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2003 NOMINATION FOR A CRITICAL USE EXEMPTION FOR METHYL BROMIDE FROM THE UNITED STATES OF AMERICA

— Executive Summary —

This document constitutes the request of the United States of America for an exemption for critical uses of methyl bromide for 2005 and 2006 consistent with the requirements of the Montreal Protocol and Decision IX/6. The United States is firmly committed to the goals of the Protocol, evidenced in particular by the strong efforts we have made over the last decade to phase out uses of methyl bromide where it has been feasible. Over that time, the United States has maintained consumption levels lower than those required under the Protocol. We remain fully committed to seeking alternatives to methyl bromide and prioritizing consideration of their registration in the context of their overall human health and environmental impact.

1. Background

In 1997, the Parties to the Montreal Protocol adjusted Article 2H of the Protocol, and agreed to accelerate the reduction in the controlled production and consumption of methyl bromide. This adjustment included a provision calling for a phaseout of methyl bromide by the year 2005 "save to the extent that the Parties decide to permit the level of production or consumption that is necessary to satisfy uses agreed by them to be critical uses." At the same time, the Parties adopted decision IX/6, the critical use exemption decision, which laid out the terms under which critical use exemptions under Article 2H would be granted.

2. Criteria for Critical Uses under the Montreal Protocol

In crafting Decision IX/6 outlining the criteria for a critical use exemption, the Parties recognized the significant differences between methyl bromide uses and uses of other ozone-depleting chemicals previously given scrutiny under the Protocol's distinct and separate Essential Use exemption process. The United States believes that it is vitally important for the MBTOC to take into account the significant differences between the critical use exemption and the essential use exemption in the review of all methyl bromide critical use nominations.

During the debate leading up to the adoption of the critical use exemption Decision IX/6, an underlying theme voiced by many countries was that the Parties wanted to phase out methyl bromide, and not agriculture. This theme was given life in various provisions of the critical use exemption, and in the differences in approach taken between the critical use exemption and the essential use exemption. Those differences are outlined below.

The Protocol's negotiated criteria for the Critical Use Exemptions for methyl bromide are much different from the criteria negotiated for "Essential Uses" for other chemicals:

Under the Essential Use provisions, in order to even be considered for an exemption, it was necessary for each proposed use to be "critical for health, safety or the functioning of society." This high threshold differs significantly from the criteria established for the methyl bromide Critical Use exemption. Indeed, for methyl bromide, the Parties left it solely to the nominating governments to find that the absence of methyl bromide would create *a significant market disruption.*

For all crops covered in the U.S. nomination, the United States has determined that the level of methyl bromide being requested is critical to ensuring that there is no significant market disruption. This determination is based on a detailed analysis of technical and economic feasibility factors that are described in greater detail in each of the sector chapters.

In the case of methyl bromide, the Parties recognized many agricultural fumigants were inherently toxic, and therefore there was a strong desire not to replace one environmentally problematic chemical with another even more damaging.

The Critical Use exemption language explicitly requires that an alternative should not only be technically and economically feasible, it must also be acceptable from the standpoint of health and environment. This is particularly important given the fact that most chemical alternatives to methyl bromide are highly toxic, and can involve threats to human health or the environment that are greater than the threats posed by methyl bromide.

In the case of methyl bromide, the Parties recognized that evaluating, commercializing and securing national approval of alternatives and substitutes is a lengthy process.

In fact, even after an alternative is tested and found to work against some pests in a controlled setting, adequate testing in large-scale commercial operations can take many cropping seasons before the viability of the alternative can be adequately assessed from the standpoint of the climate and soil for various potential users. In addition, the process of securing national and sub-national approval of alternatives may require extensive analysis of environmental consequences and toxicology. The average time for the national review of scientific information in support of a new pesticide, starting from the date of submission to registration, is approximately 38 months. In most cases, the company submitting the information has spent approximately 7-10 years developing the epidemiological and other environmental data necessary to support the registration request.

The Parties to the Protocol recognized that unlike other chemicals controlled under the Montreal Protocol, the use of methyl bromide and available alternatives could be site specific and must take into account the particular needs of the user.

The Essential Use exemption largely assumed that an alternative used in one place could, if approved by the government, be used everywhere. Parties clearly understood that this was not the case with methyl bromide because of the large number of variables involved, such as crop type, soil types, pest pressure and local climate. That is why the methyl bromide Critical Use exemption calls for an examination of the feasibility of the alternative *from the standpoint of the user*, and *in the context of the specific circumstances of the nomination*, including use and geographic location. In order to effectively implement this last, very important provision, we believe it is critical for

MBTOC reviewers to understand the unique nature of U.S. agriculture, as well as U.S. efforts to minimize the use of methyl bromide, to research alternatives, and to register alternatives for methyl bromide.

3. Overview of U.S. Agriculture

The United States is fortunate to have a large land expanse, productive soils and a variety of favorable agricultural climates. These factors contribute to and enable the U.S. to be a uniquely large and productive agricultural producer. Indeed, the size and scope of farming in the U.S. is different than in most countries. Specifically, in 2001, U.S. farm land totaled 381 million hectares, a land mass larger than the entire size of many entire countries. There were 2.16 million farms, with average farm size across all farms of 176 hectares (approximately 10 times larger than average farm sizes in the European Union). The availability of land and the fact that so many U.S. regions are conducive to outdoor cultivation of fruits and vegetables, has had an important influence on the way agriculture has developed. Specifically, these factors have meant that greenhouse production has generally proven to be very costly (in relative terms) and has as a consequence, been limited.

Other factors also affected the general development of agriculture in the U.S. While land for farming is widely available, labor is generally more expensive and less plentiful. As a result, the U.S. has developed a unique brand of highly mechanized farming practices that are highly reliant on pesticides such as methyl bromide and other non-labor inputs. The extent of mechanization and reliance on non-labor inputs can be best demonstrated by noting the very low levels of labor inputs on U.S. farms: in 2001, only 2.05 million self-employed and unpaid workers operated the 2.16 million U.S. farms, with seasonal or supplemental help from less than 1 million hired workers.

U.S. agriculture is also unique in terms of the broad range of crops produced. For example, the fruit and vegetable sector, the agricultural sector most reliant on methyl bromide, is diverse, and includes production of 107 separate fruit and vegetable commodities or groups of commodities. With this diversity, however, has come a large number of pest problems that methyl bromide has proven uniquely able to address.

Finally, the above factors have contributed to a harvest of commodities that has enabled the U.S. to meet not only its needs, but also the needs of many other countries. The U.S. produced 88.3 million metric tonnes of fruits and vegetables in 2001, up 10 percent from 1990. At the same time, the land planted in fruits and vegetables has remained stable, and individual farm size has increased as the number of farms has fallen. The related yield increases per land area are almost exclusively related to non-labor inputs, like the adoption of new varieties, and the application of new production practices, including plastic mulches, row covers, high-density planting, more effective pesticide sprays, and drip irrigation, as well as increased water irrigation practices. Optimization of yields through these and other scientific and mechanized practices make U.S. agricultural output very sensitive to changes in inputs. Therefore, as evidenced by the U.S. nomination for critical uses of methyl bromide for specific crops, the phaseout of methyl bromide can have a very significant impact on both the technical and economic viability of production of certain crops in certain areas.

4. U.S. Consideration/Preparation of the Critical Use Exemption Proposal

Work on the U.S. critical use exemption process began in early 2001. At that time, the U.S. Environmental Protection Agency (US EPA) initiated open meetings with stakeholders both to inform them of the Protocol requirements, and to understand the issues being faced in researching alternatives to methyl bromide. During those meetings, which were attended by State and association officials representing literally thousands of methyl bromide users, the provisions of the critical use exemption Decision IX/6 were reviewed in detail, and questions were taken. The feedback from these initial meetings led to efforts by the United States to have the Protocol Parties establish international norms for the details to be in submissions and to facilitate standardization for a fair and adequate review. These efforts culminated in decision XIII/11 which calls for specific information to be presented in the nomination.

Upon return from the Sri Lanka meeting of the Parties, the U.S. took a three track approach to the critical use process. First, we worked to develop a national application form that would ensure that we had the information necessary to answer all of the questions posed in decision XIII/11. At the same time, we initiated sector specific meetings. This included meetings with representatives of growers across the United States to discuss their specific issues, and to enable them to understand the newly detailed requirements of the critical use application. These sector meetings allowed us to fine tune the application so we could submit the required information to the MBTOC in a meaningful fashion.

Finally, and concurrent with our preparation phase, we developed a plan to ensure a robust and timely review of any and all critical use applications we might receive. This involved the assembly of more than 45 PhDs and other qualified reviewers with expertise in both biological and economic issues. These experts were divided into interdisciplinary teams to enable primary and secondary reviewers for each application/crop. As a consequence, each nomination received by the U.S. was reviewed by two separate teams. In addition, the review of these interdisciplinary teams was put to a broader review of experts on all other sector teams to enable a third look at the information, and to ensure consistency in review between teams. The result was a thorough evaluation of the merits of each request. A substantial portion of requests did not meet the criteria of decision IX/6, and a strong case for those that did meet the criteria has been included.

Following our technical review, discussions were held with senior risk management personnel of the U.S. government to go over the recommendations and put together a draft package for submission to the parties. As a consequence of all of this work, it is safe to say that each of the sector specific nominations being submitted is the work of well over 150 experts both in and outside of the U.S. government.

5. Overview of the 2003 Critical Use Exemption Nomination

The U.S. nomination for a critical use exemption is for the following sixteen (16) crops/uses: commodity storage, curcurbit, eggplant, food processing, forest tree seedling nursery, ginger, nursery seed bed trays, orchard nursery, orchard replant, ornamental nursery, pepper, strawberry, strawberry nursery, sweet potato, tomato, and turfgrass. The total amount of methyl bromide

nominated by the U.S. for these uses is 9,920,965 kilograms for 2005, and 9,445,360 kilograms for 2006. The detailed information supporting the U.S. nomination for each crop or use is covered in an individual chapter of the U.S. nomination.

In preparing this nomination, we consulted with the MBTOC co-chair, and we have made an effort to tailor this package to the needs of the review group. Specifically, in order to enable MBTOC to split up the nomination in a manner that would allow for sectoral teams to review individual crops, we have prepared stand alone chapters that incorporate into each chapter much of the relevant material that is included in this Executive Summary. We apologize for the redundancy that this may have brought about, but we wanted to ensure that this important information was included in each relevant section.

6. Minimizing Use/Emissions of Methyl Bromide in the United States/Stockpiles

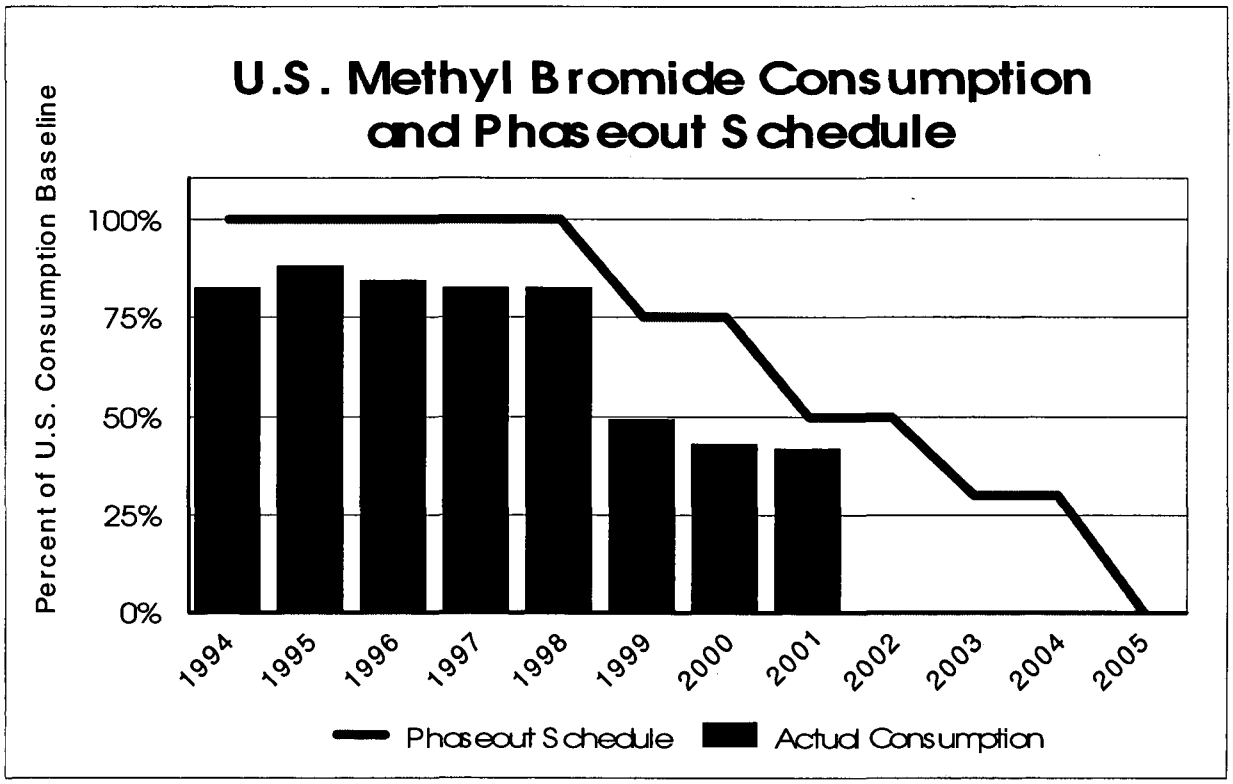
In accordance with the criteria of the critical use exemption, we will now describe ways in which we strive to minimize use and emissions of methyl bromide. While each sector based nomination includes information on this topic, we thought it would be useful to provide some general information that is applicable to most methyl bromide uses in the country

The use of methyl bromide in the United States is minimized in several ways. First, because of its toxicity, methyl bromide is regulated as a restricted use pesticide in the United States. As a consequence, methyl bromide can only be used by certified applicators who are trained at handling these hazardous pesticides. In practice, this means that methyl bromide is applied by a limited number of very experienced applicators with the knowledge and expertise to minimize dosage to the lowest level possible to achieve the needed results. In keeping with both local requirements to avoid "drift" of methyl bromide into inhabited areas, as well as to preserve methyl bromide and keep related emissions to the lowest level possible, methyl bromide is machine injected into soil to specific depths. In addition, as methyl bromide has become more scarce, users in the United States have, where possible, experimented with different mixes of methyl bromide and chloropicrin. Specifically, in the early 1990s, methyl bromide was typically sold and used in methyl bromide mixtures made up of 98% methyl bromide and 2% chloropicrin, with the chloropicrin being included solely to give the chemical a smell enabling those in the area to be alerted if there was a risk. However, with the outset of very significant controls on methyl bromide, users have been experimenting with significant increases in the level of chloropicrin and reductions in the level of methyl bromide. While these new mixtures have generally been effective at controlling target pests, it must be stressed that the long term efficacy of these mixtures is unknown. Reduced methyl bromide concentrations in mixtures, more mechanized soil injection techniques, and the extensive use of tarps to cover land treated with methyl bromide has resulted in reduced emissions and an application rate that we believe is among the lowest in the world.

In terms of compliance, in general, the United States has used a combination of tight production and import controls, and the related market impacts to ensure compliance with the Protocol requirements on methyl bromide. Indeed, over the last few years, the price of methyl bromide has increased substantially. As Chart 1 below demonstrates, the application of these policies has led to a more rapid U.S. phasedown in methyl bromide consumption than required under

the Protocol. This accelerated phasedown on the consumption side may also have enabled methyl bromide production to be stockpiled to some extent to help mitigate the potentially significant impacts associated with the Protocol's 2003 and 2004 70% reduction. We are currently uncertain as to the exact quantity of existing stocks going into the 2003 season that may be stockpiled in the U.S. We currently believe that the limited existing stocks are likely to be depleted during 2003 and 2004. This factor is reflected in our requests for 2005 and beyond.

CHART 1.



At the same time we have made efforts to reduce emissions and use of methyl bromide, we have also made strong efforts to find alternatives to methyl bromide. The section that follows discusses those efforts.

7. U.S. Efforts to Find, Register and Commercialize Alternatives to Methyl Bromide

Over the past ten years, the United States has committed significant financial and technical resources to the goal of seeking alternatives to methyl bromide that are technically and economically feasible to provide pest protection for a wide variety of crops, soils, and pests, while also being acceptable in terms of human health and environmental impacts. The U.S. pesticide registration program has established a rigorous process to ensure that pesticides registered for use in the United States do no present an unreasonable risk of health or environmental harm. Within the program, we have given the highest priority to rapidly reviewing methyl bromide alternatives, while maintaining our high domestic standard of environmental protection. A number of alternatives have already been registered for use, and several additional promising alternatives are under review at this time. Our

research efforts to find new alternatives to methyl bromide and move them quickly toward registration and commercialization have allowed us to make great progress over the last decade in phasing out many uses of methyl bromide. However, these efforts have not provided effective alternatives for all crops, soil types and pest pressures, and we have accordingly submitted a critical use nomination to address these limited additional needs.

Research Program

When the United Nations, in 1992, identified methyl bromide as a chemical that contributes to the depletion of the ozone layer and the Clean Air Act committed the U.S. to phase out the use of methyl bromide, the U.S. Department of Agriculture (USDA) initiated a research program to find viable alternatives. Finding alternatives for agricultural uses is extremely complicated compared to replacements for other, industrially used ozone-depleting substances because many factors affect the efficacy such as: crop type, climate, soil type, and target pests, which change from region to region and among localities within a region.

Through 2002, the USDA Agricultural Research Service (ARS) alone has spent US$135.5 million to implement an aggressive research program to find alternatives to methyl bromide (see Table 1 below). Through the Cooperative Research, Education and Extension Service, USDA has provided an additional $11.4 million since 1993 to state universities for alternatives research and outreach. This federally supported research is a supplement to extensive sector specific private efforts, and all of this research is very well considered. Specifically, the phaseout challenges brought together agricultural and forestry leaders from private industry, academia, state governments, and the federal government to assess the problem, formulate priorities, and implement research directed at providing solutions under the USDA's Methyl Bromide Alternatives program. The ARS within USDA has 22 national programs, one of which is the Methyl Bromide Alternatives program (Select Methyl Bromide Alternatives at this web site: http://www.nps.ars.usda.gov). The resulting research program has taken into account these inputs, as well as the extensive private sector research and trial demonstrations of alternatives to methyl bromide. While research has been undertaken in all sectors, federal government efforts have been based on the input of experts as well as the fact that nearly 80 percent of preplant methyl bromide soil fumigation is used in a limited number of crops. Accordingly, much of the federal government pre-plant efforts have focused on strawberries, tomatoes, ornamentals, peppers and nursery crops, (forest, ornamental, strawberry, pepper, tree, and vine), with special emphasis on tomatoes in Florida and strawberries in California as model crops.

Table 1: Methyl Bromide Alternatives Research Funding History

Year	Expenditures by the U.S. Department of Agriculture (US$ Million)
1993	$7.255
1994	$8.453
1995	$13.139
1996	$13.702
1997	$14.580
1998	$14.571
1999	$14.380
2000	$14.855
2001	$16.681
2002	$17.880

The USDA/ARS strategy for evaluating possible alternatives is to first test the approaches in controlled experiments to determine efficacy, then testing those that are effective in field plots. The impact of the variables that affect efficacy is addressed by conducting field trials at multiple locations with different crops and against various diseases and pests. Alternatives that are effective in field plots are then tested in field scale validations, frequently by growers in their own fields. University scientists are also participants in this research. Research teams that include ARS and university scientists, extension personnel, and grower representatives meet periodically to evaluate research results and plan future trials.

Research results submitted with the CUE request packages (including published, peer-reviewed studies by (primarily) university researchers, university extension reports, and unpublished studies) include trials conducted to assess the effectiveness of the most likely chemical and non-chemical alternatives to methyl bromide, including some potential alternatives that are not currently included in the MBTOC list.

As demonstrated by the table above, U.S. efforts to research alternatives for methyl bromide have been substantial, and they have been growing in size as the phaseout has approached. The United States is committed to sustaining these research efforts in the future to continue to aggressively search for technically and economically feasible alternatives to methyl bromide. We are also committed to continuing to share our research, and enable a global sharing of experience. Toward that end, for the past several years, key U.S. government agencies have collaborated with industry to host an annual conference on alternatives to methyl bromide. This conference, the Methyl Bromide Alternatives Outreach (MBAO), has become the premier forum for researchers and others to discuss scientific findings and progress in this field.

While the U.S. government's role to find alternatives is primarily in the research arena, we know that research is only one step in the process. As a consequence, we have also invested

significantly in efforts to register alternatives, as well as efforts to support technology transfer and education activities with the private sector.

Registration Program

The United States has one of the most rigorous programs in the world for safeguarding human health and the environment from the risks posed by pesticides. While we are proud of our efforts in this regard, related safeguards do not come without a cost in terms of both money and time. Because the registration process is so rigorous, it can take a new pesticide several years (3-5) to get registered by EPA. It also takes a large number of years to perform, draft results and deliver the large number of health and safety studies that are required for registration.

The U.S. Environmental Protection Agency regulates the use of pesticides under two major federal statutes: the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA), both significantly amended by the Food Quality Protection Act of 1996 (FQPA). Under FIFRA, EPA registers (licenses) pesticides provided its use does not pose unreasonable risks to humans or the environment. Under FFDCA, the Agency is responsible for setting tolerances (maximum permissible residue levels) for any pesticide used on food or animal feed. With the passage of FQPA, the Agency is required to establish a single, health-based standard for pesticides used on food crops and to determine that establishment of a tolerance will result in a "reasonable certainty of no harm" from aggregate exposure to the pesticide.

The process by which EPA examines the ingredients of a pesticide to determine if they are safe is called the registration process. The Agency evaluates the pesticide to ensure that it will not have any adverse effects on humans, the environment, and non-target species. Applicants seeking pesticide registration are required to submit a wide range of health and ecological effects toxicity data, environmental fate, residue chemistry and worker/bystander exposure data and product chemistry data. A pesticide cannot be legally used in the United States if it has not been registered by EPA, unless it has an exemption from regulation under FIFRA.

Since 1997, the Agency has made the registration of alternatives to methyl bromide the highest registration priority. Because the Agency currently has more applications pending in its review than the resources to evaluate them, EPA prioritizes the applications in its registration queue. By virtue of being the top registration priority, methyl bromide alternatives enter the science review process as soon as EPA receives the application request. The average processing time for a new active ingredient, from date of submission to issuance of a registration decision, is approximately 38 months. In most cases, the registrant (the pesticide applicant) has spent approximately 7-10 years developing the data necessary to support registration.

As one incentive for the pesticide industry to develop alternatives to methyl bromide, the Agency has worked to reduce the burdens on data generation, to the extent feasible while still ensuring that the Agency's registration decisions meet the Federal statutory safety standards. Where appropriate from a scientific standpoint, the Agency has refined the data requirements for a given pesticide application, allowing a shortening of the research and development process for the methyl bromide alternative. Furthermore, Agency scientists routinely meet with prospective methyl

bromide alternative applicants, counseling them through the pre-registration process to increase the probability that the data is done right the first time and rework delays are minimized

The Agency has also co-chaired the USDA/EPA Methyl Bromide Alternatives Work Group since 1993 to help coordinate research, development and the registration of viable alternatives. The work group conducted six workshops in Florida and California (states with the highest use of methyl bromide) with growers and researchers to identify potential alternatives, critical issues, and grower needs covering the major methyl bromide dependent crops and post harvest uses.

This coordination has resulted in key registration issues (such as worker and bystander exposure through volatilization, township caps and groundwater concerns) being directly addressed through USDA's Agricultural Research Service's $13.5 million per year research program conducted at more than 20 field evaluation facilities across the country. Also EPA's participation in the evaluation of research grant proposals submitted to the USDA's Cooperative State Research, Education, and Extension Service methyl bromide alternatives research program of US$ 2.5 million per year has further ensured that critical registration issues are being addressed by the research community.

Since 1997, EPA has registered the following chemical/use combinations as part of its commitment to expedite the review of methyl bromide alternatives:

1999: Pebulate to control weeds in tomatoes
2000: Phosphine to control insects in stored commodities
2001: Indian Meal Moth Granulosis Virus to control Indian meal moth in stored grains
2001: Terrazole to control pathogens in tobacco float beds
2001: Telone applied through drip irrigation - all crops
2002: Halosulfuron-methyl to control weeds in melons and tomatoes

EPA is currently reviewing several additional applications for registration as methyl bromide alternatives, with several registration eligibility decisions expected within the next year, including:

– Iodomethane as a pre-plant soil fumigant for various crops
– Fosthiazate as a pre-plant nematocide for tomatoes
– Sulfuryl fluoride as a post-harvest fumigant for stored commodities
– Trifloxysulfuron sodium as a pre-plant herbicide for tomatoes
– Dazomet as a pre-plant soil fumigant for strawberries and tomatoes

Again, while these activities appear promising, it must be noted that issues related to toxicity, ground water contamination, and the release of air pollutants may pose significant problems with respect to some alternatives that may lead to use restrictions since many of the growing regions are in sensitive areas such as those in close proximity to schools and homes. Ongoing research on alternate fumigants is evaluating ways to reduce emission under various application regimes and examining whether commonly used agrochemicals, such as fertilizers and nitrification inhibitors, could be used to rapidly degrade soil fumigants. For example, if registration of iodomethane or

another alternative occurs in the near future, commercial availability and costs will be factors that must be taken into consideration.

It must be emphasized, however, that finding potential alternatives, and registering those alternatives is not the end of the story. Those alternatives must be trialed by users and must be finally adopted, which takes time. Allowing for users to trial alternatives, so farmers can adopt them, also involves time. As noted by TEAP, a specific alternative, once available may take two or three cropping seasons of use before efficacy can be determined in the specific circumstance of the user. In an effort to reduce related time frames, the United States government has also been involved in these steps by promoting technology transfer, experience transfer, and private sector training.

8. Conclusion

On the basis of an exhaustive review of a large, multi-disciplinary team of sector and general agricultural experts, we have determined that the TEAP listed potential alternatives for the specific crops and areas covered in this nomination are not currently technically or economically viable from the standpoint of United States growers covered by this exemption request. We have also determined that the absence of methyl bromide for the nominated uses will result in a significant market disruption to the effected sectors. We have and continue to expend significant efforts to find and commercialize alternatives, and that potential alternatives to the use of methyl bromide for many important uses are under investigation and may be on the horizon. Based on this analysis, we believe those requests included in this nomination meet the criteria set out by the Parties in Decision IX/6.

9. Policy Issues Associated with this Nomination

a. Initial Nomination: We wish to note, at this time, that the U.S. submission contained in this document constitutes an initial request for an exemption from the methyl bromide phaseout. We call this an initial request, because, consistent with related decisions, Parties may submit additional requests next year for 2005 and beyond if further review indicates that important uses were left out of the initial nomination, or initially projected need was underestimated.

b. Request for Aggregate Exemption for All Covered Methyl Bromide Uses: As mandated by Decision XIII/11, the nomination information that is being submitted with this package includes information requested on historic use and estimated need in individual sectors. That said, we note our agreement with past MBTOC and TEAP statements which stress the dynamic nature of agricultural markets, uncertainty of specific production of any one crop in any specific year, the difficulty of projecting several years in advance what pest pressures might prevail on a certain crop, and, the difficulty of estimating what a particular market for a specific crop might look like in a future year. We also concur with the MBTOC's fear that countries that have taken significant efforts to reduce methyl bromide use and emissions through dilution with chloropicrin may be experiencing only short term efficacy in addressing pest problems. On the basis of those factors, we urge the MBTOC and the TEAP to follow the precedent established under the essential use exemption process for Metered Dose Inhalers (MDIs) in two key areas.

First, because of uncertainties in both markets and the future need for individual active moieties of drugs, the TEAP has never provided a tonnage limit for each of the large number of active moieties found in national requests for a CFC essential use exemption for MDIs, but has instead recommended an aggregate tonnage exemption for national use. This has been done with an understanding that the related country will ensure that the tonnage approved for an exemption will be used solely for the group of active moieties/MDIs that have been granted the exemption. We believe that the factors of agricultural uncertainty surrounding both pest pressures in future year crops, pest pressures, and efficacy of reduced methyl bromide application provide an even stronger impetus for using a similar approach here.

*c. **Recognition of Uncertainty in Allowing Margin for Safety:*** The level of unpredictability in need leads to a second area of similarity with MDIs, the essential need for a review of the level of the request which takes into account the need for a margin of safety. With MDIs, it was essential to address the possible change in patient needs over time, and in agriculture, this is essential to address the potential that the year being requested for could be a particularly bad year in terms of weather and pest pressure. In that regard, the TEAP's Chart below (Chart 2) demonstrates the manner in which this need for a margin of safety was addressed in the MDI area. Specifically, Chart 2 tracks national CFC requests for MDIs compared with actual use of CFC for MDIs over a number of years.

CHART 2

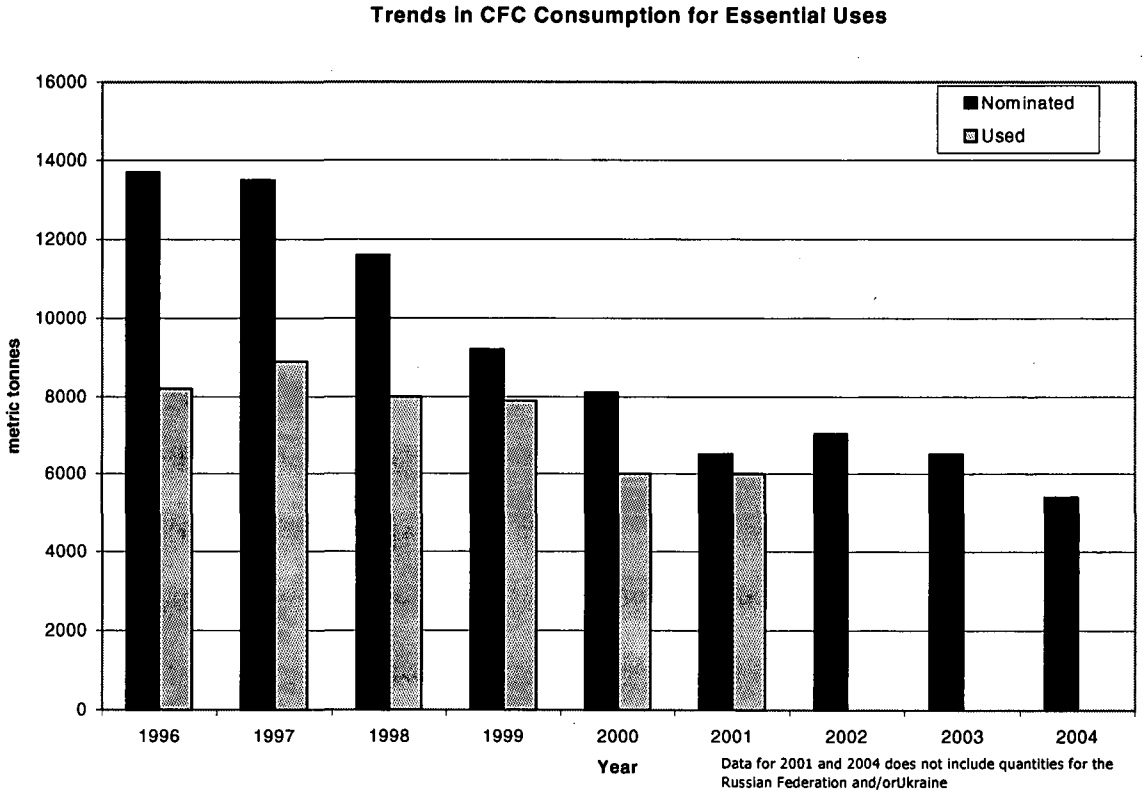


Chart 2 above demonstrates several things. First, despite the best efforts of many countries to predict future conditions, it shows that due to the acknowledged uncertainty of out-year need for MDIs, Parties had a tendency to request, the TEAP recommended, and the Parties approved national requests that turned out to include an appreciable margin of safety. In fact, this margin of safety was higher at the beginning – about 40% above usage – and then went down to 30% after 4 years. Only after 5 years of experience did the request come down to about 10% above usage. While our experience with the Essential Use process has aided the U.S. in developing its critical use nomination, we ask the MBTOC, the TEAP and the Parties to recognize that the complexities of agriculture make it difficult to match our request exactly with expected usage when the nomination is made two to three years in advance of the time of actual use.

Chart 2 also demonstrates that, even though MDI requests included a significant margin of safety, the nominations were approved and the countries receiving the exemption for MDIs did not produce the full amount authorized when there was not a patient need. As a result, there was little or no environmental consequence of approving requests that included a margin of safety, and the practice can be seen as being normalized over time. In light of the similar significant uncertainty surrounding agriculture and the out year production of crops which use methyl bromide, we wish to urge the MBTOC and TEAP to take a similar, understanding approach for methyl bromide and uses found to otherwise meet the critical use criteria. We believe that this too would have no environmental consequence, and would be consistent with the Parties aim to phaseout methyl bromide while ensuring that agriculture itself is not phased out.

d. Duration of Nomination: It is important to note that the nomination includes a request for a critical use exemption for 2005, and 2006. This multi-year request is consistent with the TEAP recognition that the calendar year does not, in most cases, correspond with the cropping year. This request takes into account the facts that registration and acceptance of new efficacious alternatives can take a long time, and that alternatives must be tested in multiple cropping cycles in different geographic locations to determine efficacy and consistency before they can be considered to be widely available for use. Finally, the request for multiple years is consistent with the expectation of the Parties and the TEAP as evidenced in the Parties and MBTOC request for information on the duration of the requested exemption. As noted in paragraphs 5 and 9b above, we are requesting that the exemption be granted in a lump sum of 9,920,965 kilograms for 2005 and 9,445,360 kilograms for 2006. While it is our hope that the registration and demonstration of new, cost effective alternatives will result in even speedier reductions on later years, the decrease in our request for 2006 is a demonstration of our commitment to work toward further reductions in our consumption of methyl bromide for critical uses. In that regard, methyl bromide is scheduled for a reregistration decision in 2005; typically re-registration actions result in additional restrictions being placed on the use of a product. At this time, however, we have not believed it possible to provide a realistic assessment of exactly which uses would be reduced to account for the overall decrease in 2006.

e. Environmental Perspective: Finally, we wish to put our request for a methyl bromide critical use exemption in historic and environmental perspective. In 1996, the United States requested 4390 ODP-tonnes for an exemption for CFCs. Using the latest TEAP best estimate of the ODP for methyl bromide (.38), the U.S. request for an initial methyl bromide critical use exemption is 3783 ODP tonnes, which is 14% below our original CFC MDI request, and it represents less than 1% of our

historic baseline consumption of all ozone depleting substances. As demonstrated by the research components of and downward trend in our request, the U.S. is fully committed to finding and implementing alternatives to methyl bromide, and proceeding to phaseout its use once technically and economically viable alternatives are available to meet the needs of U.S. users.

10. Contact Information

In order to ensure the most prompt response to any inquiries regarding the U.S. nomination, we would like inquiries to be directed to John Thompson at the U.S. Department of State. We will strive to ensure the most prompt response possible to any inquiries that may be forthcoming.

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