PPE for skin protection (clothes and gloves) aimed at operators who may come into contact with phytopharmaceutical products (PPP):

This document describes concerns that INRS (French occupational health and safety institute) has with two draft ISO standards that are newly developed under Vienna agreement.

These projects deal with PPE for skin protection (clothes and gloves) aimed at operators who may come into contact with phytopharmaceutical products (PPP):

a) **ISO DIS 27065**, version 2014-10-29

Protective clothing – Performance requirements for protective clothing worn by operators handling liquid pesticides and re-entry workers

b) ISO CD 18889, version 2014-10-29

Protective gloves for pesticides operators – Performance requirements

We recognize that there is a tremendous lack of data regarding protective performance of currently available protective garments against chemicals, and especially PPP, and that due to this lack of data it is difficult to choose proper PPE for agricultural workers. However, in our opinion, the above mention standard projects fail to address this issue.

Our main critique concerns, above all, the assignment of a performance level based on the testing of the garment against a unique PPP (Prowl 3.3 EC) and the failing of mentioning this fact in the information supplied by the manufacturer with each PPE. We believe this is in contradiction with the basic health and safety requirements of the PPE directive 89/686/EEC and will confuse the potential user, who may believe to be protected, though the garment was never tested against the specific product he or she is using.

A second one concerns the lack of precision of the scope of these standards. The scope mentions that the standards are not applicable to evaluate the garment resistance to volatile liquids, without specifying objective application limits. Of course PPP have a relatively high content of water. However water is not the worrying substance in these mixtures, active substances, co-formulants and solvents are and they have very different physical and chemical properties from water.

Specific topics in these draft standards are developed below.

A) General remarks on both projects and alternative proposals

1) Assignment of a performance level based on testing with a unique PPP and without proper information of the user.

We believe that this will be dangerous for the user, who will see a garment marked with a logo specific to PPP and could believe he or she has put on a garment which will protect him or her, though it has never been tested against his or her specific product.

In practice there are multiple PPP mixtures which contain substances (active or co-formulants) with various chemical and physical properties, affecting their penetration and permeation into the garment materials.

Besides, we believe this is not in conformity with the basic health and safety requirements of the PPE directive 89/686/EEC. The directive states in particular (Annex II, 3.10.2): "Where, by virtue of their nature and the foreseeable conditions of their use, certain dangerous substances or infective agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of efficiency. PPE which is considered to be in conformity with the test specifications must bear a mark indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's notes must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use."

Alternative proposal:

The performance level should be assigned for a specific PPP (as is generally done for protective garments against chemicals) and the information for use should display a test results table with performance levels reached by the garment for each tested PPP.

The Prowl 3.3 EC should be part of a non-exhaustive list of PPP against which the garment can be tested.

2) Lack of precision of the scope

The scope mentions that the standards are not applicable to evaluate the garment resistance to volatile liquids without specifying objective application limits. However a lot of PPP contain volatile substances (solvents) which have hazardous properties.

Alternative proposal:

The scope should be specified using objective criteria like vapour pressure and boiling point.

Besides, it would be interesting to carry out a study in order to evaluate the share of liquid PPP, which are out of the scope of these standards.

B) Specific remarks and alternative proposals

1) ISO DIS 27065, version 2014-10-29 (clothes)

a) Material resistance to penetration – garments of level 1 and 2 (§ 6.1)

It is left to the person in charge of testing to choose between method A and method B of ISO 22608. The criteria to choose the one or the other method are not clear.

Alternative proposal:

Specific choice criteria must be provided by the developer of this test method.

b) <u>Material resistance to permeation and seam resistance to penetration for level 3 garments (§ 6.2 material and 7.2 seams)</u>

The same performance level is assigned for real performance levels that are effectively different, because "level 3 garments" are not tested according to the same method depending on the fact that they are considered as "complete" body garment or as "partial body garment". Depending on the garment category (complete or partial) the PPP concentration used for the test and the test duration is different.

Alternative proposal:

Such a differentiation should not exist. A specific performance level shall be assigned according to a specific unique test method, not a variable one. Moreover "Level 3" garment are expected to offer the highest level of protection, therefore the more severe test method should be kept to test "Level 3" garments.c) Coherence of the cumulative permeation limit with the normalized permeation rate (NPR) used in EN 16523-1. The criteria for choosing a cumulative permeation limit of 1 µg/cm² are unclear. *Alternative proposal:* The cumulative permeation limit should be coherent with the NPR given in EN 16523-1.

A study should be carried out to compare the performance of materials tested with this method and materials tested with EN 16523-1.

For information: a comparative study of then available permeation methods was carried out by INRS in 2010. I attach a paper on this study [ND 2348] and its English translation: http://www.inrs.fr/accueil/produits/mediatheque/doc/publications.html?reflNRS=ND%202348

Besides, the cumulative permeation should be proposed as an alternative to the permeation method described in EN 16523-1, when EN 16523-1 cannot be applied because of poor solubility of the liquid to be tested.

2) ISO CD 18889, version 2014-10-29 (gloves)

a) Definition of level 1 gloves (§ 5.1)

We wonder about the use of such a performance level. We do not see any difference with gloves that conform to EN 374-1 5.2.1 (liquid tight gloves). *Alternative proposal:* We propose to delete this level. b) Coherence of the cumulative permeation limit with the normalized permeation rate (NPR) used in EN 374-3 (§ 5.2) The criteria for choosing a cumulative permeation limit of 1 µg/cm² are unclear.

Alternative proposal:

The cumulative permeation limit should be coherent with the NPR given in EN 374-3. A study should be carried out to compare the performance of materials tested with this method and materials tested with EN 374-3.

Besides, the cumulative permeation should be proposed as an alternative to the permeation method described in EN 374-3, when EN 374-3 cannot be applied because of poor solubility of the liquid to be tested.

c) Disappearance of "Level 3"

In the introduction a performance level 3 is mentioned, however never defined in the rest of the

document.

Alternative proposal:

We propose to delete the mention of level 3 in the introduction.

Annabelle GUILLEUX, Danielle LE ROY

Pôle Risques Chimiques / Chemical Risks Unit

INRS

Département Expertise et Conseil Technique / Technical Expertise and Consulting Division 65, boulevard Richard Lenoir 75011 Paris

@: annabelle.guilleux@inrs.fr; danielle.leroy@inrs.fr