

ANNEX A1: Hygiene Control

A contamination risk assessment shall be performed for all goods. This appendix describes the requirements regarding contamination prevention in the supplier's production processes and premises. Wherever relevant, written instructions shall be available.

Personal hygiene

A. Personal hygiene is primarily the responsibility of the individual concerned but should be enforced by management where necessary, e.g. in cases in which an employee continually ignores the established procedures.

B. Appropriately clean clothing (including clean shoes) shall be worn by all employees in all areas where raw materials, semi-finished goods and/or finished goods are exposed. This includes maintenance operations.

C. Where appropriate, employees' hair shall be tied back and covered.

D. Hand washing facilities should be available within a reasonable distance from production and packing areas.

E. Eating and drinking shall be prohibited except in designated areas (with the possible exception of drinking water in plastic bottles). Suitable separate premises should be provided where employees may eat.

F. The use of tobacco shall be prohibited except in designated areas. Such areas shall be well away from the production environment.

G. Visible and/or detectable plasters or dressings shall cover cuts or sores on exposed skin.

H. Where appropriate, hygiene regulations should be clearly displayed.

Premises and equipment

I. Premises and equipment shall be cleaned in accordance with written cleaning instructions. Records should be kept.

J. Lighting that is sufficiently intense to allow the detection of defects is required in production, inspection and storage areas.

K. Unless the supplier has equivalent expertise and resources, a reputable pest control contractor should be consulted. Written reports are to be provided after each inspection of the pest control system. Appropriate measures shall be taken to prevent insects, birds and rodents from entering the premises, e.g. by implementing fly-screening and door-closing routines.

L. All sources of glass and brittle plastic in or above the production process shall be identified. Appropriate steps shall be taken to prevent fragments from contaminating raw materials, semi-finished goods and/or finished goods after a breakage, e.g. by enclosing lights or replacing glass windows. Appropriate procedures shall be followed in the event of a breakage.

M. Solvents and cleaning agents shall be stored in appropriate designated areas. Leakage of oils and lubricants should be prevented by means of an adequate maintenance system. Process additives such as oils, greases, lubricants and cleaning agents should not be allowed to come

into contact with raw materials, semi-finished goods and/or finished goods. Contamination from dripping water, condensation, etc., should be prevented.

N. Needles, razor blades and similar items are to be kept in designated areas and away from production processes. Used blades, etc., are to be collected in designated boxes.

O. During production, all tools and unused spare parts shall be kept away from machinery.

P. All raw materials, semi-finished goods and/or finished goods at all stages of the production process shall be stored in such a way as to prevent their contamination. Pallets should be in good condition and should be kept clean and dry. If wooden pallets are used, measures should be taken to prevent contamination of the raw material, semi-finished goods and/or goods (e.g. wood splinters). Where appropriate, clean layer sheets should be used.

Q. All repairs and maintenance carried out during production shall be suitably monitored to prevent contamination.