National Phytosanitary Standard on:

Pest risk analysis for quarantine pests including analysis of ecological risk and living modified organisms

2013

This standard is approved by (NPPO and) the Quarantine Committee of Nepal on 1st December 2013 and, is notified to the WTO member states

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1. Introduction

1.1 Scope

This Standard on Pest risk analysis (PRA) is developed as a guidance document for assessing the economic risks from potential quarantine pest including the risk from living modified organisms to plants and plant products. Subsequently, it directs to evaluate the risk management measures, identifying a justifiable and practical option to achieve the required degree of safety in plants and plant products. PRA is needed in designing appropriate level of pest risk management approach in the country. The PRA methodology adopted is also applicable to carry out PRA for the forest plants, wild flora, including the analysis of risks to the environment and biological diversity (see Annex 1). NSPM preparation based on guidelines and recommendations developed within the framework of the IPPC. This standard also adopted the principles, recommendations and format of ISPM to achieve international harmonization of phytosanitary measures with the aim to facilitate trade.

1.2 References

CBD 1992 Convention on Biological Diversity Montreal, CBD

IPPC 1997 International Plant Protection Convention Rome, IPPC, FAO.

ISPM 2 1995 Guidelines for pest risk analysis Rome, IPPC, FAO [Published 1996] [Revised; now ISPM 2: 2007]

ISPM 4 1995 Requirements for the establishment of pest free areas Rome, IPPC, FAO [Published 1996]

ISPM 5 Glossary of phytosanitary terms, Rome, IPPC, FAO

ISPM 8 1998 Determination of pest status in an area Rome, IPPC, FAO

WTO 1994 Agreement on the Application of Sanitary and Phytosanitary Measures Geneva, World Trade Organization

ISPM 11 2004 Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms.

NPQP 2006**:** Generic Pest Risk Analysis of Citrus, Hariharhar Bhawan Pulchwoke

1.3 Definitions

The definitions of phytosanitary terms used in the text are from Glossary of Phytosanitory terms (ISPM 5) unless specified below with*marks

Endangered Area: An area where ecological factors favor the establishment of a pest whose presence in the area will result in economically important loss

*** Local environmental condition**: the agro ecological situation of the area in relation to which a

PRA is conducted

Entry: Movement of a pest into an area where it is not yet present or present but no widely distributed and being officially controlled

Establishment: The perpetuation, for the foreseeable future, of a pest within an area after entry.

***Introduction**: Entry of a pest resulting in its establishment.

Entry potential Area: Probability of entry : An officially defined country, part of a country or all or parts of several countries [FAO, 1990;revised FAO, 1995; CEPM, 1999; based on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures]

*** NSPM:** National Standard for Phytosanitary Measure developed to suit the local condition to safeguard the plant life and health.

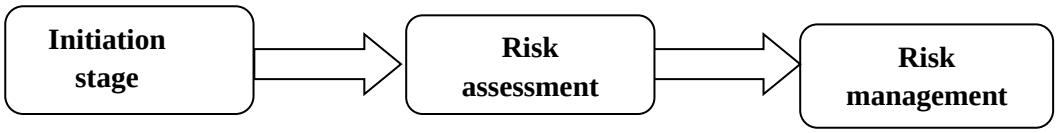
NPPO: Official service established by a government to discharge the functions specified by the IPPC [FAO, 1990; formerly Plant Protection Organization (National)]

Pathway: Any means that allows the entry or spread of a pest [FAO, 1990; revised FAO, 1995]

Pest: Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products [FAO, 1990; revised FAO, 1995; IPPC, 1997]

1.4 Outline of requirements

This National standard for Phytosanitary Measures (NSPM) on PRA is, to identify pests and/ pathways of quarantine value and analyze the potential risk, in specified endangered areas and identify where possible the risk management options for plants and plant products based on the assessment of the potential phytosanitary risk to cultivated and wild plant and plant/s products from LMOS with genetic modification (gene, new gene sequence that regulates other genes or gene product and results in new trait and characteristic) and to identify risk mitigation measures. The PRA follows a process defined by the three stages as given below;



(Fig -1): Three stages Of PRA

2. Background

The Plant Protection Act, (PPA) 2007, supports to facilitate the agro-forest trade by appropriate phytosanitary application & reduce the risks arising from the entry, establishment or spread of exotic pests. As per the prerogative of the PPA, PRA is essential to decide as to whether a particular commodity could be permitted entry or not in the country depending on the risks involved in its introduction. It is to be noted that Standards in themselves are not regulatory instruments, but come into force once the countries establish requirements within their national legislation.

National Plant Protection Organization (NPPO) is designated official contact point to maintain Coordination among the different relevant institutions, to carry out surveillance of standing crops, forest plants and plant products in storage & in transit for pest attack, & infestation management and issuance of Phytosanitary Certification for exporting plants & plant products. It is also responsible for developing, and enforcement of relevant Phytosanitary measures. However, depending upon the intensity of economic damage from the pest, a bilateral negotiation between the National Plant Protection Organizations (NPPOs) of the importing and exporting countries can be arranged and as per the need the PRA should be initiated. While defining phytosanitary management options it is necessary to take note of the principle of equivalence. Some of the globally agreed phytosanitary management options such as cold disinfestations treatments, chemical disinfestations treatments, irradiation, Pest free area, systems approaches, or combinations of the above can be considered where feasible without detailed management option analysis. NSPM, should take into account the risks /benefits that are likely to accrue from pest and introduction of the planting material. In view of the wide climatic range and agro ecological variation and likely presence of many different pests, having different geographic distributions and host ranges, importing countries may require information on PRA on specific pests and by commodity and NPPO Nepal should be well prepared on this line.

In addition to the above, initiation of Pest risk analysis should also consider factors, such as availability of trained personnel, efficacious detection techniques, capacity and skill of the inspectors, treatments at the point of entry quarantine, knowledge about the life cycle of the pest, existence of races and strains, world distribution, modes of transmission, factors favoring establishment and spread of pests/ availability of safeguards, and adequacy of the survey and surveillance program in general in local condition (see Annex 3 for ref. only).

3. Requirements

Information gathering is an essential element of all stages of PRA. All contracting party shall have official contact point in particular to cooperate to the extent practicable and provide technical and biological information necessary for PRA (IPPC Art VIII1c).

4. Three stages PRA for quarantine pests:

4.1 Initiation: This step involves mainly analysis work supporting pests and pathways identification in relation to the risk analysis in identified area/s including LMOs having characteristics to cause potential risk to plants and plant products (See Annex 2).

4.2 Risk assessment: After identification of the pest and pathways, the second steps is to verify whether the pest under evaluation falls under the category of quarantine importance or not. It is an important step in PRA as it evaluates the probability of pest entry, its establishment, and spread, causing potential economic and environmental damage. It is essential to analyze these factors critically for PRA in identified area.

4.3 Risk management: This steps supports to identify and evaluate the management options to reduce the economic or environmental damage. While analyzing the management options it should be based, on the findings from step 2 and select the options considering the efficacy, feasibility, impact and its applicability in local situation based on technical justification.

If need occurs, LMOs should be assessed following all the three steps for phytosanitary risk analysis in plants and plants material used as agricultural crops, food and feed, ornamental plants or agro–forests products. Similarly, biological control agents modified to improve their performance and pests modified to alter their pathogenic characteristic and genetically modified organisms used as bio fertilizer should also be assessed for risk in plants and plants health in similar manner. If bio agents or organism with potential threat to human and animal health is found then the NPPO should notify the relevant authorities.

PRA Stage -I

4.1.1 Initiation Stage

Usually the PRA process is initiated when:

- The pathway with potential pest hazard risk is identified
- The pest requiring phytosanitary measures is identified
- When there is revision of Phytosanitary related policies from government or its signatory body
- When a contracting party desires information on particular pests or pathways or phytosanitary measures

In case of LMOs when the NPPO feels that there is risk for plants for use in agricultural crops, for food, feed, ornamental plants, or managed forest, or used as bio control agents, modified to improve the performance, and pest modified to alter the their pathogenic characters then it should apply the PRA principle as in non LMOs and initiate the PRA.

4.1.1.2 The pathway with potential pest hazard risk is identified:

PRA should be carried out if the following condition occurs:

- International trade initiated in a commodity not previously imported into the country (a plant or plant product, including genetically altered plants) or a commodity from a new area or new country of origin.
- New plant species are imported for scientific research purposes
- New pathway other than commodity import is identified such as natural spread, packing material, mail, garbage, passenger baggage, etc.
- A list of pests likely to be associated with the pathway (e.g. carried by the commodity). It is preferable to prioritize the listing, based on expert judgment on pest distribution and types of pests and then decide if further PRA process is required or not.

4.1.1.3 PRA initiated by the identification of a pest

Identify the pests their present mode of distribution and association with host plants, commodities and if the followings situation occurs then PRA may be required:

- an emergency arises after an outbreak of a new pest within identified PRA area
- an emergency arises on interception of a new pest on an imported commodity
- a new pest risk is identified by scientific research
- a pest is introduced into an area
- a pest is reported to be more damaging in an area other than in its area of origin
- a request is made to import an organism
- an organism is identified as a vector for other pests
- an organism is genetically altered in a way which clearly identifies its potential as a plant pest

4.1.1.4 PRA initiated by the review or revision of a policy

A new or revised PRA should be developed when the following situation occurs:

- a national decision is taken to review phytosanitary regulations, requirements or operations
- a proposal made by another country or by an international organization (RPPO, FAO) is reviewed

- a new treatment or loss of a treatment system, a new process, or new information impacts on an earlier decision

4.1.1.5 Identification of PRA area

Primarily, the PRA area should be defined as precisely as possible based on the scientific Information essential to justify the PRA. The relevant information supporting identification of the area should be gathered in depth and the based on the findings of the analysis the area should be identified. Information on PRA should be collected from the official contact point of the concern contracting parties.

- **Information**

Information to identify the PRA area, include, Pests and their identification, present distribution status, associated host plants, alternate host, and other commodities. For environmental risks, the variety of sources of information will generally be wider than traditionally used by NPPOs. Broader inputs may be required including impact assessments. For LMOs, information required for a risk analysis may be included, however as mentioned earlier the matter should be discussed at NPPO meeting and take necessary action as per the decision ☹

4.1.1.6 Previous PRA

If previously done PRA exists, its status should be checked from present perspective as circumstances and information may have changed. The possibility of using a PRA from a similar pathway or pest, that may partly or entirely replace the need for a new PRA, should also be investigated. A wider discussion among the PRA specialist and NPPO body should be held and decision should be taken regarding whether pathways, pests or policies have already been subjected to the PRA process, either nationally or internationally be adopted or not .

Conclusion of Stage -1

At the end of this step, analyzed information on the pests, pathways of concern required for PRA area should be gathered and based on the analysis result decision for next step should be taken. For LMOs at the end of Stage 1 NPPO may decide whether the LMO connected organism is a potential pest and needs to be assessed further in Stage 2 or if it is not a potential pest then it needs no further analysis.

Stage II

4.2 Pest Risk Assessment

PRA should be judged against the principles of necessity, minimal impact, transparency, equivalence, risk analysis, managed risk and non-discrimination as set out in ISPM No. 1*: Principles of plant quarantine as related to international trade (FAO, 1995).* The process for pest risk assessment is broadly divided into three steps and in most cases these steps will be applied in following sequences.

4.2.1 Pest categorization

Primarily this process is to identify whether the pest concern meets the criteria to be a quarantine pest or not and based on this decision PRA is made. The categorization is done considering the following points:

- Assessment of the probability of introduction and spread and economic impact from it.
- Assessment of potential economic consequences (including environmental/social impacts) for LMOs PRA, it is assumed that the LMO once it is assessed as a potential quarantine pest due to new or altered characteristics or properties resulting from the genetic modification the Pest Risk Assessment should be carried out on a case-by-case basis.
- Identify pest/s requiring the PRA and discard the others associated with the pathways. After completing this process if the pest/s is found to be of a quarantine value then further action for risk assessment should be continued.
- It must be noted that, the evaluation of a pathway associated with a commodity, a number of individual PRAs may be necessary for the various pests potentially associated with the pathway.

4.2.1.1 Elements of categorization

The following elements should be considered while categorization of a quarantine pest is done:

- Identity of the pest
- Presence or absence in the PRA area
- Regulatory status
- Potential for establishment and spread in PRA area
- Potential for economic consequences (including environmental consequences) in the PRA area

Identity of the Pest:

The identity of the pest should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological information used in the assessment is relevant to the

organism in question and is internationally recognized. If this is not possible because the causal agent of particular symptoms has not yet been fully identified, then technical support from the international taxonomic organization should be sought.

The taxonomic unit for the pest is generally at species level. The use of a higher or lower taxonomic level should be supported by scientific rationale. In the case of levels below the species, this should include evidence demonstrating that factors such as differences in virulence, host range or vector relationships that are significant enough to affect phytosanitary status.

In cases where a vector is involved, the vector may also be considered a pest to the extent that it is associated with the causal organism and is required for transmission of the pest.

In the case of LMOs, information regarding characteristics of the recipient or parent organism, the donor organism, the genetic construct the gene or transgenic vector and the nature of the genetic modification needs to be looked at.

Presence or absence of the Pest in PRA area

The pest should be absent from all or a defined part of the PRA area. Same principle applies in case of LMO of phytosanitary concern.

Regulatory status

If the pest is present but not widely distributed in the PRA area, it should be under official control or expected to be under official control in the near future. (*Refer ISPM No. 5 Glossary of phytosanitary terms, Supplement No. 1 on official control, in particular Section 5.7. In the case of LMOs, official control should relate to the phytosanitary measures applied because of the pest nature of the LMO*)

Potential for establishment and spread in PRA area

Empirical Evidence should be available to support the conclusion that the pest could become established or spread in the PRA area. The PRA area should have ecological/climatic conditions including those in protected conditions suitable for the establishment and spread of the pest and where relevant, host species (or near relatives); alternate hosts and vectors should be present in the PRA area.

For LMOs :(Refer Annex -3)

Potential for economic consequences in PRA area

Assessment should be done in such a way that it clearly indicates that the pest is likely to have an unacceptable economic impact (including environmental impact) in the PRA area. (Refer Glossary

of phytosanitary terms, Supplement No. 2: *Guidelines on the understanding of potential economic importance and related terms*.)

4.2.2 Conclusion of pest categorization

After analyzing the information on above criteria and if observed that the pest has the potential to be a quarantine pest, the PRA process should continue. If a pest does not fulfill all of the criteria for a quarantine pest, the PRA process for that pest may be stopped. If sufficient information is not available and uncertainties' continues then PRA should be continued.

4.2.3 Assessment of the probability of introduction and spread

Pest introduction means both entry and establishment. Assessing the probability of introduction is an important step in PRA and requires an analysis of each of the pathways from its origin to its new PRA area and its establishment. In a PRA initiated by a specific pathway (usually an imported commodity), the probability of pest entry is evaluated for the pathway in question. The probabilities for pest entry with other pathways need to be investigated correspondingly.

For risk analyses that have been initiated for a specific pest, with no particular commodity or pathway under consideration, the potential of all probable pathways should be considered. The assessment of probability of spread is based primarily on biological considerations similar to those for entry and establishment.

With respect to a plant being assessed as a pest, a place where the plant can grow in the PRA area need to be assed. In the case of plants to be imported, the concepts of entry, establishment and spread have to be considered differently. Plants for planting that are imported will enter and then be maintained in an intended habitat, probably in substantial numbers and for an indeterminate period. The risk arises because of the probability that the plant may spread from the intended habitat to unintended habitats within the PRA area, and then establish in that habitat. The risk arises because of the probability that the plant may escape or be diverted from the intended use to an unintended habitat and establish there.

Assessing the probability of introduction of an LMO requires an analysis of both intentional and unintentional pathways of introduction, and intended use.

4.2.4 Probability of entry of a pest

The probability of entry of a pest depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. The higher the number of pathways, the greater the probability of the pest entering the PRA area is more. Documented pathways for the pest to enter new areas should be noted. Potential pathways, which may not

currently exist, should be assessed. Pest interception data may provide evidence of the ability of a pest to be associated with a pathway and to survive in transport or storage. In the case of plants to be imported, the plants will enter and an assessment of probability of entry will not be required.

4.2.4.1 Identification of pathways for a PRA initiated by a pest

All relevant pathways should be assessed. They can be identified principally in relation to the geographical distribution and host range of the pest. Consignments of plants and plant products moving in international trade are the principal pathways of concern. Existing patterns of such trade will, to a substantial extent, determine which pathways are relevant. Other pathways such as other types of commodities, packing materials, persons, baggage, mail, conveyances and the exchange of scientific material should be considered where appropriate. Entry by natural means should also be assessed, as natural spread is likely to reduce the effectiveness of phytosanitary measures. For LMOs, all relevant pathways of introduction should be considered (intentional and unintentional

4.2.4.2 Probability of pest being associated with pathway at origin

The probability of the pest being associated, spatially or temporally, with the pathway at origin should be estimated. Factors to consider are:

- Prevalence of the pest in the source area
- Occurrence of the pest in a life stage that would be associated with commodities, containers, or conveyances
- Volume and frequency of movement along the pathway
- Pest management, cultural and commercial procedures applied at the place of origin (application of plant protection products, handling, culling, roguing, grading).

4.2.4.3 Probability of survival during transport or storage

Factors to consider are:

- Conditions of transport and duration of the life cycle of the pest in relation to time in transport and storage
- Vulnerability of the life stages during transport or storage
- Prevalence of pest likely to be associated with a consignment
- Commercial procedures (e.g. refrigeration) applied to consignments in the country of origin,

4.2.4.4 Probability of pest surviving existing pest management procedures

Existing pest management procedures including phytosanitary procedures applied to consignments against other pests from origin to end use should be evaluated for effectiveness against the pest in

question. The probability that the pest will go undetected during inspection or survive other existing phytosanitary procedures should be estimated.

4.2.4.5 Probability of transfer to a suitable host

Factors to be considered are:

- dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host
- whether the imported commodity is to be sent to a few or many destination points in the PRA area
- proximity of entry, transit and destination points to suitable hosts
- time of year at which import takes place
- intended use of the commodity (e.g. for planting, processing and consumption) risks from by-products and waste

It is to be remembered that there is a much higher probability of introduction (e.g. planting) than others (e.g. processing). The probability associated with any growth, processing, or disposal of the commodity in the vicinity of suitable hosts should also be considered.

For LMOs, the probability of gene flow and gene transfer should be considered, when there is characteristic of phytosanitary concern that may be transferred

4.2.3 Probability of establishment

This is one of the important steps in PRA. Thus reliable biological information (life cycle, host range, epidemiology, survival etc.) should be obtained from the areas where the pest currently occurs. The situation in the PRA area can then be compared with that in the areas where it currently occurs (taking account also of protected environments such as glass-or greenhouses) and expert judgment used to assess the probability of establishment comparable pests need to be looked at.

Factors to consider are:

- Environmental suitability and availability, quantity and distribution of hosts in the PRA
- Potential for adaptation of the pest
- Reproductive strategy of the pest
- Method of pest survival
- Cultural practices and control measures

In considering probability of establishment, it should be noted that a transient pest (see ISPM 8: 1998) may not be able to establish in the PRA area (e.g. because of unsuitable climatic conditions) but could still have unacceptable economic consequences (see IPPC Article VII.3). In the case of

plants to be imported, the assessment of the probability of establishment concerns the unintended habitats. For LMOs, the survival capacity without human intervention should also be considered:

- Availability of suitable hosts, alternate hosts and vectors in the PRA area
- Hosts and alternate hosts availability and wide distribution, within geographic proximity to allow the pest to complete its life cycle,
- Whether a vector, if needed for dispersal of the pest, is already present in the PRA area or likely to be introduced
- Whether another vector species occurs

4.2.3.1 Assess suitability of environment

All a biotic factors affects the biological activities of the pests, hosts and vectors. So these these factors should be critically analyzed.

- Suitability of climate, soil, pest and host competition for the development of the pest, its host its vector, and their ability to survive periods of climatic stress and complete life cycles,
- Whether the interaction between these organisms in the area of origin is maintained in the PRA area is to the benefit or detriment of the pest
- The probability of establishment in a protected environment, (e.g. in glasshouses,) should also be considered. Where applicable climatic modeling systems may be used to compare climatic data on the known distribution of a pest with that in the PRA area.
- Cultural practices and control measures
- Practices employed during the cultivation/production of the host crops in the origin should be compared with such practices in the PRA area. It may influence its ability to establish.
- The availability (or lack) of suitable methods for eradication should also be considered where applicable.

For LMOs, it may also be appropriate to consider specific cultural, control or management practices.

Pest management programs or natural enemies present already in the PRA area which reduce the probability of establishment may be considered. Pests for which control is not feasible should be considered to present a greater risk than those for which treatment is easily accomplished.

4.2.3.2 Other characteristics of the pest affecting the probability of establishment

- ***Reproductive strategy*** of the pests and method of pest survival Characteristics, which enable the pest to reproduce effectively in the new environment, such as

parthenogenesis/self crossing, duration of the life cycle, number of generations per year, resting stage etc., should be identified and analyze .

- ***Genetic adaptability:*** Whether the species is polymorphic and the degree to which the pest has demonstrated the ability to adapt to conditions like those in the PRA area should be considered:

4.2.4 Probability of spread after establishment

- A pest with a high potential for spread may also have a high potential for establishment, and possibilities for its successful containment and/or eradication are more limited.

- To estimate the probability of spread of the pest, reliable biological information should be obtained from areas where the pest currently occurs. The situation in the PRA area can then be carefully compared with that in the areas where the pest currently occurs and expert judgment used to assess the probability of spread.
- Factors to consider are:
    - suitability of the natural and/or managed environment for natural spread of the pest
    - presence of natural barriers
    - the potential for movement with commodities or conveyances
    - intended use of the commodity
    - potential vectors of the pest in the PRA area
    - Potential natural enemies of the pest in the PRA area.
    - In the case of plants to be imported, the assessment of spread concerns, spread from the intended habitat or the intended use to an unintended habitat, where the pest may establish. Further spread may then occur to other unintended habitats. The information on probability of spread is used to estimate how rapidly a pest's potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area of low potential economic importance and then spread to an area of high potential economic importance. In addition it may be important in the risk management stage when considering the feasibility of containment or eradication of an introduced pest.

  Certain pests may not cause injurious effects on plants immediately after they establish, and in particular may only spread after a certain time. In assessing the probability of spread, this should be considered, based on evidence of such behavior.

4.2.4 Conclusion on the probability of introduction and spread

The overall probability of introduction should be expressed in terms of:

- suitability of the area,

- its environmental conditions
- Existing phytosanitary measures.

Inferences should be based on appropriate quantitative or qualitative data, along with the methods used for analysis. The probability of introduction may be expressed as a comparison with that obtained from PRAs on other pests.

4.2.5 Conclusion regarding endangered areas

The part of the PRA area where ecological factors favors the establishment of the pest should be identified in order to define the endangered area. This may be the whole of the PRA area or a part of the area.

4.2.6 Assessment of potential economic consequences

Wherever appropriate, quantitative data that will provide monetary values should be obtained to assess the effects of the pest Risk. Qualitative data may also be used. Involvement of an Agriculture economist for loss assessment is required. However, in many instances, detailed analysis of the estimated economic consequences is not necessary if there is sufficient evidence or it is widely agreed that the introduction of a pest will have unacceptable economic consequences (including environmental consequences). In such cases, risk assessment will primarily focus on the probability of introduction and spread. It will, however, be necessary to examine economic factors in greater detail when the level of economic consequences is in question, or when the level of economic consequences is needed to evaluate the strength of measures used for risk management or in assessing the cost-benefit of exclusion or control.

4.2.6.1 Pest effects

In order to estimate the potential economic importance of the pest, information should be obtained from areas where the pest occurs naturally or has been introduced lately. This information should be compared with the situation in the PRA area. Case histories concerning comparable pests can be considered.

The basic method for estimating the potential economic importance of pests includes:

- Pests affecting uncultivated/unmanaged plants weeds and/or invasive plants and pests affecting plants through effects on other organisms.
- Plants to be imported for planting, the long-term consequences for the intended habitat may be included in the assessment. Planting may affect further use or have a harmful effect on the intended habitat.
- Environmental effects and consequences considered should result from effects on plants. Such effects, however, on plants may be less significant than the effects and/or

consequences on other organisms or systems. For example, a minor weed may be significantly allergic for humans or minor plant pathos gen may produce toxins that seriously affect livestock.

Direct pest effects

For identification and characterization of the direct effects the followings points should be considered:

- Known or potential host plants (in the field, under protected cultivation, or in the wild)
- Types, amount and frequency of damage
- Crop losses, in yield and quality
- Biotic factors (e.g. adaptability and virulence of the pest) affecting damage and losses
- A biotic factors (e.g. climate) affecting damage and losses
- Rate of spread and rate of reproduction
- Control measures (including existing measures), their efficacy and cost and effect on existing production practices

Indirect pest effects

- Effects on domestic markets, including in particular effects on export market access
- Changes to producer costs or input demands, including control costs
- Environmental and other undesired effects of control measures
- capacity to act as a vector for other pests
- Social and other effects (e.g. tourism).
- Effects on human and animal health (e.g. toxicity allergenicity, water tables, tourism, recreational uses, animal grazing, hunting)

4.2.7 Analysis of economic consequences

In practice, economic consequences should be expressed with time, and may concern one year, several years or an indeterminate period. The total economic consequences over more than one year can be expressed as net present value of annual economic consequences, and an appropriate discount rate selected to calculate net present value. Appropriate analysis may be used to estimate potential economic consequences over the period of time when a pest is spreading in the PRA area. In addition, many of the factors or effects considered above could be expected to change over time, with the consequent effects of potential economic consequences. In such instances, expert judgment and estimations will be required.

4.2.7.1 Analysis of commercial consequences

As determined above, most of the direct effects of a pest and some of the indirect effects will be of a commercial nature, or have consequences for an identified market. These effects, which may be positive or negative, should be identified and quantified. Especially the consideration of the following may be useful.

- Effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices
- Effect of pest-induced changes in quantities demanded or prices paid for commodities. This could include quality changes in products and/or Quarantine-related trade restrictions resulting from a pest introduction

4.2.8 Analytical techniques

There are analytical techniques which can be used in consultation with experts in economics to make a more detailed analysis of the potential economic effects of a quarantine pest. These should incorporate all of the effects that have been identified. Economic impact is described in ISPM 5 Supplement 2 (Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations and also refer ISPM 11 and NSPM on PRA)

4.2.9 Conclusion of the assessment of economic consequences

Wherever appropriate, the output of the assessment of economic consequences described in this step should be in terms of a monetary value. However depending upon the availability of the information the economic consequences can also be expressed qualitatively or using quantitative measures without monetary terms.

4.2.10 Economic consequences at endangered area

The part or whole of the PRA area where presence of quarantine pest will cause economic loss should be identified properly.

4. 2.11 Degree of uncertainty

Mainly, because of unavailability of required science based information the estimation of the economic losses and its consequences may sometime need to be extrapolated using expert judgments, thus area of uncertainty and degree of uncertainties need to be carefully transparently documented. These estimates, with associated uncertainties, are utilized in the pest risk management stage of the PRA

4.2.12 Conclusion of pest risk assessment

After carrying out all above steps of pest Risk assessment based on the findings all or some of the categorized pests may be considered for pest risk management. A quantitative or qualitative

estimate of the probability of introduction of a pest or pests, and a corresponding quantitative or qualitative estimate of economic consequences should be documented.

Stage III

4.3 Pest Risk Management

The conclusions from pest risk assessment should be used to decide whether risk management is required or not. The guiding principle for risk management should be to manage risk to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources for the purpose. The estimates, with associated uncertainties, should be utilized while taking the decision for assessing the suitable pest risk management options.

4.3.1 Level of risk

The principle of "managed risk" (ISPM 1:1993, Principles of plant quarantine as related to International trade) states that: "Because some risk of introduction of a quarantine pest always exists, countries shall agree to a policy of risk management when formulating phytosanitary measures." In implementing this principle, NPPO should discuss and decide what level of risk is acceptable in the context of agricultural trade facilitation. Technical information required to make decisions in the pest risk management process will be based on the information collected during the preceding stages of PRA especially on reasons for initiating the process of estimation of the probability of introduction to the PRA area and evaluation of potential economic consequences.

4.3.1.2 Acceptability of risk

Overall risk is determined by the examination of the outputs of the assessments of the probability of introduction and the economic impact. If the risk is found to be unacceptable, then the first step in risk management is identifying possible phytosanitary measures that will reduce the risk to, or below an acceptable level. Measures are not justified if the risk is already acceptable or must be accepted because it is not manageable (as may be the case with natural spread).

4.3.1.3 Identification and selection of appropriate risk management options

Appropriate measures should be chosen based on their effectiveness in reducing the probability of introduction of the pest. The choice should be based on phytosanitary principles of *ISPM 1:1993:*

- ***Phytosanitary measures shown to be cost-effective and feasible.***

The benefit from the use of phytosanitary measures is that the pest will not be introduced and there will not be any potential economic consequences. The cost-benefit analysis for each of the minimum measures found to provide acceptable security may be estimated. Those measures with an

acceptable benefit-to-cost ratio should be considered the Principle of “minimal impact”. Measures should not be more trade restrictive than necessary. Measures should be applied to the minimum area necessary for the effective protection of the endangered area.

- ***Reassessment of previous requirements***

No additional measures should be imposed if existing measures are effective based on the Principle of “equivalence”. If different phytosanitary measures with the same effect are identified, they should be accepted as alternatives. If the pest under consideration is established in the PRA area but of limited distribution and under official control, the phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Likewise, phytosanitary measures should not discriminate between exporting countries of the same phytosanitary status.

- ***Principle of non-discrimination*** and the concept of official control also apply to pests affecting uncultivated/unmanaged plants weeds and/or invasive plants and pests affecting plants through effects on other organisms.

If any of these become established in the PRA area and if official control is applied, then phytosanitary measures at import should not be more stringent than the official control measures.

The major risk of introduction of plant pests is with imported consignments of plants and plant products, but (especially for a PRA performed on a particular pest) it is necessary to consider the risk of introduction with other types of pathways (e.g. packing materials, conveyances, travellers and their luggage, and the natural spread of a pest).

The measures listed below are examples of those that are most commonly applied to traded commodities. (e.g.)☺

Measures:

- applied to the consignment
- applied to prevent or reduce original infestation in the crop
- to ensure the area or place of production is free from the pest
- concerning the prohibition of commodities

4.3.1.4 Options for consignments

Measures may include any combinations of the following:

- inspection or testing for freedom from a pest or to a specified pest tolerance , sample size should be adequate to give an acceptable probability of detecting the pest
- prohibition of parts of the host a pre-entry or post-entry quarantine system

This system should be considered to be the most intensive form of inspection or testing where suitable facilities and resources are available, and may be the only option for certain pests not detectable on entry specified treatment of the consignment such treatments are applied post-harvest and could include chemical, thermal, irradiation or other physical methods restrictions on end use, distribution and periods of entry of the commodity.

- Measures may also be applied to restrict the import of consignments of pest

For LMOs, as for other organisms, information may have to be obtained concerning the risk management measures applied to the LMO in the country of export .These should be assessed to determine if they are appropriate for the conditions in the PRA area and, if appropriate, the intended use should be transparent.

For LMOs, measures may also include procedures for the provision of information on the phytosanitary integrity of consignments (e.g. tracing systems, documentation systems, and identity preservation systems).

4.3.1.5 Options preventing or reducing infestation in the crop

Measure may include:

- treatment of the crop, field, or place of production .
- growing plants under specially protected conditions (glasshouse, isolation)
- harvesting of plants at a certain age or a specified time of year
- Production in a certification scheme. An officially monitored plant production scheme usually involves a number of carefully controlled generations, beginning with nuclear stock plants of high health status. It may be specified that the plants be derived from plants within a limited number of generations.

Measures may be applied to reduce the probability that LMOs (or genetic material from LMOs) that pose a phytosanitary risk could be in other crops. These include management systems

- (e.g. buffer zones,)
- Management of genetic characteristic and host preference.
- control of reproductive ability (e.g. male sterility)
- control of alternative hosts

4.3.1.6 Options ensuring that the area, place or site of production or crop is free from pest.

Measures include

- Pest Free area development and maintenance
- pest-free production site
- inspection of crop to confirm pest freedom

4.3.1.7 Options for other types of pathways

For many types of pathways, the measures considered above for plants and plant products to detect the pest in the consignment or to prevent infestation of the consignment may also be used. For certain types of pathways, the following factors should be considered:

- Natural spread of a pest includes movement of the pest by flight, wind dispersal, transport by vectors such as insects or birds and natural migration. If the pest is entering the PRA area by natural spread, or is likely to enter in the immediate future, phytosanitary measures may have little effect.

4.3.1.8 Control measures applied in the area of origin could be considered.

- Containment or eradication, supported by suppression and surveillance, in the PRA area after entry of the pest could be considered.
- Measures for human travellers and their baggage could include targeted inspections, publicity and fines or incentives. In a few cases, treatments may be possible.
- Contaminated machinery or modes of transport (ships, trains, planes, road transport) could be subjected to cleaning or disinfestations
- Options within the importing country

Certain measures applied within the importing country may also be useful for consideration. For plants to be imported, where there is a high level of uncertainty regarding pest risk, it may be decided not to take phytosanitary measures at import, but only to apply surveillance or other procedures after entry (e.g. by or under the supervision of the NPPO).

- The potential for risk from LMO pests depends in part on the intended use. As for other organisms,
- For LMOs, as with other pests, options within the country also include the use of emergency measures related to phytosanitary risks. Any emergency measures should be consistent with Article VII.6 of the IPPC.

If no satisfactory measure to reduce risk to an acceptable level can be found, the final option may be to **prohibit importation** of the relevant commodities. This should be viewed as a measure of last resort and should be considered in light of the anticipated efficacy, especially in instances where the incentives for illegal import may be significant.

4.3.1.9 Phytosanitary certificates and other compliance measures

Risk management includes the consideration of appropriate compliance procedures. The most important of these is export certification. The issuance of phytosanitary certificates provides official assurance that a consignment is "considered to be free from the quarantine pests specified by the importing contracting party and to conform to the current phytosanitary requirements of the importing contracting party." It thus confirms that the specified risk management options have been followed. An additional declaration may be required to indicate that a particular measure has been carried out. Other compliance measures may be used subject to bilateral or multilateral agreement

- Information on phytosanitary certificates regarding LMOs (as with any other regulated articles) should only be related to phytosanitary measures (See annex 3)

4.3.1.10 Conclusion of pest risk management

The result of the pest risk management procedure will be either that no measures are identified which are considered appropriate or the selection of one or more management options that have been found to lower the risk associated with the pest(s) to an acceptable level. These management options form the basis of phytosanitary regulations or requirements.

These management options form the basis of phytosanitary regulations or requirements. It is to be remembered that the application and maintenance of such regulations is subject to certain obligations in the case of contracting parties to the IPPC.

Phytosanitary measures taken in relation to environmental hazards should, as appropriate, be notified to relevant competent authorities responsible for national biodiversity policies, strategies and action plans.

4.3.2 Monitoring and review of phytosanitary measures

The information supporting the pest risk analysis should be periodically reviewed to ensure that any new information that becomes available does not invalidate the decision taken on risk management.

5. Documentation of Pest Risk Analysis

The whole process from initiation to pest risk management should be sufficiently documented so that when a review or a dispute arises, the sources of information and rational used in reaching the management decision can be clearly demonstrated:

- purpose for the PRA
- pest, pest list, pathways, PRA area, endangered area

- sources of information
- categorized pest list
- conclusions of risk assessment probability
- consequences
- risk management
- options identified
- options selected

Annex- 1: Comments on the scope of the IPPC:

a) On environmental risks

The full range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. The coverage of the IPPC definition of plant pests includes weeds and other species that have indirect effects on plants, and the Convention applies to the protection of wild flora. The scope of the IPPC also extends to organisms which are pests because they are: Directly affect uncultivated/unmanaged plants

Introduction of these pests may have few commercial consequences, and therefore they have been less likely to be evaluated, regulated and/or placed under official control. An example of this type of pest can be peach Aphid.

In addition to pests that directly affect host plants, there are those, like most weeds/invasive plants, which affect plants primarily by other processes such as competition.

b) Pest risk analysis for living modified organisms

Phytosanitary risks that may be associated with a living modified organism are within the scope of the International Plant Protection Convention and should be considered using pest risk analysis to make decisions regarding pest risk management. The analysis of LMOs includes consideration of the following.

Some LMOs may present a phytosanitary risk and therefore warrant a PRA LMOs. However other will not present a phytosanitary risks beyond those posed by related non-LMOs and therefore will not warrant a complete PRA. For example, modifications to change the physiological characteristics of a plant (e.g. ripening time, storage life) may not present any phytosanitary risk. The pest risk that may be posed by an LMO is dependent on a combination of factors, including the characteristics of the donor and recipient organisms, the genetic alteration, and the specific new trait or traits. Therefore, part of the supplementary text (see Annex 2) provides guidance on how to determine if an LMO is a potential pest.

PRA may constitute only a portion of the overall risk analysis for import and release of a LMO.

Some cases may occur requiring the assessment of risks to human or animal health, or to the environment, beyond that covered by the IPPC. This standard only relates to the assessment a management of phytosanitary risks. As with other organisms or pathways assessed by an NPPO, LMOs may present other risks not falling within the scope of the IPPC. When an NPPO discovers potential for risks that are not of phytosanitary concern it may be appropriate to notify the relevant authorities.

Phytosanitary risks from LMOs may result from certain traits introduced into the organism, such as those that increase the potential for establishment and spread, or from inserted gene sequences that do not alter the pest characteristics of the organism but that might act independently of the organism or have unintended consequences. In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term “pest” should be understood to include the potential of an LMO to

act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk. The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs. Potential phytosanitary risks that may be associated with LMOs could also be associated with non-LMOs. It may be useful to consider risks associated with LMOs in the context of risks posed by the non-modified recipient or parental organisms, or similar organisms, in the PRA

Annex-2: Determining potential for a living modified organism to be a pest

This annex is relevant for living modified organisms only where there is potential for phytosanitary risks from the LMO associated with some characteristic or property related to the genetic modification. Other phytosanitary risks associated with the organism should be assessed under other appropriate NSPMs/ ISPM . The information requirements in determining the potential for an LMO to be a pest is same as mentioned in stage 2 of PRA. Potential phytosanitary risks for LMOs may include:

- Changes in adaptive characteristics which may increase the potential for introduction or spread, for example alterations tolerance to adverse environmental conditions (e.g. drought, freezing, salinity)
- reproductive biology
- dispersal ability of pests
- growth rate or vigour
- host range
- pest resistance
- pesticide (including herbicide) resistance or tolerance
- Adverse effects of gene flow or gene transfer including, for exampletransfer of pesticide or pest resistance genes to compatible species
- the potential to overcome existing reproductive and recombination barriers resulting in pest risks
- potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity.

Adverse effects on non-target organisms including, for example: biological control agent or organism otherwise claimed to be beneficial effects on other organisms, such as biological control agents, beneficial organisms, or soil fauna and micro flora, nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects) capacity to vector other pests negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants. Genotypic and phenotypic instability including, for example, reversion of an organism intended as bio control agent to a virulent form.

Other injurious effects, e.g.

Phytosanitary risks presented by new traits in organisms that do not normally pose phytosanitary risk novel or enhanced capacity for virus recombination, trans-encapsulation and synergy events related to the presence of virus sequences phytosanitary risks resulting from nucleic acid sequences (markers, promoters, terminators etc.) present in the insert.

The potential phytosanitary risks identified above can also be associated with non-LMOs. The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs. If there is no indication that new traits resulting from genetic modifications have phytosanitary risks, the LMO may require no further consideration. It may be useful to consider potential risks in the context of risks posed by the non-modified recipients or parental organisms, or similar organisms, in the PRA area.

In cases of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term “pest” should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene presenting a potential phytosanitary risk.

Factors that may result in the need to subject a:
LMO to Stage 2 of the PRA include:

- of knowledge about a particular modification event
- the credibility of information if it is an unfamiliar modification event
- insufficient data on the behavior of the LMO in environments similar to the PRA area
- field experience, research trials or laboratory data indicating that the LMO may pose
- phytosanitary risks (see subsections a. to e. above) where the LMO expresses characteristics that indicating the risk to plant and plant products
- LMO being a pest where there are PRAs for similar organisms (including LMOs) or risk analyses carried out for other purposes that indicate a pest potential experience in other countries.
- Factors that may lead to the conclusion that an LMO is not a potential pest and/or requires no further
- Consideration to be done include where the genetic modification in similar or related organisms has previously been assessed by the NPPO (or other recognized experts or

agencies) as having no phytosanitary risk where the LMO is to be confined in a reliable containment system and not be released evidence from research trials that the LMO is unlikely to be a pest under the use proposed experience in other countries.

Annex -2.1: Information required on LMO include

Name, identity and taxonomic status of the LMO (including any relevant identifying codes) and the risk management measures applied to the LMO in the country of export taxonomic status, common name, point o collection or acquisition, and characteristics of the donor organism description of the nucleic acid or the modification introduced (including genetic construct) and the resulting genotypic and phenotypic characteristics of the LMO details of the transformation process appropriate detection and identification methods and their specificity, sensitivity and reliability intended use including intended containment.

Quantity or volume of the LMO to be imported (Information regarding pest status is an obligation under the IPPC (Article VIII.1c) facilitated by official contact points (Article VIII.2). A country may have obligations to provide information about LMOs under other international agreements such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000; Cartagena Protocol). The Cartagena Protocol has a Bio safety Clearing-house that may contain relevant information. Information on LMOs is sometimes commercially sensitive and applicable obligations with regard to release and handling of information should be observed.

Annex-3: Pest Risk Analyses of Carnation and Gerbera (*an example of PRA done in Nepal; for reference only*).

The process of evaluating biological or other scientific and economic evidence to determine whether a pest should be regulated and the strength of any phytosanitary measures to be taken against it. This system aims to provide a framework in which the risks associated with the importation of plant commodities and the introduction of pests into new areas can be identified and assessed. It does not generate conclusions, but presents scientific information to aid the selection of appropriate measures for reducing risk and facilitating the movement of plants and plant products.
This process is known as pest risk analysis (PRA)

PRA comprises three stages:

Stage 1. Initiation

- identifying the reason for the PRA and the pests of concern to the PRA area;

Stage 2. Risk assessment

- determining the likelihood of entry, establishment, spread and economic damage of an individual pest in order to determine whether it meets the criteria of a regulated pest;

Stage 3. Risk management

- selecting the appropriate management options to reduce the risks identified in Stage 2.

Users should be familiar with the International Standards for Phytosanitary Measures (ISPMs) published by the Food and Agriculture Organization of the United Nations (FAO)

Phytosanitary regulation

Official rule to prevent the introduction and or spread of the quarantine pest or to limit the economic impact limited non quarantine pest, including establishment of the procedure for phytosanitary certification.

The main purpose of PRA for the potential quarantine pest (PQP) is to check the introduction of such pest which might cause devastating effect to the crops if entered and hence to avoid the inevitable damage due to the consequence of the plant diseases or pest damages.

In order to remain competitive in the international trade and commerce a comprehensive disease data base and PRA needs to be developed and brought out on priority especially for the banana export and import. Carnation and gerbera are an important cut flower which has great commercial and aesthetic value for export and import and would be integral part of agro-economy. In this respect plant quarantine has given terms of reference to perform Pest Risk Analysis (PRA) of Carnation and gerbera.

As per the TOR following work has been performed:

- Carnation and Gerbera Pest list have been prepared using the provided template:
- A extensive review was done to collect pertinent data with consultation of major plant protection journals, proceedings, annual reports, pamphlets, booklets, CD-ROMs' (Crop Protection Compendium, CPC 2007) etc from different National and private organizations of this country.
- Prepared global pest list (fungi, bacteria, virus, phytoplasma) known to occur on Carnation and Gerbera using the pest data sheet format.
- Crop Protection Compendium (CPC 2007) was used for Nepal pest list and global pest list preparation.
- Prepared a national quarantine and regulated non-quarantine pest (bacteria, fungi, virus, phytoplasma) list for Carnation and Gerbera

- Prepared global list of pest (bacteria, fungi, virus,viroid, phytoplasma) known to occur on Carnation and Gerbera using pest data sheet format information using CABI, CD-ROM.
- Pest Risk Analysis (PRA) on Carnation and Gerbera have been completed using CABI, CD-ROM
- Suggestions of preparing framework for annexes to be proposed plant quarantine regulation
- Provided reports of Carnation and Gerbera pest list and PRA to assist in compilation of reports

Carnation

Forty-eight pathogens (pests) have been recorded as a global pest of Carnation round the world wherever it has been grown. Out of 48 pathogens (pest), fungi were recorded thirty- seven, bacteria 4 and viruses were seven.

There are eight pathogens (pest) recorded from Nepal (CPC 2007). Seven fungal diseases have been recorded from Nepal (Table 1). There was only one bacterium pathogen has been recorded from National reports, Proceedings and Annual Reports. There are no viral diseases recorded in Nepal. Hence, presently, all together eight diseases are reported in carnation in Nepal.

A list of 40 potential quarantine pest (PQP)/pathogens were identified for pest risk analysis (PRA) which has been shown in (Table 1). This list is derived after subtracting the pests reported in *Carnation* Nepal list + reported in CPC (2007) + reported in literatures for Nepal (hosts other than carnation from the global *carnation* pests found in CPC (2007).There were 30 fungi, three bacteria and seven viruses identified for PRA.

Forty pathogen/pest list of was prepared according to its gravity of likelihood to entry, spread, risk assessment and risk management with additional declaration. The detail concerned columns could be seen in Sheet 1-48 and table 1, 2& 3

Pest Risk Analysis of the potential quarantine pests of *Carnation* indicated the following four diseases being quarantine pests in circumstances carnation material needs to import from other parts of the world to Nepal. Besides these, 12 pathogens (pest) required additional declaration and 8 (pest) pathogens does not requires additional declaration to import carnation in Nepal while sixteen pathogens have no detail information (Table 2&3).There are 19 quarantine pest (pathogens) have been identified for Nepal and need additional declaration on import. Table 3

A summary list of Global disease, Nepal list, Potential quarantine pest (PQP) of carnation has been presented in Table 4.

Table 4: Global disease, Nepal list, Potential quarantine pest (PQP) of carnation

Pest type	Global pest	Nepal list	Potential Quarantine Pest (PQP)
Fungi	37	7	30
Bacterium	4	1	3
Viruses	7	-	7
Total	48	8	40

Gerbera

Pest risk analysis (PRA) provide a framework in which the risks associated with the importation of plant commodities and the introduction of pests into new areas can be identified and assessed. It does not generate conclusions, but presents scientific information to aid the selection of appropriate measures for reducing risk and facilitating the movement of plants and plant products.

The disease causing pest of gerbera is found to be 14 globally worldwide as global pest (pathogens) and six of them are reported in Nepal and eight pest (pathogens) are considered as potential quarantine pest (PQP) for Nepal. Out of 14 global pest of gerbera 12 were fungi, one bacteria and one virus observed globally in the world. Similarly in Nepal list 5 fungi and one virus was recorded while six fungi and one bacterium pest was recorded as potential quarantine pest (pathogen) for Nepal. There are two quarantine pest (pathogens) identified in case of gerbera.

Conclusion

Forty-eight pest (pathogens) pathogens have been recorded from different parts of world globally. Among them 37 were fungal, 7 viral, and 4 were bacterial pathogens. However, only 8 pathogens are found in Nepal responsible for carnation diseases and the rest 40 were considered as potential quarantine pest for Nepal. PRA has been carried out for Potential Quarantine Pest.

Similarly in case of Gerbera there are 14 global pest (pathogens) reported worldwide. Six of them are reported in Nepal and eight pests (pathogens) are considered as potential quarantine pest (PQP) for Nepal.

Adopting similar methodology PRA for Citrus, Lentil and pest database for some other commodities were prepared