Annex to decision CRC-18/3

Rationale for the conclusion by the Chemical Review Committee that the notification of final regulatory action submitted by Colombia in respect of methyl bromide in the pesticide category meets the criteria of Annex II to the Rotterdam Convention

1. The notification on methyl bromide from Colombia has been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. This notification underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether the notification appeared to meet the requirements of the Convention.
2. The notification and the supporting documentation were made available to the Chemical Review Committee for its consideration in documents UNEP/FAO/RC/CRC.18/10 and UNEP/FAO/RC/CRC.18/INF/19. Information on trade was made available in document UNEP/FAO/RC/CRC.18/INF/6/Rev.1.

 A. Scope of the regulatory action notified by Colombia

1. The regulatory action notified by Colombia relates to the use of methyl bromide
(CAS No. 74-83-9) in the pesticide category as a soil fumigant, which includes fumigants for quarantine treatments (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.3 of the Colombia notification).
2. Resolution 2152 of 1996 of the Ministry of Health and Social Protection of Colombia severely restricted methyl bromide and authorized the importation, commercialization and use of methyl bromide, only for quarantine treatment for the control of exotic pests in fresh plant tissues at the port and border crossing level, until a viable substitute is found that allows its replacement. Its application must be in airtight fumigation chambers and with a closed pesticide recovery system.
3. Amendments were made to article 1 of resolution 2152 in order to ensure a more controlled and restrictive use of methyl bromide by resolutions 00643 of 2004, 01800 of 2006, 03587 of 2008 and 5049 of 2008. The notification indicates that resolution 2152 of 1996 and resolution 5049 of 2008 are currently in force and that the final regulatory action for all restrictions is resolution 5049 of 2008 (applies from publication date)[[1]](#footnote-1) (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.2 of the Colombia notification).

 B. 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 confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.18/10, annex, sects. 2.4.1 and 2.4.2 of the Colombia notification).
2. The notification states that the final regulatory action was based on a risk or hazard evaluation. According to the provided information, methyl bromide is an irritating and vesicant gas, which is extremely toxic to humans and affects different organs and systems, with high potential risks of producing acute poisoning by inhalation and absorption through the skin and mucous membranes. Additionally, methyl bromide is an ozone-depleting substance listed under the Montreal Protocol. The reduction of emissions of methyl bromide is expected to lead to a reduction of the destruction of the ozone layer, which is expected to contribute to a reduction of skin cancer incidence.
3. The Committee therefore concludes that the criterion in paragraph (a) of Annex II is met.

 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. The initial resolution 2152 of 1996 was supported by the analysis of the following documents, including national studies:
2. Toxicological concept developed by the Ministry of Health and Social Protection of Colombia in 1993 (UNEP/FAO/RC/CRC.18/INF/19, annex, document 5);
3. *Environmental Effects Panel Report*, November 1989 (UNEP/FAO/RC/CRC.18/INF/19, annex);
4. *1994 report of the Technology and Economic Assessment Panel for the 1995 assessment of the Montreal Protocol on Substances that Deplete the Ozone Layer* (UNEP/FAO/RC/CRC.18/INF/19, annex, document 8);
5. 2011 booklet on the use of methyl bromide in Colombia[[2]](#footnote-2) (UNEP/FAO/RC/CRC.18/INF/19, annex, document 9).
6. Taking into account the difficulties encountered in the handling of methyl bromide, the need to amend resolution 2152 of 1996 was identified. The inter-institutional working committee on the use of methyl bromide in Colombia was established and within its framework, studies on the safe use of methyl bromide and safer alternatives were continued and the notification also includes information on reviewed documents and conclusions of committee meetings (UNEP/FAO/RC/CRC.18/INF/19, annex, documents 10–16).
7. Taking into account that the risk evaluation took into account the assessments provided by the assessment panels of the Montreal Protocol in their reports of 1989 and 1994.
8. The data included in the notification and supporting documentation is considered to be scientifically sound and generated according to scientifically recognized methods, and data reviews are considered to have been performed and documented according to generally recognized scientific principles and procedures.
9. The Committee therefore confirms that the criteria in paragraph (b) (i) and (ii) of Annex II are met.

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

1. The notification notes that methyl bromide was included in the Montreal Protocol as an ozone-depleting substance under the Copenhagen Amendment. Methyl bromide was identified “as one of the most powerful depleters of atmospheric ozone and therefore indirectly favours the effects of solar radiation in the production of skin cancer (Scientific, Technical and Economic Review of the Committee of Experts of the Montreal Protocol on methyl bromide)”. This implies that, by reducing the use of methyl bromide in Colombia, there is a contribution to reducing emissions of an ozone‑depleting substance and, indirectly, to reducing the risk of skin cancer due to increased solar radiation. This was also supported by the 1989 *Environmental Effects Panel Report*, which states that though “skin cancer will increase with any increase in UV-B radiation, the relationship between skin cancer and ozone decrease is not one to one. For every 1 per cent decrease of the total ozone will result in a 3 per cent increase in the incidence of melanoma or skin cancer” (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.4.2.1 of the Colombia notification). It has also been identified that the incidence of cataracts and the severity of different infections increases since the immune system is suppressed due to radiation (UNEP/FAO/RC/CRC.18/INF/19, annex, document 7, pp. 11–24).
2. In the *1994 Report of the Technology and Economic Assessment Panel*, one of the sources of exposure to methyl bromide was its use in pre-sowing and post-harvest agricultural activities, fumigation in structures (such as containers and buildings) and in intermediate chemicals. Additionally, a predictive theoretical analysis identified that between 45 and 53 per cent of the amount used in agricultural activities could be released into the atmosphere. (UNEP/FAO/RC/CRC.18/INF/19, annex, document 8).
3. The quantities of methyl bromide used in Colombia in 1994 as a soil fumigant for different crops were reported (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.4.2.1, table 3 of the Colombia notification). This use was identified as an important source of emissions into the environment based on the assessment performed by the Technology and Economic Assessment Panel of the Montreal Protocol as published in its report of 1994 (UNEP/FAO/RC/CRC.18/INF/19, annex, document 8).
4. The notification and supporting documentation show that the risk evaluation has considered prevailing conditions in Colombia. Based on the quantities of methyl bromide used as soil fumigant in Colombia, emissions into the atmosphere were estimated taking into account the assessment undertaken under the Montreal Protocol.
5. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.
6. Consequently, the Committee confirms that the criteria in paragraph (b) of Annex II are 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 severely restricted the use of formulations containing methyl bromide (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.3.3 of the Colombia notification). Consequently, it is expected that the regulatory action will lead to a significant decrease of the quantity of the chemical used.
2. In the supporting documentation, a booklet in Spanish on the analysis of the use of methyl bromide in Colombia includes a section which provides a historical perspective and alternatives for the replacement of methyl bromide, which presents a reduction of methyl bromide use in Colombia since 1996 (UNEP/FAO/RC/CRC.18/INF/19, annex, p. 17). Additionally, the final regulatory action severely restricted the use of formulations containing methyl bromide to be used as gaseous formulations of methyl bromide, and it is only allowed for quarantine treatment in the control of quarantine pests in agricultural products and packaging at ports and border crossings, until a viable substitute is found that allows their replacement. Use of airtight fumigation chambers is required (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.3.3 of the Colombia notification). Also, the supporting documentation refers that Colombia has not been a producer of methyl bromide. Furthermore, the notification presents that no imports are registered from 2017 (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.5.1 of the Colombia notification).
3. The notification provides information on quantities of the chemical imported in 2004 (12 metric tons) and 2005 (17.5 metric tons). (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.5.1 of the Colombia notification and UNEP/FAO/RC/CRC.18/INF/19, annex, document 1, sect. 3.a of the executive summary).
4. The Committee therefore confirms that the criterion in paragraph (c) (i) is met.

*(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. The final regulatory action severely restricted the use of formulations containing methyl bromide. The remaining allowed uses are restricted to those in hermetic chambers that will minimize the release of the fumigant. Consequently, it is expected that the regulatory action will lead to a significant reduction of risk to human health by occupational exposure and indirect health effects, taking into account the reduction of emissions of ozone-depleting substances which increase solar radiation and in the long term may increase the risk of skin cancer. Also, risks to the environment are reduced through the reduction of emissions of this ozone-depleting substance (UNEP/FAO/RC/CRC.18/10, annex, sects. 2.4.2.1 and 2.4.2.2 of the Colombia notification).
2. The Committee confirms that the criterion in paragraph (c) (ii) is met.

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

1. The notification, which was based on 1996 and 2008 legislation in Colombia, stated that methyl bromide could be used in other countries, mainly in developing countries or countries with economies in transition (UNEP/FAO/RC/CRC.18/10, annex, sect. 2.5.2 of the Colombia notification).
2. Additional information on countries using methyl bromide for quarantine and pre-shipment purposes can be found in the *2018 Assessment Report of the Methyl Bromide Technical Options Committee* of the Montreal Protocol.[[3]](#footnote-3)
3. The report mentions that 50 countries were still regularly using methyl bromide for quarantine and pre-shipment. Additionally, the report mentions that almost all structural and commodity treatments with methyl bromide are carried out for quarantine and pre-shipment purposes. Consequently, the use of methyl bromide for quarantine and pre-shipment is not limited to a geographical area and it is a major use for this pesticide in many countries. Further, the report mentions that worldwide many fumigations continue to be conducted in poorly sealed enclosures, leading to high rates of leakage and gas loss.
4. It can be expected that for similar reasons as those mentioned in the Colombian notification (minimization of emissions of a highly toxic and ozone-depleting gas), other countries still using methyl bromide for quarantine and pre-shipment purposes in poorly sealed enclosures should consider introducing regulations to replace methyl bromide and/or adopt technologies to capture the fumigant and minimize its emission.
5. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

1. The Secretariat collected information on trade. The received information shows that there is evidence of ongoing trade (UNEP/FAO/RC/CRC.18/INF/6/Rev.1).
2. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

 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 concerning intentional misuse which prompted the regulatory action.
2. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

 F. Conclusion

1. The Committee concludes that the notification of final regulatory action submitted by Colombia meets the criteria set out in Annex II to the Convention.
1. See <https://www.icbf.gov.co/cargues/avance/docs/resolucion_minproteccion_5049_2008.htm> (in Spanish). [↑](#footnote-ref-1)
2. This booklet was published after the regulations of 1996. However, the document is open to the public and presents the information from 1994 that was used for resolution 2152 of 1996. [↑](#footnote-ref-2)
3. Available at https://ozone.unep.org/sites/default/files/2019-04/MBTOC-assessment-report-2018\_1.pdf. [↑](#footnote-ref-3)