BACKGROUND // DECEMBER 2019

Authorisation of Anticoagulant Rodenticides in Germany

FAQ on Environmental Risks, Risk Mitigation Measures and Best Practice

For our environment

Umwelt Bundesamt

Imprint

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FAQ on Environmental Risks, Risk Mitigation Measures and Best Practice

Content

01 Foreword

The control of rats and mice as health and material pests is mostly done using poisonous baits – so-called anticoagulant rodenticides. In the European Union, these rodenticides are subject to authorisation according to the Biocidal Products Regulation (BPR) (EU) No. 528/2012. As part of their authorisation in Germany, mandatory provisions were stipulated to ensure a safe, effective and sustainable use. This publication provides you with information about what these stipulations are and why they were established. It also gives answers to frequently asked questions (FAQ) on rodent control using anticoagulant rodenticides and the environmental risks associated with their use.

Several editions of this document have been issued since the first publication in 2012. In the meanwhile, the legal basis of the biocidal product authorisation has changed. Since the 1st September 2013, the BPR has been in force, replacing the Biocidal Products Directive 98/8/EC. These changes were taken into consideration in the 2nd edition of the FAQ on the 'Authorisation of Anticoagulant Rodenticides in Germany' issued in December 2013. In the 3rd edition, questions and answers on permanent baiting were addressed for the first time.

The present 4th edition has been issued following the re-approval of anticoagulants as biocidal active substances and the renewal of authorisations of anticoagulant rodenticides as biocidal products. It covers, among other things, the EU-wide harmonised instructions for use as well as the new classification and labelling of anticoagulant rodenticides according to the CLP Regulation. Moreover, the updated 4th edition provides information about the emerging environmental issue of anticoagulant rodenticides in fish and devotes an entire chapter to rat control in sewer systems for the very first time.

02 Introduction

In the European Union (EU), rodenticides, which are used to protect human and animal health or manmade products, are subject to authorisation according to the Biocidal Products Regulation (BPR). The purpose of the BPR is to uniformly regulate and thereby improve the free movement of biocidal products available on the internal European market while protecting both human and animal health as well as the environment from the risks associated with their use. In order to resolve this apparent conflict of objectives, the BPR stipulates a two-tiered authorisation procedure. This involves a risk assessment of the active substances and subsequently of biocidal products with regard to possible undesired effects on human and animal health and the environment (see Chapter 3). Authorisation holders need also to prove the efficacy of their products.

Most rodenticides on the EU market are bait formulations containing anticoagulant active substances. Anticoagulant rodenticides were authorised as biocides although they have unacceptable effects on the environment and thus according to the BPR do not fulfil the conditions for granting an authorisation (see Chapter 4). It was argued that not authorising them would result in negative impacts for society as other effective alternatives for rodent control were lacking. However, their authorisation is subject to strict risk mitigation measures (RMM, see Chapter 5) such as the restriction of use to (trained) professionals, setting limits to the maximum concentration of the active substance in the product or imposing mandatory instructions for use.

In Germany, all second-generation anticoagulant rodenticides (SGAR) are authorised to be used by trained professionals only. The general public and professionals not having received appropriate training are not permitted to use these products, they may only use certain first-generation anticoagulant rodenticides (FGAR) in and around buildings (see Chapter 6). For the use of anticoagulant rodenticides, three different best practice codes for each user category were published. These entail mandatory instructions for use and risk mitigation measures that

Best practice code for the application of anticoagulant rodenticides

Legally binding instructions for use have been stipulated for the use of anticoagulant rodenticides for the general public, for professional users and for trained professional users, respectively. They are part of the directions for use on the label of the respective product and as such must be adhered to. The German Environment Agency (UBA) has compiled these instructions for use and risk mitigation measures in the form of three separate best practice codes for the use of anticoagulant rodenticides, with one for each user category. The best practice codes (in German) can be downloaded from the following web pages:

www.umweltbundesamt.de/publikationen/maeuse-rattengift-sicher-wirksam-anwenden

www.umweltbundesamt.de/publikationen/gute-fachliche-anwendung-von

www.umweltbundesamt.de/publikationen/gute-fachliche-anwendung-von-0

The English translation of the ‚Best practice code for the application of anticoagulant rodenticides by trained professionals' is included in Chapter 12. The other best practice codes are only available in German (see web links above).

were stipulated within the biocidal product authorisation of anticoagulant rodenticides in Germany (see Chapter 7).

The authorisation of anticoagulant rodenticides drove many discussions and raised numerous questions among manufacturers, users and industry. The German Environment Agency (UBA) has therefore compiled answers to frequently asked questions (FAQ) on the authorisation and use of anticoagulant rodenticides in this document.

03 Authorisation procedure for biocides

What is the authorisation procedure under the Biocidal Products Regulation?

The Biocidal Products Regulation (EU) No. 528/2012 (BPR) came into force on 1st September 2013, replacing the former Biocidal Products Directive 98/8/EC. Under the BPR, biocidal products may only contain active substances that have been previously approved at EU level and that are included in the 'Union list of approved active substances' (see Figure 1a). An active substance shall be approved, if the intended use of a biocidal product containing this substance does not have unacceptable effects on humans, animals and/or the environment. Moreover, it needs to be demonstrated that the product containing this active substance is sufficiently effective and does not cause unacceptable resistance in the target animals or, in the case of vertebrates, unnecessary suffering.

Potential risks to the environment are assessed as part of the environmental risk assessment (ERA, see Figure 1b). If for an active substance unacceptable effects on the environment are identified within the ERA, it will either not be approved or it will only be approved subject to appropriate risk mitigation measures and restrictions. If an active substance is not approved, the biocidal products containing the substance can no longer be made available on the EU market after the transitional periods for its marketing have expired.

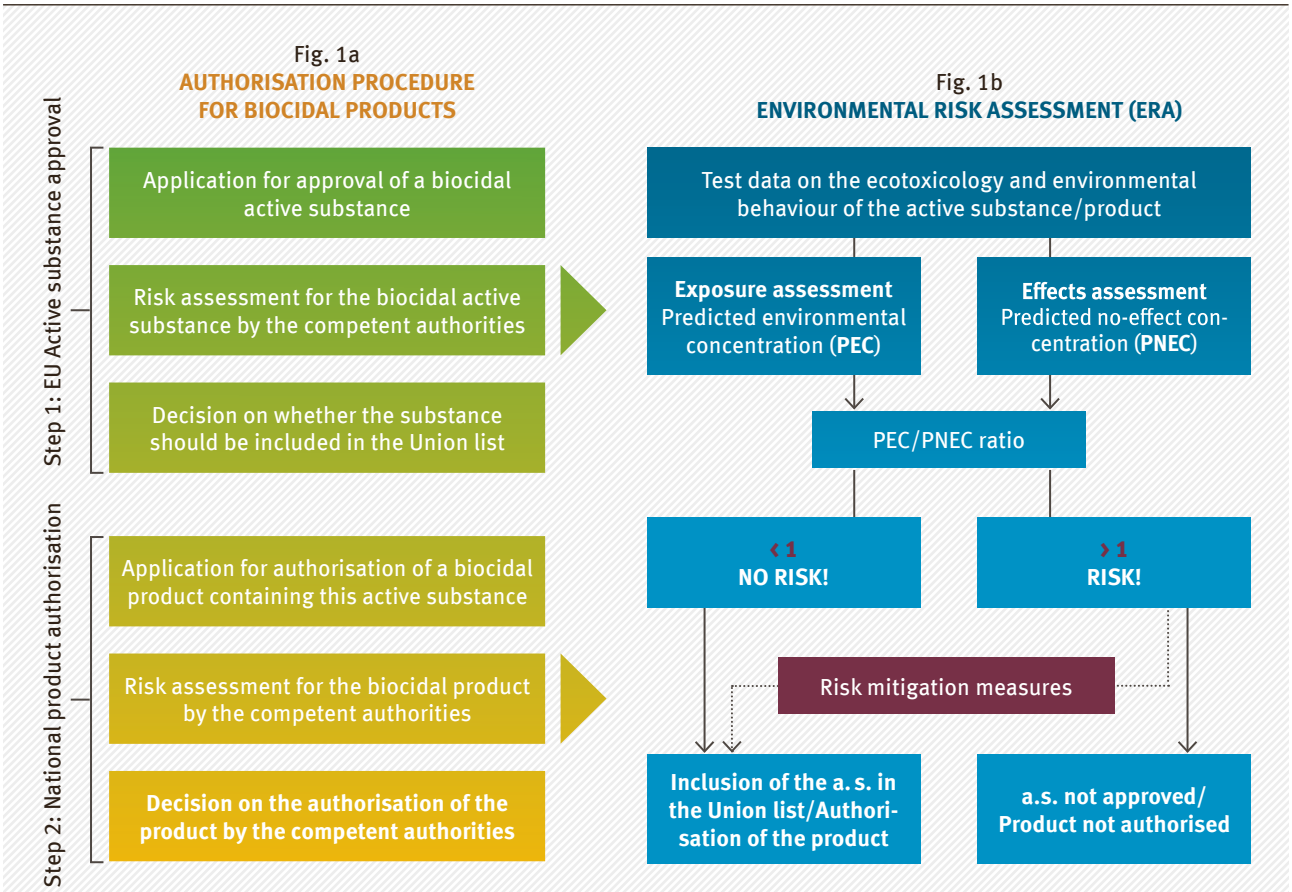
After the active substance approval at EU level, the individual products containing this active substance are assessed at national level. Subsequently, the national authorities decide on their authorisation. The product authorisation includes an examination of the co-formulants contained in the product, the efficacy testing of the product as well as the risk assessment of product uses that were previously not considered during active substance approval.

Which authorities are involved in the authorisation procedure?

In Germany, the competent authority for the authorisation of biocides is the Federal Office for Chemicals (BfC) at the Federal Institute for Occupational Safety

Figure 1

Authorisation procedure for biocidal products and environmental risk assessment



The authorisation procedure for biocidal products is split into two consecutive steps (Fig. 1a): In the first step the active substance (a. s.) is assessed at EU level under peer review of all EU Member States. This involves an environmental risk assessment (ERA; see Fig. 1b) for all concerned compartments such as soil, surface water or groundwater. The ERA consists of the exposure assessment, i. e. the calculation of the predicted environment concentration (PEC) and the effects assessment, i. e. the calculation of the predicted no-effect concentration (PNEC). If, for an environmental compartment, the calculated PEC for an active substance is below the threshold concentration that is considered to be safe for the respective environmental organisms (PNEC), i. e. the PEC/PNEC ratio is below 1, no unacceptable effects are assumed. The active substance is then included in the Union list of approved biocidal active substances and is permitted to be used in a biocidal product. However, if the PEC/PNEC ratio is above 1, then either risk mitigation measures are imposed, or the substance is not approved for use in biocidal products. For the groundwater assessment, the respective PEC must not exceed either the maximum permissible concentration laid down by Directive 98/83/EC, or the maximum concentration stipulated on the basis of toxicological data.
In the following second step, the biocidal products containing the approved active substance are assessed on national level. If the national competent authorities find the product to be sufficiently effective and that it has no unacceptable effects on humans, animals or the environment, then it is granted authorisation and can be made available on the EU market.

Source: *UBA*

and Health (BAuA). It is responsible for conducting all procedures under the Biocidal Products Regulation and coordinates the collaboration of the national authorities involved in the authorisation procedure. Division 4 of the BAuA evaluates the risk for employees. The German Environment Agency is responsible for the environmental risk assessment and, in the case of rodenticides and insecticides, also for the efficacy assessment and resistance management. The Federal Institute for Risk Assessment (BfR) assesses the effect of biocides on consumer health. The Federal Institute for Materials Research and Testing (BAM) is involved with the assessment of physical risks and the safety-technical properties of containers and packaging materials. For any other specific, technical issues the expertise of other authorities is additionally sought (Julius Kühn Institute, Robert Koch Institute).

Which rodent species are allowed to be controlled in Germany?

Under the German Protection of Species Order (BArtSchV), all mammals are fundamentally granted special protection status. According to Annex 1 of the BArtSchV, some rodent species are exempt from this protection and can therefore be controlled. These species include: House mouse (*Mus musculus*), brown rat (*Rattus norvegicus*), black rat (*Rattus rattus*), water vole (*Arvicola terrestris)*, bank vole (*Myodes glareolus*), field vole (*Microtus agrestis*), field mouse (*Microtus arvalis*).

The wood mouse (*Apodemus sylvaticus*) and the striped field mouse (*Apodemus agrigarius*), for example, are not subject to this exception and therefore must not be controlled without an appropriate permit issued by the competent local authority. The same applies to shrews, as they are insectivores and not rodents (Rodentia).

Which anticoagulant rodenticides are currently used to control rats and mice?

Most rodenticides that are commercially available as baits contain blood-clotting inhibitors, so-called anticoagulants (also referred to as vitamin K antagonists). If a rat or mouse ingests these active substances it will cause a loss of the blood-clotting ability and will usually cause death of the treated animal from internal bleeding within a few days. As a general rule, the effects will start 3–7 days after ingestion so that the rodents are unable to associate the toxic effect with the poisoned bait and therefore do not become suspicious of the bait (bait shyness).

Selected target animals of rodent control operations:
Brown rat (A), black rat (B) and house mouse (C).


(A)


(B)


(C)

Selected non-target animals of rodent control operations:
Wood mouse (D), striped field mouse (E) and shrew (F).


(D)


(E)


(F)

With anticoagulants, there is a difference between first-generation and second-generation active substances (see Table 1). Usually, baits that contain FGAR must be taken up several times by the rodent until a lethal dose has been ingested (multiple dose rodenticides).

Table 1

Anticoagulants approved as biocidal active substances in rodenticides

First-generation anticoagulant rodenticides (FGAR)
Chlorophacinone
Coumatetralyl
Warfarin
Second-generation anticoagulant rodenticides (SGAR)
Brodifacoum
Bromadiolone
Difenacoum
Difethialone
Flocoumafen

Second-generation anticoagulant rodenticides (SGAR) are more toxic and often a single intake is sufficient for the uptake of a lethal dose (single dose rodenticides). However, these active substances are less degradable than FGAR and they also tend to accumulate in organisms and in the food chain.

Why is the use of anticoagulants in rodenticides approved in spite of the high risks involved?

The conditions for an approval of anticoagulants according to Article 4 of the BPR are not met, inter alia, due to the unacceptable effects that they have on the environment (see Chapter 4). The reason that these substances were eventually approved was that effective rodent control has been deemed to be indispensable, particularly when it comes to protection against rodent-borne infectious diseases. So far, there are no equally effective and less dangerous alternatives to anticoagulants. Therefore, the risks for the environment were weighed up against their benefits for public health and hygiene. However, all anticoagulant active substances are subject to comprehensive risk mitigation measures to minimise the exposure of humans and environment in accordance with Article 19, Para. 5 of the BPR. Within the implementing regulations for their approval it was thus stipulated that in order to protect the environment all available and appropriate risk mitigation measures must be applied if anticoagulant rodenticides are authorised by the relevant national authorities.

For how long are anticoagulants approved?

As a rule, a biocidal active substance is included in the Union list of approved biocidal active substances for 10 years. The authorisation of a product that contains this active substance is valid as long as the active substance is approved. However, certain active substances, like anticoagulants for example, are subject to a shorter approval period of 5 years, after which they have to be re-evaluated. The period is shorter for anticoagulants due to the problematic environmental characteristics of the substances and the risks to the environment that they pose (see Chapter 4). After this 5-year period has expired, it will be checked whether the active substances can be replaced by lower-risk or less environmentally hazardous alternatives (comparative assessment) or if the authorisation needs to be renewed (re-authorisation).

Why have anticoagulants been authorised as biocidal active substances again?

Anticoagulants were first approved as active substances to be used in biocidal products from 2010–2012 (for a period of five years). From 2015 to 2017, the active substances were re-evaluated at EU level. The comparative assessment of anticoagulant rodenticides with other authorised rodenticides and non-chemical rodent control methods by the European Chemicals Agency (ECHA) showed that there are no equally effective and less harmful alternatives to anticoagulants currently available. Anticoagulants were thus re-approved as biocidal active substances for another 5 years. In the comparative assessment, non-chemical methods of rodent control, such as traps, could not be taken into consideration due to a lack of agreed evaluation criteria. The German Environment Agency (UBA) is committed to ensure that criteria for the assessment of the effectiveness, practicability and animal welfare of non-chemical control methods are developed, so that during the next comparative assessment, the use of anticoagulants in certain scenarios, at least, can be replaced by

biocide-free alternatives (see Chapter 11). For further information, please refer to the UBA website on 'Non-Chemical Alternatives for Rodent Control (NoCheRo)': https://www.umweltbundesamt.de/en/topics/chemicals/biocides/workshop-non-chemical-alternatives-for-rodent

Which changes resulted from the re-authorisation of anticoagulant rodenticides?

After the re-approval of anticoagulants for use as active substances in biocidal products in 2017, the renewal of existing product authorisations (re-authorisation) started. Prior to that, the European Commission (EC), together with the EU Member States, harmonised the majority of instructions for use and risk mitigation measures (RMM) for anticoagulant rodenticides across the EU. This resulted also in changes in the 'Best practice code for the application of anticoagulant rodenticides' in Germany (see Chapter 7). For example, it was decided in the EU that only products that contain difenacoum and/or bromadiolone shall be authorised for permanent baiting (see Chapter 8).

When do the new provisions from the re-authorisation need to be applied?

The new instructions for use will be implemented as part of the currently ongoing re-authorisation of anticoagulant rodenticides. They apply from the time of the re-authorisation of the respective products. By December 2019, most of the existing authorisations for anticoagulant rodenticides had already been renewed for a further five years.

Starting from the time of the re-authorisation, the competent authority will ensure a transitional period for the disposal, making available on the market and use of (old) stock. The transitional period for making products available on the market is 180 days, starting from the day of the (re-)authorisation, while (old) stock can continue to be used for up to 360 days after the issued (re-)authorisation.

Hazard pictogram 'Health hazard'

When does the new classification of anticoagulants need to be applied?

Regulation (EU) No. 2016/1179 entered into force on 1st March 2018. With that, all anticoagulants that have been approved as active substances for biocidal products are now classified as toxic for reproduction (either Category 1A or 1B) and as specific target organ toxicants at repeated exposure (STOT RE)[1].

From this date onwards, all rodenticides that are commercially available, and that contain anticoagulants in a certain concentration (see Table 2), must be labelled accordingly. The classification of anticoagulant rodenticides (products) as toxic for reproduction or target organ toxic has direct implications on their authorisation (see below). Moreover, products that have been classified as specific target organ toxic Category 1 or toxic for reproduction Category 1A or 1B are subject to the requirements of the German Chemical Prohibition Ordinance, which – among other things – regulate sales of such classified chemicals.

1 A definition of the hazard classifications 'reproduction toxicity' and 'specific target organ toxicity' can be found in the list of key terms (see index, Chapter 15).

Table 2

Concentration limits for the classification of anticoagulant rodenticides as toxic for reproduction or target organ toxic according to Regulation (EU) No. 2016/1179, as well as the highest permissible concentrations of the active substances in the product [given in ppm]

Active substance	Concentration limit Toxic for reproduction	Concentration limit Specific target organ toxic		Highest permissible concentration of the active substance in the product
	Repr. Cat. 1A*/1B**	STOT RE Cat. 1	STOT RE Cat. 2	
Warfarin*	30	5000	500	790
Chlorophacinone**	30	1000	100	50
Coumatetralyl**	30	10000	1000	375
Bromadiolone**	30	50	5	50
Difenacoum**	30	200	20	75
Brodifacoum*	30	200	20	50
Difethialone**	30	200	20	25
Flocoumafen**	30	500	50	50

Whether a rodenticide (product) is classified as being toxic for reproduction and/or target organ toxic depends on the concentration of the active substances contained in the product. If the concentration limits listed above are reached or exceeded, the product will be classified accordingly (see Table 3). If the concentration of the active substance in the product is below the concentration limits listed above, the product will not be classified as toxic for reproduction or target organ toxic.

What are the consequences of the classification as toxic for reproduction?

Rodenticides that have been classified as toxic for reproduction Category 1A and 1B shall not be authorised for the use by the general public according to Article 19, Para. 4 of the BPR. This applies also to FGAR, which were allowed for this user category until now. The product labels contain information on the user categories allowed to use the product.

What are the consequences of the classification as specific target organ toxic?

According to the German Hazardous Substances Ordinance, anticoagulant rodenticides that have been classified as specific target organ toxic shall only be used by trained professional users. This includes trained pest controllers and professionals with comparable qualifications that have been recognized as equivalent by the competent authority (see Chapter 6).

How can I recognise if a product is classified as specifically target organ toxic and/or toxic for reproduction?

This information is provided on the product label (see Table 3).

What are the user categories relevant for the authorisation of rodenticides and how are they defined?

In the context of the authorisation of rodenticides, there is a distinction made between the following user categories: the general public, professional users and trained professional users.

The **general public** (synonyms: amateurs, consumers, non-professional users) is considered to use rodenticides in private premises outside of professional activities. It is likely that these users will not always strictly follow the instructions for use in all cases, that they do not have the necessary specialist knowledge to follow these instructions and that they will not use personal protective equipment, like gloves.

Table 3

Labelling requirements for products classified as specific organ toxic and toxic for reproduction

Products classified as 'Specific target organ toxicity Category 1 or 2' must be labelled as follows:
Hazard symbol: 
SPECIFIC TARGET ORGAN TOXIC CATEGORY 1 (STOT RE) Hazard information: H 372 – Caused damage to organs (here: blood) through prolonged or repeated exposure. Signal word: Danger
SPECIFIC TARGET ORGAN TOXIC CATEGORY 2 (STOT RE) Hazard information: H 373 – May cause damage to organs (here: blood) through prolonged or repeated exposure. Signal word: Attention
Products classified as 'Toxic for reproduction Category 1 A/B' must be labelled as follows:
Hazard symbol: 
TOXIC FOR REPRODUCTION CATEGORY 1 A/B (REPR. 1 A/B) Hazard information: H360D – May damage the unborn child Signal word: Danger

Professional users (not having received any specific training in rodent control) regularly use rodenticides as part of their profession, although this job does not primarily involve rodent control. This user category includes, for example, caretakers, specialist cleaning staff or sewage workers. They neither have a qualification in using rodenticides nor are they trained for the specific application. With regard to knowledge about how to use biocidal products and the associated risks for humans, animals and the environment, there is almost no difference between professional users (not having received any training) and the general public.

Trained professional users have specialist knowledge about handling rodenticides and use such products on a regular basis as part of their profession. This user category includes trained pest controllers and professional users, like sewage workers, who have received appropriate training in using rodenticides. Appropriate forms of training are listed in Chapter 6 'Qualifications' and in Table 6.

What are the field(s) of use relevant for the authorisation of rodenticides and how are they defined?

Within the authorisation of rodenticides in general, a distinction is made between various fields of use (also referred to as scenarios): 'indoors', 'in and around buildings', 'open areas (incl. burrow baiting)', 'sewer systems', 'bank slopes' and 'landfill sites', and fumigation in rodent burrows in the ground. For these scenarios, the applied amount of product or type and number of applications, etc., can vary depending on the given scenario. These aspects are relevant input parameters for the environmental emission estimation and exposure assessment- i. e. the calculation of the predicted environmental concentration (PEC, see above). The potential exposure of the environment to rodenticides during their use is assessed by means of standardised models, which are agreed at EU level for these different uses (emission scenario documents, ESD). The assessment and subsequent authorisation of uses will only cover uses which are intended for the specific product by the applicant. For example, if only the use in and around buildings is requested by the applicant, the product can only be authorised for this intended use. On principle, the fields of use for anticoagulant rodenticides formulated as baits can be described as follows:

Indoors

The use is restricted to closed buildings and premises. For this scenario, it is essential that the target rodents cannot move freely between indoor and outdoor areas. The rodenticide is applied in bait stations. Only trained professional users are allowed to apply bait without bait stations in areas that must be inaccessible to children and non-target animals. Examples of such areas include cable funnels, areas between

partition walls and switch cabinets. In indoor areas, it is particularly the risk of poisoning to children and pets that plays an essential role. However, rodents may also move between indoor and outdoor areas and therefore there may also be a risk of secondary poisoning of predatory wildlife and pets (like cats) in outdoor areas.

Areas in and around buildings

In order to ensure an efficient pest rodent control, it may be necessary to place bait indoors and in areas directly adjacent to the outside of the building. The baits must be placed in bait stations, which are placed directly next to the wall of the building in outside areas. In this case, the risk of non-target animals feeding on the bait is naturally disproportionately greater than when that bait is used indoors – particularly if the bait is scattered around outside of the bait station by rats or mice.

Open areas (incl. burrow baiting)

This scenario refers to the use of rodenticides in urban, suburban or rural areas and is not associated with buildings, e. g. in parks, playgrounds, sports grounds, for dyke protection or on golf courses. In contrast to products that have been approved for use in and around buildings, products approved for this field of use can be applied away from buildings in 'open areas'. Unless indicated otherwise on the product label or in the directions for use, products authorised for 'open areas' can also be used in rodent burrows in the ground. After inserting the bait into a burrow, the burrow must be covered for example with a stone to prevent the bait from being rejected. Due to the particularly high risk of primary or secondary poisoning, only trained professionals are allowed to use rodenticides in 'open areas'.

Sewer systems

Only trained professionals, such as trained sewage workers or trained pest controllers, are allowed to use rodenticides in sewers. The bait is either applied on a wire in a manhole or in a waterproof bait station, which is installed in the manhole. Care must be taken to ensure that the bait does not come into contact with water and is not washed away (see Chapter 9).

Landfill site

This is a special scenario, differing from those 'in and around buildings' or in 'open areas' with regards to the amount of rodenticide applied and the frequency of application. In addition, inserting the bait into the ground, e. g. into rat burrows, is not permitted for this scenario of use, in contrast to the scenario 'open areas'. When using rodenticides at landfill sites, they must be placed in bait stations or in areas that cannot be accessed by children or non-target animals.

Mouse in a building, bait station next to a building and a rat burrow in an open area (from top to bottom)

04

Environmental risks from anticoagulant rodenticides

What are the environmental risks from the use of anticoagulant rodenticides?

The environmental risk assessment, carried out at EU level under the BPR, showed that the use of anticoagulant rodenticides poses very high risks to wildlife. Not only target rodents but also other animals might feed on the baits, resulting in accidental poisoning of non-target animals. This type of direct poisoning is referred to as **primary poisoning**. Animals feeding on poisoned rodents also exhibit a very high risk of poisoning. They may still die from residual rodenticide levels in their prey. Species at high risk include, above all, raptors such as common buzzards and owls, but also predatory mammals such as foxes and weasels. This indirect type of poisoning is referred to as **secondary poisoning**. The reason for these high risks is that anticoagulants inhibit blood clotting. As the blood clotting mechanism in mammals and in birds is very similar anticoagulant rodenticides are toxic to all of these organisms, regardless of whether they are pests, wild animals or humans. This applies to both first and second-generation anticoagulant rodenticides.

What are PBT/vPvB substances?

These are chemical substances that show persistent (P), bioaccumulative (B) and toxic (T) or very persistent (vP) and very bioaccumulative (vB) behaviour. They are poorly degradable (= persistent) under environmental conditions, accumulate in organisms, and therefore also in the food chain, (= bioaccumulative), and are poisonous (= toxic) to humans and/or other organisms in the environment. On principle, release of PBT substances into the environment should be avoided, irrespective of their concentration (e. g. in biocidal products) and quantities, considering that these substances can persist in water bodies, in the soil compartment and in the food chain for a long period of time.

In comparison to SGAR, FGAR do not tend to bioaccumulate and were shown to be less toxic. According to the Biocidal Products Regulation (EU) No. 528/2012 (Article 19, Paragraph 4, Letter c), biocidal products that contain active substances with PBT or vPvB properties must not be authorised for use by the general public.

Table 4

Results of the environmental risk assessment of anticoagulants

	Active substances	PBT	Primary Poisoning PEC/PNEC	Secondary Poisoning PEC/PNEC	Max. content in product (in %)
FGAR	Coumatetralyl	–	562–271,875	0.9–15,000	0.0375
	Chlorophacinone	–	1,200–155,767	1.7–7,545	0.005
	Warfarin	–	10.3–60,770	1.4–6,415	0.079
SGAR	Difenacoum	✓	1,733–500,000	823–23,500	0.0075
	Bromadiolone	✓	2,100–263,000	705–590,000	0.005
	Difethialone	✓	5,700–383,000	77–68,000	0.0025
	Brodifacoum	✓	125,000–1,582,031	15,000–855,855	0.005
	Flocoumafen	✓	22,120–297,000	‹ 622–97,000	0.005

FGAR: First-generation anticoagulant rodenticides **SGAR:** Second-generation anticoagulant rodenticides
PEC: Predicted Environmental Concentration **PNEC:** Predicted No-Effect Concentration **PBT:** Persistent, bioaccumulative & toxic

PEC/PNEC ratios for primary and secondary poisoning of various bird and mammal species, information about PBT properties and the maximum content of the active substances allowed in a product. Data taken from the 'Assessment reports' and the implementing regulations for the approval of the active substance for use in biocidal products.

As shown in Table 4, the risk ratios (PEC/PNEC) for primary and secondary poisoning of non-target animals are in the six-digit range for some substances. Unacceptable effects are indicated by a PEC/PNEC ratio › 1. Therefore, very high risks to non-target animals need to be assumed. Although the risk ratios for primary and secondary poisoning are lower for FGAR in comparison to SGAR, FGAR also poses a high risk of poisoning.

In contrast to the environmental risk assessment, the PBT assessment of a substance is only based on its inherent properties and therefore, is not related to the active substance concentration in the final product.

Is there a risk even if the concentration of anticoagulants in products is very low?

Yes. The environmental risk assessment of products is based on the concentration of the active substance in the product. For anticoagulant rodenticides, the maximum permissible concentration of an active substance in a product was determined at the stage of active substance approval at EU level (see Table 4). Despite low active substance concentrations, the products still pose substantial environmental risks that are considered unacceptable, if no risk mitigation measures are applied.

Is there a risk for the environment if anticoagulant rodenticides are applied indoors?

Restricting the use of anticoagulant rodenticides exclusively to indoor environments has been discussed as a measure of minimising the risks identified for non-target animals. On principle, this risk mitigation measure can lead to a significant reduction of the potential risk for poisoning for non-target animals (particularly wildlife). Direct access to rodent baits would be prevented, thus reducing the risk of primary poisoning. However, the risk of pets being poisoned would remain. Moreover, the risk of secondary poisoning of wildlife cannot be completely ruled out. Rodents that feed on the bait and move between indoors and outdoors remain a risk for predators for several days and even weeks after ingesting a lethal or sublethal dose. Furthermore, some species such as barn owls are known to hunt also in buildings (e. g. barns) and feed on house mice, particularly during the winter season (Schneider 1964). Hence, a restriction of anticoagulant rodenticides to indoor areas alone would not result in a sufficient mitigation of risks described above. In addition, it may be necessary to apply baits also along runways and in nesting places in outdoor areas (e. g. around buildings) in order to achieve successful control.

Are there studies documenting the risks of anticoagulant rodenticides to non-target animals?

There have been numerous scientific studies worldwide, which have documented residues of anticoagulant rodenticides, mainly SGAR, in various

Barn owl

non-target animals and thus identified a risk to these animals. Residues of anticoagulant rodenticides were detected, for example, in barn owls (Newton et al. 1990/Great Britain, UK), tawny owls (Walker et al. 2008/UK), boobooks (Lohr 2018/Australia), common buzzards (Berny et al. 1997/France), golden eagles (Langford et al. 2012/Norway), and also in polecats (Shore et al. 1996/UK), minks (Fournier-Chambrillon et al. 2004/France), weasels (McDonald et al. 1998/UK), hedgehogs (Dowding et al. 2010/UK) and foxes (Tosh et al. 2011/UK, McMillin et al. 2008/USA). In addition to predatory mammals and birds that feed on (contaminated) mice or rats, granivorous non-raptor birds are also at risk. They may feed directly on the bait, as it mostly consists of cereals (Eason et al. 2002, Vyas 2017).

The scope of the reviewed studies, i. e. the number of animals examined, study duration and spatial extent, varied from detection of anticoagulants in a number of individuals in one region to monitoring of entire populations in individual countries over several years. In general, the percentage of animals with residues of anticoagulants detected varied between 10 and 97 %. A study carried out by Walker et al. (2008) found residues of at least one anticoagulant in 20 % (33 of 172) of the tawny owls examined in Great Britain. In a study conducted in Scotland, residues of anticoagulants were detected in 70 % of 114 red kites examined (Hughes et al. 2013). In studies carried out in Denmark, residues of anticoagulants were detected in almost all of the weasels examined (124 out of 130) (Elmeros et al. 2011). In a Spanish study, residues of anticoagulants were found in 39 % (155) of 401 non-target animals examined. In 140 cases, a lethal effect of these substances could not be ruled out (Sanchez-Barbudo et al. 2012). In Northern Ireland, residues of anticoagulants were found in 84 % (out of a total of 115) of foxes examined (Tosh et al. 2011).

In a study commissioned by the UBA and carried out by the Julius Kühn Institute (JKI), a systematic analysis of residues of anticoagulants in wild animals was performed for the very first time in Germany. The results show that residues of anticoagulants could be detected in several small mammalian species such as wood mice and shrews, which are both non-target animals and protected species in Germany (Geduhn et al. 2014), as well as in owls and birds of prey – particularly in common buzzards (Geduhn et al. 2016). Furthermore, residues of anticoagulants were found in 61 % of liver samples collected from 265 foxes (Geduhn et al. 2015). The final report for the project can be found on the following UBA web page: https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2018-01-10_texte_04-2018_rodentizide_v2.pdf

Residues of anticoagulants are mainly analysed in the livers of animals that have been found dead. In retrospect, it is often impossible to establish a link between the concentration of anticoagulant rodenticides found in these animals and the possible cause of death (Thomas et al. 2011). The concentrations detected in the liver samples range mostly from ng/g to µg/g based on wet weight; however, the concentrations leading to death vary depending on the species. For example, barn owls that died verifiably of anticoagulant poisoning showed hepatic concentrations in the very low µg/g range (Newton et al. 1990).

Yet, residual rodenticide concentrations detected in studied non-target animals have at least in some cases caused their death. In addition to lethal effects, long-term effects on the behaviour and reproduction of exposed animals are likely, considering the high potential of SGAR to persist and accumulate

Kestrel

Stoat

in organisms. Based on the available studies, it can be concluded that non-target animals are likely to become directly or indirectly exposed to anticoagulant rodenticides every time they are used (Laakso et al. 2010). Ultimately, the risk of secondary poisoning to wild animals can only be minimised and not avoided entirely.

Are anticoagulant rodenticides also harmful to aquatic organisms such as fish?

In laboratory tests with daphnia, algae and fish, respectively, a high acute toxicity of anticoagulants for aquatic organisms was observed. The concentration at which half of the tested species died or were negatively affected following short-term exposure to the active substance (LC_{50}/EC_{50} value) ranged between 65 mg/l (warfarin, LC_{50} fish) and 0.004 mg/l (difethialone, EC_{50} daphnia). Nevertheless, no unacceptable effects were identified for aquatic organisms during the environmental risk assessment of anticoagulant rodenticides as the predicted environmental concentration (PEC) of the active substances in surface water was well below the concentration threshold (PNEC, see Figure 1b), above which adverse effects are to be expected.

Although acute effects on aquatic organisms are not to be expected according to the predicted concentration in surface water, chronic exposure at low environmental concentrations and the high bioaccumulation potential of SGAR via the aquatic food chain may pose a more severe threat to (higher) aquatic organisms as well as top predators than indicated by the calculated PEC/PNEC ratio for surface water (Regnery et al. 2019a).

Indeed, residues of anticoagulant rodenticides in freshwater fish from various large watercourses in Germany were recently detected in a study commissioned by the UBA and carried out by the Fraunhofer Institute for Molecular Biology and Applied Ecology (Kotthoff et al. 2018). Liver samples of bream (*Abramis brama*) had been collected in 2015 from different surface water sites, i.e the rivers Danube, Elbe and Rhine, as well as two lakes and screened for rodenticides. Results indicated widespread occurrence of SGAR in fish from large watercourses. At least one SGAR was detected in every fish sample from the 16 river sampling sites across Germany. In contrast, no anticoagulant rodenticides were detected in fish liver samples from both lakes. Brodifacoum was detected in almost 90 % of the 18 examined fish

Red fox

liver samples with a maximum content of 12.5 µg/kg wet weight. Difenacoum and bromadiolone were also present in 44 % and 17 % of analysed samples, respectively. The results clearly show that not only terrestrial animals but also aquatic species are exposed to anticoagulant rodenticides.

Potential emission pathways for anticoagulant rodenticides to reach the aquatic environment are currently investigated by the Federal Institute of Hydrology (BfG) in Koblenz, Germany within a research project commissioned by the UBA. So far, study results showed incomplete removal of anticoagulants during conventional wastewater treatment and confirmed exposure of aquatic organisms via municipal effluents. Furthermore, it was demonstrated that sewer baiting contributes to the release of anticoagulant rodenticides into the aquatic environment (Regnery et al. 2019b).

ADDITIONAL INFORMATION

The Environmental Specimen Bank uses bream as a biological indicator species for water monitoring. Additional information about the work that the Environmental Specimen Bank conducts using bream is provided via the following website:

https://www.umweltprobenbank.de/en/documents/profiles/specimen_types/10037

05

Risk mitigation measures

What are risk mitigation measures (RMM)?

A biocidal product that does not fulfil the conditions for granting an authorisation, e. g. because it has unacceptable effects on the environment, may nevertheless be authorised, if its non-authorisation would result in negative impacts for society, for instance in terms of infection prevention. However, according to the BPR, its authorisation then shall be subject to appropriate measures to ensure that exposure of humans and the environment to that product is minimised. These so-called risk mitigation measures may include, for example, a restriction of the area of use, the exclusion of certain categories of users (e. g. the general public) or technical instructions for use.

Who is authorised to use anticoagulant rodenticides?

Table 5 shows which user categories are authorised to use anticoagulant rodenticides according to the biocidal product authorisation in Germany. This information shall apply without prejudice to any further requirements which may be applicable because of legal provisions regarding consumer protection and occupational safety (e. g. GefStoffV, ArbSchG), and it is subject to the actual authorisation of individual products and the results of their risk assessments. The classification of anticoagulant rodenticides as toxic for reproduction and specific target organ toxic has also a direct impact on which user categories are permitted to use the respective products (see Chapter 1). In general, biocidal products that are authorised for use by professional users or trained professional users, can only be used by these user groups. The product label must show the categories of users to which the biocidal product is restricted.

What RMM apply to first-generation anticoagulant rodenticides?

As shown in Table 5, products containing the active substances warfarin, coumatetralyl or chlorophacinone, i. e. first-generation anticoagulant rodenticides (FGAR), may still be used by the general public. However, this does not apply for FGAR that have been labelled as ‘toxic for reproduction’ (see Chapter 1). The use of FGAR by the general public is restricted to

Table 5

Overview of authorised users of first-generation and second-generation anticoagulant rodenticides (FGAR/SGAR) for rodent control[1] in Germany in different fields of use

USER CATEGORY / FIELD OF USE	General public	Professionals	Trained professionals		
		Without qualifications in rodent control	Professionals with qualifications[2]	Qualified professionals according to Annex 1 No. 3.4 GefStoffV	Professional pest controllers according to SchädlBekAusbV
Indoors	FGAR[3]	FGAR[4]	FGAR/SGAR[4]	FGAR/SGAR	FGAR/SGAR
Sewer system	No	No	FGAR/SGAR[4]	FGAR/SGAR	FGAR/SGAR
In and around buildings (residential buildings, barns, etc.)	FGAR[3]	FGAR[4]	FGAR/SGAR[4]	FGAR/SGAR	FGAR/SGAR
Open areas (e. g. parks, golf courses), waste dumps, dykes, etc.	No	No	FGAR/SGAR[4]	FGAR/SGAR	FGAR/SGAR

[1]Control of rats, house mice and a number of vole species (e. g. bank voles and field voles) for the protection of human and animal health and materials. The use for plant protection purposes is not permitted.
[2]Proof of qualification in accordance with the Ordinance Governing Specialist Qualification in Plant Protection or participation in a training course (see Chapter 6).
[3]Not applicable for products classified as 'toxic for reproduction' (see Chapter 1).
[4]Not applicable for products classified as 'specific target organ toxic' and whose uses fall under the scope of Annex 1 No. 3 GefStoffV (see Chapter 1).

the private, domestic area in and immediately around buildings. When using these products, they must adhere to the best practice code for the application of anticoagulant rodenticides by the general public (see Chapter 7).

Professional users (without qualifications in rodent control) may use FGAR in and around buildings as part of their occupation. When using these products, they must adhere to the best practice code for the application of anticoagulant rodenticides by professional users (without qualifications) (see Chapter 7).

On the contrary, trained professional users (see table 5) can also use FGAR in open areas or in sewers. When doing so, they must adhere to the best practice code for the application of anticoagulant rodenticides by trained professional users (see Chapter 7).

The best practice codes for the application of anticoagulant rodenticides for the general public, professional users and trained professional users can be downloaded (in German) from the following web page: https://www.umweltbundesamt.de/themen/chemikalien/biozide/biozidprodukte/rodentizide

The English translation of the best practice code for the application of anticoagulant rodenticides for trained professionals is included in Chapter 12.

What RMMs apply to second-generation anticoagulant rodenticides?

Second-generation anticoagulant rodenticides (SGAR) are only authorised to trained professionals (see Chapter 6). The field of use is not restricted for these users. Trained professionals may apply SGAR both indoors and outdoors (see Table 5). During use, the best practice code for the application of anticoagulant rodenticides by trained professional users must be adhered to (see Chapter 7).

The general public as well as professionals that do not have the necessary qualifications are not authorised to use SGAR.

Are RMM legally binding?

Yes. Risk mitigation measures are an essential part of an authorisation, which stipulates the terms and conditions relating to the use of the biocidal product. RMM are individually stipulated in the authorisation

of the respective product, must be included in the directions for use on the product label and thus must be adhered to when the product is being used.

From when do the RMM apply?

Authorisations for biocides are granted on a product-by-product basis. Therefore, all instructions for use as well as RMM become legally binding as soon as the authorisation of the product is issued or renewed (re-authorisation). It should be noted that a period of grace is granted for the disposal, making the products available on the market and use of existing stocks of biocidal products whose authorisation has been revoked or that have changed as part of their re-authorisation. The period of grace for making the existing stocks available on the market is 180 days, while the transitional period for the disposal and use of existing stocks is up to 360 days after the product's (re-)authorisation. Due to these transitional regulations, it may be that different deadlines for complying with RMMs may apply for comparable products, depending on when they were authorised.

For an overview of biocidal products already authorised in Germany check the BAuA biocidal product database:
https://www.baua.de/EN/Topics/Safe-use-of-chemicals-and-products/Chemicals-law/Biocides/Database-biocidal-products.html

Why are these restrictions (RMM) necessary and why were they established?

The measures established for anticoagulant rodenticides and, above all, the best practice code for their application are primarily intended to generally minimise the high risks for primary and secondary poisoning of non-target animals. Table 4 shows that for some substances the risk ratios (PEC/PNEC) calculated within the environmental risk assessment are in the six-digit range. An unacceptable risk is already indicated, if the PEC/PNEC ratio is greater than 1.

The rationale behind the decision to restrict the use of SGAR to trained professionals is that users who have not received appropriate training do not have the expertise required to comply with the compulsory yet extensive set of RMM, especially if it concerns baiting campaigns outdoor or treating resistant rodent populations. Non-qualified users cannot ensure a significant reduction of the identified risks while using a minimum quantity of rodenticides to achieve efficient control of pest rodents.

This is also why the general public is only permitted to use FGAR in their private, domestic area and not in open areas or public places, for example.

Do the same RMM apply throughout Europe?

Basic risk mitigation measures for the use of a biocidal product may already be determined at EU level within the active substance approval. This was also the case when anticoagulants were first approved as active substances. The European Commission stipulated that EU Member States had to apply all appropriate and available risk mitigation measures during the consecutive national biocidal product authorisation. These measures include, in particular, the restriction to professional use only, the setting of an upper limit to packaging sizes and the obligation to use tamper-resistant bait boxes. However, due to national differences, e. g. related to the infrastructure of professional pest control within the EU, different authorisation policies and RMM were established in the individual EU Member States within the first authorisation of anticoagulant rodenticides. As part of the re-approval of anticoagulants in 2017, the European Commission has harmonised the provisions for use and the RMM. Nevertheless, there may still be some individual variations within the national product authorisation, for example, with regards to the qualification requirements for trained professional users. The harmonised risk mitigation measures at EU level largely correspond to the previously determined provisions for the use of anticoagulant rodenticides in Germany.

Bait station

In the future, how will it be ensured that only trained users use these products and that they cannot be accessed by the general public?

The EC stipulated in the implementing regulations for the renewal of the approval of anticoagulants as biocidal active substances that persons making products for (trained) professionals available on the market shall make sure that these products are not supplied to other persons than (trained) professionals.

In addition, the product labels must clearly show the categories of users to which the biocidal product is restricted. Users are obliged to comply with the provisions of use stipulated in the authorisation and printed on the product label. It is the responsibility of the German Federal States (Bundesländer) to ensure that provisions resulting from the biocidal products authorisation are complied with. In the medium term, national regulations on the sale of biocidal products in Germany are to be established.

06 Qualifications

What proof of qualification is required for the use of anticoagulant rodenticides?

In order to use anticoagulant rodenticides that are only authorised for use by trained professional users, **one** of the types of vocational training or proof of qualification listed in Table 6 is required.

Why are these qualifications considered appropriate?

So far, there is no legal regulation that stipulates the qualification requirements for the use of biocides under German law. Thus, Germany has restricted the use of anticoagulant rodenticides to user groups who are assumed to have the expertise to use them properly (see Table 6). First and foremost, this applies to trained pest controllers, but also to professionals that have a comparable qualification (in accordance with Annex 1 No. 3 of the GefStoffV). Professionals with a qualification under the Ordinance Governing Specialist Qualification in Plant Protection are also included in the category of trained professional users of anticoagulant rodenticides.

In order to give (untrained) professional users the opportunity to get training, it is also sufficient to attend a training course that provides knowledge on rodent control. The content of such courses has been laid down in the authorisation of anticoagulant rodenticides (see Table 6). Such training is intended to ensure that professional users are able to correctly carry out rodent control with anticoagulant rodenticides as part of their occupation, e. g. as a caretaker, cleaning specialist or sewage worker.

The recognition of these different qualifications ensures that the number of users authorised to carry out rodent control with anticoagulant rodenticides is sufficient to assure effective protection against rodent-borne infectious diseases in Germany.

These qualification requirements have been established for a transitional period. In the midterm, it is planned to regulate qualification requirements for the use of biocidal products with regard to type, scope and certification of training courses in a uniform manner under national legislation.

Table 6

Overview of recognised qualifications for the use of anticoagulant rodenticides by trained professional users in Germany

Trained pest controller
▸ Persons who have completed vocational training according to the Ordinance on Occupational Training for Pest Control Officers (SchädlBekAusbV).
Professionals with qualification according to Hazardous Substances Ordinance
▸ Persons with a qualification equivalent to that of pest controllers according to Annex I No. 3.4 Hazardous Substances Ordinance (GefStoffV). ▸ Proof of qualification recognised by the competent authority according to the Technical Rule for Hazardous Substances 523 – Pest control using highly toxic, toxic and health hazardous substances and preparations (TRGS 523) in the field of protection of human health and stored products.
Professionals with qualification according to Ordinance Governing Specialist Qualifications in Plant Protection
▸ Professionals such as farmers, foresters, horticulturists, viticulturists, plant protection laboratory assistants, etc. as stipulated in the Ordinance Governing Specialist Qualifications in Plant Protection (PflSchSachkV). ▸ Persons who have passed an appropriate examination according to PflSchSachkV. ▸ Any other training or advanced training courses recognised by authorities under PflSchSachkV.
Professionals with certificate of participation for a training course as laid down in the authorisation of anticoagulant rodenticides
Persons who have attended a certified training course covering the following topics: ▸ Behaviour and biology of rodents ▸ Legal basis of rodent control ▸ Best practice code for the application of anticoagulant rodenticides by trained professionals incl. integrated pest rodent control and resistance management ▸ Mode of action of anticoagulants ▸ Hazards and risks to humans and the environment involved in the use of rodenticides ▸ Risk mitigation techniques in particular regarding the primary and secondary poisoning of non-target animals and handling of PBT/vPvB substances ▸ Application techniques/procedure and documentation ▸ Behaviour and control of rats in sewer systems

07

Best practice code for the application of anticoagulant rodenticides in Germany

What is the ‘Best practice code for the application of anticoagulant rodenticides’?

The best practice code for the application of anticoagulant rodenticides entails instructions for use and risk mitigation measures that were stipulated within the biocidal product authorisation of anticoagulant rodenticides. The purpose of this best practice code is to minimise the risks associated with the use of anticoagulants and to make the rodent control as effective and sustainable as possible. The provisions in the best practice code are an essential part of the product labels of anticoagulant rodenticides. Thus, they are legally binding and must be adhered to when using these products.

Different provisions apply for the general public, professional users (without qualifications) and trained professional users. Consequently, an individual best practice code was compiled for each of these three user categories.

What do you have to pay attention to when using anticoagulant rodenticides?

Basically, in order to apply rodenticides in a safe, effective and legal correct manner the ‘Best practice code for the application of anticoagulant rodenticides’ has to be followed. This implies also the consideration and use of non-chemical rodent control measures such as traps, prior to the use of rodenticides. Traps are particularly suitable for the control of mice, voles and occasionally appearing rats (see Chapter 11). If traps turned out to be insufficient or inadequate, then rodenticides can be an effective control method when used properly.

However, there are numerous provisions that must be followed when using anticoagulant rodenticides. For example, the bait must always be deployed inaccessible to children and non-target animals, e. g. by using tamper-resistant bait stations. Also, any persons that may come into contact with the bait must be informed about the risk of poisoning with warning signs, for example (see below). In accordance with the best practice code, the bait points must be inspected at

certain intervals in order to replace eaten bait, collect and dispose of dead rodents and any spilled bait, or bait that has been scattered by rodents.

Furthermore, it is crucial for a successful control to determine the rodent species, the cause of the infestation and the preferred places of rodents prior to the use of anticoagulant rodenticides. At the end of the baiting campaign, i. e. when the bait is no longer being taken by the rodents, remaining bait must be collected and disposed of as hazardous waste.

All mandatory use instructions are included in the 'Best practice code for the application of anticoagulant rodenticides'. Please see Chapter 12 for the English translation of the best practice code for trained professionals.

Is it allowed to use anticoagulant rodenticides where no rodent activity has been detected?

The use of anticoagulant rodenticides is generally forbidden if no rodent activity has been detected prior to the control measure. In exceptional cases, trained pest controllers are authorised to conduct a strategic permanent baiting even though no signs of rodent activity have been previously observed (see Chapter 8).

Is it allowed to use anticoagulant rodenticides without bait stations?

Deploying bait without a bait station is generally prohibited. Only trained professional users, such as trained pest controllers are authorised to apply anticoagulant rodenticides without bait stations in protected areas that are inaccessible to children or non-target animals, such as mouse and rat burrows, closed cable routes and piping or cavities in walls and wall panelling.

Some products were identified to have risk for soil-dwelling organisms within the environmental risk assessment. As a consequence, their use in burrows (in the earth) has been prohibited. The uses for which the biocidal product is authorised are shown on the product label.

Never apply rodenticides accessible to children or non-target animals. Collect and dispose of spilled bait and dead rodents.

Is it allowed to use bait stations made out of cardboard?

No. Bait stations made out of cardboard are neither sufficiently stable nor tamper-resistant. This is, however, a basic requirement for bait stations in order to prevent children and non-target animals from accessing the bait. Cardboard boxes can be easily destroyed by animals and opened by children.

How often must the baiting points be inspected?

At the beginning of the campaign, the baiting points must be inspected at least every 2–3 days (when controlling mice) or first after 5–7 days (when controlling rats) and at least on a weekly basis afterwards. This applies to both the general public and professional users (without qualifications).

Trained professionals must visit the baiting points after at least 5 days at the beginning of the campaign and at least on a weekly basis afterwards. These visits are important to check whether the rodents have taken the bait, to replace bait or to relocate baiting points if the bait has not been taken. Regularly visits ensure a targeted, fast and efficient rodent control. At each inspection of the baiting points, spilled or scattered bait and dead rodents must be collected and disposed of to avoid an accidental poisoning of humans and non-target animals.

How should warning signs be applied and what should they look like?

As a general rule, warning signs should be posted in any place where anticoagulant rodenticides are applied. However, this is not required in buildings where the bait and bait stations are placed inac-

Example of a warning sign

cessible to the general public. This may be the case in a supermarket, for example. In such cases, it is sufficient to inform any person that may come into contact with the bait during their job (e. g. cleaning or maintenance work).

The number of warning signs as well as the places where warnings are to be affixed should correspond to the number of baiting points and the size of the treated area. Warnings should sufficiently inform persons in the direct vicinity of the baiting points about the risks to humans, animals and the environment involved in the use of these biocidal products. Warnings must be large enough to display the information that must be included according to the 'Best practice code' (see example above). Moreover, warnings should be clearly identifiable (e. g. by choosing a signal background colour), placed at eye level, and easy to read.

The labels on the bait station should contain the following information as a minimum: 'Do not move or open', 'Contains rat/mouse poison', 'Product name', 'Active substance(s)' and 'In case of incident, call a poison centre [insert telephone number]'.

What happens if the mandatory provisions for use are not adhered to?

The German Hazardous Substances Ordinance states that biocidal products shall be used properly, i. e. in accordance with the provisions for use resulting from the authorisation and the labelling of the respective product.

Under the Chemicals Act, any non-compliance with the provisions for use of an authorised biocidal product is classed as a regulatory offence and may be subject to a fine of up to 50,000 EUR. The German Federal States are responsible for the prosecution of offences.

Does the 'Best practice code' also apply to the use of anticoagulant rodenticides in sewers?

Only trained professionals (see Chapter 6) are authorised to use anticoagulant rodenticides in sewer systems. Accordingly, they are obliged to follow the 'Best practice code for the application of anticoagulant rodenticides by trained professional users'. However, there are significant differences in the application of rodenticides in sewer systems compared to above-ground rodent control measures in buildings or in open areas (see Chapter 9).

08

Permanent baiting

What is ‘permanent baiting’?

Permanent baiting is an infestation-independent application technique for baits containing anticoagulant rodenticides. The baits are typically applied in bait stations in areas where actually no target rodents are present. The idea behind permanent baiting is to monitor and at the same time to intercept intruding target rodents before they become established. Until lately, it has been common practice to install bait stations at short intervals along walls in and around buildings and/or along the property borders of premises (perimeter baiting) to be protected, and to re-fill them four to six times a year. Usually, bait stations were prepared with an amount of 100 to 300 g of a second-generation anticoagulant rodenticide, which is supposed to be lethal to the target rodents after a single feed.

Why shall anticoagulant rodenticides not be used for permanent baiting?

The application of anticoagulant rodenticides around buildings or in the open area without previous detection of rodent species and without frequent controls of the baiting points poses a significant and unacceptable risk for the environment. Indiscriminately and permanently displayed rodenticides are likely to be taken by non-target small mammals such as wood mice, which in turn drive secondary exposure of predatory species such as barn owls (Geduhn et al. 2016). Non-target small birds may also enter bait stations and feed on the bait. The combination of high amounts of permanently deployed anticoagulant rodenticides and only a few visits to the baiting points across the year may in addition significantly contribute to the risk of resistance development (see Chapter 10).

At the same time, permanent baiting is not essential for disease vector control and at least questionable in terms of effectiveness. The idea to intercept brown rats, which are intruding from neighbouring plots onto premises, or house mice, which are introduced with incoming goods to a warehouse, by anticoagulant baits in bait stations is counteracted by the delayed mode of action of anticoagulants and the neophobic nature of these rodent species. Even

if target rodents – despite bait avoidance or bait shyness – will feed on the industrially manufactured bait, it will take several days until the lethal effect settles in, enough time for rodents to still enter buildings, cause damage or transmit diseases.

Finally, there are widely available biocide-free control measures and technical innovations for a comprehensive rodent monitoring. This is why the use of anticoagulant rodenticides to prevent rodent infestations and/or to monitor rodent activity is prohibited in Germany.

Is it allowed to use anticoagulant rodenticides permanently to control an ongoing rodent infestation?

Yes, in the event of an ongoing infestation, for example due to the continuous intrusion of rodents from an adjacent area into the premises to be protected, the control measure might last for longer than the commonly assumed rodent control period of about one month (long-term treatment). In such cases, it must be checked whether there are suitable measures that can be used to counteract any recurring rodent infestations. It should be noted that in case of a long-term control, the baiting points must be visited at least once a week (as is the rule for a treatment of an acute infestation).

Are there exemptions to the ban of permanent baiting?

Yes, under certain conditions trained pest controllers are allowed to conduct a **strategic permanent baiting** using anticoagulant rodenticides even if no rodents or rodent signs have been observed in the given area.

Strategic permanent baiting differs methodologically from a large-scale random baiting of a treated area. It is defined as a prophylactic system of permanent baiting points installed at preferred entry points and nesting sites of rodents inside of buildings or outside in the immediate vicinity of buildings. Strategic permanent baiting is strictly limited to sites with a high risk of rodent infestation and where other methods of rodent control have been proven to be insufficient. Only anticoagulant rodenticides containing the active substances difenacoum and/or bromadiolone are authorised to be used for strategic permanent baiting.

The baiting points have to be inspected at least on a monthly basis and have to be installed after prior on-site assessment by the trained pest controller. All mandatory use-specific instructions for the strategic permanent baiting are included in the ‘Best practice code for the application of anticoagulant rodenticides by trained professional users’ (see Chapter 12).

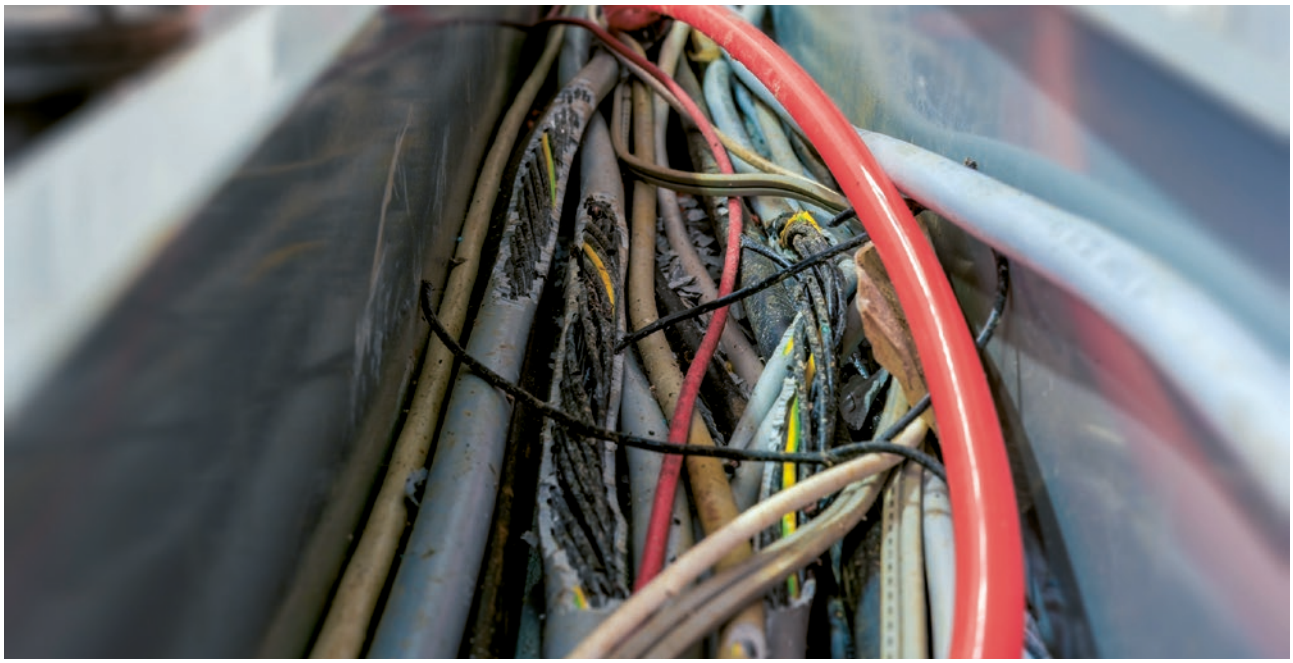
Under what conditions is it allowed to conduct a strategic permanent baiting?

A strategic permanent baiting is permitted in exceptional cases when:

- it is used exclusively as a prophylactic system of regularly visited tamper-resistant bait stations that are installed at **preferred rodent entry and nesting sites in and directly around buildings** following an on-site assessment performed by the trained pest controller,
  and
- if an **increased risk of rodent infestation**, which poses a major threat to the health or safety of humans or animals, was determined by the trained pest controller during the on-site assessment
  and
- if the risk of infestation cannot be averted with **reasonable measures**, such as organisational or constructive methods or the use of suitable biocide-free rodent control or prevention methods (such as traps).

A strategic permanent baiting using rodenticides containing difenacoum and/or bromadiolone may be carried out only when all of these three conditions are met. The trained pest controller has to check, determine and document these pre-conditions **in each individual case**. Rodenticides containing active substances other than difenacoum and/or bromadiolone are not authorised to be used for a strategic permanent baiting.

Covered and protected application of anticoagulant rodenticides without using tamper-resistant bait stations is permitted for trained professionals as long as the same level of protection for non-target species and humans is provided as by tamper-resistant bait stations (e. g. in cable routes, bases of electrical devices).



Rodent bite marks on cables

When is the risk of a rodent infestation increased?

The pest controller analyses and documents whether the conditions for a strategic permanent baiting are fulfilled as part of the on-site assessment **in each individual case** (see above). This entails the assessment of all location-specific factors that may be pertinent when assessing the risk of a rodent infestation (e. g. food sources, risk through regularly incoming goods, migration from the area surrounding the premises) which is the basis for the trained pest controller to make a prediction about the likeliness of future infestations. If the likeliness is high, then there is a higher risk of infestation.

What constitutes a major threat to the health or safety of people and animals?

A major threat to the health of humans and animals is the transmission of pathogens. A major threat to the safety of people and animals may be assumed if a potential infestation could, with a sufficient degree of probability, cause damage to equipment, appliances or materials, which in turn could pose a direct or indirect threat to human or animal health. A potential infestation with rodents is defined as the infestation that would result, if no control measures were taken.

Who can carry out a strategic permanent baiting in exceptional cases?

The planning, execution and documentation of a strategic permanent baiting using anticoagulant rodenticides, as well as the examination of the pre-conditions must be carried out by a trained pest controller or by someone under his or her supervision. An additional servicing of the bait points, i. e. in addition to the monthly visits by the pest controller, can also be carried out by trained professional users (see Chapter 6) after consultation with the responsible pest controller.

Where can a strategic permanent baiting be carried out in exceptional cases?

A strategic permanent baiting can only be carried out at rodent entry and nesting points **indoors and outdoors directly around buildings** for example, on premises where food, feed or pharmaceuticals are manufactured, processed, distributed from or stored, or in disposal or storage facilities. A strategic permanent baiting in open areas, for instance along property borders (perimeter baiting), is prohibited.

How often shall the bait points be inspected when conducting a strategic permanent baiting?

The bait points shall be inspected **at least once a month** by a trained pest controller. Weekly inspections of baiting points are required, if signs

of rodents, e. g. sightings of dead or living rodents, droppings or gnawing marks, are observed during the monthly control visits, making additional acute control measures necessary.

Why is it only allowed to use rodenticides containing difenacoum and/or bromadiolone for strategic permanent baiting?

First-generation anticoagulant rodenticides (FGAR), i. e. warfarin, coumatetralyl or chlorophacinone were not approved for permanent baiting because of the risk of (cross) resistance developing in the target animals. This risk is higher for FGAR in comparison to SGAR as they have a lower toxicity. While acute rodent control measures of rodents using FGAR require weekly inspections of the treated area, permanently applied baits need to be checked at intervals of up to one month. Thus, resistance may not be identified early enough to avoid the establishment of a resistant rodent population. As such, permanent baiting was restricted to more potent second-generation anticoagulant rodenticides when they were first authorised in Germany.

Within the following re-authorisation of anticoagulant rodenticides, the European Commission, together with the EU Member States, decided to only approve rodenticides containing difenacoum and bromadiolone for permanent baiting since their toxicity and potential of accumulation in animals and the food chain is lower compared to brodifacoum, difethialone and flocoumafen. This restriction therefore aims at minimising the risk of poisoning of non-target animals, as this is particularly high with regards to permanent baiting.

What is ‘pulsed baiting’?

Pulsed baiting is an application technique for the most potent SGAR (brodifacoum, diefethialone, flocoumafen) that is pre-dominantly used in Great Britain. As opposed to standard baiting or permanent baiting, sometimes also referred to as surplus or saturation baiting, the principal of pulse baiting is to only deploy small amounts of bait (in the two-digit gram range) at each bait point. As a general rule, the baiting campaign lasts for 21 days, during which the bait points are inspected and, if necessary, baits re-filled at intervals of up to seven days. If all the bait is taken during this time then the number of bait points can be increased, although again only a small amount of bait will be deployed at each bait point. The idea behind pulse baiting is to reduce intentionally the amount of bait in order to make it more attractive to rodents and to avoid that they take a mutliple lethal dose of the poison, thereby reducing the risk of secondary poisoning to rodent-feeding predators or scavengers. Pulse baiting is only authorised for rodenticides that contain difethialone, brodifacoum or flocoumafen.

09 Rat control in sewers

Which instructions apply to the use of anticoagulant rodenticides in sewers?

Only trained professionals are authorised to use anticoagulant rodenticides in sewer systems. Consequently, the 'Best practice code for the application of anticoagulant rodenticides by trained professional users' has to be followed (see Chapter 12). As stated in the 'general directions for use' section in the best practice code, anticoagulant rodenticides shall only be applied in areas with observed rodent infestation. Hence, conducting a pre-baiting survey (i. e. rodent monitoring) is mandatory before rodenticides can be used in the sewers (see section below for more details). According to the use-specific instructions of the best practice code for sewer baiting, baits must be deployed in the sewers in a way so that they do not come into contact with water and are not washed away. Furthermore, it is required to inspect bait points in sewer systems initially after 14 days and subsequently every two to three weeks (at the latest). At each inspection bait uptake must be documented and the consumed bait must be replaced by fresh bait. At the end of the rodent control campaign, all remaining baits must be removed from the sewer system and disposed of as hazardous waste in accordance with local requirements.

How to carry out a rodent monitoring in the sewer system?

Although sewer systems are a complex rodent habitat, rats might be located indirectly e. g. by fecal droppings or rat tracks in the manhole. In addition, monitoring feeding activity of rats by installing and checking non-toxic baits at selected manholes in the sewer network allows identifying hot spots. If bait uptake is recorded, the non-toxic bait should be replaced by anticoagulant rodenticides. Once the infestation has been eliminated and no further bait consumption is documented, baits containing anticoagulants should be removed and replaced by non-toxic bait.

Nowadays, several monitoring tools equipped with digital transmission technology are available on the market. With these devices it is possible to detect rats in sewers and transmit these findings to a computer

or mobile phone without manual inspection of the manholes. Increased reports of rat sightings above ground can also indicate a possible rodent infestation in nearby sewer sections. In such cases, coordination of aboveground control measures and sewer baiting campaigns is highly recommended.

Hot to ensure that baits deployded in the sewers do not come into contact with water?

Prolonged exposure of baits to moist or wet conditions or direct contact of baits with wastewater in sewers is problematic, for both the aquatic environment as well as the efficacy and the attractiveness (also referred to as palatability) of the bait. Active ingredients will leach from bait formulations into the water when baits are scoured by wastewater and/or stormwater runoff. As anticoagulant rodenticides are not sufficiently removed during conventional wastewater treatment, they are discharged into surface waters where they can accumulate in water organisms and thus enter the aquatic food chain (Regnery et al. 2019b). Moreover, bait can often develop mould within a short period of time (i. e. several days/weeks) if applied under damp conditions and therefore is no longer consumed by rats. As a consequence, either waterproof bait stations should be used or baits exclusively deployed in manholes free from backing-up and/or runoff pouring in to avoid release of rodenticides to watercourses and to keep the bait attractive to rats. When baits are attached to step irons or the manhole's gully trap on a wire just above the berm, close monitoring of operational conditions in baited sewer sections and timely inspections are required. For example, wastewater levels in combined sewer systems can rise quickly following heavy rain events or due to backlogs, causing the hanging bait to be immersed in the sewage or even flushed away. In such scenarios, early/immediate removal of bait from the sewer is mandated.

Is permanent baiting with anticoagulant rodenticides permitted in sewers?

No, anticoagulant rodenticides are not authorised for permanent baiting in sewers. While strategic permanent baiting is allowed under certain circumstances 'in and around buildings' (see Chapter 8), it is absolutely not permitted in sewers. After completion of sewer baiting campaigns, i. e. when no further bait uptake is documented within two to three weeks after deployment, baits must be removed from manholes and appropriately disposed of as hazardous waste.

Waterproof bait stations that are equipped with an automated monitoring system can be operated beyond the stipulated inspection interval of two to three weeks without manual inspections of baiting points. However, rodenticides are only allowed to be applied in bait stations if an infestation has been detected, e. g. by prior use of non-toxic monitoring baits (see above). As applies for above-ground baiting campaigns, anticoagulant rodenticides are not allowed to be used to prevent rodent infestations or to monitor rodent activity in sewer systems (cf. best practice code for trained professionals, Chapter 12).

Are warning signs required when rodenticides are used in sewers?

Provided that the baiting points are not accessible to third parties, warning signs in the sewers are not required.

Which organisational and construction measures can curb the spread of rats in the sewers?

Rats use sewer systems as hidden and secured pathways to move from one place to another and to obtain food. Therefore, food should never be 'disposed of' by flushing it down the toilet. Constructional measures such as rodent proof mud traps and manhole covers or omission of step irons in manholes, which are used by rats to reach the surface, can help to make it difficult for rats to enter or leave the sewers. The use of trap systems and rat stops in sewage pipes can also act as access barriers. In addition, maintenance and restructuring measures can eliminate any areas in the sewer network that rats may use as shelter or nesting sites. Such measures can be effectively implemented particularly in urban developments, to hinder rat populations from entering the sewers and from spreading.

Are there effective, environmentally-friendly and sustainable ways of controlling rats in the sewers?

Based on a survey conducted among German municipal pest control officials in 2008, Krüger and Solas (2010) estimated an amount of over 600 tons of bait material containing anticoagulant rodenticides that were used annually in Germany to control rat infestations in sewers. Rodenticide baits were often applied extensively, permanently and in large quantities to control rat infestations in sewers. Common practice usually included bait points in every other manhole

in a sewer network. Their preventative use was based on the false assumption that rats are ubiquitously present throughout the sewer system. Pre-baiting monitoring as well as follow-up inspections of baiting points were mostly not carried out. However, both of these steps are crucial to ensure an effective and sustainable rat control in the sewers.

The aim of the monitoring is to locate specific places in the sewers where rats are present, allowing for a targeted baiting approach with anticoagulant rodenticides. Compared to the widespread random application of rodenticides across the entire sewer network, this approach saves time (baiting at selected infested manholes only) and money (less bait material and workload). It is also more environmentally-friendly due to the reduced use of biocides.

Subsequent to a completed sewer baiting campaign, a monitoring of success should be conducted. For example, this can be done by deploying non-toxic baits at previous baiting points to check for anew bait uptake at regular intervals over the next couple of months. Nowadays, there are also biocide-free methods of rodent control and/or monitoring for use in sewers available.

What has to be considered in open calls for tenders with regard to the use of anticoagulant rodenticides for rat control in sewers?

In principle, open calls for tenders for rodent control must comply with the law. Therefore, any calls for tenders are required to stipulate that the provisions in the ‘Best practice code for the application of anticoagulant rodenticides by trained professional users’ (see Chapter 7) must be strictly adhered to.

Regarding the use of rodenticides in sewers, calls for tenders should demand a monitoring prior to the application of rodenticides, the baiting of identified rat hot spots in the sewer and a follow-up monitoring to evaluate the effectiveness of the control campaign. In areas with significant infestations, repeated application of bait may be required. Finally, the complete removal and lawful disposal of uneaten or leftover bait as hazardous waste at the end of the control measure should also be a specified component of calls for tenders. They should also explicitly state that solely rodenticides authorised for use in sewers in Germany according to the Biocidal Products Regulation (EU) No. 528/2012 should be used.

Ideally, the development of a concept as part of a rodent control strategy by the potential contractor taking the legal requirements as well as the available budget into consideration, should also be subject of the calls for tenders. As a matter of fact, contractors must have the required qualifications for using anticoagulant rodenticides in sewers (see Chapter 6). While adherence to and awareness of other regulations is another important aspect of calls for tenders or contracts, e. g. relating to occupational and traffic safety, this will not be addressed in more detail here.

Are sachets intended to be thrown into the manhole authorised to be used in sewers?

According to the best practice code for trained professionals (see Chapter 12), baits must be applied in the sewer system in a way so that they do not come into contact with water/wastewater and are not washed away. Therefore, sachets or any other type of formulation, intended to be thrown into or placed at the bottom of the manhole are not authorised to be used during sewer baiting.

10 Resistance

What is meant by the term resistance?

This term refers to the heritable ability of rats and mice to consume toxic bait over a longer period of time without dying from it (genetic resistance). Genetic resistance must be differentiated from behavioural resistance, i. e. the reluctance of rodents to take rodenticidal baits or to approach and enter rodent control equipment, such as bait boxes and traps (RRAC 2019). A crucial factor for finding the cause of failure in the control measure using anticoagulant rodenticides is therefore the determination of the rodent activity in relation to bait acceptance (see below).

How do resistances develop?

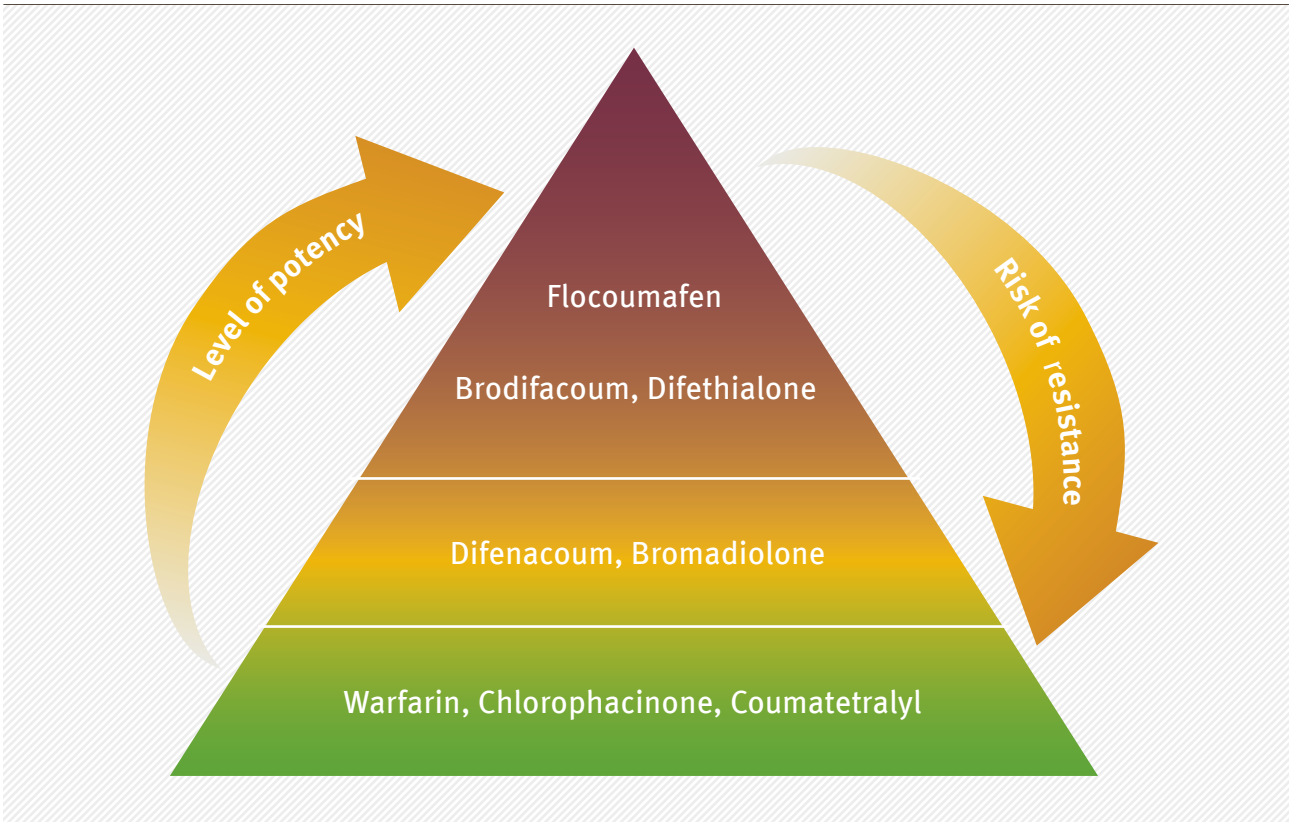
Rodents naturally react to anticoagulants with different levels of sensitivity because of their genetic structure. The permanent use of rodenticides without regular and proper inspections of the bait points can therefore lead to the extinction of the more sensitive animals in a population while genetically less sensitive animals survive and produce offspring that are also less sensitive to the rodenticides (selection). Thus, under the permanent influence of rodenticides a resistant population of rats or mice can emerge (evolutionary pressure). Permanent baiting, without established infestation and inspection intervals of up to one month, is therefore particularly critical with regards to the emergence and detection of resistant rodents.

How can I identify and successfully control resistant rodents?

Resistance of target rodents against the applied active substance may exist, if a rodenticide has been used properly and the bait is still being consumed by the rodents in the same way after around one month, **without** identifying a decrease in rodent activity. In such cases, an active substance with a higher potency must be used (see Figure 2). However, it must be taken into consideration that such a failure of control measures may also be caused by a continued immigration of the rodents. The general public and professional users are not permitted to use highly-potent second-generation anticoagulants and

Figure 2

Anticoagulant resistance hierarchy



Using different anticoagulants that have a comparable or lower potency is not a safe option for resistance management as all anticoagulants have an identical mode of action and the type of resistance is similar as well. If a resistance is detected and the use of active substances with different modes of action is impossible, anticoagulants with a higher level of potency should be used. Trapping should also be considered as an alternative control measure.

therefore should immediately call a professional pest controller to take care of the situation if they suspect that there may be a resistance.

Are there already rodents in Germany that are resistant to anticoagulants?

Resistances to anticoagulant rodenticides has been detected in populations of brown rats in the North-West of Germany and there have also been some individual cases outside of the resistance area found in large cities (e. g. Hannover). For house mice, resistant populations have been found in many large cities across Germany (e. g. Berlin, Frankfurt/Main, Stuttgart, cities in the Ruhr region, see Pelz et al. 2012 for more information) but there is no regional boundary/border like there is with brown rats. The only substances to which there has not yet been any resistance detected among house mice and brown rats are brodifacoum, flocoumafen and difethialone. The resistance situation with regards to black rats has not yet been examined. Resistance maps published by the Julius Kühn Institute (JKI) in Münster and the Rodenticide Resistance Action Committee (RRAC) give a good and up-to-date overview of the resistance situation (for additional information, see Chapter 13).

Is warfarin an effective substance for pest rodent control in view of resistances that may develop?

Warfarin, chlorophacinone and coumatetralyl can still be considered as effective against brown rats outside of the resistance area in the North-West of Germany. With house mice, the situation is somewhat less clear as the resistance is not limited to certain regions.

11 Alternatives to anticoagulant rodenticides

Are there authorised non-anticoagulant rodenticides?

Yes, apart from anticoagulants there is also carbon dioxide, aluminium phosphide, hydrogen cyanide and alphachloralose, all of which have been approved for the use as biocidal active substances in rodenticides. Carbon dioxide, hydrogen cyanide and aluminium phosphide are fumigants authorised for use by specially trained professionals in certain scenarios. Products containing alphachloralose can be used by the general public in indoor areas to control house mice. Alphachloralose is a narcotic agent. At low ambient temperatures mice will go into a coma, cool down and eventually die of hypothermia. Therefore, rodenticides containing alphachloralose can only be used in premises where the ambient temperature is not too high, and it is only sufficiently effective when used to control small animals, like mice.

In addition, powdered corn cob has been included in the European Union's list of authorised biocidal active substances. However, studies carried out by the German Environment Agency have shown that the effectiveness of corn cob is not comparable to that of anticoagulants, as 11 out of 12 brown rats survived a forced feeding of a corn cob preparation over a period of 10 days (Schmolz 2010).

With cholecalciferol being approved as an active substance for use in biocidal products in April 2019, another non-anticoagulant rodenticide will become available on the European market soon. The oral intake of cholecalciferol bait, a highly dosed Vitamin D3 formulation, leads to increased plasma calcium concentrations and stimulation of calcium transfer from bones to plasma causing mineralization of soft tissue and eventually death due to organ/heart failure (hypercalcemia). Cholecalciferol has some critical properties with regard to endocrine disruption as well as accidental poisoning of non-target species and thus rodenticides containing cholecalciferol will be subject to comparable RMM as anticoagulant rodenticides, such as the restriction to professional users (see Commission Implementing Regulation (EU) 2019/637). The application for the

approval of the active substance alpha-bromadiolone for use in rodenticides under the BPR is still under review.

As of 2019, it still must be concluded that there are no other approved biocidal active substances that have a similar level of efficacy against rats and at the same time pose less environmental risks to replace anticoagulants.

What non-chemical rodent control measures are available to the general public?

Particularly, when dealing with individuals of rats or mice in indoor areas such as private households and small commercial premises traps should be preferred over biocidal products. The use of biocidal products should be a last resort and the amount of product used should also be kept as low as possible.

What do you have to pay attention to when using traps?

Traps for mice and rats should be placed on rodent runways, e. g. along walls or under furniture and cupboards. Peanut butter, nougat crème, cheese or pieces of bacon can be used as bait. Ideally, traps should be baited before activating the traps for a few days. This is particularly important with rats. This way, the whole population will get used to the traps which means that they will be caught more quickly and efficient. When setting the traps, care must be taken to ensure that they cannot be accidentally triggered by children or pets. This can be prevented by placing the traps in commercially available protection station. Activated traps must be inspected at least once a day, ideally twice a day. Dead rodents can be disposed of along with domestic waste or at a rendering plant.

Does the use of anticoagulants comply with animal welfare principles?

The EU Member States recognised within the authorisation procedure that slow acting anticoagulant rodenticides do cause pain for several days in rodents and are generally not considered as a humane method to control rodents (cf. opinion of the Biocidal Products Committee on the application for renewal of the approval of anticoagulant active substances). This is one reason as to why their use is only justifiable if all other measures of rodent control have failed and if there are no alternatives left.

Is the use of traps in accordance with animal welfare?

Snap traps can be more humane than poison, even though users may intuitively assume the opposite. Using snap traps may make users more aware and

Mouse trap in a protection station

Glue trap

lead to a more immediate perception of the fact that animals are killed. However, animals are still killed when poison is used, the only difference is that poisoned rodents normally die out of sight. Tests have shown that properly constructed and applied traps may cause less suffering to the animals than poisoning with anticoagulant rodenticides (see above). The German Environment Agency currently elaborates test methods and guidelines for traps to evaluate their efficacy and humaneness and to improve the quality and acceptance of non-chemical alternatives. (for additional information, see Chapter 13).

Are glue traps in accordance with animal welfare?

No. As rodents are vertebrates, the use of glue traps is of greatest concern in the regard of animal welfare. According to Binder (2010) glue traps are neither indispensable, nor do they constitute an appropriate measure for controlling rodents and as such they do not meet the requirements of the Animal Welfare Act (*TierSchG*). Animals caught in these traps will suffer extreme stress, often for several hours, they may inflict injury on themselves when trying to escape or they may die of suffocation if their mouth and nose becomes glued (Mason & Littin 2003). This is why glue traps are absolutely no suitable alternative to anticoagulant rodenticides, even if they are checked daily or even more frequently, and should not be used.

What preventative measures can be taken to avoid a rodent infestation?

Various measures can be taken to prevent rodent infestations:

- Make entrances to indoor areas (like gaps, holes, cat flaps, drains, etc.) inaccessible to rodents, or close them completely
- Do not dispose food through the toilet
- Do not discard food carelessly
- Store food (food, animal feed, stocks, etc.) where rodents have no access
- Clean out areas that may be accessible to rats and remove anything that they could use to hide
- Do not feed birds (like ducks and pigeons)
- Compost correctly
- Clear up rubbish and waste that rodents could use to hide

These preventative measures can help to reduce the risk of a rodent infestation. You can find more information about biocide-free alternatives on the biocide web-portal of the German Environment Agency (for additional information, see Chapter 13).

12

Best practice code for the application of anticoagulant rodenticides by trained professionals

The following instructions for use apply to anticoagulant rodenticides, which are authorised as biocidal products for the control of mice and rats by trained professional users in Germany. This best practice code entails general instructions for rodenticide use within all baiting scenarios as well as use-specific instructions for use for permanent baiting, pulsed baiting, burrow baiting and sewer baiting.

Common Safety Rules

- Wear protective chemical resistant gloves during product handling phase.
- Place the product away from food, drink and animal feeding stuff, as well as from utensils or surfaces that have contact with these.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- Store the product in places prevented from the access of children, birds, pets and farm animals.

Planning and documentation

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Do not use anticoagulant rodenticides in areas where resistance to the active substance can be suspected.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove water sources and food which is readily attainable for rodents (e. g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this disturbs the rodent population and could reduce bait acceptance.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Determine the extent of documentation in agreement with the customer. A site plan of all baiting points and recordings of the regular inspections constitute the minimum requirements for operations that produce, market, store or sell foodstuffs. In any case, the documentation must include the place, purpose, the biocidal products applied (including the specific amounts) and the person in charge of the rodent control. The documentation has to be kept for a minimum of five years.
- Label all baiting points and bait stations with appropriate warnings. The client has to be informed about all ongoing control measures. The client is obliged to inform his employees as well as external service providers. If necessary, he has to place additional warnings. The person

in charge of the control measure has to supply the client with sufficient information and generally understandable warnings on the risks of primary or secondary poisoning.

- The client and the person in charge of the control measure have to agree upon the responsibility for putting the warnings in place. As a minimum requirement, the information material or the respective warnings have to include the following details:
  - First measures to be taken in case of poisoning,
  - Measures to be taken in case of bait spillage and the discovery of dead rodents,
  - Name of the product and the active substance(s) incl. concentration
  - Contact information of the person in charge of the rodent control measure,
  - Telephone number of a poison information centre and the name of the antidote,
  - Date of the beginning of the campaign, i. e. when the baits were deployed first.
- The aim of a baiting campaign is to eradicate the target rodents in the infested area/building.

Application and servicing

- Instructions for use such as the application rate, application frequency and area of use have to be followed.
- Bait stations have to be used. Only in areas (e. g. closed cable routes, sub-constructions of e. g. electric appliances or high voltage cabinets, cavities in walls and panellings) which are inaccessible for children and non-target animals, baiting without tamper-resistant bait stations is allowed.
- Bait stations must be labelled with the following information: 'do not move or open'; 'contains a rodenticide'; 'product name'; 'active substance(s)' and 'in case of incident, call a poison centre [national phone number to be inserted by the authorisation holder]'
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e. g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations have to be mechanically stable and tamper-resistant.
- Bait stations have to be designed in a way which prevents the access from non-target organisms as far as possible.
- Bait should be secured within the bait station so that it cannot be dragged away.
- When placing bait points close to surface waters (e. g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.
- If used outdoor, protect bait from the weathering (e. g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Do not use rodenticides in pulsed baiting treatments or as permanent baits for the prevention of rodent infestation or monitoring of rodent activities, unless the product is explicitly authorised for this use. In this case, follow the below stated use-specific instructions for permanent baiting and pulsed baiting, respectively.
- Do not apply rodenticides directly in rodent burrows, unless the product is explicitly authorised for burrow baiting. In this case, follow the use-specific instructions for burrow baiting, as stated below.

Inspections

- At the beginning of the campaign, visit the bait points at the latest after 5 days and at least on a weekly basis afterwards. The same applies to baiting campaigns that last for more than 35 days.

- Replace consumed baits at each visit; the uptake of bait has to be documented.
- Replace any bait which has been damaged by water or contaminated by dirt.
- Search for and dispose dead rodents in the infested area at each visit to prevent secondary poisoning.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- If after a treatment period of 35 days rodents still take up bait and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents.
- In case of suspected resistance, consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes.

Termination of the rodent control campaign

- Remove and dispose of all baits in accordance with local requirements at the end of the treatment period in order to prevent primary poisoning.
- At the end of the treatment, dispose of the uneaten bait and the packaging in accordance with local requirements. Avoid contact of the product with skin.
- Undamaged bait stations and by rodents untouched baits may be reused.
- The success of the control measure has to be documented and proven. All relevant documents of the control measures have to be provided to the client as well as competent authorities upon request.

Post treatment action and preventive measures

- Take the following preventive measures to avoid re-infestation after a successful control:
  - Remove potential sources of food and water for rodents (food- and feeding stuff, rubbish, etc.) or make them inaccessible to rodents as far as possible.
  - Remove debris and waste that might be used as hideouts and harbourages. Vegetation in the immediate vicinity of buildings should be removed as well.
  - As far as possible, all existing entries for rodents to buildings (e. g. cleaving, loopholes, cat flaps, drainages) have to be made inaccessible.
- Inform the client of possible preventive measures against re-infestation.

Use-specific instructions for use for sewer baiting

- Baits must be applied in a way that they do not come into contact with water and are not washed away.
- Bait points in sewer systems have to be visited for the first time at the latest after 14 days and subsequently every 2 to 3 weeks.
- Remove and dispose all baits in accordance with local requirements at the end of the treatment period.

- Do not use rodenticides for pulsed or permanent baiting.

Use-specific instructions for strategic permanent baiting

- Only rodenticides containing difenacoum or/ and bromadiolone are authorised to be used for strategic permanent baiting.

- Strategic permanent baiting is restricted to areas with a high potential for reinvasion of target rodents when other methods of control have proven to be insufficient.

- Strategic permanent baiting should be distinguished from large scale permanent baiting or perimeter baiting (cf. DIN 10523).

- Strategic permanent baiting is permitted only for trained pest controllers having the required competence according to German Hazardous Substances Ordinance (Gefahrstoffverordnung), Annex 1, No. 3.

- It is only permitted to carry out a strategic permanent baiting if all of the following conditions are met:

  - Permanent baiting is solely used as a prophylactic system, which is composed of permanent bait points at preferred entry points and nesting sites of rodents inside or in the immediate vicinity of buildings. The baits have to be inspected on a regular basis and have to be installed after prior analysis by the trained pest controller carrying out the treatment. Tamper-resistant and secured bait stations have to be used. As in the case of a regular control measure, an exception can be made for situations, in which the bait is elsewise protected (e. g. cable lines, sub-construction of electric appliances).

  - An increased risk of infestation which poses a major threat to health or security of humans or animals has to be identified by the trained pest controller during an on-site assessment.

  - This risk cannot be averted by other proportional measures, for example organisational or constructional measures or the use of suitable non-chemical control or prevention measures (e. g. traps). The proportionality principle includes, amongst others, a consideration of economic aspects. Alternative measures have to be proportional, i. e. they need to be necessary in order to protect constitutional rights.

- A case of a major threat to the health of humans or animals is, amongst others, the risk of disease transmission. There is a specific danger to the security of humans or animals, if a potential infestation could, with a sufficient degree of probability, cause damage to equipment, appliances or materials, which in turn could pose a direct or indirect threat to human or animal health. A potential infestation with rodents is defined as the infestation that would result, if no control measures were taken.

- In these cases the use of permanent bait containing the active substance bromadiolone or difenacoum is exceptionally permitted, even though an actual infestation with rodents has not been identified in an operation or establishment. Whether or not the conditions for an exception according to the above mentioned criteria are met, has to be established by the trained pest controller in each individual case. In each case, the trained pest controller has to verify, declare and document that all of the aforementioned criteria are met. Under these circumstances, exceptions to the ban on permanent baiting can be made for rodent control on e. g. premises where food or feeding stuff, pharmaceutical or medical products are produced, processed, marketed or stored; or for waste disposal companies or storage businesses or warehouses.

- Permanent baiting with rodenticides containing bromadiolone or difenacoum may only be implemented by or under the supervision of a trained pest controller with competence according to German Hazardous Substances Ordinance, Annex 1, No. 3 and is exclusively allowed inside or in the direct vicinity of buildings. The above mentioned criteria that allow for the exception to the ban on permanent baiting have to be verified

by the pest control company in charge. The pest control company also has to plan and carry out the relevant measures.

- It is at the discretion of the trained pest controller to define the inspection intervals of the campaign. However, the inspection intervals shall not last longer than 1 month. Weekly inspections have to be carried out if, according to the trained pest controller additional control measures have to be taken due to an actual infestation. In this case, an infestation implies signs of rodents within the protected area. These can be living or dead animals, signs of gnawing and feeding on food- or feeding stuff, materials or baits, traces of faeces, tracks or traces of grease. In each case, these signs need to have been observed within the last four weeks.

- Additional inspections of the permanent bait points may be carried out not only by the professional user with competence according to German Hazardous Substances Ordinance, Annex 1, No. 3 but also by other trained professional users with the relevant expertise in consultation with the pest control company in charge, provided that this user category has been authorised for the use of the respective product.

Use-specific instructions for pulsed baiting

- Only rodenticides containing difethialone, brodifacoum and flocoumafen are authorised to be used for pulsed baiting.

- Pulsed baiting is an application technique for the most potent anticoagulants which as a rule are lethal after a single feed to mice and rats. As opposed to standard baiting or permanent baiting, sometimes also referred to as surplus or saturation baiting, the principal of pulse baiting is to only deploy small amounts of bait (in the two-digit gram range) at each bait point. As a general rule, the baiting campaign lasts for 21 days, during which the bait points are checked first after 3 days and then after maximum 7 days. If all the bait is taken during this time, then the number of bait points can be increased, although again only a small amount of bait will be deployed at each bait point. By intentionally reducing the amount of bait, it is intended to make it more attractive to rodents and to avoid that they take an overdose of the poison, thereby reducing the risk of secondary poisoning to rodent-feeding predators or scavengers.

- Collect any spilled bait and dead rodents.

Use-specific instructions for use for burrow baiting

- Bait must be placed in a way that minimise the exposure to non-target species and children.

- Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.

- Remove and dispose spilled and rejected baits and dead rodents in accordance with local requirements in order to prevent primary and secondary poisoning.

- The bait have to be applied deeply into the rodent corridors and afterwards every corridor must be closed with the soil previously removed to open the gallery. Grass, straw or paperboard etc. may be used to stabilise the cover, to minimise the risk of consumption by other animals or children.

- Do not use in burrows during times of rainfall.

13 Additional Information

Best practice code for the application of anticoagulant rodenticides by the general public (German)
https://www.umweltbundesamt.de/publikationen/maeuse-rattengift-sicher-wirksam-anwenden

Best practice code for the application of anticoagulant rodenticides by professionals (German)
https://www.umweltbundesamt.de/publikationen/gute-fachliche-anwendung-von

Best practice code for the application of anticoagulant rodenticides by trained professionals (German)
https://www.umweltbundesamt.de/publikationen/gute-fachliche-anwendung-von-0

Database of authorised biocidal products in Germany (German)
https://www.baua.de/EN/Topics/Safe-use-of-chemicals-and-products/Chemicals-law/Biocides/Database-biocidal-products.html

Detection of resistant rats and mice in Germany (German), April 2013
https://www.julius-kuehn.de/media/Institute/GF/FA_Rodentizidresistenz/Download/Funde_von_resistenten_Ratten_und_Maeusen_in_Deutschland_April_2013.pdf

Federal Institute for Risk Assessment (Biocides)
https://www.bfr.bund.de/en/biocidal_products_and_treated_goods-568.html

For questions about biocidal product authorisation in Germany: National Biocide Helpdesk
https://www.reach-clp-biozid-helpdesk.de/DE/Home/Home-English_node.html

Federal Office for Chemicals – German competent authority for the authorisation of biocides
https://www.baua.de/EN/Topics/Safe-use-of-chemicals-and-products/Chemicals-law/Biocides/Biocides_node.html

Information about resistance provided by the Rodenticide Resistance Action Committee
www.rrac.info

Information on the development of test methods and guidelines for non-chemical alternatives for rodent control (NoCheRo):
https://www.umweltbundesamt.de/en/topics/chemicals/biocides/workshop-non-chemical-alternatives-for-rodent

Information on the identification of resistant rats and house mice provided by the Julius Kühn Institute (German)
https://www.julius-kuehn.de/media/Institute/GF/FA_Rodentizidresistenz/Managementstrategie/Faltblatt_Ratten_erfolgreich_bekaempfen_Resistenz_erkennen.pdf

https://www.julius-kuehn.de/media/Institute/GF/FA_Rodentizidresistenz/Managementstrategie/Faltblatt_Hausmaeuse_erfolgreich_bekaempfen_Resistenz_erkennen.pdf

List of approved active substances from the European Chemicals Agency (ECHA)
https://echa.europa.eu/de/information-on-chemicals/biocidal-active-substances

UBA guideline for the classification and labelling of chemicals (German)
https://www.umweltbundesamt.de/en/publikationen/neue-einstufungs-kennzeichnungssystem-fuer

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BIOCIDAL PRODUCTS DIRECTIVE: Directive 98/8/EC of the European Parliament and of the Council of the 16th February 1998 regarding the placing of biocidal products on the market.

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Index

Anticoagulants
A group of active substances whose common feature is that they prevent blood clotting (coagulation).

Biocide
A chemical substance, mixture or microorganism intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by any means other than mere physical or mechanical action. Harmful organism are defined as organisms such as bacteria, fungi, algae, pathogens, insects or rodents which are undesirable or harmful to humans, animals, the environment or for any human made materials. Biocides shall not be used to protect plants or plant products (plant protection products).

Bioaccumulation
An increase in the concentration (accumulation) of substances in organisms via food uptake or uptake through the surrounding medium (water, air).

Best practice code for the application of anticoagulant rodenticides
Compilation of all general and use specific instructions for use as well as risk mitigation measures that were mandatory stipulated within the biocidal product authorisation of anticoagulant rodenticides in Germany. Different versions of the best practice code are available for the general public, professionals and trained professionals, respectively.

LC_{50}/EC_{50} Value
Concentration of a substance in a standardised test system, where 50 % of the exposed test organisms die (lethal concentration, LC) or show adverse effect (effect concentration, EC) after a defined testing period.

Non-target organisms
All organisms that are not the target of control measures or the intended application of a biocidal product.

PBT/vPvB substance
Persistent, bioaccumulative and toxic substance (PBT) or very persistent and very bioaccumulative substance (vPvB).

Perimeter baiting
Permanently application of (second-generation) anticoagulant rodenticides along the property borders of a company's premise or around buildings with the aim to intercept intruding rodents regardless of the potential risk of a rodent infestation. This application technique is prohibited.

Permanent baiting
Permanent application of (second-generation) anticoagulant rodenticides in bait stations in and around buildings independent of the potential risk of a rodent infestation with bait points being inspected typically four to six times a year. This method of application is prohibited.

Persistence
Inherent property of substances to remain in the environment for extended periods of time without being transformed or degraded by physical, chemical or biological processes.

Predicted Effect Concentration (PEC)
Estimated concentration of an active substance in the environment, e. g. in surface water or in soil, calculated using harmonised emission scenario documents.

Predicted No Effect Concentration (PNEC)
A calculated threshold concentration of the active substance below which no adverse effects on environmental non-target organisms are expected.

Primary poisoning
Poisoning of non-target animals due to direct uptake of poisonous bait.

Pulsed baiting
An application technique that uses limited amounts of the most potent second-generation anticoagulant rodenticides and where the user must check and replace bait at short time intervals.

Reproductive toxicity
Substances and mixtures are classified as toxic for reproduction if experiences on humans and/or animals indicate adverse effects on sexual function and fertility in adult organisms or developmental toxicity in the offspring. There are three categories defined depending on the significance of the available evidence: Category 1A: Known human reproductive toxicants based on data from humans, Category 1B: Presumed human reproductive toxicants based on animal studies, Category 2: Suspected human reproductive toxicant based on a limited database.

Rodenticides
Products used for the control of rodents. Product-type 14 under the Biocidal Products Regulation (EU) No. 528/2012.

Secondary poisoning
Poisoning of non-target animals due to indirect intake of the poison by feeding on poisoned animals.

Strategic permanent baiting
Preventative system of monthly-inspected bait points at selected rodent entry and nesting points, in and directly around buildings, which is installed following an on-site assessment of pre-defined conditions by a trained pest controller.

Union list
A list of active substances that have been approved for use in biocidal products under the Biocidal Products Regulation (EU) No. 528/2012. Formerly Annex I to the Biocidal Products Directive 98/8/EC.

Specific target organ toxicity
Substances and mixtures are classified as target organ toxic based on experiences of humans and/or animal studies if they are known to have clear toxic effects on humans after single (SE) or repeated exposure (RE, Category 1), or if it can be assumed that they can have a harmful effect on the health of humans (Category 2). This includes all clear effects on a person's health that can affect body function, regardless of whether this is reversible or not and regardless of whether this appears immediately or after a delay, provided that these effects are not specifically included in another hazard class.

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Abbreviations

ArbSchG: *Arbeitsschutzgesetz* [Occupational Health and Safety Act]

a. s.: active substance

BAM: *Bundesanstalt für Materialforschung und -prüfung* [Federal Institute for Materials Research and Testing]

BAuA: *Bundesanstalt für Arbeitsschutz und Arbeitsmedizin* [Federal Institute for Occupational Safety and Health]

BfC: *Bundesstelle für Chemikalien* [Federal Office for Chemicals] (Competent authority for biocidal products in Germany)

BfG: *Bundesanstalt für Gewässerkunde* [Federal Institute of Hydrology]

BfR: *Bundesinstitut für Risikobewertung* [Federal Institute for Risk Assessment]

BPR: Biocidal Products Regulation (EU) No. 528/2012 regarding the placing on the market and use of biocidal products

CLP Regulation: Regulation (EC) No. 1272/2008 regarding the classification, labelling and packaging of substances and mixtures

ECHA: European Chemicals Agency

EC: European Commission

ERA: Environmental risk assessment

ESD: Emission Scenario Document

EU: European Union

FAQ: Frequently asked questions

FGAR: First-generation anticoagulant rodenticides

GefStoffV: *Gefahrstoffverordnung* [German Hazardous Substances Ordinance]

JKI: Julius Kühn Institute

NoCheRo: Non-Chemical Alternatives for Rodent Control

PEC: Predicted Environmental Concentration (see index, Chapter 15)

PflSchSachkV: *Pflanzenschutz-Sachkundeverordnung* [Ordinance Governing Specialist Qualifications in Plant Protection]

PNEC: Predicted No Effect Concentration (see index, Chapter 15)

ppm: parts per million

RKI: Robert Koch Institute

RMM: Risk mitigation measures

SchädlBekAusbV: *Verordnung über die Berufsausbildung zum Schädlingsbekämpfer/zur Schädlingsbekämpferin* [Ordinance on Occupational Training for Pest Control Officers]

SGAR: Second-generation anticoagulant rodenticides

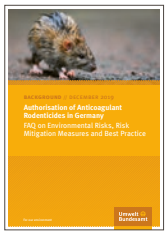
STOT RE: Specific target organ toxicity, repeated exposure

TRGS: *Technische Regeln für Gefahrstoffe* [Technical Rule for Hazardous Substances]

UBA: *Umweltbundesamt* [German Environment Agency]

UK: United Kingdom

USA: United States of America



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