

UN/SCETDG/21/INF.33

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-first session, 1-10 July 2002,
agenda item 7)

Comments of the Netherlands with respect to document ST/SG/AC.10/C.3/2002/16

General remarks

First of all we would like to express our recognition for the excellent initiative which Canada and the other countries of the working group have undertaken and the constructive work which has been done at the Informal Meeting in Paris. The proposal constitutes a tremendous improvement on the current situation, especially in so far as structure and classification is concerned.

However, some doubts and comments have arisen within the different Dutch authorities that are competent in these matters, which we have put forward here below. It took a considerably amount of time to collect the comments from the different authorities that deal with this matter in the Netherlands, as a result of which our reaction is somewhat late. Therefore, we are still working on the issue and hope to refine the comments and proposals in the coming period. Maybe the UN meeting can answer some of our questions.

As a general remark we would like to mention the relationship between the provisions formulated in the Model Regulations and international rules applicable in other sectors, such as the medical and environmental context. For example the fact that the division in WHO risk-groups has been changed into a the Categories A and B will probably also need adjustments in other regulations. Vice versa, developments in other contexts, such as the Convention on Biodiversity, are relevant for the discussions in the UN SC-ETDG.

The Dutch authorities whose comments are dealt with in this document are:

- Ministry of Transport and Water Management
- National Inspectorate for Health and the Environment
- Ministry of Housing, Spatial Planning and the Environment
- Ministry of Social Affairs and Employment
- Working Group on the Prevention of Infection, WIP
- Health Inspectorate
- Ministry of Health, Welfare and Sport

Proposal number 1.

2..6.3.1.1. Definition infectious substances

Comment (content):

In the definition of ‘infectious substance’ it is not clear what is understood by *“plasmids (...) which can cause disease in humans or animals”*.

What is the reason that ‘recombinant organisms’ have been deleted from the definition for pathogens?

Comment (content):

The current definition of “*Pathogens*” is limited to human or animal pathogens. The ICPP norms also comprise plant pathogens, why are they absent in the current definition?

Comment (content)

“*Pathogens*” current definition: “(...) *micro-organisms* (...), that are known or reasonably expected to cause infectious disease in animals or humans”

New: “(...) *plasmids and other agents such as prions, which can cause disease in humans or animals*”

Doubts have arisen about the scope of this definition: is the phrase “can cause disease” versus “known, or reasonably expected to” edited with the purpose to include more or fewer micro-organisms.

Comment (editorial)

The definition of infectious substances in 2.6.1. (b) should be adapted to the new definition.

2.6.3.1.2. Biological Products:

Comment (content)

This definition still contains “regulatory requirements”, whereas the justification on page 7 expresses the intention of separating the definitions of any requirements or exemptions attached to them. “products derived from living organisms, *which are manufactured and distributed in accordance with the requirements of national governmental authorities, which may have special licensing requirements, and are used for...*”. In the draft version of September 2001 these criteria are not mentioned.

2.6.3.1.3. Cultures

Comment (content)

The term “concentrations” does not completely cover the content, because the risk of infection is defined by a combination of concentrations and quantities of pathogens.

Comment (content)

Why has the definition of “diagnostic specimens” been deleted, and has been replaced by a different definition of “cultures”. These terms express different subjects to which different rules apply. Moreover, diagnostic specimens are mentioned later in the text (proposal number 4) in the context of the special provisions applicable to UN 3373.

2.6.3.1.4. Genetically modified micro-organisms and organisms

Comment (content)

In the context of the Convention of Biodiversity (CBD) and its Biosafety Protocol (BSP), genetically modified organisms and micro-organism are referred to as living modified organisms and have a different definition from the definition in mentioned here. It would be desirable to endorse the definitions which are being used in the BSP context. Moreover, in technical terms, organisms comprise micro-organisms, the question is why these terms have been separated in this definition. Moreover, the Biosafety Protocol does not make this distinction.

As we understand this definition, genetically modified organisms, in contrast with genetically modified micro-organisms, would comprise plants and animals. Is that correct?

2.6.3.2. Classification.

Comment (content)

Category A does not mention disease to plants as a criterion for inclusion; does this mean that infectious substances which can cause diseases in plants fall outside the scope of the Model Regulations? If it does fall within the scope of Category B, the problem remains that the definition of pathogens and infectious substances do not refer to disease in plants.

Comment (content)

No connection is being made between the risk of infection and the classification under Category A or B. The WIP and the IGZ are in favour of a distinction between infectious substances which can cause disease by any physical contact or even by aerosols on the one hand (“*exposure*”), and, on the other hand, substances which need to be consumed or transmitted by a host organisms (e.g. mosquito) before they can be contagious.

In the former document on the Transport of infectious substances (UN/SCETDG/20/INF.22) the description of Category A does refer to the risk of infection: “*These substances that cause serious or fatal disease, are easily transmitted directly or indirectly and for which there are no treatment or preventive measures*”.

2.6.3.2.2.1. Category A

Comment (content)

The description of Category A mentions the word ‘transported’ to indicate what should be understood as an infectious substance classifying under A (“*An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease (...)*” In the former document on the Transport of infectious substances (UN/SCETDG/20/INF.22) this category is described as “*These substances that cause serious or fatal disease, are easily transmitted directly or indirectly and for which there are no treatment or preventive measures*”.

In our opinion the use of the word “transported” might be confusing as it might be understood as transport in the sense of the transport regulations in stead of the medical expression of “transmitted”.

2.6.3.2.2.2. Category B

Comment (content)

The criteria for inclusion in this category are not quite clear. Whereas Category A mentions permanent disability, life-threatening or fatal disease to humans or animals, Category B does not refer to any specific clinical picture.

2.6.3.4. GMMOs and GMOs

Comment (content)

No reference is made to the work which is being done by the ICCP (Intergovernmental Committee for the Cartagena Protocol on Biosafety) of the Convention of Biodiversity (CBD) with respect to the handling, transport, packaging and identification of living modified organisms, although the former document (UN/SCETDG/20/INF.22) states: “*Genetically modified micro-organisms are currently under discussion by the parties to the Biodiversity Convention and, consequently, no change has been made to the existing requirements in the Model Regulations*”. In this context, an in-depth study is going on about measures which should be taken to avoid adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and in particular the

way to deal with food and feed and Processing. Therefore, insofar as GMOs or GMMOs are concerned, the requirements should be synchronized.

2.6.3.4.1. and 2

Comment (content):

A fundamental distinction is being made between GMMOs and GMOs whereby the former refers to the definition of infectious substances, and the latter mentions the phrase: “*which are known or suspected to be dangerous to humans, animals and the environment*”. The question is why this distinction has been made, as, in technical terms micro-organisms form part of the wider group of organisms.

2.6.3.4.4.

Comment on the current provision (editorial):

The formulation of the last part of this provision “... *which do not meet the definition of infectious substances but which are capable of altering animals, plants or microbiological substances in a way not normally the result of natural reproduction ...*” is remarkable from a technical point of view, because a GM(M)O would, when released into the environment, only be able to alter animals, plants etc. by way of natural reproduction. It would improve clarity of the text to refer to possible dangers to ecosystems or the environment in this way.

Proposal 3 and 4

Chapter 3.2. and 3.3. Dangerous Goods List, UN 3373

Comment (content)

The description of “diagnostic or clinical specimens” in the special provision referring to UN 3373 seems to have a broader scope than the proper shipping name in proposal number 3.

Comment (editorial)

Moreover, it would be better to relocate this description to the part which contains all definitions. This will enhance the transparency and logic structure of this Chapter.

Proposal 5 and 6,

Packing Instruction P620

Comment (content)

Packing instruction P650 is divided in part 1, which specifies requirements for receptacles that do not exceed 500 ml/g and part 2. for receptacles that do exceed this quantity. Packing instruction P620 does not mention any maximum quantity, whereas it deals with the more dangerous infectious substances assigned under UN 2814 or UN 2900.

Proposal 6.

Comment (content)

The mark for UN 3373 is very similar to the mark for Limited Quantities in ADR/RID. Why not put the infectious sign on top, just like the marks for UN 2900 and 2814. Moreover, it would be a good idea to add a color (green) to the mark for division 6.2.
