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Report on the implementation of the decisions adopted by the Conference of the Parties at its sixth meeting

Work on hazard characteristics

Note by the Secretariat

Addendum

Approach to Basel Convention hazard characteristic H11: characterization of chronic or delayed toxicity

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I. Introduction

1. The present document discusses criteria for classifying wastes under the Basel Convention with regard to the Annex III hazard characteristic H11, delayed or chronic toxic hazard. A key goal of the Basel Convention is to ensure the protection of human health and the environment during the transboundary movement and disposal of waste. In general terms, this means that people and the environment should be protected against potential adverse effects caused by the generation, transport, handling and disposal of waste being transported between countries that are parties to the convention. The Annex III hazard characteristics work with the Annex VIII and IX waste lists to help accomplish this goal. The H11 hazard characteristic (delayed or chronic toxicity) is intended to ensure protection from wastes or waste constituents that can cause adverse health effects following very low but prolonged exposure of people to the waste, with the adverse effects occurring either during the exposure period, or after exposure has ceased. When the hazard posed by a waste is too great, the waste is classified as Basel hazardous, and the range of Basel controls and protections will apply.

2. In determining the status of a waste under the Basel Convention, reference is first made to Annexes VIII and IX. These two annexes list wastes that have already been considered and classified by the Basel Convention. Hazardous wastes appear in Annex VIII on list A, and non-hazardous wastes appear in Annex IX, which contains list B. In any particular case (i.e., for any particular batch of waste, or waste generated by a particular generator or facility), the presence of a waste on either list A or list B does not, however, preclude an assessment using the Annex III criteria, and reclassification of that particular waste on the basis of the assessment. The Annex III hazard characteristics would also be used with the other Annex III characteristics to evaluate a waste not previously assessed by the Basel Convention.

3. 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 by people can occur during any phase of waste management: storage, transportation, treatment, and disposal. Accordingly, a critical component of implementing the H11 classification system is data on the adverse health impact on people exposed to waste constituent chemicals by any of these exposure routes. These data are in the form of studies on the toxic effects and potency of waste constituent chemicals by the oral, dermal or inhalation exposure routes. A system for classifying wastes with regard to the H11 characteristic will therefore require data describing the chemical composition of wastes, used in conjunction with chemical hazard data.

4. As noted in the H12 ecotoxicity characteristic (Basel Convention 2003), classification of wastes should be independent of local or regional conditions. The Basel Convention aims to control the 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 H11 classification because the result of basing classifications on site-specific conditions and analysis would be different classification determinations at different sites for the same waste, which would be confusing at best. Consistent consideration of exposure is necessary to create a classification system that can be practically implemented and is combined with the principle of using intrinsic hazard of the waste or its chemical constituents as the basis for classification.

5. Proper waste classification is the critical first step in ensuring safe waste management and disposal. Proper classification informs everyone associated with the waste about the hazards posed, and allows protective safety measures specific to the type of hazard posed to be instituted. If waste is not properly classified, it cannot be safely managed, because those responsible for its management will not know what protections are needed. Understanding waste hazards is critical to ensuring that wastes transported across borders are safely managed in receiving countries.

6. The classification system for waste must also be harmonized with international conventions for assessing and describing chemical hazard. That is, waste classification under the Basel Convention, in order to protect people and environments exposed to waste, must also be consistent with those conventions, so that both sending and receiving countries understand the hazards posed by the waste. The Globally Harmonized System of Classification and Labelling of Chemicals (GHS)[1] provides a framework for such harmonization in terms of the first step of classification, or hazard identification. GHS provides a consistent foundation for hazard classification and communication for chemical substances and mixtures (defined as mixtures or solutions composed of two or more substances in which they do not react), which is intended to support the development of national chemical safety programs. For purposes of classification of chronic hazards under GHS, potency and exposure are generally not considered. While GHS itself does not address risk assessment or management, beyond hazard identification and communication, the GHS framework can be used as the foundation of a waste classification system. For wastes being transported across borders, the consistent classification and hazard identification by labelling supports the fundamental goals of the Basel Convention to ensure safe management of this waste.

II. Scope and Definitions

A. Scope of the work

7. The scope of the current work is to derive criteria more fully defining the Annex III hazard characteristic: H11 toxic (chronic or delayed) and to create a practical tool for the classification of wastes with regard to their chronic toxicity. The criteria are based on parameters that are generally accepted as indicators of chronic or delayed hazard, such as 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 H11criteria may therefore be used for evaluation of specific wastes which are listed in Annexes VIII or IX, but which may have different properties than those anticipated in placing the waste on either of the lists, or for evaluation of wastes which are not included in these annexes. The intended use of the criteria is not for routine evaluation of individual wastes, as the costs will generally be too large for this purpose. Routine classification of individual wastes is intended to be performed by reference to Annexes VIII and IX.

B. Definitions

8. 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 one or two weeks, 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. The length of the delay is irrelevant to the H11 classification, however, as long as a causal connection between the exposure and adverse effects is scientifically established. Carcinogenicity offers prominent

[1] See UN, 2003 in the bibliography.

examples of this. Environmental cancers typically occur either after long term, low level exposures, or in some case, years after exposure has ended.[2]

9. The definition of the H11 hazard characteristic under the Basel Convention encompasses a number of GHS hazard categories. These include specific target organ systemic toxicity following either a single exposure (GHS chapter 3.8; delayed effects) or repeated exposures (GHS chapter 3.9); carcinogenicity (GHS chapter 3.6); and some aspects of reproductive toxicity (GHS chapter 3.7). Waste constituent chemical classification under any of these GHS categories could provide the initial basis for considering classification with regard to the H11 characteristic.

1. Chemical toxicity

10. Chemicals can act to cause adverse health effects in exposed people 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. Added to which, 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 include carbon monoxide, hydrogen cyanide, or organophosphate pesticide poisoning.

11. Chronic or delayed toxicity describes the situation where lower exposures (which do not cause adverse effects observable at the time of initial exposure) occur over some period of time, 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 identified thresholds for injury; differences in response will also occur within any exposed population. Toxic potency for threshold chronic effects is expressed as a maximum daily dose of a chemical (in mg chemical/kg body weight-day) that is estimated can be tolerated by an exposed population without individuals suffering adverse effects[3]. For chemicals acting without thresholds[4], at any dose level there is some possibility of an individual having an adverse effect related to the chemical exposure. Non-threshold toxic potency is expressed as the probability of an adverse effect developing in a person receiving a particular dose on a regular basis, or risk/mg/kg body weight-day. However, the distinction between threshold and non-threshold modes of action is unrelated to the severity of the adverse effects chemicals may cause.

12. Distinguishing between threshold and non-threshold modes can be difficult as a practical matter. Chemicals without identified thresholds for toxicity, which may appear to act in a non-threshold manner, may in fact have thresholds at doses below those tested to date, so classification of a chemical as “non-threshold” may in effect be provisional. Many carcinogens are considered to operate in a non-threshold mode (particularly those that act by damaging DNA), although some have been shown to have thresholds. This is a topic of current research and scientific debate, and choices about applying low-dose extrapolation models to experimental data can be guided by information on modes of action, but also nearly always involve some policy

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

[3] The maximum dose that is estimated can be tolerated by an exposed population without suffering adverse effects is variously called the acceptable daily intake (ADI), tolerable daily intake (TDI), or, by USEPA, the reference dose or concentration (RfD or RfC). These values are typically based on animal toxicity or human epidemiology studies that identify either the highest dose producing no adverse effect, or the lowest dose that produces some measurable adverse health effect. Uncertainty factors or safety factors, are applied to this value to account for different individual response within an exposed population, uncertainties in extrapolating data from test animals to humans, and other uncertainties. Safety and uncertainty factors may be as low as a factor of 3, but more typically range from 10 to 100-fold, or where uncertainties are greater, 1,000; they rarely exceed 1,000. See: WHO, 2001 in the bibliography.

[4] Chemicals without identified thresholds for their adverse effects, including carcinogens, may in fact have thresholds that have not yet been identified, either through lack of adequate study, or because the thresholds occur at very low dose levels that are difficult to identify in standard testing approaches.

considerations. Clearly, the most current peer-reviewed research on a particular chemical is the appropriate starting point for new classifications or those under review.

13. Exposure is also an important consideration. Exposure to toxic chemicals can occur by ingestion or inhalation of a chemical, or by skin contact with the chemical. Exposure by any of these routes can cause either acute or chronic adverse effects, including both threshold and non-threshold chronic adverse effects, depending on the chemical. While ingestion may be the most common exposure route, volatile chemicals can cause inhalation exposures, and handling of material can cause dermal exposures. Inhalation exposure to non-volatiles can occur from chemicals that can form dusts which become airborne.

14. Finally, the bioavailability of chemicals can be very important in assessing their hazards. This can be particularly important for metals, because the various salts (and oxidation states) of a metal will have different degrees of solubility and other properties that may affect the hazard of the metal, and may also affect its environmental mobility. For pure chemicals (as used in industry or commerce), it may be possible to know what salt of a metal is being used, and hazard information specific to that salt may be used for classification. Many metals in elemental or metallic form may be relatively harmless (with mercury a notable exception). Wastes are often complex mixtures of chemicals, however, and both the oxidation state and the particular metal salt present in the waste may be unknown. In these instances, hazard determinations may need to be based on the best and most relevant information available.

2. Using chemical toxicity information to classify wastes

15. 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 is closely related to classification of hazard, as in the classification of wastes under the Basel Convention.

16. 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. Substances may produce more than one adverse effect on a chronically exposed person, and the hazard posed by a chemical may also be specific to a particular exposure route.

17. 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. Dosing or exposure may occur via ingestion, inhalation, or by dermal absorption, and some chemicals may have different potency by different exposure routes. 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 – or is presumed to be – smoother and more 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.

18. 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[5]. Most data are based on testing in animals; human epidemiological studies are available for only a few chemicals. It should be noted that there is considerable variability in the availability of toxicity data by the three H11 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.

[5] These include the Integrated Risk Information System (IRIS) database of USEPA, IARC, WHO and others. GHS section 1.3.2.4 supports the use of existing test data and expert judgment in classifying chemicals where of adequate quality.

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.

19. Hazard classification systems can be applied to wastes[6] through the use of de minimis cut-off values for each of 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 exceed the de minimis value for the toxic chemicals which they contain would be classified as possessing hazard characteristic H11. The highest level of chronic exposure to wastes and waste constituents by the three H11 exposure routes will occur for those in direct contact with the waste and its constituents in the course of storage, transport, recycling or disposal. This 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 (by any or all of the three exposure routes).

20. For chronic health effects, in the absence of scientifically sound data on mixtures, GHS provides cut-off values when considering mixtures for classification (see, for example, GHS table 3.9.3). GHS also provides for the use of cut-off values lower than the generic GHS levels for mixtures containing chemicals for which the hazard will be evident below the generally recommended cut-off level (see GHS section 1.3.3.2).

21. Because of the complexity of evaluating and interpreting chronic toxicity and carcinogenicity data, reliance on expert assessment of all data on a particular chemical is warranted and such assessments should be used when available. They can more comprehensively consider the quality and completeness of all data, and assess the implications of the data, to estimate values that can be considered to be below a threshold, or to estimate the incremental risk of different exposure levels to non-threshold chemicals. GHS requires this comprehensive evaluation of the data (see, for example, GHS section 3.9.2).

22. The H11 classification system is quantitative. For any waste, if the concentrations of the waste's hazardous constituents are known and chronic toxicity data are available, the waste can be assessed and classified under the Basel Convention as hazardous (or not classified), with regard to characteristic H11. Accordingly, while consistent with the GHS classifications of hazards presented by wastes, it does not rely solely on GHS. This is appropriate, because classification of waste as hazardous under the Basel Convention triggers hazardous waste management obligations,. Basel Convention classification is a hazard management determination, and thus goes beyond the basic GHS classification, as described in GHS section 1.1.2.6.1.

23. GHS provides only for qualitative classification of chemicals. International or national assessments, such as those carried out by the World Health Organization (WHO) or national programmes, that credibly estimate carcinogenic potency may be used for H11 evaluation of waste constituent chemicals, consistent with the qualitative GHS classification for the waste constituent chemical.

24. As noted earlier, international classification systems are used in countries with highly differing environmental conditions and technological development levels. This requires criteria that are independent of time and place and that indicate the potential for harm if release or exposure should take place. The classification criteria are based on chemical and waste intrinsic properties, which do not take site-specific conditions into consideration.

[6] Wastes are mixtures of many chemical substances, some of which are toxic and some not. Since wastes are not deliberately produced to a given product specification, their composition can vary from one batch to the next, or over time to continuously generated wastes.

C. Relation of hazard characteristic H11 to the Stockholm Convention on Persistent Organic Pollutants

25. The Stockholm Convention requires parties to undertake a number of efforts and actions with regard to the persistent organic pollutant (POPs) chemicals identified by the Convention. These party obligations include taking appropriate measures so that POPs wastes are managed and disposed of in an environmentally sound manner. In addition, parties are to take appropriate measures so that POPs wastes are treated to destroy or irreversibly to transform the POPs content of the waste so that the waste does not exhibit the characteristics of the POPs chemicals, unless such treatment is not the environmentally preferred option or the POPs content of the waste is low, as set out in detail in article 6, paragraph 1 (d) (ii), of the Stockholm Convention.

26. Contamination with any of the Stockholm POPs chemicals could cause a waste to be qualified as hazardous under Basel Convention hazard characteristic H11 (and, potentially, under other Annex III characteristics). Many wastes containing these chemicals are listed as hazardous under the Basel Convention (see Annex VIII). Many of the POPs chemicals are classified as carcinogenic by different national and international evaluation organizations, such as the International Agency for Research on Cancer (IARC), WHO, United States Environmental Protection Agency and others, while others pose other hazards to human health as a result of long-term, low-level exposures.

27. The Stockholm Convention does not directly define what wastes are POPs wastes. In identifying obligations of Parties to the Convention, however, article 6, paragraph 1, states:

> "1. In order to ensure that stockpiles consisting of or containing chemicals listed either in Annex A or Annex B *and wastes, including products and articles upon becoming wastes, consisting of, containing or contaminated with a chemical listed in Annex A, B or C,* are managed in a manner protective of human health and the environment, each Party shall: […]" [*emphasis added*]

The Stockholm Convention Conference of Parties has not yet convened, and thus has not yet had an opportunity to provide any further guidance on the definition of POPs wastes. Accordingly, the relationship between the Basel Convention and the Stockholm Convention has not been fully defined. For example, the definition of de minimis for H11 is not necessarily the same as the Stockholm Convention term "low POPs content"; these two sets of values have different functions in each of the conventions, and may, once defined, have different bases[7]. Furthermore, some of the POPs chemicals (e.g., DDT) may pose greater hazards to ecosystems than to humans. Waste can only be evaluated for classification (or de-classification) purposes as hazardous under the Basel Convention by reference to the full set of Annex III hazard characteristics, and not solely on the basis of an assessment with regard to characteristic H11.

III. Assessment strategy

28. As described above, classification of a waste in terms of its hazard characteristics is based on a tiered approach with the following steps:

(a) Initial assessment based on lists of hazardous and non-hazardous wastes, namely, Basel Convention Annexes VIII and IX); and

(b) Assessment based on the content of hazardous chemicals in the waste (i.e., total concentration in the whole waste) and the Annex III criteria.

[7] The H11 values will be used to classify wastes not previously considered by the Basel Convention, or, on a case-by-case basis, to declassify wastes classified as hazardous under the Basel Convention. The "low POPs content" will be used to identify POPs wastes that can be managed and disposed by environmentally sound methods other than "destruction or irreversible transformation". In addition, the H11 levels have a health basis. The "low POPs content" levels may well have a technology basis – the limits of treatment or reliable analytical measurement, or possibly another basis.

The first step of the strategy followed in applying H11 is to determine whether the hazardous properties of the waste have already been evaluated according to the Basel Convention and appears on either the Annex VIII list A (Basel hazardous wastes) or Annex IX list B (not Basel hazardous). Appearance on either of these lists indicates presumptive classification as either hazardous (list A) nor non-hazardous (list B). In any given case, however – i.e., for any particular batch of waste, or waste generated by a particular generator or facility – the presence of a waste on either of the lists in Annexes VIII and IX does not preclude an assessment using the Annex III criteria, and reclassification on the basis of that assessment[8].

29. If the waste does not appear on either of these lists, an evaluation according to step 2 is conducted. The evaluation of the toxic (delayed or chronic) hazard is made, based on the total concentration of chemicals of concern found in the waste and classified under GHS. Wastes containing more than the de minimis concentration[9] of chemicals, that can be classified by GHS, would be H11 toxic, and therefore hazardous under the Basel Convention. As a practical matter, the following method should be followed for classification under H11:

(a) Identify the chemical constituents of potential concern in the waste;

(b) Identify the H11 hazard category for each of the constituents of concern using GHS and expert assessments of chemical toxicity data. If no expert assessment has previously been conducted, classification should be based on the best data available, consistent with GHS 1.3.2.4, GHS 1.3.3, and WHO 2001;

(c) Identify the total concentration in the waste of each of the constituents of concern[10]. If the concentration of any waste constituent chemical exceeds an established de minimis level, the waste is classified as H11.

30. Many wastes may contain more than one constituent of concern. If the waste can be classified as H11 based on any single waste constituent, such as the presence of a chemical above its established de minimis level, then the waste is classified as possessing hazard characteristic H11. If no individual constituent is present at a concentration above its de minimis level, then the waste would not be classified as H11. If, however, there are specific and credible data identifying synergistic or potentiation interactions between two or more of the chemicals present, and with the potential to cause adverse health effects at the levels present, the waste should be classified as H11 (see GHS section 3.9.3.4.4).

31. For H11 implementation, there is no third step of creating new test data as there is under the H12 criteria, owing to the expense and difficulty of generating chronic toxicity or carcinogenicity data. Determinations of hazard characteristic H11 will need to be made using expert assessments of the best available data. Repeated need for chronic toxicity data on a particular chemical may, in the long run, support or encourage development of such data.

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[8] Presumably if one were using the Annex III criteria to reclassify a waste as “not Basel hazardous”, the waste would need to meet the non-hazardous criteria for all 13 of the Annex III hazard characteristics.

[9] Until deminimis levels are established under the Basel Convention, trigger values for labelling under GHS may be used.

[10] Chemical analysis of waste should be performed in a manner consistent with the OECD guidelines on good laboratory practice, and related documents on the mutual acceptance of data. See OECD 1998.

[11] See USEPA 2004, *Risk Assessment Guidance for Superfund, Volume I, Part E, Supplemental Guidance for Dermal Risk Assessment*. Exhibits 3 and 4 identify dermal absorption rates from soil for 10 chemicals, ranging from 0.1% for cadmium to 25% for pentachlorophenol. Data on dermal absorption from chemicals in water are much more widely available, as illustrated by exhibit B-3 of the same document.

Appendix

Bibliography and additional sources of information

Publications

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WHO 2001. *Guidance Document for the Use of Data in Development of Chemical-Specific Adjustment Factors (CSAFs) for Interspecies Differences and Human Variability in Dose/Concentration Response Assessment*. July, 2001. WHO/PCS/01.4

Additional sources of information

The United States Environmental Protection Agency IRIS chemical toxicity database is at: http://www.epa.gov/iris/

WHO Drinking Water Guidelines assess the hazards of many chemicals. These are available at: http://www.who.int/docstore/water_sanitation_health/GDWQ/Updating/draftguidel/2003gdwq8.pdf

The guidance on test methods for evaluating solid wastes: physical/chemical methods developed by the United States Environmental Protection Agency (also known as “SW-846”) is available at: http://www.epa.gov/epaoswer/hazwaste/test/main.htm