UN/SCETDG/23/INF.27
UN/SCEGHS/5/INF.13

COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the Transport of Dangerous Goods
(Twenty-third session, 30 juin-4 July 2003
Agenda item ou 7(b))

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals
(Fifth session, 7-9 July 2003,
Agenda item 3)

Cooperation with other international organizations

GHS promotion/ Basel Convention

Transmitted by the secretariat

The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal held the first session of its Open-Ended Working Group in Geneva, 28 April to 2 May 2003. This Group has been created to advise on and continuously review the implementation of the Convention and of its decisions. In particular it rewieved the progress made on Decision VI/37 on the hazardous characteristics of certain categories of waste (H6.2 infectious subtstances), H10 (liberation of toxic gases), H11 (toxic/delayed or chronic) and H13 (capable , by any means after disposal, of yielding another material).

Extracts of the draft session report of the Open-Ended Working Group regarding current and further work on this issue and decisions made by the Group regarding issues linked to the TDG and GHS are attached in the following pages. The draft guidance paper prepared by the United Kingdom on hazardous characteristics H6.2 (infectious substances) is inserted as annex 1 to this document. The draft scoping paper of the United States on hazardous characteristic H11 (toxic, delayed or chronic) is included as annex 2. Both papers have been posted on the Basel Convention website for comments.

Extracts of the report of the 1st session of the Open-ended Working Group of the Basel Convention

[……] G. Decision VI/37 – Work Programme of the Open-ended Working Group

1. Finalization of work on the hazardous characteristics H6.2, H10, H11 and H13

74. The Working Group took up the sub-item at its fifth meeting, on the morning of Wednesday, 30 April.

75. The Working Group had before it a note by the secretariat on the finalization of work on the hazardous characteristics H6.2, H10, H11 and H13 (UNEP/CHW/OEWG/1/8), a draft scoping paper by the United States of America on hazardous characteristic H11 (UNEP/CHW/OEWG/1/INF/8), a status report by a consultant on hazardous characteristic H13 (UNEP/CHW/OEWG/1/INF/9) and a conference room paper containing a report and draft guidance paper by the United Kingdom on hazard characteristic H6.2. The draft guidance paper as submitted by the United Kingdom will be posted on the Basel Convention web site for comment.

76. The representative of the United Kingdom introduced the report and draft guidance paper prepared by his delegation on hazardous characteristic H6.2 (infectious substances) and referred to the possible need to revise the characteristic to take into account changes in the definition of infectious substances in the Model Regulations of the Subcommittee of Experts on the Transport of Dangerous Goods (UNSCETDG) of the United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals.

77. The view was expressed that the H6.2 definition should indeed be brought into line with the UNSCETDG changes: the existing definition did not reflect the fact that many pathogens were not infectious outside their hosts, and was more suited to the risks posed by laboratory work than those posed by the wastes and activities within the scope of the Basel Convention. It was suggested also that it should be borne in mind how the revised definition would be interpreted on the ground: it had been observed that people in the medical profession and the transport sector often had different understandings. The draft guidance should also include a table comparing the approaches taken by the World Health Organization and UNSCETDG.

78. The representative of the Netherlands reported on progress on a draft paper being prepared by his delegation on the hazardous characteristic H10 (liberation of toxic gases), which was not yet ready.

79. The observer from UNECE explained that the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) had been adopted in December 2002, with the goal of protecting people and the environment from the harmful effects of chemicals, and was available, in English and French, to all who wished to use it on web site http://www.unece.org/trans/danger/publi/ghs/ghs.html. GHS had been developed pursuant to chapter 19 of Agenda 21,[1] and the Johannesburg Summit had encouraged countries to implement it in full by 2008.[2] GHS covered 26 classes of hazard, of which 16 were physical hazards which corresponded to the categories established for the transport of hazardous materials referred to in Annex III of the Basel Convention. Also, GHS included a class for materials presenting a serious hazard to human health and eight others covered the chronic (H11) hazards posed by eye, skin and respiratory irritants, carcinogens, mutagens and genotoxic substances. Each hazard class was subdivided into categories by degree of hazard depending on specific threshold concentration levels of the chemical. GHS was based on the intrinsic properties of the chemicals and described hazard rather than risk, which depended on both the hazard and the exposure to that hazard and therefore

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[1] *Report of the United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992* (United Nations publication, Sales No. E.93.I.8 and corrigenda), vol. I: *Resolutions adopted by the Conference*, resolution 1, annex II.

[2] *Report of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August-4 September 2002* (United Nations publication, Sales No. E.03.II.A.1 and corrigendum), chap. III, subpara. 23 (c).

varied depending on the situation. GHS also made provision to communicate the hazard classification for purposes of labelling or for posting in the workplace. In that connection, GHS had pictograms for every hazard type, including chronic hazards to human health. GHS had obvious relevance for the waste classification work under the Basel Convention, in which the sister body to UNSCETDG, the Subcommittee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (UNSCEGHS), was very interested: indeed, the Basel Convention secretariat had been invited to give a presentation on the Basel approach to waste classification at the next session of UNSCEGHS, in July 2003.

80. The representative of the United States of America introduced the draft scoping paper prepared by the United States Environmental Protection Agency (UNEP/CHW/OEWG/1/INF/8) on hazardous characteristic H11 (toxic (delayed or chronic)). The comment was made that the waste constituent hazard categories in appendix A of the draft paper appeared to be realistic and also to conform to the approach taken by the Inter-Organization Programme for the Sound Management of Chemicals (IOMC) in the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS). The point was made that there should be agreement on the source to be used for chronic toxicity data and on what should be done when such data was incomplete or unavailable.

81. In the discussion on hazardous characteristic H13 (capable, by any means after disposal, of yielding another material), one representative recommended that the way forward suggested by the consultant in paragraph 11 of document UNEP/CHW/OEWG/INF/9 should be incorporated into the draft decision of the Working Group on that issue.

82. The draft decision on hazardous characteristics was adopted, as orally amended, and is reproduced in annex I to the present report as decision OEWG-I/7.

OEWG-I/7 Finalization of work on the hazardous characteristics H6.2, H10, H11 and H13; and initiation of work on the other hazardous characteristics of Annex III

The Open-ended Working Group,

Recalling decision VI/37 insofar as it refers to the work on hazardous characteristics H6.2, H10, H11 and H13,

Noting that the Open-ended Working Group was requested by the Conference of the Parties at its sixth meeting by that same decision to continue its work on the hazardous characteristics H6.2, H10, H11 and H13,

Recognizing the usefulness of developing practical guidance on all Annex III hazardous characteristics to assist Parties and other stakeholders to implement the Basel Convention effectively,

H6.2

1. Invites the small intersessional working group to continue providing guidance to the delegation of the United Kingdom in completing work on characteristic H6.2;

2. Encourages the delegation of the United Kingdom, with the support of the small intersessional working group and other Parties and stakeholders, to finalize the paper on the hazardous characteristic H6.2 for consideration by the Open-ended Working Group at its third session and submission to the Conference of the Parties at its seventh meeting;

3. Invites Parties and other stakeholders to provide comments to the United Kingdom, with copy to the secretariat, by 30 September 2003, to enable the delegation of the United Kingdom to finalize the paper on hazardous characteristic H6.2;

H10

4. Also invites Parties and others to provide comments to the delegation of the Netherlands, with copy to the secretariat, by 31 October 2003 to enable the delegation of the Netherlands to prepare a consolidated revised version of the draft paper on the hazardous characteristic H10 for consideration by the Open-ended Working Group at its third session and submission to the Conference of the Parties at its seventh meeting;

H11

5. Further invites Parties and others to provide comments to the delegation of the United States of America, with a copy to the secretariat, by 30 September 2003 on the hazardous characteristic H11;

6. Requests the secretariat to prepare a consolidated paper on the hazardous characteristic H11 for consideration by the Open-ended Working Group at its third session and submission to the Conference of the Parties at its seventh meeting;

H13

7. Invites Parties and others to provide the secretariat with comments by 30 September 2003 on the hazardous characteristic H13;

8. Requests the secretariat to continue to work on the elaboration of the assessment procedure for leachate and to gather additional information about practical experience and suggestions for potential worst-case scenarios for other materials;

9. Further requests the secretariat to prepare a consolidated revised version of the paper on the hazardous characteristic H13 for submission to the Open-ended Working Group at its third session and for submission to the Conference of the Parties at its seventh meeting;

Initiation of work on hazardous characteristics not yet covered

10. Invites Parties and others to contribute technically and financially to the initiation of work on other Basel Convention Annex III hazardous characteristics ;

Communication

11. Requests the secretariat to display the ongoing or planned work on hazardous characteristics on the Basel Convention web site to enable Parties and others to review progress, exchange views and provide comments on a regular basis.

OEWG-I/14 Decision VI/40: Follow-up to the World Summit on Sustainable Development

The Open-ended Working Group,

Recalling decision VI/40 of the Conference of the Parties, and in particular its paragraph 3 requesting the secretariat to propose a way forward in implementing concrete activities in this area within the available resources,

1. Requests the secretariat to undertake a review of ongoing and planned activities funded in the context of the Strategic Plan with a view to identifying activities that support the objectives of the World Summit on Sustainable Development directly, in an incremental way or indirectly;[3]

2. Also requests the secretariat to review the business plans prepared by the Basel Convention Regional Centres to identify how each Centre is supporting, can support or will support the objectives of the Johannesburg Summit;

3. Further requests the secretariat to identify the principal international initiatives and programmes, including but not limited to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), the Intergovernmental Forum on Chemical Safety (IFCS), the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), the Pollutant Release and Transfer Register (PRTR) initiative and the Strategic Approach to International Chemicals Management (SAICM), in which the waste dimension must be adequately taken into account to meet the expectations and objectives of the Johannesburg Summit in respect of the life-cycle management of materials;[4]

4. Requests the secretariat to prepare a report on the above matters, including proposals for the way forward, for consideration by the Open-ended Working Group at its third session.

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[3] See *Report of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August-4 September 2002* (United Nations publication, Sales No. E.03.II.A.1 and corrigendum), chap. I, resolution 2, annex.

[4] Ibid., chap. III, para. 23.

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OPEN-ENDED WORKING GROUP OF THE BASEL CONVENTION ON THE CONTROL OF TRANSBOUNDARY MOVEMENTS OF HAZARDOUS WASTES AND THEIR DISPOSAL
First session
Geneva, 28 April to 2 May 2003

Item 5 (g) (i) of the provisional agenda*

HAZARDOUS CHARACTERISTIC H11 – TOXIC (DELAYED OR CHRONIC)

Attached is the draft scoping paper on hazardous characteristic H11 as submitted by the United States.

* UNEP/CHW/OEWG/1/1

Draft Scoping Paper for Elaboration of
Basel Annex III Hazardous Characteristics
H-11, Toxic (Chronic or Delayed)

A Proposed Approach to the
Basel Convention Hazardous Characteristic: H-11

CHARACTERIZATION OF CHRONIC OR DELAYED TOXICITY

Prepared by the US EPA
March 28, 2003

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1. Introduction

The present document discusses proposed criteria for classifying wastes with regard to the delayed or chronic toxic hazard, H-11, under the Basel Convention. A key goal of the Basel Convention is ensuring protection of human health and the environment during the management and transboundary movement of waste. The Annex III hazardous characteristics work with the Annex VIII and IX waste lists to accomplish this goal. In general terms, this means that people and the ecology should be protected against potential adverse effects caused by the generation, transport, handling and recycling or disposal of waste. In terms of delayed or chronic toxicity, protection is to be ensured when those adverse effects may result from very low but prolonged exposure of people to waste, or adverse effects occurring long after exposure has ceased. When the hazards posed by a waste are too great, the waste is classified as Basel hazardous, and the range of Basel controls and protections will apply.

According to the Basel Convention, Annex III, the hazard characteristic: H11 "Toxic (Delayed or chronic)" is defined as:

> "Substances or wastes which, if they are inhaled or ingested, or if they penetrate the skin, may involve delayed or chronic effects, including carcinogenicity."

The delayed or chronic impact of a chemical substance, or waste, depends on the ability of the chemical substance or waste to have a toxic effect on people, as well as on exposure to the waste or chemical. Exposure to people can occur during any phase of waste management: storage, transportation, treatment, and disposal or reuse. The recent contractor's report (Senes, 2002) addressing the H-11 characteristic identified several aspects of developing a classification system for chemicals with regard to chronic toxicity to humans.

A critical aspect of the H-11 classification system is data on the adverse health impact to people exposed to the constituents of the waste. These data are in the form of studies on the toxic effects and potency of waste constituent chemicals. Therefore, a successful H-11 classification system will be built first on the waste lists in Annexes VIII and IX, and secondarily on data describing the chemical composition of wastes, used in conjunction with chemical hazard data.

Also, as noted in the recently finalized discussion of waste ecotoxicity, H12 under the Basel Convention (cite), classification of wastes should be independent of local or regional conditions. The Basel Convention aims to control transboundary movement of hazardous wastes, and the principles for evaluation should be harmonized across all the Annex III characteristics in order to facilitate implementation. Site specific analysis is inappropriate for Basel H-11 classification, since Basel is applied across such a wide variety of site conditions. Consistent consideration of exposure is necessary to create a classification system that can be practically implemented, and is harmonized with the principle of using intrinsic hazard of the waste or its chemical constituents as the basis for classification.

2. Scope and Definitions

2.1 Scope of the work

The scope of the current work is to derive criteria for the hazard characteristic: H11 Toxic (Chronic or delayed) in order to obtain a tool for the classification of wastes with regard to their chronic toxicity. The proposed criteria are based on parameters that are generally accepted as indicators of chronic or delayed hazard (e.g. carcinogenicity or organ system toxicity following long-term low level exposure, or adverse health effects occurring some time after exposure of any duration ceases). While classification of most wastes can be made by referencing Annexes VIII and IX, the presence of a waste type in Annex VIII or IX of the Basel Convention does not preclude evaluation according to the hazard characteristics in Annex III in a particular case. The criteria may thus be used in specific cases, for evaluating a possible hazard of a waste indicated in these annexes, or for evaluation of specific wastes, which are not included in Annexes VIII or IX. The intended use of the proposed criteria is not, however, for routine evaluation of individual wastes as

the costs and time consumption will be too large for this purpose. The daily evaluation of individual wastes is therefore done by reference to Annexes VIII and IX.

2.2 Definitions

It is important to have a common understanding of the definition of the hazard characteristic: H11 Toxic (chronic or delayed) before consensus on criteria can be achieved. The fundamental definition of the H 11 characteristic is:

> Toxic (Delayed or chronic): Substances or wastes which, if they are inhaled or ingested, or if they penetrate the skin, may involve delayed or chronic effects, including carcinogenicity.

This definition implies an assessment of hazard to people resulting from long-term, low-level exposure, or adverse health effects occurring at some point in time after exposure has stopped. The delay in occurrence of an adverse effect associated with chemical or waste exposure could be as short as a week or two, or as long as several years or even decades. Long latency for the appearance of adverse effects may make it more difficult, as a scientific matter, to establish a causal connection between chemical exposure and adverse health impact. However, the length of the delay is irrelevant to the H11 classification, as long as a causal connection between the exposure and adverse effects is scientifically established. Carcinogenicity offers prominent examples of this. Environmental cancers typically occur either after long term, low level exposures, or in some case, years after exposure has ended[1].

Chemicals act to cause adverse health effects in several different ways. Acute toxicity describes a situation in which a single, usually high-dose exposure to a chemical produces adverse health effects immediately or very soon after the exposure. Acute toxicity occurs when the dose exceeds the ability of the body to accommodate, excrete, or detoxify the chemical. Below this threshold, there may be no injury, while above it, serious injury or death may result. Also, in any population there will be a range of individual threshold doses, which can be identified by testing or careful evaluation of poisoning incidents. The mode of action of chemicals in acute toxicity often involves either severe damage to an organ or organ system (causing it to fail), or when the chemical overwhelms a critical biochemical pathway, resulting in death or injury to organs. Examples would be carbon monoxide, hydrogen cyanide, or organophosphate pesticide poisoning.

Chronic or delayed toxicity describes the situation where lower exposures (which do not cause adverse effects observable at the time of exposure), occur over some time period, and adverse effects develop either during the exposure or after it ends. Many adverse effects of chronic exposure occur only above some threshold dose level, but others may not have thresholds for injury. Most carcinogens are considered to not operate in a threshold mode, although this is a topic of scientific debate. That is, at any dose level, there is some possibility of an individual developing cancer related to the chemical exposure. Therefore, the toxic potency of carcinogenic and non-carcinogenic chronic toxins are expressed differently. Toxic potency for threshold chronic effects is expressed as daily dose, called the reference dose (RfD), in mg chemical/kg body weight-day. Carcinogen potency is expressed as the probability of cancer developing in a person receiving a low dose over some time period, or risk/mg/kg body weight-day.

Assessment of two properties intrinsic to chemicals, hazard and toxic potency, are used to create a classification system for chemicals or wastes. Hazard assessment, or hazard identification, is commonly used in risk management of chemical substances and closely related to classification of hazard, e.g. a classification of wastes according to the Basel Convention.

Hazard identification is a qualitative determination that specifies the adverse effects the chemical can cause which would classify it as hazardous. A substance may, for example, be hazardous because of its potential for carcinogenicity, toxicity to a particular organ or organ system, or an ecotoxicological property.

[1] The occurrence of lung cancer in asbestos workers is a good example of the latency effect.

Toxic potency, or dose-response assessment, is a quantitative assessment that provides information on the dose of a chemical required to cause the toxic effect. Chemicals acting with thresholds typically show a steep rise (sharp change in slope) in toxic response over some narrow range of dose, that allows for the identification of a dose at which most individuals will suffer the chemical's adverse effects. For non-threshold chemicals, the dose-response curve is more smooth and uniform (constant slope), and intersects the dose-response plot at the zero point. In creating a classification system, the hazard assessment determines that a chemical should be in the system, and the dose response assessment identifies the specific category within the system (e.g., Class A, B, or C, etc.) for each chemical warranting classification.

Carcinogenicity and chronic toxicity data are widely available in the published literature, and a number of sources have collected key studies on particular chemicals to develop a critical assessment of the hazard posed[2]. Most data are based on testing in animals; human epidemiological studies are available for only a few chemicals. There is also considerable variability in the availability of toxicity data by the three H-11 exposure routes. While data on toxicity or carcinogenicity by oral ingestion of chemicals is available for many chemicals of interest, data on hazards from inhalation exposure are available for many fewer chemicals. For exposure by dermal absorption, data are available for only a handful of chemicals. Extrapolation of toxicity data between exposure routes is difficult to do reliably, and in some cases adverse effects are specific to a particular route of exposure[3].

Hazard classification systems are applied to wastes[4] through the use of *de minimis* cut-off values corresponding to the different classes in the system, since the degree of hazard is different for the different chemicals and classes. Wastes being examined under the H11 system which are found to exceed the *de minimis* value for their toxic chemical constituents would be Basel H 11 hazardous. The three exposure routes defined by H-11 to be incorporated in evaluations of hazard are: oral ingestion, inhalation, and dermal absorption. The highest level of chronic exposure to wastes and waste constituents by these three exposure routes, will occur for those in direct contact with the waste and its constituents in the course of storage, transport, recycling or disposal. *De minimis* values can be developed by considering the highest plausible exposure for these waste management operations. Protecting the most exposed persons will also protect all less-exposed persons. This proposed approach will harmonize classification of wastes for H11 toxicity (chronic or delayed) with hazard and dose-response assessment, and allow for consistent classification of waste based on the intrinsic hazard of the waste's constituent chemicals.

As noted in the recently approved elaboration of the Basel H 12 (ecotoxic) characteristic, international classification systems are used in countries with highly different environmental conditions and technological development levels. The classification criteria proposed are based on chemical and waste intrinsic properties, which do not take the site-specific exposure situation or the specific environmental conditions into consideration. This classification would be independent of time and place and indicate the potential impact if release or exposure should take place.

3. Proposed Assessment Strategy

The proposed strategy is based on that used in development of the Basel H 12 (ecotoxic) characteristic. It relies on a tiered approach with the following steps:

1. Initial assessment based on lists of hazardous and non-hazardous wastes (i.e. Basel Convention Annexes VIII and IX).

[2] These include USEPA's IRIS data base, IARC, WHO, and others.

[3] A model being developed by the US EPA may be useful for assessing dermal hazards.

[4] Wastes are mixtures of many chemical substances, some of which are toxic and some not.

2. Assessment based on the content of hazardous chemicals in the waste (i.e., total concentration in the whole waste).

As with implementation of the H 12 characteristic, the first step of the strategy to implement H 11 is to determine whether the hazardous properties of the waste have already been evaluated according to the Basel Convention (i.e. the waste appears in either Annex VIII or Annex IX). If the waste does not appear on either of these lists, an evaluation according to Step 2 is conducted. It should, however, be noted that in any particular case, the presence of a waste on the lists in Annexes VIII and IX does not preclude an assessment according to Annex III.

The evaluation of the toxic (delayed or chronic) hazard in Step 2 would be made by reference to a classification table similar to the one below. However, the current table considers only ingestion hazards; data on inhalation and dermal exposure hazards is yet to be considered.

There is no third step of creating new test data for purposes of H-11 implementation, due to the expense and difficulty of generating chronic toxicity or carcinogenicity data. Basel H-11 determinations will need to be made using the best available data. Repeated need for chronic toxicity data on a particular chemical may support development of such data over the long-run.

Finally, the approach taken in the H-12 characteristic elaboration can also be used with the H-11 characteristic for assessment of wastes containing multiple chemicals of concern.

Appendix A

Basel H-11 Waste Constituent Categories and *De Minimis* Concentrations in Waste

Waste Constituent Hazard Category		*De Minimis* Waste Concentration (Waste is not H-11 hazardous below this value)
Category A:	Unit cancer risk of greater than 1 per mg/kg-d Chronic toxicity RfD less than 10^{-3} mg/kg-d	100 ppm
Category B:	Unit cancer risk of 10^{-1} to 1 per mg/kg-d Chronic toxicity RfD between 10^{-3} and 10^{-2} mg/kg-d	1000 ppm (0.10%)
Category C:	Unit cancer risk of 10^{-2} to 10^{-1} per mg/kg-d Chronic toxicity RfD between 10^{-2} and 10^{-1} mg/kg-d	1.0%
Category D:	Unit cancer risk less than 10^{-2} per mg/kg-d Chronic toxicity RfD greater than 10^{-1} mg/kg-d	10%

(Note: Arsenic, with unit cancer risk of 1.5 per mg/kg-d would fit in Category A)

(Note: Benzene, with unit cancer risk of 5.5×10^{-2} per mg/kg/d would fit in Category C)

CONSIDERATION OF THE HAZARD CHARACTERISTIC H6.2

Report by the UK

1. At TWG 20 the UK reported on the UN Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG) proposals to change their model regulations' definition of "infectious", instigated by the WHO. These changes were intended to provide a new basis for the definition, which had previously depended on the four WHO "risk" criteria used for laboratory work.

2. The basis for the elaboration of the definition of H6.2 in the context of the Basel Convention also depended on the WHO risk criteria, so consideration had to be given as to how to proceed with the draft H6.2 paper. Four possible options arose:

i. Revise Annex III of the Basel Convention to align with the draft UNSCETDG definition of infectious substances;
ii. Defer the work of the TWG on this topic until the UNCETDG has adopted the revised definition;
iii. Recognising that UNCEDTG process takes time to be implemented and Basel needs an elaboration of H6.2, maintain the current draft as a basis for the independent elaboration of the characteristic under Basel for TWG 20 with a view to its interim adoption for COP VI;
iv. Revise the TWG paper to take into account the new information obtained from UNSCETDG as far as possible, its interim adoption for COP VI;

3. Initially it was agreed to pursue option 4. In the event it did not prove possible to undertake this work before COPVI.

4. The UNSCETDG has now adopted a revised definition that comprises two categories of infectious substance, A and B:

Category A is the high risk category. With it is a table that contains an indicative list of examples of substances that fit the criteria for inclusion in this category. Guidance discusses exposure, that the table is not exhaustive and infectious substances, including new and emerging pathogens, not included in the table but that meet the criteria for Category A should be assigned to that category. If there is doubt as to whether or not it meets the Category A criteria it should be assigned to that category.

Category B includes infectious substances that do not meet the criteria for inclusion in Category A.

Assignment should be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

5. Category A contains named organisms in non-exclusive list and is similar to risk Group 4 of the WHO but includes for example some risk Group 3. Category B includes all other pathogens broadly comparable with risk Groups 2 and 3. There is no list.

How to Proceed Now

6. Using the original H 6.2 paper as the starting point it is possible to adapt the text to remove the linkage with the WHO Risk Groups yet retain the linkage with the UN class H6.2.

7. The text of the paper, attached as Annex I to this document is highlighted with text in square brackets to indicate where some changes will be necessary in the discussion of the background and basis for the elaboration of the criterion. The operative paragraph (para 31) is presented with two options bis 1 and bis 2.

8. Comments are welcomed from the OEWG on this approach.

Roy Watkinson

BASEL CONVENTION TECHNICAL WORKING GROUP

ANNEX III HAZARD CHARACTERISTICS OF WASTES

DETERMINATION OF HAZARD PROPERTY H6.2 - INFECTIOUS SUBSTANCES

Section 1. Introduction - purpose and scope of this document

1. This document provides guidance on the application of the characteristic H6.2: "Infectious substances" in relation to wastes covered by the Basel Convention. It is intended to assist in determining whether that characteristic in a waste is displayed to a degree sufficient to render it hazardous. The determination may be made for several purposes including: consideration of wastes to be allocated to Annexes VIII or IX of the Basel Convention (Lists A and B); determining whether a particular waste on a case by case basis, should be treated as hazardous or; assisting the Secretariat to the Basel Convention (SBC) in providing technical support for individual requests.

2. The guidance is intended for use by all Parties, for reference, but it does not supersede determinations made, using objective criteria, set by Parties by their own domestic legislation, standards or guidelines.

3. This guidance is subject to review and updating as new information is made available.

Section 2. Background

4. Under the Basel Convention hazardous wastes are defined according to a list of substances (Annex I - categories of waste to be controlled) and their characteristics. Some of the characteristics have not been well defined for this purpose.

5. The hazard characteristic H6.2 "Infectious" is described in Annex III to the Convention. It defines this characteristic as:

> "Substances or wastes containing viable micro organisms or their toxins which are known or suspected to cause disease in animals or humans"

6. This definition has no objective elaboration, requiring further interpretation to enable assessments of individual wastes to be made on this basis. This is made clear by the footnote to Annex III, headed "Tests" which states that:

> "The potential hazards posed by certain types of wastes are not yet fully documented; tests to define quantitatively these hazards do not exist. Further research is necessary in order to develop means to characterise potential hazards posed to man and/or the environment by these wastes. Standardised tests have been derived with respect to pure substances and materials. Many countries have developed national tests which can be applied to materials listed in Annex I, in order to decide if these materials exhibit any of the characteristics listed in this Annex."

7. The characteristic H6.2 falls into this category. Opinions vary as to what wastes may be deemed hazardous by reason of infectiousness according to national laws, standards and classifications. Many Parties to the Convention have already adopted definitions and classifications to provide a basis for declaring a waste stream to be infectious. This guidance does not supplant those definitions but provides a reference point for common understanding of the nature of the characteristic.

8. An inspection of Annexes VIII and IX of the Convention shows that it is unlikely that any of the wastes listed in either of the annexes needed to have been tested for, or assessed against, the H6.2 characteristic. Either they will have been deemed hazardous by virtue of one of the other characteristics or they are unlikely to possess the characteristic in accordance with Article 1.1(a) of the Convention. There are some cases where the potential for infectiousness has been recognised. For example Annex IX contains two entries:

> B3060 "Wastes arising from agro-food industries provided it is not infectious"
>
> B3110 "Fellmongery wastes not containing hexavalent chromium compounds or biocides or infectious substances"

as listings regarded as not normally considered to be infectious but having the potential to be so. There are also two entries on Annex VIII:

> A3110 "Fellmongery wastes containing hexavalent chromium compounds or biocides or infectious substances"
>
> A4020 "Clinical and related wastes: that is wastes arising from medical, nursing, dental, veterinary or similar practices, and wastes generated in hospitals or other facilities during the investigation or treatment of patients, or research projects"

9. A3110 is a "mirror" listing to B3110, regarded as normally considered to be infectious (but having the potential not to be). Infectiousness is known or suspected to be commonly associated with the wastes described in A4020 and there is no "mirror" entry to Annex IX. A4020 wastes may also possess a number of the other Annex III characteristics.

10. This small number of entries does not preclude the possibility that wastes, as yet not listed, might need to be assessed for the H6.2 characteristic to enable them to be listed. Also it would help the Parties to the Convention if they a commonly agreed interpretation when deciding which waste categories s they consider to be infectious.

11. Deciding whether a waste should be classed as hazardous by reason of infectiousness depends on the criteria and method of analysis adopted. One way, often used, is to examine the potential for causing infection by employing a risk-assessment methodology. This approach identifies the type of organism, the likelihood of its presence, the potential for causing disease and the likelihood of its transmission to others. [This particular approach has been used to classify wastes as hazardous in many countries. For example, reference is often made to the World Health Organisation (WHO) classification of infectious substances to determine whether a waste should be classed as hazardous.]

12. A [similar] risk-based approach was used in the European Community investigation into the health care waste stream under the Priority Waste Stream project, carried out in the early 1990s. This identified two main types of waste and the associated risk according to the origin of the waste. General waste from health care activities was classed as "health care waste" and that likely to contain infectious organisms as "health care risk waste".

13. The following sections of this document discusses these issues and provide an interpretation of the characteristic H6.2

Section 3. Reasons why Infectiousness is considered not to be an "intrinsic" property

Intrinsic nature of other Basel hazard characteristics

14. The Basel Convention considers the hazard characteristics of wastes from the definition in Article 1.1(a) that distinguishes those wastes that "possess" the characteristics and those that do not. Although the term is not used in the text of the Convention, possession of a characteristic is commonly discussed by reference to the term "intrinsic characteristic (or property)". This clearly holds true for a large number of substances, whose characteristics can be readily and accurately identified by reference to their chemical properties, exhibited in relation to their concentration, which do not vary when subject to commonly defined test procedures.

15. The ordinary definition of the word "intrinsic" is an essential quality of something. In the case where wastes are to be considered to be infectious they will have been exposed to and become contaminated with micro-organisms to the degree that they can exhibit such a property. Here the "essential quality" is that exhibited by the micro-organisms themselves which have the "intrinsic" property and confer it upon the waste with which they are associated.

16. This description assumes that the association of waste and micro-organism enables the infectious micro-organism to continue to be capable of giving rise to infection on subsequent exposure by some route (such as absorption, ingestion or inhalation). This may not always be the case. For example some substances which may be chemically hazardous may also be sterilants and kill infectious organisms with which they come into contact, chlorine-based bleaches, for example.

17. Therefore, although the potential exists for any waste to be contaminated in such a way, only a few, specific, waste types are so intimately associated with infectious organisms that this can be regarded as a true "intrinsic" hazard. In general wastes do not have or exhibit an intrinsic hazard of infectiousness, except in very specific cases. Those most likely to be are wastes from health care and the practice of medicine (including veterinary medicine) as listed under A4020 in Annex VIII.

Infectiousness changes with time

18. Time is a significant factor that influences the likelihood of a potentially infectious waste to display this property. The property may become more, or less, enhanced. This is in contrast to many of the other Basel hazard characteristics. For example: a flammable solvent remains flammable or an acid remains corrosive because these properties are an intrinsic quality of their chemical composition.

19. The concentration of micro-organisms changes with time in several ways. They may lose their viability and so infectiousness declines. Micro-organisms may multiply, or even become dormant but still retain the ability to be revived under more favourable environmental conditions. This change depends on factors such as:

- the type of organism (some form resistant spores),
- nutrient availability
- ambient conditions ,
  - moisture
  - temperature and
  - exposure to light (or other forms of radiation).

Infectiousness not, therefore, an intrinsic hazard

20. Infectiousness is an inherently unstable and variable property dependending on biological qualities. Different results can even be obtained at different times with the same test conditions.

21. The characteristic cannot therefore be assessed as an "intrinsic characteristic" in a reliable and consistent manner. A different approach has to be taken when determining whether a waste is infectious or not compared with other Basel hazard characteristics.

22. Often, this property is judged to be present without undertaking confirmatory analysis using a risk based approach. Here the combination of the type of waste, its source, treatment and handling are considered to be indicators of whether there has been sufficient contact with or contamination by, infectious organisms to render it liable to be infectious.

23. The assessment of a waste according to H6.2 then depends on a simple, systematic evaluation of the risk.

Section 4. Risk Assessment approach

Definition of infectious organisms, degree of pathogenicity and route of exposure/infection

24. The common approach to classifying infectiousness is by reference to categories of specific risk groups of organisms according to their potential to cause and spread infection and their potential for clinical treatment.

25. [A widely known and used system is the UN classification of Infectious Substances (UN Division 6.2) included in UN Recommendations in relation to the transport of Dangerous goods. Micro-organisms are divided into four "risk groups" based on criteria developed and published in the World Health Organisation (WHO) Laboratory Biosafety Manual. A risk group is characterised by:

- pathogenicity of the organism,
- the mode and relative ease of transmission,

- the degree of risk both to an individual and the community and
- reversibility of the disease through the availability of known and effective preventative agents and treatment.]

26. [The criteria for each risk group according to the level of risk are as follows:

a) Risk Group 4 (high individual risk, high community risk,) comprises pathogens that usually cause severe human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly and for which effective treatment and preventative measures are not usually available.

b) Risk Group 3 (high individual risk, low community risk,) comprises pathogens that usually cause severe human or animal disease but do not ordinarily spread from one individual to another, and for which effective treatment and preventative measures are available.

c) Risk Group 2 (moderate individual risk, low community risk,) comprises pathogens that can cause human or animal disease, but are unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatment and preventative measures are available and the risk of spread of infection is limited.

d) Risk Group 1 (low individual and community risk,) comprises micro-organisms that are unlikely to cause human or animal disease.]

27. [These groups are used in the UN classification for Dangerous Goods for assignment of packing classes to materials for transportation.]

28. [Similar groupings were used in a study conducted in the EU "The European Priority Waste Stream Project" which considered the various wastes commonly arising across Europe from clinical treatment and other sources and the health risks they posed. It concluded that a class of waste should be called "healthcare risk waste". A subset of this waste was called infectious waste. The definition of healthcare risk waste (infectious) was given as:

"any healthcare waste known or clinically assessed to be at risk of being contaminated with any of the biological agents mentioned in Article 2(d) groups 3 and 4 of the Council Directive (90/679/EEC) of 26th November 1990 on the protection of workers from risks related to exposure to biological agents, of Article 16(1) of Directive 89/391/EEC, or with viable biological agents artificially cultivated to significantly elevated numbers."]

29. The risk assessment method allows, without testing, a professional, reasoned, judgement to be made to determine whether or not a waste may be deemed hazardous.

Section 6. Criterion for Determination by non-test risk assessment method

30. Non-test methods for infectiousness avoid the hazards to the operator associated with testing. These rely on knowledge of the origin, type and other properties of the waste to establish whether it is likely to have been in contact with infectious micro-organisms. If the waste in question meets with

the relevant criteria it would be deemed to be hazardous by virtue of H6.2. A second stage of testing can be applied where checking of a result from non-test assessment is desired.

31. The criterion for determining whether a waste is considered to be hazardous by virtue of the characteristic H6.2 is:

[“Any waste known or clinically assessed to be at risk of being contaminated with any of the biological agents mentioned in groups 3 and 4 of the UN Division 6.2 or with viable biological agents artificially cultivated to significantly elevated numbers.]

bis: 1 [“Any waste known or dinically assessed to be at risk of being contaminated with any of the biological agents mentioned in Category A of the UN Division 6.2]

bis 2 [“Any waste known or clinically assessed to be at risk of being contaminated with any of the biological agents mentioned in Categories A and B of the UN Division 6.2.]

Section 7. Wastes to which H6.2 might apply

32. Wastes to be controlled are listed in Annex I to the Basel Convention. With respect to H6.2 some of these wastes are more likely than others to possess the characteristic. Those most likely to be infectious waste have been mentioned in paragraph 8 above. The majority of waste types would not be expected to be intrinsically infectious. Annex 1 waste streams Y1, Y2 and Y4 would need to be considered.

33. The wastes included under A4020 are those most commonly associated with infectious micro-organisms. Not all will be contaminated or contain pathogens and may not be hazardous by virtue of H6.2 (but may by reason of some other Annex III hazard characteristic).

Section 8. Consideration of regional variations

34. The section on background recognises that variations occur as national legislation, standards and guidelines may impose different interpretations of the hazard characteristic. These may be a result of the consideration of risk to the environment and health and safety; climatic differences and approaches to health care.

35. Those standards will be important factors in determining on a regional or national level the categorisation of some wastes.

Section 5. When analysis is needed

36. A range of procedures exists that are usually performed in micro-biological and pathology laboratories to identify viable micro-organisms capable of causing diseases. (the United Kingdom Public Health Laboratory Service for example has an extensive range of protocols available). These are well documented in medical and scientific literature and many are now available in electronic format and on the internet. For determination of wastes a complete procedure would require a protocol for sampling and analysis from the target waste stream.

37. Typically, a protocol to detect whether organisms are present would involve sample collection, preservation, culturing and identification. A number of different methods exist. These range from:

    - traditional cultivation in defined laboratory nutrient media, with morphological examination of the culture and its biochemical reactions or ability to grow in a defined nutrient medium
    - to rapid tests and
    - genetic typing.

38. The sensitivity of these tests can be very high. A micro-organism may be recovered from a sample that itself was not able to confer infection on a human being (or animal) because there were insufficient numbers of viable micro-organisms to supply an infective dose.

39. Testing has inherent variation. Obtaining a reliable, representative sample can be difficult due to several factors including:

    - their inherent instability,
    - random distribution of the micro-organisms,
    - changes in viability and preservation prior to testing, especially where the organism is unknown.

    Additionally sampling poses health and safety risks that might be better avoided.

40. This approach may be used to assist determinations for example: where risk assessment may indicate more precision is required or a waste stream is being examined for the first time or is proposed to be listed.

41. Appendix B provides representative references of commonly used test methods.

[Appendix A - References

[Laboratory Biosafety Manual, World Health Organisation, 2nd Edition 1993 ISBN 9241544503]

[Recommendations on the Transport of Dangerous Goods, Model Regulations, 10th Revised Edition, United Nations 1997 ISBN 92-1-139057]

[Technical Guidelines on Biomedical and Healthcare Wastes (draft), UNEP Basel Convention.]

Appendix B - National and International standards and test methods

The literature on medical microbiology and tests for micro-organisms – bacteria viruses and fungi is extensive, both in print and on the internet. Major publishers have considerable lists of textbooks. Many countries, which have centres for disease control and reporting mechanisms, also have their own public health laboratory services. These often have devised protocols for tests and publish them. The

health authorities in these countries are also sources of relevant information on test methods and standards.

Standard Operating Procedures- Public Health Laboratory Service UK

Special Wastes – A technical Guidance Note on their definition and classification, Section B9 Assessment of Hazard H9 Infectious, pp IB.44-45, Environment Agency (for England and Wales-UK), 1999, ISBN 0 11 310158 9.
