

Description of the BPR enforcement authorities in Romania

Government Decision no. 617/2014 on establishment of institutional framework and of measures for enforcement of Regulation no. 528/2012 (Regulation) concerning the making available on the market and use of biocidal products provided the following aspects:

- The Ministry of Health is assigned as competent authority for coordination of national-level measures required for enforcement of the Regulation.
- The following entities are assigned as authorities responsible for performance of official controls on compliance with Regulation's requirements as per provisions of art. 65 para. (2) in Regulation, as shown below:
 - a) Ministry of Health (State Sanitary Inspectorate) through public health directions;
 - b) Ministry of Environment and Climate Change through the National Environmental Guard;
 - c) National Sanitary Veterinary and Food Safety Authority through its regional / Bucharest sanitary-veterinary and food safety directions.
- The offenses related to noncompliance with the articles of Regulation.
- The value of penalties is set in according with the risk.
- Assessment of offenses and application of penalties are provided by personnel appointed by authorities set, as per legal competences.

Order no. 726/1178/96/2015 on determination of measures needed for official controls performed by assigned representatives of relevant public authorities as set in GD no. 617/2014 on establishment of institutional framework and of measures for enforcement of Regulation (EU) no. 528/2012 concerning the making available on the market and use of biocidal products

- The assigned representatives shall perform official controls based on competences, as follows:
 - ❖ Assigned representatives of the Ministry of Health perform official controls on manufacturers, importers, distributors and professional / industrial end users for the following product types:
 - a) disinfectants for human hygiene;
 - b) disinfectants and algacide not destined to direct application to humans or animals;
 - c) disinfectants for human potable water, in accordance with the Order of the Minister of Health, Minister of Environment and Forests and of the President of the National Sanitary Veterinary and Food Safety Authority no. 10/368/11/2010 on approval of homologation procedure for biocidal products marketed within Romania, as further amended and supplemented;
 - d) disinfectants for equipment, recipients, consumer tools, surfaces or pipes used in manufacturing, transport, storage or consumption of food products, as per competences set forth in relevant regulations;
 - e) rodenticides;
 - f) insecticides, acaricides and products for control of other arthropods;
 - g) repellents and attractants;
 - h) fluids used in embalming and taxidermy.

❖ Assigned representatives of the National Environmental Guard perform official controls on manufacturers, importers, distributors and professional / industrial end users for the following product types:

- a) preservatives for products during storage;
- b) film preservatives;
- c) wood preservatives;
- d) preservatives for fibers, leather, rubber and polymerized materials;
- e) preservatives for construction materials;
- f) preservatives for liquid cooling and processing systems;
- g) slimicides;
- h) preservatives for fluids used in machining or cutting;
- i) avicides;
- j) molluscicides, vermicides and products for control of other invertebrates;
- k) piscicides;
- l) antifouling products.

❖ Assigned representatives of the National Sanitary Veterinary and Food Safety Authority, through its regional / Bucharest sanitary-veterinary and food safety directions, perform official controls on manufacturers, importers, distributors and professional / industrial end users for the following product types:

- a) disinfectants for veterinary hygiene;
- b) disinfectants for equipment, recipients, consumer tools, surfaces or pipes used in manufacturing, transport, storage or consumption of food products, as per competences set forth in relevant regulations;
- c) disinfectants for equipment, recipients, consumer tools, surfaces or pipes used in manufacturing, transport, storage or consumption animal food;
- d) disinfectants for animal potable water, in accordance with the Order no. 10/368/11/2010;
- e) products for control of other vertebrates.

➤ The official control may include investigation of biocidal product, including collection of samples during targeted control action and, in case of suspicions, to assess the respective product in an accredited laboratory to certify that the biocidal product is compliant with legal provisions and requirements set forth in the administrative document for marketing of biocidal products or in the assessment report, as the case may be. If the biocidal product is noncompliant, costs incurred by analysis of biocidal product sample are charged to the manufacturer / importer / distributor, as the case may be.

➤ The Ministry of Health, through the National Public Health Institute, allows to the assigned representatives access to the updated database, which includes the administrative documents for marketing of biocidal products issued by the National Commission for Biocidal Products.

➤ The assigned representatives have access to all locations, documents and information related to marketed and used biocidal products, based on their respective competences.

➤ The assigned representatives perform official controls based on:

- a) annual official control plans, with predetermined targets;
- b) claims and complaints, when issues claimed require such control;

c) requests from other authorities.

- Public authorities set forth in GD no. 617/2014 prepares annual official control plans and notifies the same to the Ministry of Health until December 15th of each year. The Ministry of Health elaborates, each year, the national sectoral program for supervision of biocidal products market, as per provisions in Regulation (EC) no. 765/2008.
- Public authorities set forth in GD no. 617/2014 shall send annually to the same to the Ministry of Health, until March 31st of each year, the results of official control activities performed during the previous year, as per information requested by the Ministry of Health.
- The Ministry of Health, in its position of competent authority in accordance with GD no. 617/2014, shall send every five years, starting in 2015, no later than June 30th, a report to the European Commission concerning the results of official control activities performed during previous years, as per information requested by the European Commission.

Websites for enforcement authorities in Romania

1) Ministry of Health – State Sanitary Inspectorate

<http://www.ms.ro/organizare/inspectia-sanitara-de-stat/>

2) National Environmental Guard

<http://www.gnm.ro>

3) National Sanitary Veterinary and Food Safety Authority

<http://www.ansvsa.ro/sanatate-bunastare-si-nutritie-animala/biocide/>