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## Biocidal products for use in food production, on animals and in stables

Before any biocidal products that come into contact with food, feed, animals used in food production or drinking water for animals can be accepted by the Danish Environmental Protection Agency (EPA), they also have to be evaluated by the Danish Veterinary and Food Administration (DVFA). Once the EPA has received an application it will be forwarded to the DVFA. The final acceptance will be issued by the EPA.

## Evaluation of the consequences for food safety

The DVFA will look at the amount, if any, of residual levels of biocides in food in order to evaluate whether there are any health risks from consuming food that has been in contact with biocides. If the active substance in a biocidal product is already approved as a pesticide or as a veterinary medicinal product it shall be evaluated whether or not the MRL value of the substance in foodstuffs will be exceeded.
Residual levels of biocides can be present due to direct contact between the biocidal product and the food or via treatment of animals, feed or drinking water for animals used in food production.
The starting point of an evaluation is to make an estimate of the residual level of biocide present under the intended use. Then the exposure level is compared to the available knowledge about the toxicity of the substance (e.g. the ADI value). There are different scenarios for this evaluation:

1. If the food producing animal or organs used as foodstuff are exposed to the active substance or its toxic degradation products at a level of less than 4 µg/kg, then the exposure is regarded negligible from a food safety point of view.
2. If an MRL value has already been set for the active substances in the biocidal product (e.g. if the substances is already approved as a pesticide or as a veterinary medicinal product) an exposure assessment shall be made. If this assessment shows that the MRL will not be exceeded, there is no concern for food safety.
3. If there is no MRL value for the active substances in the biocidal product, but an ADI value exists an exposure assessment shall be made. If the total exposure is less than 30% of ADI, there is no concern for food safety. If the total exposure is more than 30% of ADI, a specific evaluation of the consequences of use for food safety shall be made.
4. If there is no ADI value for the active substances in the biocidal product an exposure assessment shall be carried out along with a specific evaluation of the consequences of use for food safety.

## Which products require an evaluation of residual levels of biocides?

All biocidal products that come or may come into contact with animals used in food production (i.e., fur animals excepted), food and feed and drinking water for animals used in food production require evaluation by the DVFA. Examples are biocidal products that

- are used in kitchens or on equipment that come in contact with food
- are used in storage rooms where food and feed is kept
- are used in stables or directly on animals used in food production (i.e., fur animals exepted )



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- in other ways may come into contact with food or feed.

## Which products do not require an evaluation of residual levels of biocides?

If no animals, feed or food come into contact with the biocidal product, e.g. if the product is used for treatment of empty warehouses, then there will be no need for an evaluation of residual levels of biocides. If an empty warehouse or similar is treated with a biocide containing product it shall be ensured that no foodstuff is put back into the premises before all of the product has evaporated or been cleaned of.
A biocidal product used only on animals that have been excluded as food producing animals do not need an evaluation of residual levels of biocides.

## Special requirements on information to the end user of a biocidal product

If a biocidal product is intended for use within the food industry or in food production the product shall be accompanied by information on how the product should be used in order to prevent any unacceptable contamination of foodstuffs. This information can be given on the product label or as a separate guidance document following the product.

## Data requirements and cost

1. A chemical identification of the active substance, including the CAS number or the unique chemical name.
2. Genotoxicity data and data from a 28-day study in rodents. The studies must comply with the OECD[1] guidelines. There may be a need for further data on food safety, the responsibility for providing this lies on the applicant. Evaluation reports from international organizations often contain enough information.
3. A very precise explanation of where and how the product is intended to be used. E.g. if it can be used both in warehouses that store food and feed? Type of foodstuff to be stored in these warehouses (e.g. food of animal or plant origin)? Dosage for use of the product? How often is treatment required? Etc.
4. Information shall be give on whether the food and/or feed at the warehouse is packed securely or stored in open containers?
5. When a product is used in stables it should be stated whether or not feeding troughs or similar are covered during treatment.
6. An assessment of residual levels of biocide in food or feed shall be provided and an evaluation of the amount present (e.g. as mg biocide/kg foodstuff).
7. An assessment of residual levels of biocide in any live animals.
8. If an MRL in food has already been set, there should be an assessment of whether or not this value will be exceeded when the biocidal product is also used as a pesticide or as a veterinary medicinal product.
9. An explanation of the analytical methods used for measurement of residual levels of active substances in food shall always be provided.

[1] OECD: Organization for Economic Co-operation and Development



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