

A Resolution of the Czech Parliament EU Committee on the EU SoHo Regulation was adopted on 5 October. The official Czech version is here: <https://www.psp.cz/sqw/text/text2.sqw?idd=218130>. An indicative English translation is included below.

RESOLUTION

of the Committee on European Affairs
of the 15th meeting
of 5 October 2022

on the proposal for a regulation of the European Parliament and of the Council on quality and safety standards for substances on the quality standards of substances of human origin intended for human use and repealing Directives 2002/98/EC and 2004/23/EC /Council Code 11396/22, COM(2022) 338 final/

The Committee on European Affairs of the Chamber of Deputies of the Parliament of the Czech Republic, having heard information by the Deputy Minister of Health Radek Policar, after hearing the rapporteur report of the Deputy Minister of the Presidency of the Council of the European Parliament, Mr. Petr Fifka and after the debate

1. Approves the proposed EU legislation on blood, human tissues and cells;
2. Adopts the opinion of the Government of the Czech Republic on this document;
3. Notes the efforts of the European Parliament and the Council to regulate the above-mentioned area in the above-mentioned area in the light of its significant development and the latest scientific knowledge, in particular with regard to increasing the availability and safety of therapies for European patients and reducing dependence on third countries, in particular in the supply of blood plasma for the production of life life-saving medicines and recommends the expansion of compensated blood plasma collection and other steps necessary to ensure the self-sufficiency of European Union countries;
4. Considers it essential for the functionality, efficiency and transparency of the system, a clear definition of the roles, responsibilities and establishment of the EU expert bodies (EDQM, ECDC, EMA and the newly established Coordination Group for substances of human origin) responsible for regulation, rule-making and decision-making in the field of human substances in particular with regard to the competences of individual EU Member States;
5. Calls on the Chair of the Committee on European Affairs to forward this resolution to the President of the European Commission