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# A NEW APPROACH TO ADOPTION OF POTENTIAL ALTERNATIVE QUARANTINE TREATMENTS WORLD-WIDE

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## ABSTRACT

The recent GATT agreement concerning the way plants and plant products are traded is expected to lead to more transparent and scientifically justified quarantine regulations on a worldwide basis. Following the guidelines set by the FAO for regulating quarantine specifications and entry conditions, many countries are now starting to develop justifiable Import Standards. These must be based on the principles of Pest-Risk Analysis, a three-stage process involving the production and categorisation of pest lists, scientific and realistic assessment of pest risk from both economic and biological viewpoints and development of transparent risk management requirements. New treatments and technologies arise from the need to satisfy risk management requirements. Whether the implementation of new technologies is delayed by the actions of quarantine agencies depends on the quality of scientific research and the clarity with which the justification for new treatments is presented. This paper illustrates the new challenges to trade in stored products by describing the approach being taken by New Zealand. In response to the FAO initiatives, New Zealand has mandated standards for the import of fresh produce, nursery stock, grain, seed for sowing and processed products, and standards for Pest-Risk Analysis (PRA) as well. While PRA for items of fresh produce and nursery stock is well advanced, there are still many problems to overcome in applying PRA principles to the import of stored products.

## INTRODUCTION

There is increasing awareness that all quarantine decisions which affect the movement of plants and plant products among countries must be based on sound scientific advice and, therefore, be fully justifiable and transparent. The objective of this approach is to prevent quarantine regulations from being used as barriers to trade. Importing countries should state quite clearly the pests and diseases they wish to exclude ("quarantine pests"), publish specifications which reflect their tolerance to the listed pests and propose scientifically justifiable risk-management options (entry conditions). The exporting country has the responsibility of responding to the specifications by informing the importing party what systems and/or treatments will be applied to the product to ensure that the specifications are met. Actions must also meet the criteria of openness and full scientific justification. Quarantine authorities should be prepared to consider the principle of equivalence (i.e. that there may be several treatments of equivalent merit) and not adopt a dogmatic approach to risk management.

In 1995 the Food and Agriculture Organisation of the United Nations produced draft standards as guidelines for the regulation of quarantine specifications and entry conditions (FAO, 1995). In response to this initiative, many countries, including New Zealand, are now starting to develop justifiable Import Standards for the full range of plants and plant products. These must be based on the principles of Pest-Risk Analysis (PRA) which demand the production and categorisation of pest lists, the realistic scientific assessment of pest risk from both the economic and biological viewpoint and the development of transparent risk management options. While the initial thrust is to apply the new methods to the trade in fresh produce, it is inevitable that they will also be applied to the movement of all forms of plant products, including such stored products as grain, seeds and food items. Whether the implementation of these new technologies is delayed by the actions of quarantine agencies will depend on the quality of scientific research and the clarity with which the justification for new treatments is presented. This paper explores the new challenges to the trade in stored products by describing the approach being taken by New Zealand in response to the FAO initiatives.

## DEVELOPMENT OF STANDARDS

Quarantine authorities have always imposed conditions, usually in the form of government regulations simply stating the required entry conditions, on the import of plant products. How these were derived was not usually disclosed, and they were based on subjective perceptions of pest risk rather than on formal assessments. Entry conditions ranged from one extreme (no treatment or inspection at all) to the other (total prohibition). Once the need to justify entry conditions was realised, it became evident that full documentation in the form of a standard would be required. At the same time it was seen that, if entry conditions were to be scientifically justified, there would be a need to declare a quantifiable tolerance based on as objective an assessment of risk as was possible. The idea of so-called zero tolerance, leading to the prohibition of certain products, also became untenable in the new atmosphere of trade's being allowed to proceed without artificial "quarantine" barriers.

The New Zealand Ministry of Agriculture Regulatory Authority has progressed along this path, formally declaring tolerances (specifications) for pests and including them in standards for all forms of plant and plant-product imports. This, one of the main differences between the old and the new systems, was made possible by the parallel development of a quantified pest-risk analysis system.

## DEVELOPMENT OF PEST-RISK ANALYSIS

New Zealand is a small isolated island nation which has managed to avoid many of the world's more serious pests. There was concern in the 1980's that New Zealand was becoming more vulnerable to pest invasion because of both rapidly increasing plant-product imports and the growth in tourism. This led scientists to question the inspection systems then in place and to explore methods of quantifying the risk of importing hosts of serious pests. The work was started with fruit flies because New Zealand is the only major fruit-producing country that has remained free of important economically deleterious fruit-fly species. The concept of a maximum pest limit (*MPL*) (as a means of setting a realistic limit — or tolerance — to the number of pests on imported produce) was developed as an alternative to an overly restrictive import policy (Baker *et al.*, 1990). This led to the development of a Pest-Risk Analysis Standard using the *MPL* as a specification (Baker *et al.*, 1993). Improvements to the first model have just been published and incorporated into a revised standard (MAFRA, 1997; Whyte *et al.*, 1996). Using the two PRA standards, scientists at the New Zealand Plant Protection Centre have processed 40 pest-risk assessments to date, expanding the concept beyond fruit flies to include other insects, plant pathogens, weed seeds and mites. The most recent assessment was of a serious pest of stored seeds and grain, *Trogoderma variabile*.

A PRA entails three distinct requirements for any product being considered for import: production of a pest list, some form of pest-risk assessment leading to a specification and formulation of risk management options.

Pests are classified as quarantine or non-quarantine according to the FAO (1995) definition of a quarantine pest ("A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled"). The pest list clearly informs the exporter which pests are to be excluded from the product (quarantine pests) and which will be allowed in with the product (non-quarantine pests). It does not, however, indicate the level of tolerance which the importing country is willing to accord each pest. This can only be done by completing a pest-risk assessment. Two levels of pest-risk assessment are recognised: simple and full. Clearly, a fairly simple assessment is required for the majority of quarantine pests because of the vast number of them associated with some products. The compromise is to declare a general level of tolerance to the majority of quarantine pests and perform a full assessment only on those likely to cause serious problems. In New Zealand, for example, a general specification for quarantine pests is set at 0.5%, i.e. pest infestations up to the level of 0.5% are tolerated for most pests in imported produce. A full pest-risk assessment can be carried out and a different specification arrived at for the serious pests. Once specifications are known, risk management options allowing import but excluding pests, within an accepted level of risk, can be calculated. Naturally, there is no such thing as a zero risk unless all trade and travel is banned completely; quarantine authorities must therefore be aware of the risks they are prepared to accept with any import system.

A full pest-risk assessment consists of a biological assessment plus an economic impact assessment. The purpose of the biological assessment is to determine the probability that an infested host would result in the establishment of a pest population. This is known as the probability of introduction ($\Phi$) and is a function of a number of conditions which must be fulfilled if the entry and establishment of a pest would be successful. The reciprocal of the probability of introduction, $1/\Phi$, denotes a threshold for establishment in terms of the number of infested units leading, on average, to a single establishment. The derivation of $\Phi$ is obtained by considering the factors which affect the number of surviving pests from an infested host as well as the factors affecting whether conditions will be suitable for survival. The former conditions refer to the survival of individuals, and the latter to abiotic factors. The calculation of $\Phi$ also depends on the mode of reproduction of the pest organism. A full explanation of the use of $\Phi$, with derivation of the formulae used in its calculation, is given by Whyte *et al.* (1996). Once $\Phi$ is known, the *MPL* is readily calculated and transformed into an import specification. The specification for import is $M_s = MPL \times 100\%$.

## RESPONSE TO SPECIFICATIONS

A specification is declared so that justifiable risk management options can be decided on. The simplest form of risk management is inspection of the product on arrival, and this is appropriate for pests having a *MPL* of 0.005, provided the pest is easily detected. In this case the specification would be declared as an infestation level not exceeding 0.5%, and the risk management would consist of an inspection of 600 items of the product (units) with an acceptance number of 0. This is considered the limit of normal inspection procedures as inspecting larger numbers of units is extremely time consuming and, therefore, expensive. For pests where the specification is less than 0.5%, some form of offshore treatment is the most appropriate form of risk management. This may take the form of production through a quality system, selection of a non-host cultivar, a declaration of area freedom, an intensive inspection during plant production or a treatment such as fumigation, pesticides, heat, cold or irradiation. If the *MPL* is extremely low (e.g. $M_s$ around $1 \times 10^{-3}\%$, as it is for some fruit fly species) often a combination of risk management options is required.

To avoid costly delays and the potential loss of exported products, it is essential that the exporting country develop treatments, in consultation with the regulatory organisation, in response to the specifications. This will ensure that any newly developed treatment or technology is at the level appropriate to satisfy the quarantine security of the importing country. In the past many treatments were developed at inappropriately high levels of efficacy, often made to satisfy a perceived need for efficacy levels around probit 9, an overkill in most instances, which involved vast, expensive trials using 100,000 or so test insects. With a set specification, scientists are able to calculate the specific level of efficacy required and, consequently, the number of test subjects needed to satisfy the quarantine authorities. It is also important that the research scientists conduct their experiments in a fully transparent manner, using documented procedures and showing sources and estimates of variability as well as manifesting the willingness to declare "raw" results if required. While most of the New Zealand work on quarantine security has involved fruit flies, the principles used can be applied to other pests and in other situations. The concepts which are the basis of New Zealand's quarantine security using quantified systems are based on the publications of Baker *et al.*, 1990; Cowley *et al.*, 1991; Harte *et al.*, 1992; Cowley *et al.*, 1992; Cowley *et al.*, 1993; Baker *et al.*, 1993; Harte *et al.*, 1995 and Whyte *et al.*, 1996.

## APPLICATION TO STORED-PRODUCT PESTS

Although the principles of PRA apply to all forms of imports, progress with implementation has been easier with fresh produce than with some other products. This is because the basic item, the "unit", is readily defined for most forms of fresh produce as a single fruit or vegetable. It is also assumed that a pest establishment must come from a single infested unit, as the probability that several infested units will be disposed of together is generally considered extremely small for fresh produce. The unit is important in the calculation of the *MPL* as the total number of units imported has a bearing on the chances of pest establishment. The more often a product is imported (i.e. the greater the number of units) the greater the chance of infested items also being imported. This is clearly shown in the formula used to calculate the *MPL*:

$$MPL = 1 - \sqrt[Nm]{\frac{1 - A_R}{\Phi}}$$

where $N$ = number of units per consignment; $m$ = number of consignments per year; $A_R$ = maximum acceptable risk; $\Phi$ = the probability of introduction.

Defining the number of units expected for any product is therefore crucial for calculating the *MPL* and hence the specification. For stored products a number of different definitions of "unit" are possible. With pathogens it is quite feasible to consider a single seed as a unit because one infected seed could produce sufficient spores to establish a disease. A typical *MPL* calculation for a seed-borne pathogen is illustrated by the case of *Ustilago zeae* (NZPPC, 1995). Here *Nm* was calculated, from knowledge of past import levels, as $6 \times 10^8$ units per year and $\Phi$, from a detailed study of many biological and abiotic factors, as $2 \times 10^{-4}$. If $A_R = 0.05$ (a level of risk frequently used), then the specification ($M_s = MPL \times 100\%$) of $4 \times 10^{-5}\%$ is obtained. A specification of such low magnitude indicates a high-risk pest for which quite stringent quarantine measures are justified. It would be difficult to prove in this instance that a treatment had the required efficacy (which, in this case, must equal the *MPL*) to reduce the level of disease to the required level. However, a combination of treatments could be shown to reduce the level of infection below the value of the *MPL*. Alternatively, a declaration by the exporting state or country of freedom from the pest is likely to be acceptable as a risk management option. Similar results have been obtained with other seed borne pathogens such as

*Clavibacter michiganensis* subsp. *nebraskensis* (Goss's wilt on maize) and *Tilletia controversa* (dwarf bunt on wheat).

An attempt to calculate the *MPL* for *Trogoderma variabile* (warehouse beetle) has highlighted some of the problems encountered with stored-product insect pests. This insect is a common pest of seeds and grains but may also be sustained by such high protein sources as dead animals and food items. Thus, while the biological characteristics and the abiotic factors leading to establishment can be readily assembled to provide a calculation of Φ, the debate over the correct meaning of the "unit" for this case study continues. It is probable that the issue is similar for most stored-product insect pests because they roam freely over many host items instead of being associated with a single entity such as one seed or fruit. It is quite likely that for items exported in packets or sacks the single packet or sack constitutes the unit. However, for products exported in bulk it is more practical to consider either the entire consignment or one heap of produce on a warehouse floor as a unit. At present this issue is side-stepped by taking a given weight of produce as a unit. At present, for example, the *MPL* for quarantine insect pests in imported grain is listed as 0.9 per kg (i.e. less than 5 per 5 kg, the standard quantity used for sampling). However, this definition of a unit implies that the pests are confined to individual 1- or 5-kg lots, whereas in reality they are free to roam from one lot to another.

Another problem characteristic of stored-product consignments is the nature of pest-distribution within the product. With fresh produce it is usually safe to assume that distribution is relatively homogeneous since all components of a single consignment will have been through a uniform system of grading and packaging. Whyte *et al.* (1995), however, showed that this was certainly not the case with the distribution of weed seeds, which showed significant heterogeneity, within grain shipments. It is likely that the distribution of insects in bulk shipments also shows heterogeneity. The demonstration of heterogeneity would result in more stringent rules for inspection of products for quarantine pests. For quarantine weed seeds in grain shipments to New Zealand, for example, a maximum limit of three per kg has been set. Based on a random (Poisson) distribution, finding eight or fewer quarantine seeds in a 5 kg sample would give 95% confidence that the mean is less than the *MPL*. However, because the distribution is clumped rather than random, it was necessary to suggest that a lower acceptance number of two seeds in 5 kg was more appropriate. It is important to note that the *MPL* was not changed; the acceptance number needed to ensure compliance, however, was tightened significantly.

## DISCUSSION

This paper has illustrated how, in the future, quarantine authorities may set specifications for all plant and plant-product imports, including stored products. Using the PRA system would prevent arbitrary decisions about risk management leading to misunderstanding the intent of the quarantine regulations. It should also ensure that both importers and exporters clearly understand what the requirements are and are assured that they are justified on scientific grounds. Some fundamental problems remain to be solved before the PRA system described here can be fully applied to stored-product pests. In particular, a "unit" must be defined, and the problem of uneven distribution of pests within a shipment must be solved. These are the issues needing attention.

With the eventual phasing out of methyl bromide as a standard fumigation treatment for many products, there will be increasing research into new treatments and technologies. It is vital that such new research take place in consultation with quarantine authorities in order to ensure that treatment efficacies adequately meet their needs. This would not only guarantee that the new treatments are optimal but would also prevent unnecessary effort from being expended to produce treatments which exceed required efficacies. The desirable sequence of events in producing a new treatment of known efficacy consists of seven interchanges between the exporting country (A) that wishes to export a product and the importing country (B). First, A provides B with a list of pests known to infest the product. Then B categorises each pest on the list as a quarantine or a non-quarantine pest. B then provides the specifications ($M_s$) and suggests possible risk management options. If a new treatment is required, A consults with B over protocols for experimentation. A then conducts the necessary research, bearing in mind that the efficacy must be sufficient to ensure that the *MPL* is not exceeded. A reports the results of this research, including estimates of variability, to B, and B incorporates the new treatment into the schedule of risk management.

The keys to success for both parties are that consultations be open and frank and that discussions take place between their scientists as well as between their quarantine officials. The aim must always be to promote rather than stifle trade while at the same time preventing, as much as possible, the expansion of pest distribution.

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