



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Brussels
SANTE.DDG1.B.4/

NOTE FOR THE ATTENTION OF NATIONAL COMPETENT AUTHORITIES

**Subject: COVID-19 and Substances of Human Origin
Cross-Border shipments of SoHO as essential goods and services**

The European Commission has clarified that Substances of Human Origin (SoHO) are considered to be essential goods/services for which **free circulation within the EU** is crucial¹.

In particular shipments of following SoHO are critical or essential²:

- Organs for transplantation
- Bone marrow or cord blood for transplantation (haematopoetic stem cells)
- Blood for transfusion
- Plasma for transfusion
- Plasma for manufacturing medicinal products

The template attached to the communication might be useful for drivers of vans/cars who do not have a certificate of professional competence (or at least a certificate recognised at EU level).

[Commission'guidelines](#) for border measures to protect health and keep goods and essential services available stipulate a.o. that control measures should not cause serious disruption of supply chains or of essential goods/services of general interest and Member States should designate priority lanes for freight transport (e.g. via 'green lanes').

For **import into the EU** (from third/non-EU countries) of human organs and other human or animal tissue or human blood suitable for permanent grafting, implantation or transfusion, in case of emergency and in order to ensure their timely delivery and use, the Commission has foreseen some facilitation in this respect, in the amendments to the UCC Delegated Act that are to be adopted. The new legislation allows that organs and other

¹https://ec.europa.eu/transport/sites/transport/files/legislation/2020-03-23-communication-green-lanes_en.pdf

² <https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-supply-substances-human-origin.pdf>

human or animal tissue or human blood, where not declared using other means, are deemed to be declared for release for free circulation by any of the following acts:

- a) going through the green or 'nothing to declare' channel in a customs office where the two-channel system is in operation;
- b) going through a customs office which does not operate the two- channel system;
- c) affixing a 'nothing to declare' sticker or customs declaration disc to the windscreen of passenger vehicles where this possibility is provided for in national provisions;

Though this provision is under its adoption process, European Commission has modified it in order to make it applicable retroactively, so that MS can use this solution in order to facilitate the imports of these goods in the present crisis situation. Member States and their national competent authorities still remain responsible for ensuring the compliance of the transportation and import of human organs with the relevant national, EU or international rules governing the trade of these goods.

Further contact: for urgent questions on ongoing allocation and shipment you can contact the national competent authorities [for organ transplantation](#) or for bone marrow the national registries members of the [World Marrow Donor Association](#).

The SoHO Team