

Pursuant to Article 16(2) of the Law on Radiation and Nuclear Safety in BiH (Official Gazette of BiH, 88/07) and Article 61 (2) of the Law on Administration (Official Gazette of BiH, 32/02 and 102/09), the director of the State Regulatory Agency for Radiation and Nuclear Safety issues the

## REGULATION

### ON THE CONCENTRATION LIMITS FOR RADIONUCLIDES IN FOOD, FEED, MEDICINES, ITEMS OF GENERAL USE, BUILDING MATERIALS, AND OTHER GOODS PLACED ON THE MARKET

#### Article 1 (Subject)

This regulation governs the concentration limits for radionuclides in food, feed, medicines, items of general use, building materials, and other goods placed on the market.

#### Article 2 (Definitions)

The terms, as used in this regulation, mean:

- a) **Activity (A)**: The quantity A for an amount of radionuclide in a given energy state at a given time, defined as:

$$A = \frac{dN}{dt}$$

where  $dN$  is the expectation value of the number of spontaneous nuclear transformations from the given energy state in the time interval  $dt$ . The unit of activity is the becquerel [Bq];

- b) **Becquerel (Bq)**: The term for the unit of activity. One becquerel is equal to one transformation per second:  $1 \text{ Bq} = 1 \text{ s}^{-1}$ ;
- c) **Effective dose**: The weighted sum of the equivalent doses in all tissues and organs of the human body;
- d) **Organ- or tissue-equivalent dose**: The absorbed dose averaged over an organ or tissue that includes the relative biological effectiveness for the given incident radiation, the unit of which is the sievert ( $\text{Sv} = \text{J/kg}$ );
- e) **Annual limit on intake (ALI) for an individual**: The activity value of intake of a radionuclide that would result in a committed dose equal to the prescribed dose limit;
- f) **Food**: Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans but not including feed for animals that do not or are not kept for food production, live animals unless they are prepared for placing on the market for human consumption, plants prior

to harvesting, picking or gathering, medicines and medicinal products, cosmetic products, tobacco and tobacco products, narcotics or psychotropic substances, residues and contaminants, and as well natural ingredients of herbal or animal origin with harmful effect on human health. "Food" includes drink, chewing gum food additives and any substance, intentionally incorporated into the food during its manufacture, preparation or treatment;

- g) **Feed:** Any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for feeding to food-producing animals or animals used in food production;
- h) **Radionuclide derived concentrations in the environment:** The limit values for environmental contamination, which were derived from primary or secondary limits on the basis of the standardized models and the application of which ensures that the prescribed limits are not exceeded.
- i) **Natural radiation sources:** Ionizing radiation sources of natural terrestrial or cosmic origin;
- j) **Items of general use** are the following items:
  - 1) dishes, utensils, equipment, devices and packaging used in food business;
  - 2) children toys;
  - 3) personal hygiene, face and body care products, and their packaging;
  - 4) cleaning products;
  - 5) tobacco, tobacco products, and smoking accessories;
  - 6) certain items that, when used, come into direct contact with skin or mucous membrane.
- k) **Sievert:** The unit of equivalent dose and effective dose. One sievert is equal to one jule per kilogram:  $1 \text{ Sv} = 1 \text{ J kg}^{-1}$ ;
- l) **Artificial sources:** Ionizing radiation sources other than natural sources;
- m) **Drinking water:**
  - 1) All water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers;
  - 2) All water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent authorities are satisfied that the quality of the water cannot affect the wholesomeness of the food in its finished form.

### **(Prohibition to incorporate radionuclides)**

- (1) It shall be prohibited to intentionally incorporate radionuclides in food, feed, toys, personal hygiene, face and body care products, and jewelry in the production process.
- (2) It shall be prohibited to export and import goods referred to in paragraph (1) in which radionuclides are intentionally incorporated.

#### Article 4

### **(Concentration limits)**

Concentration limits for radionuclides in food, feed, medicines, building materials, and other goods placed on the market are determined by annual limits on intake of radionuclides in the human body by inhalation –  $GGU_{inh}$  and ingestion –  $GGU_{ing}$ , and as well by radionuclide derived concentrations in the environment (IK) under the "Regulation on radiation protection in occupational and public exposure" (Official Gazette of BiH, 102/11).

#### Article 5

### **(Concentrations in drinking water)**

- (1) Radionuclide derived concentrations in drinking water,  $IK_v$ , for the general public are calculated as follows:

$$IK_v = \frac{GD}{e(g)ing,n \cdot Vv}$$

where:

- a) GD – the value of effective dose limit for a member of the public. In calculations of radionuclide derived concentrations in drinking water, GD is assumed to be 0.1 mSv/year;
  - b) V [L] – the average water intake by a member of the public in a year (730 L).
- (2) The contribution to the effective dose arising from the intake of tritium  $^3H$ , potassium  $^{40}K$ , radon  $^{222}Rn$ , thoron  $^{220}Rn$  and radon daughters through drinking water is not included in the value of effective dose limit of 0.1 mSv/year.
  - (3) The limit value for  $^3H$  activity in drinking water shall be 100 Bq/L, for the total activity of alpha unstable radionuclides 0.5 Bq/L, and for the total activity of beta unstable radionuclides 1 Bq/L.
  - (4) If the measured total activity value for alpha or beta unstable radionuclides in drinking water exceeds the values referred to in paragraph (3), the identification and determination of individual radionuclide concentration shall be required. Drinking water may not be prohibited for use due to the measured total activity value for alpha or beta unstable radionuclides unless the individual radionuclide concentration is not determined.
  - (5) Derived concentrations of individual radionuclides in drinking water are provided for in Annex to this regulation.

#### Article 6

### **(Concentration in food)**

The radionuclide derived concentration in food,  $IK_h$ , is calculated for the general public as follows:

$$IK_h = \frac{GD}{e(g)_{ing,n} \cdot m}$$

where:

- a)  $GD$  – the value of effective dose limit for a member of the public. In calculations of radionuclide derived concentrations in foodstuffs largely present in the nutrition (vegetables, fruit, cereals, meat and meat products, eggs, milk and milk products, pork fat, cooking oil, sugar, coffee, sweets, alcoholic and non-alcoholic beverages),  $GD$  is assumed to be 0.1 mSv/year. The contribution to the effective dose arising from the intake of naturally occurring radionuclide  $^{40}K$  is not included in the value of effective dose limit of 0.1 mSv/year;
- b)  $m$  [kg] – the amount of food intake by a member of the public in a year.

### Article 7

#### **(Concentration limits for feed)**

- (1) Concentration limits for radionuclides in water for animals shall be equal to the limits prescribed for drinking water.
- (2) Concentration limits for radionuclides in feed shall be equal to the limits prescribed for food.

### Article 8

#### **(Concentration limits for medicines)**

- (1) Concentration limits for radionuclides in medicines shall be equal to the limits prescribed for drinking water. The limits for medicines in solid form shall be equal to the limits prescribed for drinking water, expressed in Bq/kg, in which the volume of 1 L is substituted by the mass of 1 kg.
- (2) The provision referred to in paragraph (1) does not apply to radiopharmaceutical preparations.

### Article 9

#### **(Concentration limits for personal hygiene, face and body care products, and children toys)**

Concentration limits for radionuclides in personal hygiene, face and body care products, and children toys shall be equal to the limits prescribed for drinking water.

### Article 10

### **(Concentration limits for tobacco and tobacco products)**

The total activity limit of alpha unstable radionuclides in dry tobacco and tobacco products shall be 37 Bq/kg.

#### Article 11

### **(Concentration limits for two or more radionuclides)**

If any goods placed on the market contain two or more identified radionuclides, concentration limits for those radionuclides shall meet the following requirement:

$$\sum \frac{K_n}{IK_n} \leq 1$$

where:

- a)  $K_n$  [Bq/L, Bq/kg] – concentration of a radionuclide  $n$  in the goods placed on the market;
- b)  $IK_n$  [Bq/L, Bq/kg] – derived concentration of a radionuclide  $n$  in the goods placed on the market.

#### Article 12

### **(Concentration limits for indoor building materials in architectural engineering)**

(1) Concentration limits for radionuclides in indoor building materials in architectural engineering amount to:

- a) for radium ( $^{226}\text{Ra}$ ):  $3 \cdot 10^2$  Bq/kg;
- b) for thorium ( $^{232}\text{Th}$ ):  $2 \cdot 10^2$  Bq/kg;
- c) for potassium ( $^{40}\text{K}$ ):  $3 \cdot 10^3$  Bq/kg.

(1) Gamma index for building materials referred to in paragraph (1) shall be less than 1 and is calculated as follows:

$$I = \frac{C_{Ra}}{300} + \frac{C_{Th}}{200} + \frac{C_K}{3000}$$

where:

- a)  $C_{Ra}$  – concentration of radium ( $^{226}\text{Ra}$ ) in Bq/kg;
- b)  $C_{Th}$  – concentration of thorium ( $^{232}\text{Th}$ ) in Bq/kg;
- c)  $C_K$  – concentration of potassium ( $^{40}\text{K}$ ) in Bq/kg.

#### Article 13

### **(Concentration limits for outdoor building materials in architectural engineering)**

(1) Concentration limits for radionuclides in outdoor building materials in architectural engineering amount to:

- a) for radium ( $^{226}\text{Ra}$ ):  $4 \cdot 10^2$  Bq/kg;
- b) for thorium ( $^{232}\text{Th}$ ):  $3 \cdot 10^2$  Bq/kg;

c) for potassium ( $^{40}\text{K}$ ):  $5 \cdot 10^3$  Bq/kg.

- (2) Gamma index for building materials referred to in paragraph (1) shall not exceed 1, and is calculated as follows:

$$I = \frac{C_{Ra}}{400} + \frac{C_{Th}}{300} + \frac{C_K}{5000}$$

where:

- a)  $C_{Ra}$  – concentration of radium ( $^{226}\text{Ra}$ ) in Bq/kg;
- b)  $C_{Th}$  – concentration of thorium ( $^{232}\text{Th}$ ) in Bq/kg;
- c)  $C_K$  – concentration of potassium ( $^{40}\text{K}$ ) in Bq/kg.

#### Article 14

##### **(Concentration limits for building materials in construction engineering)**

- (1) Concentration limits for radionuclides in building materials used in construction engineering as the base for roads, playgrounds and other structures in construction engineering structures (under the top overlay) so that it does not increase the absorbed dose rate of gamma radiation in the air amount to:

- a) for radium ( $^{226}\text{Ra}$ ):  $7 \cdot 10^2$  Bq/kg;
- b) for thorium ( $^{232}\text{Th}$ ):  $5 \cdot 10^2$  Bq/kg;
- c) for potassium ( $^{40}\text{K}$ ):  $8 \cdot 10^3$  Bq/kg.

- (2) Gamma index for building materials referred to in paragraph (1) shall not exceed 1 and is calculated as follows:

$$I = \frac{C_{Ra}}{700} + \frac{C_{Th}}{500} + \frac{C_K}{8000}$$

where:

- a)  $C_{Ra}$  – concentration of radium ( $^{226}\text{Ra}$ ) in Bq/kg;
- b)  $C_{Th}$  – concentration of thorium ( $^{232}\text{Th}$ ) in Bq/kg;
- c)  $C_K$  – concentration of potassium ( $^{40}\text{K}$ ) in Bq/kg.

#### Article 15

##### **(Other radionuclide concentration limits)**

- (1) Concentration limits for radionuclides with half-life greater than 60 days that are not laid down in an applicable regulation for powder or liquid substances intended for general use shall be 10 times greater than limits for radionuclides in drinking water. The volume of 1 L of drinking water is substituted with the mass of 1 kg.
- (2) Concentration limits of radionuclides with half-life shorter than 60 days in powder or liquid substances intended for general use shall be 100 times greater than limits for radionuclides in drinking water.

- (3) Concentration limits for radionuclides in solid compact items of general use shall be 1,000 times greater than limits for radionuclides in drinking water, in which the ambient equivalent dose rate arising from the tested product is less than 1  $\mu\text{Sv/h}$  at a distance of 10 cm from the product surface. At a distance of 1 m from the product surface, the limit of the ambient equivalent dose arising from the tested product shall be 0.1  $\mu\text{Sv/h}$  greater than the value of background radiation.
- (4) In case of concentration limits for natural radionuclides, the provision referred to in paragraph (3) shall apply.

#### Article 16

##### **(Concentration limits in radiological emergency conditions)**

- (1) In case of declaring a radiological emergency which indicates the possibility of food contamination with radionuclides, the concentration limits for radionuclides in food and feed specified in table 2 of Annex II to the "Regulation on maximum permitted levels of radioactive contaminants of food and feed following a nuclear incident or other radiological emergencies" (Official Gazette of BiH, 39/12) shall apply.
- (2) Concentration limits referred to in paragraph (1) shall apply as long as the above condition is in force.
- (3) Food or feed that does not meet required concentration limits for radionuclides referred to in paragraph (1) may not be placed on the market as long as these limits are applicable.

#### Article 17

##### **(Prohibition to place on the market)**

Any goods that do not meet the requirements laid down in this regulation may not (or must not) be placed on the market in the territory of BiH. It shall be prohibited to place on the BiH market the goods the use of which does not comply with the provisions of this regulation.

#### Article 18

##### **(Entering into force)**

This regulation shall enter into force on the 8th day following its publication in the Official Gazette of BiH.

DIRECTOR  
**Emir Dizdarević**

## ANNEX

### DERIVED CONCENTRATIONS OF INDIVIDUAL RADIONUCLIDES IN DRINKING WATER

<b>Radionuclide</b>	<b>Derived concentration (Bq/L)</b>
C-14	2,3E+02
Co-60	4,0E+01
Sr-90	4,9E+00
I-131	6,2E+00
Cs-134	7,2E+00
Cs-137	1,0E+01
Pb-210	2,0E-01
Ra-224	2,1E-01
Ra-226	4,9E-01
Ra-228	2,0E-01
Th-232	5,9E-01
U-235	2,9E+00
U-238	3,0E+00
Pu-239	5,5E-01
Am-241	6,8E-01