated, randomized design. The method, rate and timing of the appropriate pesticide formulation should equate to the recommended use pattern which gives maximum efficacy. The harvest to the recommended use pattern which gives maximum efficacy. The harvest technique and method of preparation of the crop for analysis are also critical. A reliable clean-up and analytical procedure should be used. The quantification of residues is also required in crops treated with pesticides for post-harvest storage and in animal products (meat, milk, eggs) for human consumption following the consumption by the animals concerned of feed which contains residues (animal transfer studies). It may be necessary to determine residues in following crops which are grown on the same site as the primary crop which was treated with the pesticide, for example, when the pesticide is persistent in soil and residues may be translocated from the soil

into the crop growing in that soil.

3B. Environment. Residues in food. Risk assessment and management.

Included in the information needed for risk assessment is an understanding of which residue-bearing parts of the treated plant are likely to be fed to man and animals, and what happens to the residues during the preparation and processing of the harvested commodity before it is consumed. The risk management process required actions to ensure Good Agricultural Practice is implemented. Also, maximum residue limits for pesticides in food (trading standards) are established by national regulatory authorities and by the Food and Agriculture Organization within the JMPR and CODEX processes. Market basket surveys of pesticide residues in food show that they are rarely above analytical detection limits (about 0.05ppm) and almost never in excess of the maximum residue limit.

4A. Environment. Environmental behaviour. Hazard assessment.

This assessment is usually made in laboratory studies using technical material, though formulated product may also be used. Knowledge of the physico-chemical characteristics of the pesticide is valuable. In the soil, determinations of adsorption-desorption characteristics, rate of degradation, metabolism, leaching potential (parent and metabolites) and photolysis are required. In water, for both parent and any metabolites transferred from the soil, hydrolysis, photolysis and degradation in water-sediment systems should be studied. In air, again for both parent and metabolites transferred from other environmental compartments, photolysis and reaction with atmospheric constituents should be investigated.

4B. Environment. Environmental behaviour. Risk assessment and management.

This involves the monitoring of residues occurring in the various environmental compartments, and the use of simulated or in-field systems and mathematical modelling techniques. In the manufacturing situation, risk management can involve control of effluent discharge into all environmental compartments, prevention and containment of spillages and safe destruction or disposal of waste products. At the farmer level, education and training in the safe and judicious use and disposal of pesticides is important, aided by good labels, pictograms and other literature. Collection schemes for surplus pesticides and empty packs are becoming more popular.

5A. Environment. Ecotoxicology. Hazard assessment.

This involves conducting laboratory studies with technical material and formulated product to determine their toxicology in earthworms, beneficial soil insects, soil micro-organisms, fish, shellfish, aquatic invertebrates, wild mammals, birds, bees and other beneficial flying insects.

5B. Environment. Ecotoxicology. Risk assessment and management.

Investigation of effects on wildlife species at risk from exposure to pesticides in the environment can be conducted in the field, but it is often difficult to unambiguously associate an observed effect with the pesticide under consideration. The risk management actions are similar to those for environmental behaviour, which are designed to reduce environmental residue levels of pesticides.

Overall Risk Assessment and Management

For all critical risk aspects, it is important to take into consideration the dose-response relationships, the no adverse effect levels/benchmark dose levels and the exposure levels in practice. The overall risk assessment should be made on a sound technical basis. The strengths and weaknesses in the database, and the assumptions, extrapolations, judgements and uncertainties in the assessment must be recognized and taken into account. The options for risk management of pesticides overall, in increasing order of stringency, include label precautions during use, restrictions on the rate and number of applications, restrictions on the number of crop outlets, restrictions on who can use the pesticide, use the pesticide in a wider regime (integrated pest management), replacement of the pesticide with a safer alternative (if one exists) and finally abandon the pesticide.

Overall Risk-Benefit Assessment

It is valuable if the overall risks and benefits can be quantified in financial terms as far as possible. In the assessment, which should be made at national or local level, it is critical to make objective judgements, to maintain a balanced perspective and to take into account the prevailing agronomic, socio-economic and political circumstances. The assessor should not be unduly influenced by decisions made in other countries or by lobby groups. A good assessment requires knowledge, expertise, skill, judgement, political awareness and courage.

Paraquat : an Example of Risk-Benefit Assessment

Benefits of Paraquat

Paraquat is a contact herbicide which acts on a wide variety of weed types. It begins to kill

green tissue within 2-4 hours, and is rain-fast within an hour giving the farmer flexibility in using the product. It is used for weed control in the cultivation of a large number of crops in a wide variety of agricultural situations worldwide. Because it is rapidly bound and deactivated on contact with soil it can be used immediately before sowing and it is not translocated into crops through the root system. Further, it is not translocated within the plant, so any crops which are affected by low levels of spray drift can quickly recover. Weed control in tropical plantations is a particularly important use of paraquat, where it has the valuable property of not being absorbed through the bark of trees. There are only about 4 weeds which have become resistant to paraquat during 30 years of use. It is compatible with many other herbicides which created possibilities for mixture development and tank mixing opportunities. In parts of the world where soil erosion occurs, paraquat has enabled the development of no-till or minimum-till agriculture to lessen this significant environmental problem. Paraquat is also used in water weed control. Overall, paraquat allows the farmer to produce higher yields of better quality crops which contain negligible residues, whilst reducing energy and labour costs in agricultural production; it also enables flexible and environment-preserving agricultural practices.

Hazard and Risk Assessment of Paraquat

1. Man. Occupational use.

Paraquat is non-volatile and the spray particles are not respirable, thus there is no inhalation hazard. It has moderate acute toxicity, and is in WHO Class II. It is not mutagenic *in vivo*, and possesses no teratogenic, immunotoxic or neurotoxic hazard. The formulation concentrate is irritant to the skin and eyes, and it is recommended that protective clothing is worn

when handling it. Poisoning incidents have occurred, and whilst there is no specific antidote (this is true for the majority of pesticides), treatment is effective if it is applied quickly enough. Suicide using paraquat is regarded as a sociological problem because if paraquat was not available, some other means would be used. Nevertheless, three safety features (dye, stench and emetic) have been included in paraquat as alerting agents and to minimise the effects of ingestion. Also, hospitals and doctors worldwide are provided free of charge with Fuller's Earth adsorbent, urine test kits and treatment instructions. Paraquat has a good occupational safety record when it is used as recommended; its poor absorption through the skin and its rapid excretion from the body due to its high solubility in water are major contributory factors.

2. Man. Consumption of residues in food.

Paraquat is not carcinogenic or reprotoxic, it is not metabolized and it is rapidly excreted. The target organ for chronic toxicity is the lung, for which a no adverse effect level is established; on this basis a full ADI (0.004mg/kg/day) was established by the JMPR in 1986 and this is still effective.

3. Environment. Residues in food.

In the vast majority of crops, residues of paraquat are present at less than the analytical detection limit (0.05 or 0.1ppm). However, there are certain crops for which paraquat is used as a desiccant to aid harvesting and finite residues are found in these crops. Maximum residue limits have been established by JMPR and CODEX.

4. Environment. Environmental behaviour.

Some photolytic breakdown to non-toxic products occurs immediately after application to

soil and plant surfaces. Paraquat is rapidly and strongly bound to the organic matter and clay components of the soil, which has beneficial environmental implications. These are loss of biological activity, no transfer into plants through the root system, no leaching into groundwater, no transfer into surface water (if soil particles are washed into surface water, the paraquat remains strongly bound to them) and no displacement by fertilizers or other pesticides. Nevertheless, there is slow breakdown of paraquat in soil by micro-organisms.

5. Environment. Ecotoxicology.

Paraquat has slight or low toxicity to wildlife. The level of exposure of wildlife to paraquat in practice is very low due to its strong soil-binding property. More importantly, paraquat is non-toxic to soil micro-organisms, including those which degrade it.

Overall Risk Assessment of Paraquat

Paraquat presents negligible risk to man and to the environment when it is used as recommended. Positive steps have been taken to prevent accidental or deliberate ingestion, and to enable treatment to be administered rapidly if ingestion should occur.

Overall Risk-Benefit Assessment of Paraquat

In countries where agriculture is a key part of the economy, paraquat provides many significant agronomic, economic and social benefits. These greatly outweigh the attendant risks.

Pesticides in Perspective

It has already been stated that of all the techniques which have improved agricultural food production efficiency this century, pesticides have probably had the greatest impact. In a

study in the USA, it has been estimated that if the use of all pesticides and fertilizers was to be stopped, the yield reduction for major agricultural commodities such as corn, soya, wheat and cotton would be 37-62%, and production cost increases would be 45-118%. The economic impact across all crops is estimated to result in an average family food bill increase of \$430 per year ; this represents a 12% increase for a middle-income family and a 44% increase for a low income family in the United States of America .

The pesticide industry spends huge sums of money assessing the safety of pesticides in food, yet pesticides comprise only a very small proportion of the total amount of food eaten by man. Over 99.9% of chemicals eaten by man are naturally occurring, but very little is known about their safety. Plants(edible and non-edible) use their own natural chemical defences to deal with attacks by pests and diseases, and these chemicals must also be toxic. Some of the most potent pharmacological agents known to man are naturally occurring and of plant origin (for example atropine, digitalis, opium) and they are toxic at low doses. Examples of other plant poisons found in common foods are solanum alkaloids(potatoes), aflatoxins(peanuts), hydrazines(mushrooms), alkyl isothiocyanate(cabbage, broccoli) and methoxypsoralen(celery) . Further, salmonella is by far the most common cause of food poisoning. Whilst

recognizing that pesticides are designed to be toxic, much more time and money is spent on the evaluation of their safety than for any of the other chemicals in our diet, some of which pose greater risks.

Finally, some statistics which were also generated in the USA attempt to put the risk associated with pesticides into context with that associated with other everyday occurrences. The cancer risk for pesticides and other chemicals in USA is deliberately regulated to be at or less than 1 death per million of the population. By the same measure, other risks are higher, namely bee sting(14), tornado(40), electrocution (370), burns from fire(1400), drowning (1680), accidents in the home(7700) and motor vehicle accidents(13720) .

This information helps to keep the risks of pesticides in the correct perspective.

Conclusions

The principles of risk and benefit assessment of pesticides, and the approaches to the different elements of the assessment, have been described. An example of a 'general assessment using paraquat has been shown. It is important to keep the risks of pesticides in context with those in events in everyday life ; in an overall context, the risks associated with pesticides are small.