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Position Paper

Precautionary Approach

1. INTRODUCTION

- The Global Crop Protection Federation (CropLife International) represents the crop protection manufacturers and their regional associations in Africa/Middle East, Asia-Pacific, Europe, Japan, Latin America and North America. In all CropLife International covers approximately 90% of the world's research-based Crop Protection Industry in more 73 countries. Its substantial investment in agricultural R&D – over US\$ 3 billion or about 10% of its 1998 turnover – indicates its long-term commitment to developing innovative science-based solutions in the context of sustainable agriculture.

The science-based Crop Protection industry has a major interest in how a precautionary approach is interpreted and applied. In light of the new WTO Round, a precautionary approach is likely to become an important discussion topic, CropLife International would like to contribute to the discussion on how this approach should be defined and under what conditions it should be applied.

- In the context of Risk Assessment and Risk Management policies, CropLife International supports the application of a precautionary approach as a preventive measure, when there is a threat of serious or irreversible damage to human health or to the environment and the relevant science is not sufficiently certain.

On the other hand, the lack of an agreed definition and criteria can give rise to abuse and undesirable results. For example, use of the so-called "Precautionary Principle" could hinder scientific and technological progress, a loss for all concerned parties, and CropLife International is thus concerned about an observed tendency away from scientific considerations toward political and emotional factors. Further, application of this "Precautionary Principle" can create disguised trade

restrictions and obstacles to the free movement of goods. Given such potential negative effects of the "Precautionary Principle," it is imperative to ensure that a precautionary approach is defined and applied in an appropriate and consistent manner.

- The absence of generally accepted guidelines for the application of a precautionary approach needs to be remedied. In this regard, a consensus on the interpretation of a precautionary approach as such and the conditions for its application should be urgently established, preferably at international level. The new trade round indeed offers an opportunity to make the international trade system more responsive to legitimate environmental and human health concerns.

2. INTERNATIONAL CRITERIA FOR THE DEFINITION OF A PRECAUTIONARY APPROACH AND RELATED REGULATORY MEASURES

- CropLife International supports the interpretation and application of a precautionary approach along the lines set out in the UNCED Rio Declaration and subsequently Agenda 21, and the WTO Agreement on the application of Sanitary and Phytosanitary Measures (SPS Agreement). Principle 15 of Agenda 21, has two main elements:

∅ Appropriate measures can be taken in the absence of full scientific certainty;

∅ Only the threat of a serious or irreversible damage justifies the application of the approach.

- Principle 12, dealing with the international trade context, further implies that measures based on a precautionary approach should be proportionate. It specifies that trade measures for environmental purposes should not constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. In other words, regulatory action based on a precautionary approach must be non-discriminatory and

∅ Proportionate to the objective to be achieved and to the risk to be avoided.

CropLife International believes that proportionality should be the key guiding principle in implementing this approach.

- The SPS Agreement adds guidance on appropriate application. Article 5.7 of the SPS Agreement mentions two essential conditions for

invoking measures in cases where relevant scientific evidence is insufficient:

Ø On-going scientific evaluation even after the measure is in place, with a view to further clarifying the actual risk;

Ø All restrictive measures should be provisional and include a time limit for its validity or an obligation of revision within a fixed time.

The SPS Agreement further assumes the performance of a science-based Risk Assessment as a pre-condition for applying a precautionary approach.

3. APPLYING THE INTERNATIONAL CRITERIA

- Concerning the application of a precautionary approach, CropLife International supports key principles and guidelines already identified by governments to make the principle manageable in the context of Risk Assessment and Risk Management policies.
- CropLife International believes that science-based Risk Assessment should be the starting point for defining policy options. Once potential risks are identified, independent scientists should perform an objective Risk Assessment, identifying at each stage the degree of scientific certainty. For credibility purposes, and to avoid the politicisation of science, it is essential that the Risk Assessment remains functionally separated from the process of Risk Management.
- A precautionary approach should only be considered in the context of Risk Management, if the Risk Assessment process would confirm that there is the threat of serious or irreversible damage and that the relevant science is not sufficiently certain.

However,

At least a credible proportion of the scientific community must, following the Risk Assessment, conclude that a serious or irreversible damage may occur in the absence of Risk Management action.

It is essential that the Risk Management process is completely transparent and involves all stakeholders. Once the results of the Risk Assessment stage are available, a wide-ranging consultation of

scientists, representatives of civil associations and the business community will both support decision-makers in weighing policy alternatives and allow the inclusion of social, political and economic factors in the decision-making process.

- When the Risk Assessment process has concluded that the relevant science is not sufficiently certain and, as a consequence, a precautionary approach is invoked, a number of criteria need to be respected. These include proportionality and the completion of an assessment both short- and long-term costs and benefits for society associated with any course of action or inaction. A regulatory impact analysis should be added to ensure that any measure that is taken incorporates the principles of proportionality and non-discrimination.
- CropLife International has noted and supports governments' caution that measures based on a precautionary approach should not necessarily give rise to prohibitions on products or experiments. Depending on the specific circumstances of the case, measures could be less extreme, for example, monitoring of products. Any action based on the approach must incorporate the periodic re-evaluation to take into account new scientific evidence.
- CropLife International believes that in applying a precautionary approach, the burden of proof needs to be decided on a case-by-case basis. This would be consistent with the Rio Declaration and WTO case law.

4. APPROVAL OF CROP PROTECTION PRODUCTS

- National and regional legislation authorising the marketing and sales of Crop Protection Products provides for a transparent regulatory framework that safeguards human health and the environment. Under such legislation approval is granted only when the manufacturers or registrant has scientifically demonstrated quality, safety and, in most cases, efficacy of these products. Safety evaluations, based on accepted Risk Assessment and Risk Management procedures, address possible hazards and risks for workers, consumers and the environment. The burden of proof is placed on the producer.

CropLife International believes that this rigorous science-based approval system constitutes a sound regulatory approach for these products. Governments themselves consider that this system conforms to a precautionary approach. Therefore, any further restrictive action allegedly grounded on the "Precautionary Principle" must be closely scrutinised to avoid abuse for political or unfair trade objectives.

- Initiatives of the Crop Protection industry – like Integrated Crop Management (ICM) and Integrated Pest Management (IPM) which are

broadly recognised as environmentally-friendly practices – as well as the Product Stewardship and the Responsible Care initiatives of the chemical industry, further demonstrate the commitment of industry to a responsible approach. CropLife International explicitly supports and promotes these developments.

5. In conclusion

- 5.1 In the context of Risk Assessment and Risk Management policies, CropLife International supports the application of a precautionary approach as a preventive measure when there is a threat of serious or irreversible damage to human health or to the environment and the relevant science is not sufficiently certain. The Risk Assessment proceedings must be conducted independently of political considerations.
- 5.2 Crop Protection Products are subject to thorough safety evaluation based on accepted Risk Assessment and Risk Management procedures embodied in national and regional registration legislation. Therefore there should be no need for further regulatory action and notably no need for action based upon a precautionary approach. However should such an action prove necessary according to the Assessment-procedures supported herein, the action must conform to the proportionality principle.
- 5.3 In order to avoid an application of a precautionary approach that may paralyse innovation and create disguised trade barriers, clear and precise criteria need to be adopted. CropLife International believes that a proper interpretation and application of a precautionary approach should be based upon international criteria and at least include the following:
 - Ø Only the threat of a serious or irreversible damage justifies the application of a precautionary approach;
 - Ø A credible proportion of the scientific community must, following the Risk Assessment, conclude that a serious or irreversible damage may occur in the absence of Risk Management action;
 - Ø A decision applying a precautionary approach must ensure ongoing scientific evaluation even after the measure is in place, with a view to further clarifying the actual risk;

- ØThe measure should be proportionate to the objective to be achieved and to the risk itself;
- ØAll restrictive measures based on a precautionary approach should be provisional and include a time limit for their validity or an obligation of revision within a fixed time.