

## II.

### PROCEDURES FOR TOXICITY DETERMINATIONS 1/

In March 1982 consultations were held, involving 32 experts from 25 countries, i.a. on toxicity determination.

As a result of the discussions, the participants in the consultations unanimously agreed to recommend standardized operating procedures for acute subcutaneous toxicity determinations and for acute inhalation toxicity determinations. These unanimously agreed recommendations were submitted as Annexes III and IV to document CD/CW/WP.30.

It is understood that further work may be needed to take into account technical developments since 1982. In order to facilitate this work Annexes III and IV to CD/CW/WP.30 are reproduced below.

#### Recommended standardized operating procedures for acute subcutaneous toxicity determinations

##### 1. Introduction

Three categories of agents were defined on the basis of their toxicity:

- (i) super-toxic lethal chemicals;
- (ii) other lethal chemicals;
- (iii) other harmful chemicals.

Lethality limits in terms of LD<sub>50</sub> for subcutaneous administration were established to separate three toxic categories at 0.5 mg/kg and 10 mg/kg.

##### 2. Principles of the test method

The test substance is administered to a group of animals in doses corresponding exactly to the category limits (0.5 or 10 mg/kg respectively). If in an actual test the death rate was greater than 50 per cent, then the material would fall into the higher toxicity category; if it was lower than 50 per cent the material would fall into the lower toxicity category.

##### 3. Description of the test procedure

3.1 Experimental animal Healthy young adult male albino rats of Wistar strain weighing 200 ± 20 g should be used. The animals should be acclimatized to the laboratory conditions for at least five days prior to the test. The

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1/ It was understood that these recommended standardized operating procedures for toxicity determinations might be supplemented or modified and/or, if necessary, reviewed.