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The Supply of Medical Radioisotopes

Policy Options for Ensuring Long-term Supply Security of Molybdenum-99 and/or Technetium-99m Produced Without Highly Enriched Uranium Targets

NUCLEAR ENERGY AGENCY

Foreword

Following the shortages of the key medical radioisotopes, molybdenum-99 (^{99}Mo) and its daughter technetium-99m (^{99m}Tc), the OECD-Nuclear Energy Agency (NEA) created the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). Since 2009, this group has identified the reasons for the isotope shortages and developed a policy approach to address the challenges to a long-term secure supply of these important medical isotopes.

On top of the ongoing concerns related to long-term reliability, all current long-term major ^{99}Mo-producing nations have agreed to convert to using low-enriched uranium (LEU) targets for the production of ^{99}Mo. This decision was made based on important non-proliferation reasons; however, the conversion will have potential impacts on the global supply chain – both in terms of costs and available capacity.

Recognising that conversion is important and will occur, and also recognising the need to ensure a long-term secure supply of ^{99}Mo/^{99m}Tc, the NEA, along with stakeholders, examined potential policy options that could be used by to ensure a reliable supply of ^{99}Mo and/or ^{99m}Tc produced without highly enriched uranium (HEU), consistent with the timeframes and policies of the HLG-MR.

This discussion paper is the result of that examination. The paper is meant to present a range of ideas to start discussion on the best policy option(s). It represents a collection of the possible policy options, described briefly, with the advantages, disadvantages and potential variations for each. This discussion paper provides these policy options to enable individual countries to examine the various options in more detail, either individually or collectively. While countries may have differing views on the various options, given their own economic, regulatory, or political situation, this discussion paper attempts to provide a brief review of the options from the starting point of the HLG-MR policy approach to achieving a long-term reliable supply of ^{99}Mo/^{99m}Tc[1].

The NEA and its HLG-MR are not endorsing any of the policy options mentioned below via this discussion paper. The information provided in this discussion paper is not meant to provide a legal perspective on the implications of the different policy approaches. Any government or organisation examining these options should seek their own legal advice on the implications, especially related to international trade agreements. The use of the World Trade Organization's Agreement on Subsidies and Countervailing Measures (WTO ASCM) in this discussion paper is for illustrative purposes as to what may be considered an acceptable subsidy in the context of the HLG-MR policy approach. The interpretations within this discussion paper are not to be considered legal advice.

This discussion paper was prepared by the NEA Secretariat of the HLG-MR in consultation with HLG-MR members and ^{99}Mo/^{99m}Tc supply chain participants. It does not necessarily represent a consensus view of the HLG-MR but is presented to enable discussions and further analysis among the members of the HLG-MR, other stakeholders and decision-makers. The individuals and organisation that contributed to the paper are not responsible for the opinions or judgements it may contain.

1. Refer to the publications, *The Supply of Medical Radioisotopes: the Path to Reliability,* (OECD-NEA, 2011) for a full description of the policy approach.

Acknowledgements

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This report was written by Chad Westmacott and Ron Cameron of the NEA Nuclear Development Division. Detailed review and comments were provided by the HLG-MR and medical radioisotope stakeholders.

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Policy options for ensuring long-term supply security of molybdenum-99 and/or technetium-99m produced without highly enriched uranium targets

NEA discussion paper

This discussion paper is meant to present a range of ideas to start discussion on the best policy option(s) to ensure a reliable supply of molybdenum-99 (^{99}Mo) and/or technetium-99m (^{99m}Tc) *produced without HEU*, consistent with the timeframes and policies of the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). The NEA and its HLG-MR are not endorsing any of the policy options mentioned below via this discussion paper. The information provided in this discussion paper is not meant to provide a legal perspective on the implications of the different policy approaches. Any government or organisation examining these options should seek their own legal advice on the implications, especially related to international trade agreements. The use of the World Trade Organization's Agreement on Subsidies and Countervailing Measures (WTO ASCM) in this discussion paper is for illustrative purposes as to what may be considered an acceptable subsidy in the context of the HLG-MR policy approach. The interpretations within this discussion paper are not to be considered legal advice.

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Introduction

Following the shortages of the key medical radioisotopes, molybdenum-99 (^{99}Mo) and its daughter technetium-99m (^{99m}Tc), the OECD-Nuclear Energy Agency (NEA) created the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). Since 2009, this group has identified the reasons for the isotope shortages and developed a policy approach to address the challenges to a long-term secure supply of these important medical isotopes (OECD-NEA, 2011).

On top of the ongoing concerns related to long-term reliability, all current major long-term ^{99}Mo-producing nations have agreed to convert to using low-enriched uranium (LEU) targets for the production of ^{99}Mo[2]. This decision was made for non-proliferation reasons; however, the conversion will have potential impacts on the global supply chain – both in terms of costs and available capacity.

2. All current producing nations (and expected new major entrants) agreed to the principle of eliminating the use of HEU in civilian applications, including in the production of ^{99}Mo through the work plan of the Washington Nuclear Security Summit (April, 2010). At the Seoul Nuclear Security Summit (April 2012), Belgium, France, the Netherlands and the United States reaffirmed their commitment to convert to LEU targets and to ensure a reliable supply of medical isotopes for patients worldwide. South Africa and Australia are already producing LEU-based ^{99}Mo for the global market. Canada has indicated that they will not be producing ^{99}Mo from its NRU reactor after 2016.

In addition, it is important to realise that there may not be global access to a long-term supply of highly-enriched uranium (HEU) for $^{99}Mo/^{99m}Tc$ production[3]. As a result, long-term security of supply of these important medical isotopes requires the move to non-HEU based production, through converting to LEU targets for ^{99}Mo production in existing (and new) producers or through the use of new technologies. This long-term secure supply is important for the millions of patients globally that rely on the isotopes for effective and non-invasive diagnostic tests for key medical ailments, such as cancer and heart disease.

Recognising that conversion is important and will occur, and also recognising the need to ensure a long-term secure supply of ^{99}Mo and/or ^{99m}Tc, the NEA and its HLG-MR is undertaking a study to quantify the expected capacity and cost impacts of LEU target conversion. The results of this study are expected later in 2012.

As part of the overall project, the study is looking at potential policy options to ensure a reliable supply of ^{99}Mo and/or ^{99m}Tc produced without highly enriched uranium (HEU), consistent with the timeframes and policies of the HLG-MR. This discussion paper discusses the need for policy and presents the policy options to achieve that reliable supply without HEU.

The need for policy action

Although all the current long-term global suppliers have committed to converting to LEU targets – or are already using LEU targets – there are differences in the expected timing of conversion, although most suppliers have targeted conversion by 2015. In addition, there are potential new entrants that current information indicates will enter the market using HEU targets and who have not confirmed they will convert to using LEU targets. Indications on possible timeframes for conversion for these new entrants – if it will occur – are not as aggressive as current producers. These different timeframes create a difficulty for those irradiation sources and processors currently producing non-HEU based ^{99}Mo and/or ^{99m}Tc and for those that are undertaking the target conversion process.

The study to quantify the capacity and cost impacts of LEU-target conversion demonstrates that there will be negative impacts on available capacity and production, as well as higher costs along the supply chain as a result of the conversion (OECD-NEA, 2012b)4. As a result, producers of converted LEU-based ^{99}Mo will likely face a market disadvantage compared to producers of HEU-based ^{99}Mo, especially if the production of HEU-based ^{99}Mo is still subsidised by national governments[5]. The study demonstrates that the first movers will be further disadvantaged by the fact that the HEU-based ^{99}Mo supply will be sufficient to supply the market over the next few years, meaning that a customer will be able to choose the lower priced HEU-based ^{99}Mo and fully meet their needs.

In addition, non-reactor-based irradiation sources for non-HEU-based production could also face a market disadvantage, as reactor-based irradiation sources appear to be more efficient producers based on currently available public information (OECD-NEA, 2010b). While there is currently no publicly available information from an actual global

3. For example, the American Medical Isotopes Production Act of 2011 (S.99), which has passed the US Senate and is currently in front of the US House of Representatives, includes provisions to restrict the export of HEU from the United States for the purposes of medical isotope production.

4. This report assumes that suppliers have incorporated waste management costs under either infrastructure changes for conversion or full cost recovery, when estimating the impact on their total costs from LEU conversion.

5. Refer to the publications, *The Supply of Medical Radioisotopes: the Path to Reliability,* (OECD-NEA, 2011) and *The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain,* (OECD-NEA, 2010a) for a discussion on the economic situation in the $^{99}Mo/^{99m}Tc$ market.

supplier using non-reactor based irradiation sources, anecdotal evidence indicates that these suppliers would also face an economic disadvantage compared to HEU-based ^{99}Mo/^{99m}Tc subsidised by national governments. This disadvantage may hinder their ability to enter the market, reducing supply reliability, and reduce the long-term options for production when HEU is no longer available or acceptable for ^{99}Mo and/or ^{99m}Tc production.

A final – and very important – reason supporting the need for policy action is that the conversion to LEU targets resulting from the need to minimise civilian use of HEU is clearly an economic externality being imposed on the market, albeit for very good reasons. The commitment to LEU-target conversion was made by governments to ensure non-proliferation. However, the decision imposes costs on producers and users of ^{99}Mo/^{99m}Tc, without a clear direct benefit for the producers or users. At the moment, there is no market justification for most ^{99}Mo producers to undertake conversion; end users (doctors, patients, health insurance systems) see no difference between ^{99m}Tc produced from HEU or LEU targets and therefore have no direct reason to pay more for the LEU-based product. Time is required to convert facilities, and if there is no encouragement to convert these facilities the process may not occur until it is too late to ensure global supply security.

This externality on producers and customers may hinder the uptake of converted LEU-based ^{99}Mo and/or ^{99m}Tc and more generally, non-HEU-based ^{99}Mo and/or ^{99m}Tc, again possibly affecting long-term supply security. As documented in other NEA studies (OECD-NEA, 2012a), there is a serious concern related to the long-term capacity of supply infrastructure and new irradiators and processors are required to avoid potential shortages that could occur as early as 2016. It is essential that there is sufficient irradiation and processing capacity over the medium to long term, which is not certain given the planned permanent shutdown of a number of currently producing reactors.

These issues clearly demonstrate that there is a role for governments to consider policies to encourage development and uptake of non-HEU-based ^{99}Mo and/or ^{99m}Tc, including through LEU target conversion at existing (and new entrant) producers and the development of new production technologies. This is necessary to ensure that there will be sufficient supply in the long term, when HEU may not be globally available for ^{99}Mo/^{99m}Tc production. In that context, there is a need for a reliable supply of LEU to ensure long-term sustainability for production technologies separating ^{99}Mo from irradiated LEU targets.

Purpose of policy options

The NEA was asked by its HLG-MR to examine the policy options that could be used by producing and/or consuming nations to encourage the uptake by producers and consumers of ^{99}Mo and/or ^{99m}Tc produced without HEU and respecting the need for a reliable supply of the medical isotopes. An expert working group examined the various policy options, as part of the larger LEU conversion market assessment project. The objective of the group was to determine policy options that could potentially be used to:

- Ensure a reliable supply of ^{99}Mo and/or ^{99m}Tc produced without HEU, consistent with the timeframes and policies of the HLG-MR.

Broadly speaking, the policy options examined and described in this document principally have one of three roles:

- Making the option of purchasing or producing non-HEU-based ^{99}Mo and/or ^{99m}Tc more attractive (an incentive).
- Making the option of purchasing or producing HEU-based ^{99}Mo and/or ^{99m}Tc less attractive (a deterrent).
- Limiting access to HEU-based ^{99}Mo and/or ^{99m}Tc (another deterrent).

Under these three roles, there are policy options that would be directed more towards changing producer behaviour and production decisions, and others that would be directed more towards changing consumer behaviour and purchasing decisions. In addition, some of the policy options should only be done individually to avoid "double-dipping"[6] into government support, while others could be compatible when coupled together. This paper will indicate which options have the potential to create a situation of "double-dipping" when coupled with other options.

This document represents the first stage in the process: a collection of the possible policy options, described briefly, with the advantages, disadvantages and potential variations for each. The purpose of providing these policy options is to enable individual countries to examine the various options in more detail, either individually or collectively. For example, further assessment would be required to determine the expected degree of impact from any of the suggested policy options, and the specific details of how to implement a policy option. While countries may have differing views on the various options, given their own economic, regulatory, or political situation, this discussion paper attempts to provide a brief review of the options from the starting point of the HLG-MR policy approach to achieving a long-term reliable supply of ^{99}Mo/^{99m}Tc[7].

One key issue examined and discussed in this discussion paper is whether the policy option is consistent with the HLG-MR principle of moving the ^{99}Mo/^{99m}Tc supply chain to full-cost recovery (FCR). The HLG-MR policy approach also recommends that governments consider encouraging LEU-target conversion and the development of non-HEU-based ^{99}Mo and/or ^{99m}Tc production, respecting the notion of FCR. Within this context, the NEA examined the options in this paper against the World Trade Organization's Agreement on Subsidies and Countervailing Measures (WTO ASCM) as a guide to what could be considered an acceptable subsidy (i.e. not distorting the market and negatively affecting the industry, thus respecting the notion of FCR), and what may be considered a non-acceptable subsidy within the context of the HLG-MR policy approach. Select relevant articles of the WTO ASCM are included in Annex 1 of this report.

The following table presents the potential policy options with a brief assessment for consideration by governments interested in taking policy action to encourage a reliable supply of ^{99}Mo and/or ^{99m}Tc produced without HEU. When governments are considering the options they should be cognisant of the available capacity to produce medical isotopes using LEU targets or alternative technologies and ensure that the chosen policy recognises the time required to build up that capacity[8]. For example, if a government prohibits HEU-based ^{99}Mo before there is sufficient capacity, this would only create shortages.

It should be noted that the policy options described in this document are not meant to be enacted by the NEA or necessarily solely by government departments represented on the HLG-MR; some of the policies presented in the following table would be the responsibility of other departments or private players (e.g., health insurers). Further, any and all of these policy options related to production from LEU targets start from the premise that there will be sufficient LEU available to global ^{99}Mo producers.

6. Double-dipping, in the context of this paper, refers to the situation where an entity would be paid twice for the same action. For example, double-dipping may occur if a processor were to receive a payment from government to cover their LEU-target conversion costs and the ^{99}Mo/^{99m}Tc produced from their facility were also to receive a premium payment for being sourced from a non-HEU-based sources, if the additional benefit was greater than required to create the incremental action. Incentives to create both a push and pull effect in the market may be acceptable (and not double-dipping) if both incentives were necessary to create the intended behavioural change.
7. Refer to the publication, *The Supply of Medical Radioisotopes: the Path to Reliability*, (OECD-NEA, 2011) for a full description of the policy approach.
8. Refer to the forthcoming publication, *The Supply of Medical Radioisotopes: Market Impacts of Converting to Low-Enriched Uranium Targets for Medical Isotope Production,* OECD-NEA (2012) for a description of available global non-HEU-based capacity.

Objective: Ensure a reliable supply of ^{99}Mo and/or ^{99m}Tc produced without HEU, consistent with the timeframes and policies of the HLG-MR

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns
Policy options to make the option of purchasing or producing non-HEU-based ^{99}Mo and/or ^{99m}Tc more attractive			
Premium pricing for non-HEU based ^{99m}Tc, based on data from NEA's LEU conversion impact study • Through health care system reimbursement rates **Beneficial if coupled with:** • A labelling system **Potential for concern if coupled with:** • Funding for non-HEU-based ^{99}Mo and/or ^{99m}Tc production capacity • Direct funding for capital costs of conversion projects	• The US Center for Medicare and Medicaid Services (CMS) has already proposed an incremental payment for ^{99m}Tc from non-HEU sources with full-cost recovery, starting in 2013 (pending final ruling in November 2012) • Might be possible to implement elsewhere in a quick timeframe (i.e. within a year in Europe) • Supports the concept of full-cost recovery as it is the payer that supports conversion • May provide an incentive to producers to convert to LEU targets or begin production without HEU targets (virtuous circle) rather than a penalty to HEU-based ^{99}Mo producers (vicious circle) • Could be a strong signal to producers to convert • Supports the HLG-MR policy approach recommendation that governments consider financially addressing the price differential until there is a level playing field between producers (when a majority of producers use non-HEU based sources)	• Could cause problems for those in transition; they are incurring costs but would not have access to the premium pricing • Generator manufacturers tend to blend the ^{99}Mo; they are not solely using HEU-based ^{99}Mo or LEU-based ^{99}Mo if they have any HEU-based ^{99}Mo in their supply chain, restricting access to premium pricing unless resolved • Could have an impact on health care budgets and therefore could require actions to ensure that insurers and governments are willing to pay premium prices and have the budgets to do so • Depending on the country, government mandates may only affect a small segment of the total health care market, thus not being sufficient to ensure that all insurers pay a premium price; however, spill-over effects may result in non-government insurers implementing similar premium pricing • This initiative would require auditing, creating an extra burden for the insurer, government health systems and/or industry • Potential for double-dipping if coupled with certain other policy options	• Premium pricing could be based on a ratio of non-HEU-based ^{99}Mo to HEU-based ^{99}Mo in the generator to recognise the transition phase, with a sliding scale on the premium based on the ratio, or a minimum content could be used to have access to premium pricing, increasing over time to encourage the move to 100% non-HEU-based ^{99}Mo content • However, reducing the premium price to account for this lesser content ratio due to blending may result in a premium price that is too insignificant for the hospital administration to account for it in their reporting, thus nullifying any potential benefits • It should be easy to audit a minimum amount content rule to support this scaled approach • A related (but less direct) option would be to provide a purchase incentive (see pp. 139 of the National Academies Report (National Research Council, 2009)), funded by domestic governments for a limited time (aligned with the majority of processors being converted); this could be provided to processors or generator manufacturers • Unbundling reimbursement of the isotope from the radiopharmaceutical and from the procedure could facilitate the implementation of premium pricing

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns
Labelling for sources of non-HEU-based ^{99}Mo and/or ^{99m}Tc **Beneficial if coupled with:** • Premium pricing • Tax incentives for non-HEU-based producers to help recover capital costs • Regulations or taxes on sales of HEU-based ^{99}Mo/^{99m}Tc • Preferential purchasing **Potential for concern if coupled with:** • No estimated direct impacts on/from other policies	• Sends a message to users of the implications of their purchase for reliability of supply and non-proliferation • Could be done quickly through a voluntary system; but could be supported through a longer-term move to mandatory labelling • Supportive of other policies	• Could cause problems for those in transition as they could face an unreceptive market while they are converting – affecting their business revenues possibly to the point where they could not continue producing ^{99}Mo/^{99m}Tc • Generator manufacturers tend to blend the ^{99}Mo; they are not using solely HEU-based ^{99}Mo or LEU-based ^{99}Mo if they have any HEU-based ^{99}Mo in their supply chain • Mandatory labelling would require some authority to provide and verify criteria and endorsement to the labelling; it would also require international consistency on the application of the criteria and issuance of certification	• A company that is converting but not yet completed could be labelled as " in transition" • Other related policies could be based on a ratio of non-HEU-based ^{99}Mo to HEU-based ^{99}Mo in the generator (e.g., a minimum non-HEU-based ^{99}Mo content), recognising this transition phase • It should be easy to audit a minimum amount content rule
Ensure expedient health regulatory approval for non-HEU based ^{99}Mo and/or ^{99m}Tc via government mandate to health regulatory agencies • Once approached by a commercial entity **Beneficial if coupled with:** • Any other policy as health approval is prerequisite for market access **Potential for concern if coupled with:** • No estimated direct impacts on/from other policies	• Would ensure a more streamlined path to approval for non-HEU-based ^{99}Mo producers • Could reduce regulatory costs and challenges for non-HEU-based ^{99}Mo producers • Health regulatory approvals are a minimum requirement for any of the other initiatives to work – if the non-HEU-based ^{99}Mo and/or ^{99m}Tc cannot be legally used in a country, none of the other initiatives will make a difference • Such expeditious health regulatory approval was provided in Canada and the US during the supply shortages, providing a good model for other countries to follow (and for Canada and the US to continue even in the post-shortage situation)	• Could be seen as circumventing appropriate health regulatory oversight	• Need to find the balance between expediency and appropriate regulatory oversight

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns
Funding for research and development of non-HEU-based ^{99}Mo and/or ^{99m}Tc production (e.g., developing (harmonised) new high-density targets) **Beneficial if coupled with:** • No estimated direct impacts on/from other policies **Potential for concern if coupled with:** • No estimated direct impacts on/from other policies	• R&D funding is a traditionally accepted government role where it supports its priorities • Non-proliferation is a priority of governments and therefore if R&D is required to convert to using LEU targets, or more broadly, for the production of non-HEU based ^{99}Mo and/or ^{99m}Tc, there could be a role for government support, with equal access to all firms, including working through relevant international organisations • Efforts are currently ongoing that could bring the open source R&D to a certain point of development • HLG-MR policy approach recommends government support for R&D related to LEU target conversion, if necessary • High-density target may be considered necessary to fully recover from the effects of the conversion externality • Following the example set by Article 8.2(a) of the WTO ASCM (see Annex 1), government support for R&D (respecting certain limits) is considered to be non-market distorting and acceptable within the context of the HLG-MR policy approach	• Target development is seen as a competitive advantage for the commercial companies in the supply chain and therefore international co-operation could be difficult • Conversion to densified LEU targets is necessary for non-proliferation reasons. Conversion to new high-density targets is a business decision and therefore government funding beyond generally accepted open-source R&D may not be appropriate, except for generally accepted open-source R&D	• Governments should ensure that funding is truly for R&D and does not become ongoing production or capital subsidies

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns

Funding for non-HEU-based ^{99}Mo and/or ^{99m}Tc production capacity:
• Financial support by governments for new non-HEU-based ^{99}Mo and/or ^{99m}Tc production capacity (not operating costs), including relevant components of research reactors or non-reactor based infrastructure and/or processing facilities
• Increase government investments in capital for developing domestic non-HEU-based ^{99}Mo producers (not operating costs)
 	
Beneficial if coupled with:
• Other policy actions as long as it does not result in double dipping
 	
Potential for concern if coupled with:
• Premium pricing
• Tax incentives for non-HEU-based producers to help recover capital costs
	• Supports new non-HEU-based ^{99}Mo production capacity that may not be able to proceed in today's current economic situation, which is still not based on full-cost recovery
	• Recognises that support for R&D may not be sufficient
	• Supports short-term supply as it encourages new infrastructure through direct funding, recognising that new infrastructure is required in the next few years to address the exit from the supply chain of some current irradiators
	• An argument can be made for funding ^{99}Mo related capital costs to accelerate new projects where such funding would not cause market distortions; for example, where the share of funding should not significantly affect the final full-cost recovery price; this appears to be supported under the original WTO ASCM article 8.2, related to assistance for pre-competitive development activity
	• May encourage a diversity of technologies to enter the market, leading to a more adaptable and reliable supply in the long term
	• The HLG-MR policy approach recognised that government financial support *with appropriate returns* could be necessary to facilitate infrastructure investments given the size of the required investments
		• Following the logic of the WTO ASCM, such funding may be market distorting if it causes serious prejudice by: providing a total ad valorem subsidisation of a product exceeding 5% for existing producers (for more information see article 6.1(a) and Annex IV of the WTO ASCM in Annex 1 of this paper); or providing funding to a start-up where the overall rate of subsidisation exceeds 15% of the total funds invested (for more information see Annex IV provided in Annex 1 of this paper)
		• If one global producing country does not implement full-cost recovery (by providing a significant share of new infrastructure funding), those remaining producers that do not have government financial support (most of the current and future major producing countries) may suffer from insufficient funds for infrastructure reinvestment and long-term security of supply could be threatened
		• May encourage non-commercial technologies to enter the market, that may lead to the long-term consequence of project failure or ongoing government funding for the additional infrastructure to ensure long-term security of supply; recently, this government funding has not been available for some of the current irradiation fleet
		• The HLG-MR policy approach stressed that the appropriate place for government funding of these important medical isotopes should be through the health care system as the desired product is effective diagnostic tests
		• Potential for double-dipping if coupled with certain other policy options
			• Some options (among others) that could potentially facilitate upfront investments with appropriate returns are:
			  • Government-backed loans
			  • Government funding of deferred loans
			  • Government purchases of equity positions in the project
			  However, these measures would have to be examined further to ensure that they do not confer a "benefit", as described in the WTO ASCM (refer also to the WTO overview of the ASCM at: www.wto.org/english/tratop_e/scm_e/subs_e.htm)
			• A government should be careful if they are implementing both differential pricing and significant funding for investments in capital to ensure that they are not creating the potential for double dipping

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns
Direct funding for capital costs of conversion projects **Beneficial if coupled with:** • No estimated direct impacts on/from other policies **Potential for concern if coupled with:** • Premium pricing (for ^{99}Mo and/or ^{99m}Tc from converted projects, but not from new projects) • Tax incentives for non-HEU-based producers to help recover capital costs	• LEU conversion is a clear externality to the market: there is no difference to the patient between LEU-based and HEU-based ^{99}Mo and/or ^{99m}Tc • Direct funding would recognise this externality and support conversion efforts • Supports the HLG-MR policy approach that recognises that there could be a role for governments to support general capital costs for conversion projects, *with appropriate returns* • Direct funding for capital costs of conversion projects could be considered an acceptable subsidy within the context of the HLG-MR policy approach, following the logic of the WTO ASCM, with the original Section 8, *Identification of Non-Actionable Subsidies,* Part (c), where assistance is deemed acceptable when it is to promote adaptation of existing facilities to new environmental requirements that result in greater constraints and financial burden on firms, provided that it is a one-time non-recurring measure and limited to 20 per cent of the cost of adaptation, etc.	• Such an initiative could result in general capital costs being supported, rather than capital costs for LEU-target conversion (e.g., new hot cells that are not required for conversion) as the distinction may not always be clear; if this were to occur, the initiative could be in conflict with the HLG-MR policy principle of FCR • If all governments do not provide equivalent funding for conversion projects, there could be market distorting effects by some global suppliers receiving greater funding than others • Potential for double-dipping if coupled with other certain policies	• Governments should ensure that funding would not become ongoing production or capital subsidies • Market-based policy approaches (such as preferential pricing policies) would avoid the confusion between capital funding and would focus support at the health system level

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns
Tax incentives for non-HEU-based producers to help recover capital costs **Beneficial if coupled with:** • A labelling system **Potential for concern if coupled with:** • Premium pricing • Funding for non-HEU-based ^{99}Mo and/or ^{99m}Tc production capacity • Direct funding for capital costs of conversion projects	• Tax incentives are a common tool and therefore could be considered acceptable in international commerce	• This initiative would only support domestic non-HEU based producers and would not encourage conversion by non-domestic global producers as they would not have access to the tax incentives; it could potentially discourage non-domestic suppliers from converting if it makes them less competitive, such that they will be further disadvantaged if they convert • In order to implement tax incentives, legislative approval may be required in most countries (if not all) and therefore may be difficult, and take a long time, to put in place • This action may be inconsistent with the HLG-MR policy principle of FCR, following the logic of Article 1.1 (ii) of the WTO ASCM, which indicates that a tax credit would be considered a subsidy, but would only be an actionable subsidy if it caused serious prejudice to the interest of international producers importing into the same market (as defined in Article 6.1) • Potential for double-dipping if coupled with other certain policies • The HLG-MR policy approach stressed that the appropriate place for government funding of this health product should be through the health care system as the desired product is effective diagnostic tests	• This option would require further examination by the considering government to determine whether the value of the possible tax incentive would be considered to create serious prejudice following the logic under Article 6.1 of the WTO ASCM • The considering government should ensure that the measures being considered would not create a situation of “double dipping” by converting or new non-HEU-based ^{99}Mo producers

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns
Policy options to make the option of purchasing or producing HEU-based ^{99}Mo and/or ^{99m}Tc less attractive			
Market must move to FCR • Governments require operators to move to full-cost recovery • Supply chain takes action to be able to support full-cost recovery, including through reimbursement rates **Beneficial if coupled with:** • Premium pricing **Potential for concern if coupled with:** • No estimated direct impacts on/from other policies	• This policy option is already a key recommendation to ensure the long-term supply of ^{99}Mo and/or ^{99m}Tc and therefore should already be being implemented • Moving to full-cost recovery is a necessary condition for the supply chain to be able to convert to using LEU targets and ensure long-term security of supply, since current irradiation of HEU targets is often subsidised by governments • Without the move to full-cost recovery, non-HEU-based ^{99}Mo will be competing with *subsidised* HEU-based ^{99}Mo, with a more significant cost differential than non-subsidised HEU-based ^{99}Mo • Without full-cost recovery, the mid- to long-term supply capacity is threatened, which would be further exacerbated by a move to LEU conversion	• The full-cost recovery policy was agreed to by all major producers and consumers; however, there is concern on the timing and actual commitment to implementation • It must be recognised that moving to full-cost recovery is not a sufficient policy action to ensure LEU conversion, but is a necessary policy to be coupled with other policy actions	• Unbundling of reimbursement rates so that reimbursement for the isotope is separate from the radiopharmaceutical and from the procedure is a tool to increase transparency on the necessary price increases, which could support the move to FCR

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns
Regulations or taxes on sales of HEU-based ^{99}Mo/^{99m}Tc **Beneficial if coupled with:** • A labelling system **Potential for concern if coupled with:** • No estimated direct impacts on/from other policies	• Would discourage the sale of HEU-based ^{99}Mo, and thus encourage the accelerated uptake of non-HEU based ^{99}Mo and/or ^{99m}Tc • Would be technology neutral as any non-HEU based ^{99}Mo and/or ^{99m}Tc could be encouraged • Regulations or taxes imposed in a few major consumer markets would force changes globally as it would likely be uneconomical for a producer to maintain HEU-based production only for smaller markets	• Imposing these regulations or taxes would require legislative approval in most countries (if not all) and therefore may be difficult, and take a long time, to put in place • Such an action sends a negative message and does not recognise the efforts of those in the conversion phase, punishing them while they are trying to convert	• This could be an initiative that is set aside for the current time and could be reconsidered once a majority of producers are using non-HEU sources. This would recognise those that are currently making efforts, giving them the time to undertake the conversion, but would provide a form of "back-stop" to ensure that all producers move to non-HEU sources • Another option would be to set a tax to begin in a few years time, giving all producers an incentive to convert on a particular schedule, thus removing the "negative message" concern • Revenues from taxes could be used to fund projects related to LEU-target conversion • Regulations could be based on: a) limiting imports of HEU-based ^{99}Mo, or b) limiting the percentage of HEU-based ^{99}Mo in total ^{99}Mo sold by a domestic company, either a processor or generator manufacturer • A regulation could be developed to only provide new health approvals for ^{99}Mo that comes from non-HEU based sources; however, this could be controversial since: a) there is no health-based difference between HEU- and non-HEU based sources of ^{99}Mo, and b) this would only affect new suppliers entering the market and would not directly affect those suppliers that already have health approval

Description of Policy Action	Advantages of policy	Disadvantages or concerns of policy	Potential variations on policy option to address concerns
Limiting access to HEU-based ^{99}Mo and/or ^{99m}Tc			
Preferential purchasing for non-HEU based ^{99}Mo and/or ^{99m}Tc through government mandate • Restrictions on health care funding being used for HEU-based ^{99}Mo/^{99m}Tc **Beneficial if coupled with:** • A labelling system **Potential for concern if coupled with:** • No estimated direct impacts on/from other policies	• Provides an incentive to producers to convert to LEU targets or begin production without HEU targets (virtuous circle) rather than a penalty to HEU-based ^{99}Mo producers (vicious circle) • Can be a strong signal to producers to convert • Depending on the country, government mandates may affect a large segment of the total health care market • Supports the HLG-MR policy approach recommendation for the development of market mechanisms to encourage conversion	• Depending on the country, government mandates may only affect a small segment of the total health care market • Could cause problems for those in transition as they could face an unreceptive market while they are converting – affecting their business revenues possibly to the point where they could not continue producing ^{99}Mo/^{99m}Tc • Generator manufacturers tend to blend the ^{99}Mo; they are not using solely HEU-based ^{99}Mo or LEU-based ^{99}Mo if they have any HEU-based ^{99}Mo in their supply chain and thus could face difficulties being purchased even with LEU-based ^{99}Mo content • Could reduce overall reliability in the short- to midterm if the preferential purchasing prevented HEU-based ^{99}Mo suppliers from appropriately accessing the market	• A company that is converting but not yet completed could be labelled as "in transition" • Preferential purchasing could be based on a ratio of non-HEU- to HEU- based ^{99}Mo in the generator (e.g., a minimum non-HEU-based ^{99}Mo content), recognising this transition phase • It should be easy to audit a minimum amount content rule • May require a waiver that this would be applicable "as long as a sufficient supply of non-HEU ^{99}Mo and/or ^{99m}Tc is available"
The US (as the major supplier of HEU) sets an end date on HEU exports or increases prices substantially (for HEU for ^{99}Mo production) • Variation could be a staged process of making access more difficult **Beneficial if coupled with:** • No estimated direct impacts on/from other policies **Potential for concern if coupled with:** • No estimated direct impacts on/from other policies	• Very direct and excellent motivator – if no HEU is available for ^{99}Mo/^{99m}Tc production, the supply chain will not be able to produce HEU-based ^{99}Mo/^{99m}Tc	• It would be very difficult for the US to increase HEU prices; they are required to operate on a full-cost recovery basis and do not have great flexibility to increase prices further • It is likely that changing HEU prices for non-proliferation reasons would be seen as manipulating the international trade system and would be counter to international commitments by the US • It is not clear what additional impacts such restrictions could add, given existing provisions in the US Energy Policy Act of 2005, proposed provisions in S.99 and the commitments in the *Belgium-France-Netherlands-United States Joint Statement on Minimisation of HEU and the Reliable supply of Medical Radioisotopes* (Seoul Nuclear Security Summit); Russia has its own source of HEU, European producers have agreed to convert through other agreements, Canada has declared that it will no longer produce ^{99}Mo from the NRU after 2016; however, these commitments and proposed provisions should be respected/enacted	• Additional detail on the specific criteria that could be used to justify export restrictions through the S.99 or the Energy Policy Act of 2005 would be useful. These criteria and progress towards meeting them should be communicated proactively to ensure that the supply chain is prepared for the restrictions, if they were to come into effect • In order to ensure supply security, this policy action may require a waiver that it would be applicable "as long as a sufficient supply of non-HEU ^{99}Mo and/or ^{99m}Tc is available for the global market"

Conclusion

This discussion paper provides the various policy options available to governments to encourage a reliable supply of ^{99}Mo and/or ^{99m}Tc produced without HEU. The examination of these options was done through the lens of ensuring a reliable supply, consistent with the timeframes and policies of the HLG-MR.

The options described in this document are meant to meet this objective by taking one of three general actions:

- Making the option of purchasing or producing non-HEU-based ^{99}Mo and/or ^{99m}Tc more attractive.
- Making the option of purchasing or producing HEU-based ^{99}Mo and/or ^{99m}Tc less attractive.
- Limiting access to HEU-based ^{99}Mo and/or ^{99m}Tc.

This paper presents the options in each category and provides some views on the advantages and disadvantages of each policy option, including their potential consistency with the HLG-MR policy approach. In addition, the WTO ASCM was used to provide clarity on what options may be considered as market distorting subsidies within the context of the HLG-MR policy approach and thus should be avoided.

Recognising that countries may have different views on the feasibility or desirability of implementing the options described in this document, the discussion paper provides the foundation for countries to undertake their own examination of which policies support their own economic, regulatory, or political situation. Additional assessment would be required by countries (individually or collectively) to determine, for example, the expected degree of impact from any of the suggested policy options and the specific details of how to implement a policy option. Policies selected for further evaluation should be consistent with the HLG-MR policy approach and governments should be careful not to unintentionally create a double-dipping effect.

The NEA, by developing this discussion paper, has provided the views of various experts on the full range of policy options available and has done its best to provide a brief assessment of the various options. The NEA and its HLG-MR, at the current time, does not necessarily endorse any of the options presented in this document; they are provided for information purposes only. However, the NEA strongly encourages further work to develop and implement policy options to encourage a reliable supply of ^{99}Mo and/or ^{99m}Tc produced without HEU, consistent with the timeframes and policies of the HLG-MR. Without such action, the long-term reliable supply of ^{99}Mo and/or ^{99m}Tc could continue to be threatened.

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Annex 1. Select passages from the World Trade Organization's

Agreement on Subsidies and Countervailing Measures[9]

Part I: General provisions

Article 1

Definition of a Subsidy

1.1. For the purpose of this Agreement, a subsidy shall be deemed to exist if:

(a)(1) there is a financial contribution by a government or any public body within the territory of a Member (referred to in this Agreement as "government"), i.e. where:

(i) a government practice involves a direct transfer of funds (e.g. grants, loans, and equity infusion), potential direct transfers of funds or liabilities (e.g. loan guarantees);

(ii) government revenue that is otherwise due is foregone or not collected (e.g. fiscal incentives such as tax credits)[10];

(iii) a government provides goods or services other than general infrastructure, or purchases goods;

(iv) a government makes payments to a funding mechanism, or entrusts or directs a private body to carry out one or more of the type of functions illustrated in (i) to (iii) above which would normally be vested in the government and the practice, in no real sense, differs from practices normally followed by governments;

or

(a)(2) there is any form of income or price support in the sense of Article XVI of GATT 1994;

and

(b) a benefit is thereby conferred.

Part II: Prohibited subsidies

[Note: Not relevant to us as related to being contingent on export performance or on using domestic over imported goods. Neither directly apply in the case of isotopes.]

9. Taken from www.wto.org/english/docs_e/legal_e/24-scm.pdf.

10. In accordance with the provisions of Article XVI of GATT 1994 (Note to Article XVI) and the provisions of Annexes I through III of this Agreement, the exemption of an exported product from duties or taxes borne by the like product when destined for domestic consumption, or the remission of such duties or taxes in amounts not in excess of those which have accrued, shall not be deemed to be a subsidy.

Part III: Actionable subsidies

Article 5

Adverse Effects

No Member should cause, through the use of any subsidy referred to in paragraphs 1 and 2 of Article 1, adverse effects to the interests of other Members, i.e.:

(a) injury to the domestic industry of another Member[11];

(b) nullification or impairment of benefits accruing directly or indirectly to other Members under GATT 1994 in particular the benefits of concessions bound under Article II of GATT 1994[12];

(c) serious prejudice to the interests of another Member.[13]

This Article does not apply to subsidies maintained on agricultural products as provided in Article 13 of the Agreement on Agriculture.

Article 6

Serious Prejudice

6.1. Serious prejudice in the sense of paragraph (c) of Article 5 shall be deemed to exist in the case of:

(a) the total ad valorem subsidisation[14] of a product exceeding 5 per cent[15];

(b) subsidies to cover operating losses sustained by an industry;

(c) subsidies to cover operating losses sustained by an enterprise, other than one-time measures which are non-recurrent and cannot be repeated for that enterprise and which are given merely to provide time for the development of long-term solutions and to avoid acute social problems;

(d) direct forgiveness of debt, i.e. forgiveness of government-held debt, and grants to cover debt repayment.[16]

6.2. Notwithstanding the provisions of paragraph 1, serious prejudice shall not be found if the subsidising Member demonstrates that the subsidy in question has not resulted in any of the effects enumerated in paragraph 3.

6.3. Serious prejudice in the sense of paragraph (c) of Article 5 may arise in any case where one or several of the following apply:

(a) the effect of the subsidy is to displace or impede the imports of a like product of another Member into the market of the subsidising Member;

11. The term "injury to the domestic industry" is used here in the same sense as it is used in Part V.
12. The term "nullification or impairment" is used in this Agreement in the same sense as it is used in the relevant provisions of GATT 1994, and the existence of such nullification or impairment shall be established in accordance with the practice of application of these provisions.
13. The term "serious prejudice to the interests of another Member" is used in this Agreement in the same sense as it is used in paragraph 1 of Article XVI of GATT 1994, and includes threat of serious prejudice.
14. The total ad valorem subsidisation shall be calculated in accordance with the provisions of Annex IV.
15. Since it is anticipated that civil aircraft will be subject to specific multilateral rules, the threshold in this subparagraph does not apply to civil aircraft.
16. Members recognise that where royalty-based financing for a civil aircraft programme is not being fully repaid due to the level of actual sales falling below the level of forecast sales, this does not in itself constitute serious prejudice for the purposes of this subparagraph.

(b) the effect of the subsidy is to displace or impede the exports of a like product of another Member from a third country market;

(c) the effect of the subsidy is a significant price undercutting by the subsidised product as compared with the price of a like product of another Member in the same market or significant price suppression, price depression or lost sales in the same market;

(d) the effect of the subsidy is an increase in the world market share of the subsidising Member in a particular subsidised primary product or commodity[17] as compared to the average share it had during the previous period of three years and this increase follows a consistent trend over a period when subsidies have been granted.

For the purpose of paragraph 3(b), the displacement or impeding of exports shall include any case in which, subject to the provisions of paragraph 7, it has been demonstrated that there has been a change in relative shares of the market to the disadvantage of the non-subsidised like product (over an appropriately representative period sufficient to demonstrate clear trends in the development of the market for the product concerned, which, in normal circumstances, shall be at least one year). "Change in relative shares of the market" shall include any of the following situations: *(a)* there is an increase in the market share of the subsidised product; *(b)* the market share of the subsidised product remains constant in circumstances in which, in the absence of the subsidy, it would have declined; *(c)* the market share of the subsidised product declines, but at a slower rate than would have been the case in the absence of the subsidy.

6.5. For the purpose of paragraph 3(c), price undercutting shall include any case in which such price undercutting has been demonstrated through a comparison of prices of the subsidised product with prices of a non-subsidised like product supplied to the same market. The comparison shall be made at the same level of trade and at comparable times, due account being taken of any other factor affecting price comparability. However, if such a direct comparison is not possible, the existence of price undercutting may be demonstrated on the basis of export unit values.

6.6. Each Member in the market of which serious prejudice is alleged to have arisen shall, subject to the provisions of paragraph 3 of Annex V, make available to the parties to a dispute arising under Article 7, and to the panel established pursuant to paragraph 4 of Article 7, all relevant information that can be obtained as to the changes in market shares of the parties to the dispute as well as concerning prices of the products involved.

6.7. Displacement or impediment resulting in serious prejudice shall not arise under paragraph 3 where any of the following circumstances exist[18] during the relevant period:

(a) prohibition or restriction on exports of the like product from the complaining Member or on imports from the complaining Member into the third country market concerned;

(b) decision by an importing government operating a monopoly of trade or state trading in the product concerned to shift, for non-commercial reasons, imports from the complaining Member to another country or countries;

(c) natural disasters, strikes, transport disruptions or other *force majeure* substantially affecting production, qualities, quantities or prices of the product available for export from the complaining Member;

17. Unless other multilaterally agreed specific rules apply to the trade in the product or commodity in question.

18. The fact that certain circumstances are referred to in this paragraph does not, in itself, confer upon them any legal status in terms of either GATT 1994 or this Agreement. These circumstances must not be isolated, sporadic or otherwise insignificant.

(d) existence of arrangements limiting exports from the complaining Member;

(e) voluntary decrease in the availability for export of the product concerned from the complaining Member (including, *inter alia*, a situation where firms in the complaining Member have been autonomously reallocating exports of this product to new markets);

(f) failure to conform to standards and other regulatory requirements in the importing country.

6.8. In the absence of circumstances referred to in paragraph 7, the existence of serious prejudice should be determined on the basis of the information submitted to or obtained by the panel, including information submitted in accordance with the provisions of Annex V.

6.9. This Article does not apply to subsidies maintained on agricultural products as provided in Article 13 of the Agreement on Agriculture.

Part IV: Non-actionable subsidies

Article 8

Identification of Non-Actionable Subsidies

8.1. The following subsidies shall be considered as non-actionable[19]:

(a) subsidies which are not specific within the meaning of Article 2;

(b) subsidies which are specific within the meaning of Article 2 but which meet all of the conditions provided for in paragraphs 2(a), 2(b) or 2(c) below.

8.2. Notwithstanding the provisions of Parts III and V, the following subsidies shall be non-actionable:

(a) assistance for research activities conducted by firms or by higher education or research establishments on a contract basis with firms if:[20] ,[21] ,[22]

19. It is recognised that government assistance for various purposes is widely provided by Members and that the mere fact that such assistance may not qualify for non-actionable treatment under the provisions of this Article does not in itself restrict the ability of Members to provide such assistance.

20. Since it is anticipated that civil aircraft will be subject to specific multilateral rules, the provisions of this subparagraph do not apply to that product.

21. Not later than 18 months after the date of entry into force of the WTO Agreement, the Committee on Subsidies and Countervailing Measures provided for in Article 24 (referred to in this Agreement as "the Committee") shall review the operation of the provisions of subparagraph 2(a) with a view to making all necessary modifications to improve the operation of these provisions. In its consideration of possible modifications, the Committee shall carefully review the definitions of the categories set forth in this subparagraph in the light of the experience of Members in the operation of research programmes and the work in other relevant international institutions.

22. The provisions of this Agreement do not apply to fundamental research activities independently conducted by higher education or research establishments. The term "fundamental research" means an enlargement of general scientific and technical knowledge not linked to industrial or commercial objectives.

the assistance covers[23] not more than 75 per cent of the costs of industrial research[24] or 50 per cent of the costs of pre-competitive development activity[25], [26]; and provided that such assistance is limited exclusively to:

(i) costs of personnel (researchers, technicians and other supporting staff employed exclusively in the research activity);

(ii) costs of instruments, equipment, land and buildings used exclusively and permanently (except when disposed of on a commercial basis) for the research activity;

(iii) costs of consultancy and equivalent services used exclusively for the research activity, including bought-in research, technical knowledge, patents, etc.;

(iv) additional overhead costs incurred directly as a result of the research activity;

(v) other running costs (such as those of materials, supplies and the like), incurred directly as a result of the research activity.

(b) assistance to disadvantaged regions within the territory of a Member given pursuant to a general framework of regional development [27] and non-specific (within the meaning of Article 2) within eligible regions provided that:

(i) each disadvantaged region must be a clearly designated contiguous geographical area with a definable economic and administrative identity;

(ii) the region is considered as disadvantaged on the basis of neutral and objective criteria[28], indicating that the region's difficulties arise out of more

23. The allowable levels of non-actionable assistance referred to in this subparagraph shall be established by reference to the total eligible costs incurred over the duration of an individual project.

24. The term "industrial research" means planned search or critical investigation aimed at discovery of new knowledge, with the objective that such knowledge may be useful in developing new products, processes or services, or in bringing about a significant improvement to existing products, processes or services.

25. The term "pre-competitive development activity" means the translation of industrial research findings into a plan, blueprint or design for new, modified or improved products, processes or services whether intended for sale or use, including the creation of a first prototype which would not be capable of commercial use. It may further include the conceptual formulation and design of products, processes or services alternatives and initial demonstration or pilot projects, provided that these same projects cannot be converted or used for industrial application or commercial exploitation. It does not include routine or periodic alterations to existing products, production lines, manufacturing processes, services, and other ongoing operations even though those alterations may represent improvements.

26. In the case of programmes which span industrial research and pre-competitive development activity, the allowable level of non-actionable assistance shall not exceed the simple average of the allowable levels of non-actionable assistance applicable to the above two categories, calculated on the basis of all eligible costs as set forth in items (i) to (v) of this subparagraph.

27. A "general framework of regional development" means that regional subsidy programmes are part of an internally consistent and generally applicable regional development policy and that regional development subsidies are not granted in isolated geographical points having no, or virtually no, influence on the development of a region.

28. "Neutral and objective criteria" means criteria which do not favour certain regions beyond what is appropriate for the elimination or reduction of regional disparities within the framework of the regional development policy. In this regard, regional subsidy programmes shall include ceilings on the amount of assistance which can be granted to each subsidised project. Such ceilings must be differentiated according to the different levels of development of assisted regions and must be expressed in terms of investment costs or cost of job creation. Within such ceilings, the distribution of assistance shall be sufficiently broad and even to avoid the predominant use of a subsidy by, or the granting of disproportionately large amounts of subsidy to, certain enterprises as provided for in Article 2.

than temporary circumstances; such criteria must be clearly spelled out in law, regulation, or other official document, so as to be capable of verification;

(iii) the criteria shall include a measurement of economic development which shall be based on at least one of the following factors:

- one of either income per capita or household income per capita, or GDP per capita, which must not be above 85 per cent of the average for the territory concerned;
- unemployment rate, which must be at least 110 per cent of the average for the territory concerned;

as measured over a three-year period; such measurement, however, may be a composite one and may include other factors.

(c) assistance to promote adaptation of existing facilities[29] to new environmental requirements imposed by law and/or regulations which result in greater constraints and financial burden on firms, provided that the assistance:

(i) is a one-time non-recurring measure; and

(ii) is limited to 20 per cent of the cost of adaptation; and

(iii) does not cover the cost of replacing and operating the assisted investment, which must be fully borne by firms; and

(iv) is directly linked to and proportionate to a firm's planned reduction of nuisances and pollution, and does not cover any manufacturing cost savings which may be achieved; and

(v) is available to all firms which can adopt the new equipment and/or production processes.

Part V: Countervailing measures

Article 11

Initiation and Subsequent Investigation

11.8. In cases where products are not imported directly from the country of origin but are exported to the importing Member from an intermediate country, the provisions of this Agreement shall be fully applicable and the transaction or transactions shall, for the purposes of this Agreement, be regarded as having taken place between the country of origin and the importing Member.

Article 14

Calculation of the amount of a subsidy in terms of the benefit to the recipient

For the purpose of Part V, any method used by the investigating authority to calculate the benefit to the recipient conferred pursuant to paragraph 1 of Article 1 shall be provided for in the national legislation or implementing regulations of the Member concerned and its application to each particular case shall be transparent and adequately explained. Furthermore, any such method shall be consistent with the following guidelines:

(a) government provision of equity capital shall not be considered as conferring a benefit, unless the investment decision can be regarded as inconsistent with the

29. The term "existing facilities" means facilities which have been in operation for at least two years at the time when new environmental requirements are imposed.

usual investment practice (including for the provision of risk capital) of private investors in the territory of that Member;

(b) a loan by a government shall not be considered as conferring a benefit, unless there is a difference between the amount that the firm receiving the loan pays on the government loan and the amount the firm would pay on a comparable commercial loan which the firm could actually obtain on the market. In this case the benefit shall be the difference between these two amounts;

(c) a loan guarantee by a government shall not be considered as conferring a benefit, unless there is a difference between the amount that the firm receiving the guarantee pays on a loan guaranteed by the government and the amount that the firm would pay on a comparable commercial loan absent the government guarantee. In this case the benefit shall be the difference between these two amounts adjusted for any differences in fees;

(d) the provision of goods or services or purchase of goods by a government shall not be considered as conferring a benefit unless the provision is made for less than adequate remuneration, or the purchase is made for more than adequate remuneration. The adequacy of remuneration shall be determined in relation to prevailing market conditions for the good or service in question in the country of provision or purchase (including price, quality, availability, marketability, transportation and other conditions of purchase or sale).

Article 15

Determination of Injury[30]

15.1. A determination of injury for purposes of Article VI of GATT 1994 shall be based on positive evidence and involve an objective examination of both *(a)* the volume of the subsidised imports and the effect of the subsidised imports on prices in the domestic market for like products[31] and *(b)* the consequent impact of these imports on the domestic producers of such products.

15.4. The examination of the impact of the subsidised imports on the domestic industry shall include an evaluation of all relevant economic factors and indices having a bearing on the state of the industry, including actual and potential decline in output, sales, market share, profits, productivity, return on investments, or utilisation of capacity; factors affecting domestic prices; actual and potential negative effects on cash flow, inventories, employment, wages, growth, ability to raise capital or investments and, in the case of agriculture, whether there has been an increased burden on government support programmes. This list is not exhaustive, nor can one or several of these factors necessarily give decisive guidance.

15.5. It must be demonstrated that the subsidised imports are, through the effects[32] of subsidies, causing injury within the meaning of this Agreement. The demonstration of a causal relationship between the subsidised imports and the injury to the domestic industry shall be based on an examination of all relevant evidence before the authorities. The authorities shall also examine any known factors other than the subsidised imports

30. Under this Agreement the term "injury" shall, unless otherwise specified, be taken to mean material injury to a domestic industry, threat of material injury to a domestic industry or material retardation of the establishment of such an industry and shall be interpreted in accordance with the provisions of this Article.

31. Throughout this Agreement the term "like product" ("*produit similaire*") shall be interpreted to mean a product which is identical, i.e. alike in all respects to the product under consideration, or in the absence of such a product, another product which, although not alike in all respects, has characteristics closely resembling those of the product under consideration.

32. As set forth in paragraphs 2 and 4.

which at the same time are injuring the domestic industry, and the injuries caused by these other factors must not be attributed to the subsidised imports. Factors which may be relevant in this respect include, *inter alia*, the volumes and prices of non-subsidised imports of the product in question, contraction in demand or changes in the patterns of consumption, trade restrictive practices of and competition between the foreign and domestic producers, developments in technology and the export performance and productivity of the domestic industry.

Annex IV: Calculation of the total ad valorem subsidisation (Paragraph 1(A) of Article 6)[33]

1. Any calculation of the amount of a subsidy for the purpose of paragraph 1(a) of Article 6 shall be done in terms of the cost to the granting government.

2. Except as provided in paragraphs 3 through 5, in determining whether the overall rate of subsidisation exceeds 5 per cent of the value of the product, the value of the product shall be calculated as the total value of the recipient firm's[34] sales in the most recent 12-month period, for which sales data is available, preceding the period in which the subsidy is granted.[35]

3. Where the subsidy is tied to the production or sale of a given product, the value of the product shall be calculated as the total value of the recipient firm's sales of that product in the most recent 12-month period, for which sales data is available, preceding the period in which the subsidy is granted.

4. Where the recipient firm is in a start-up situation, serious prejudice shall be deemed to exist if the overall rate of subsidisation exceeds 15 per cent of the total funds invested. For purposes of this paragraph, a start-up period will not extend beyond the first year of production.[36]

5. Where the recipient firm is located in an inflationary economy country, the value of the product shall be calculated as the recipient firm's total sales (or sales of the relevant product, if the subsidy is tied) in the preceding calendar year indexed by the rate of inflation experienced in the 12 months preceding the month in which the subsidy is to be given.

33. An understanding among Members should be developed, as necessary, on matters which are not specified in this Annex or which need further clarification for the purposes of paragraph 1(a) of Article 6.
34. The recipient firm is a firm in the territory of the subsidising Member.
35. In the case of tax-related subsidies the value of the product shall be calculated as the total value of the recipient firm's sales in the fiscal year in which the tax-related measure was earned.
36. Start-up situations include instances where financial commitments for product development or construction of facilities to manufacture products benefiting from the subsidy have been made, even though production has not begun.