**Mandate of the contact group on the development of a rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Ruritania in respect of one-shot ethyl meets the criteria of Annex II to the Rotterdam Convention**

To prepare a draft rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Ruritania in respect of one-shot ethyl meets the criteria of Annex II to the Rotterdam Convention using a draft rationale prepared by the contact group established on the matter at its previous meeting as the starting point for its deliberations. This draft rationale has been reproduced in the annex below, without formal editing.

**Annex**

Rationale for the conclusion by the Chemical Review Committee that the notification of final regulatory action submitted by Ruritania in respect of one-shot ethyl meets the criteria of Annex II to the Rotterdam Convention

1. A notification from Ruritania for one-shot ethyl has been determined to [meet][not meet] the information requirements of Annex I and the criteria set forth in Annex II to the Rotterdam Convention.
2. The notification and supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.23/15 and Add.1and 2.
3. **Ruritania**
4. **Scope of the notified regulatory action**
5. The final regulatory action (Resolution-XYZ/3/2015 of 8 January 2015: technical rule for the active ingredient one-shot ethyl) was to ban the use of one-shot ethyl as an insecticide and/or acaricide, including its sale, import and export. [This action was based on the results of a toxicological re-evaluation and resulted in a ban of all uses of one-shot ethyl as a pesticide.] The results of that re-evaluation are outlined in a technical note on the toxicological re-evaluation of one-shot ethyl prepared by the National Health Surveillance Agency (RUNAHSA). The decision entered into force on 8 January 2015.
6. **Annex II paragraph (a) criterion**

*(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;*

1. The Committee confirmed that the final regulatory action had been taken to protect human health [and the environment].
2. Resolution-XYZ/3/2015 of 8 January 2015 considered the pesticide one-shot ethyl to be [extremely acutely] toxic, neurotoxic and immunotoxic and to cause endocrine toxicity, reproductive toxicity and developmental toxicity.
3. The analysis carried out by RUNAHSA found residues of one-shot ethyl in various foods for which the use of one-shot ethyl was not allowed (cucumber, fresh tomatoes and strawberries) or restricted. This was considered a public health problem because those foods are usually eaten raw in Ruritania. In addition, several studies showed that poisonings and deaths were linked to [occupational exposure to] one-shot ethyl in Ruritania. [It also noted that the pesticide was present in waterbodies in the range of 0.01 ppm concluding that it causes serious ecological damage.]

**(c) Annex II paragraph (b) criteria**

*(b) Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:*

*(i) Data have been generated according to scientifically recognized methods;*

*(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;*

1. A detailed review conducted on behalf of the government of Ruritania concluded that one-shot ethyl was neurotoxic and immunotoxic and caused endocrine toxicity, reproductive toxicity and developmental [and environmental] toxicity. The technical note on the re-evaluation of one-shot ethyl provided an assessment of the potential exposure and hazards [in accordance with internationally recognized data and methodologies], including data and methodologies of the World Health Organization, the Food and Agriculture Organization of the United Nations, the Organization for Economic Cooperation and Development, the United States Environmental Protection Agency and the European Union. There is an [extensive] list of references cited in the technical note on the re-evaluation of one-shot ethyl from a wide range of sources including [well-known international journals] such as [Toxicology Letters], the International Journal of Environmental Research, Perspectives in Public Health and Environmental Health Perspectives.
2. Thus, the Committee established that the data reviewed for the risk evaluation were generated [according to scientifically recognized methods and that the data reviews were performed according to generally recognized scientific principles and procedures].

*(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action;*

1. The use of pesticides in Ruritania has been reported to have serious consequences for the health of agricultural workers and consumers of crops treated with those products [and to the environment]. In most cases, the effects are conditioned by factors such as the high toxicity of the pesticide and the improper use and non-use of personal and collective protective equipment. The climatic, socioeconomic conditions and cultural practices of the majority of the field workers increase their vulnerability to toxic pesticides.
2. The analysis carried out by RUNAHSA found residues of one-shot ethyl in various foods for which the use of one-shot ethyl was not on the label (cucumber, fresh tomatoes and strawberries). That was considered a public health problem, because those foods are usually eaten raw in Ruritania. Residues of one-shot ethyl were detected above the legal maximum concentration limits.
3. Several Ruritanian researchers identified one-shot ethyl as one of the most widely used pesticides in Ruritania, resulting in the contamination of crops and [drinking water].One-shot ethyl.
4. Poisonings and deaths linked to [occupational exposure] to one-shot ethyl have been reported in several studies of direct or indirect poisonings in Ruritania.
5. The risk evaluation took into account national studies, [including studies on occupational exposure under the prevailing conditions in Ruritania], and the toxicological endpoints for one-shot ethyl. Therefore the Committee concluded that this criterion [was] [was not] met.

**(d) Annex II paragraph (c) criteria**

*(c) Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:*

*(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;*

1. The final regulatory action prohibits all uses of one-shot ethyl as a pesticide, including production, trade and import. It also prohibits registration of all technical products and pesticide formulations based on one-shot ethyl as the active ingredient. It will therefore lead to a significant decrease in the quantity of one-shot ethyl used, as indicated by the data on imports and production provided by Ruritania.

*(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;*

1. Since the regulatory action will significantly reduce human exposure to one-shot ethyl, it is expected that it will also lead to a significant reduction of risk to human health [and to the environment].

*(iii) Whether the considerations that led to the final regulatory action been taken are applicable only in a limited geographical area or in other limited circumstances;*

1. [Similar health issues are likely to be found in other countries where one-shot ethyl is used, especially in developing countries. Therefore, the considerations that led to the final regulatory action are not limited to Ruritania.]

*(iv) Whether there is evidence of ongoing international trade in the chemical;*

1. No information on ongoing trade is available to the Secretariat. However, Ruritania has indicated that there should be ongoing international trade. It therefore [can] [cannot] be excluded that international trade takes place.

**(e) Annex II paragraph (d) criterion**

*(d) Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.*

1. There is [no] indication in the notification or supporting documentation that concerns for intentional misuse prompted the final regulatory action.

**(f) Conclusion**

1. The Committee concluded that the notification of final regulatory action by Ruritania [met] [did not meet] the criteria set out in Annex II to the Convention.