

Useful information for businesses and farmers for the authorisation, placing on the market and use of plant protection products

- Plant protection products are placed on the market and used after an authorisation for placing on the market and use has been granted in accordance with the requirements of Regulation (EC) No 1107/2009, the Plant Protection Act and Ordinance No 5 authorising the placing on the market and use of plant protection products, as well as in compliance with approved standard operating procedures of the [Plant Protection Products, Fertilisers and Control Directorate \(PPPC\)](#), published on the BFSA website.
- An authorisation for the placing on the market and use of a plant protection product shall be granted by the Executive Director of the BFSA or by an official authorised by him to a person established on the territory of a Member State.
- A plant protection product shall be authorised for placing on the market and use where it complies with Section 1 of Chapter III of Regulation (EC) No 1107/2009. Compliance of a plant protection product with the requirements of Section 1 of Chapter III of Regulation (EC) No 1107/2009 shall be established by carrying out evaluations of the product. Evaluations are carried out by the Risk Assessment Centre on Food Chain, after receiving a copy of the required documents, which are officially sent by the BFSA.
- For the authorisation of plant protection products, with the exception of assessments with evaluation reports for plant protection products, the corresponding fees shall be paid in accordance with the Tariff for fees collected by the BFSA.
- Plant protection products shall be classified in accordance with Regulation (EC) No 1272/2008 (CLP), labelled in accordance with Regulation (EC) No 1107/2009, Regulation (EU) No 547/2011 and Regulation (EC) No 1272/2008 (CLP) and placed on the market in original packaging or repackaged, labelled in Bulgarian.
- Plant protection products are categorised into two categories of use, professional and non-professional. The professional use category is divided into two subcategories — first professional and second professional. The use category of a plant protection product shall be determined when it is authorised for placing on the market and for use in accordance with certain criteria. The use category shall be included in the authorisation for the placing on the market and use of the plant protection product.
- Plant protection products containing a candidate for substitution active substance shall be categorised as a professional category.
- Plant protection products containing low-risk active substances or basic substances shall be categorised as non-professional.
- The holder of an authorisation for the placing on the market and use of a plant protection product shall be responsible for the plant protection products placed on the market. The appointment of an authorised representative shall not exempt the holder of the authorisation from liability.
- Holders of authorisations for the placing on the market and use of plant protection products shall submit to the Headquarters of the BFSA a declaration in accordance with Article 67(3) of Regulation (EC) No 1107/2009.
- Persons who produce, repackage, place on the market and market plant protection products-shell keep records in accordance with Article 67(1) of Regulation (EC) No 1107/2009.
- Persons supplying plant protection products shall provide a safety data sheet in Bulgarian in accordance with Article 31 of Regulation (EC) No 1907/2006 (REACH).

- Persons placing plant protection products on the market shall develop and implement a system for blocking and withdrawing plant protection products from the market.
- Persons placing plant protection products on the market and persons repackaging plant protection products shall develop and implement a system for recalling empty packaging by the final user of plant protection products, in accordance with the Waste Management Act.
- Persons holding authorisations for the placing on the market and use of plant protection products and not established in the territory of the Republic of Bulgaria shall provide information to the Headquarters of the BFSA on the commercial entities to whom they have granted the right to distribute authorised plant protection products. The information shall be provided within three months of the authorisation or of any change.

THE FOLLOWING SHALL BE PROHIBITED:

1. The advertising of an unauthorised plant protection product or of a product outside its authorised use;
2. Advertising and publication of false indications on the marketing, storage and use of a plant protection product;
3. The provision of incorrect advice on the use of a plant protection product;
4. The indication of non-existent qualities of a plant protection product;
5. Failure to indicate the hazardous properties of a plant protection product;
6. The use of words that present a plant protection product as safe or make it possible to underestimate its danger;
7. Comparing the qualities of an advertised plant protection product with the qualities of similar products to other producers.
8. The import, introduction into the country, placing on the market or use of:
unauthorised or unfit plant protection products;
plant protection products from persons who are not authorised to place on the market and use.

Plant protection products shall be unfit where:

- their expiry date has expired;
- their physical, chemical or technical characteristics, their composition, the type of formulation or their other characteristics do not correspond to those approved at the time of authorisation and/or have damaged packaging or labels.