



DEPARTMENT OF THE TREASURY  
WASHINGTON, D.C.

OFFICE OF FOREIGN ASSETS CONTROL

Western Balkans Stabilization Regulations  
31 CFR part 588

GENERAL LICENSE NO. 3A

**Authorizing Certain Transactions Related to Agricultural Commodities,  
Medicine, Medical Devices, Replacement Parts and Components, Software Updates, or  
Medical Prevention, Diagnosis, or Treatment, or Clinical Trials Involving  
Certain Blocked Entities**

(a) Except as provided in paragraph (d) of this general license, all transactions prohibited by the Western Balkans Stabilization Regulations, 31 CFR part 588 (WBSR), involving one or more of the blocked entities described in paragraph (b) related to the following are authorized: (1) the production, manufacturing, sale, transport, or provision of agricultural commodities, agricultural equipment, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices; (2) the prevention, diagnosis, or treatment of any disease or medical condition; or (3) the conduct of clinical trials or other medical research.

(b) The authorization in paragraph (a) of this general license applies to the following blocked entities:

- (1) Orka Holding AD;
- (2) Infinity International Group d.o.o. Banja Luka;
- (3) Sirius 2010 d.o.o. Banja Luka; or

(4) Any entity in which one or more of the above persons own, directly or indirectly, individually or in the aggregate, a 50 percent or greater interest.

(c) For the purposes of this general license, agricultural commodities, medicine, and medical devices are defined as follows:

(1) Agricultural commodities. Agricultural commodities are products that fall within the term “agricultural commodity” as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602) and are intended for use as:

(i) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(ii) Seeds for food crops;

(iii) Fertilizers or organic fertilizers; or

(iv) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) Medicine. Medicine is an item that falls within the definition of the term “drug” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) Medical devices. A medical device is an item that falls within the definition of “device” in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(d) This general license does not authorize any transactions otherwise prohibited by the WBSR, including transactions involving any person blocked pursuant to the WBSR other than the blocked persons described in paragraph (b) of this general license, unless separately authorized.

(e) Effective June 18, 2024, General License No. 3, dated November 16, 2023, is replaced and superseded in its entirety by this General License No. 3A.

**Note to General License No. 3A.** Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies.

**Bradley T. Smith**

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Smith

Date: 2024.06.18 09:34:57 -04'00'

Bradley T. Smith

Director

Office of Foreign Assets Control

Dated: June 18, 2024