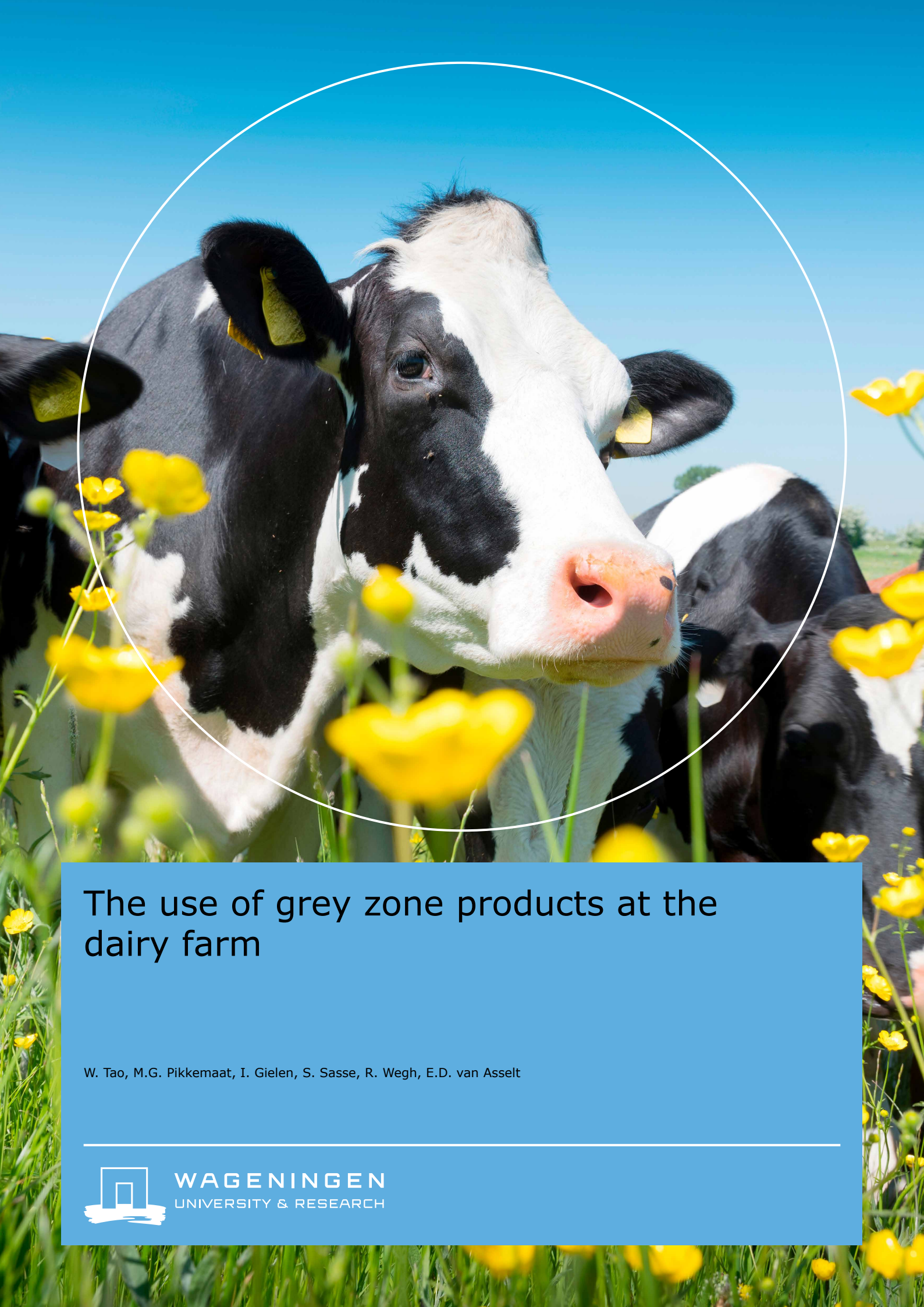

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Contents

Summary

Farmers use a wide range of products for their livestock for prevention or treatment of health issues in dairy cows and to clean or disinfect the milking system. Besides registered veterinary medicinal products and biocides, there are many other products available for this purpose; the so-called grey zone products. The use of these grey zone products may pose a potential health risk to livestock and consumers of animal derived products. The aim of this study was to gain more insight in the use of grey zone products at dairy farms, the potential presence of illegal substances and the potential human health risks related to the use of these grey zone products. For this purpose, the following steps were followed: 1. Exploring the use of grey zone products by interviewing dairy farmers and experts; 2. Online search on availability of grey zone products; 3. Chemical analysis of a selection of these grey zone products and 4. Development of a risk classification method for grey zone products.

Interviews with experts and a limited number of dairy farmers were performed. This showed that grey zone products are most frequently used in relation to udder and claw care. Main incentives for use were the need to reduce or omit antibiotics use and to find effective alternatives for persistent problems like mastitis and Mortellaro (digital dermatitis). Products can be obtained from veterinarians, animal supply shops (e.g. Welkoop) and wholesalers. Also, a large product range is offered on online web shops. As grey zone products are expected to be easily obtained online, an online screening of cattle care products was performed. In total, 18 web shops were found to offer a substantial product range of cattle care products. These web shops were screened using expert judgment for products with a potential risk to human health when residues are found in dairy products. This resulted in 42 grey zone products of which 11 products were selected for chemical analysis of their composition. Reasons for selection were unclear ingredient declarations (n=3) and discrepancies between claims and declared composition (n=9). An example of the latter is a product claiming antibacterial or anti-inflammatory effects, which cannot be substantiated by the listed ingredients. Such products could indicate the presence of illegitimate substances. The products could be categorised into skin care products (n=3), dry-off products (n=2), respiratory care products (n=2), immune system supporters (n=3) and gastrointestinal product (n=1). An analytical protocol was developed to determine whether the selected products contained illegal and/or undeclared substances. The analytical strategy was based on an untargeted LC-HRMS method combined with the data processing tool Compound Discoverer. Additional analyses were performed, but due to time and budget constraints, only focused on painkillers, hormones and coccidiostats. Analysis of these selected 11 products with this strategy did not yield illegitimate or undeclared substances with potential risks.

Apart from the chemical analysis, a risk classification method was developed that allows for a food safety risk prioritization of grey zone products. Google Scholar and Scopus were used to perform a literature study on general risk ranking methods of products. No pre-existing risk ranking strategy was found that can prioritize products on food safety risk. The literature study revealed only methods that can prioritize active substances within products. Therefore, a risk classification strategy was developed using scores for severity with respect to human health, probability of exposure and the exposure intensity. Because of the wide variety of grey zone products that are available, a decision tree to rank the severity when using grey zone products was established. Based on expert judgement, a selection of products (n=10) obtained from the online screening was used to test and adjust the risk classification method. Many products state a health or disinfection claim without registration or authorization as a veterinary medicine or biocidal product. Based on the final classification of products, follow up actions can be taken. Overall, the product testing showed that the developed risk ranking method allowed for a classification of grey zone products based on a potential food safety risk.

The results of this study show that many grey zone products are available for use at the dairy farm. The developed risk classification method can be used to select those products which need further attention. Although no illegitimate substances or chemical hazards were identified in the selected products, potential legal issues related to discrepancies between claims and composition were found. Also, it revealed significant prevalence of incomplete or unclear ingredient declarations.

1 Introduction

A wide range of products is being used as input for livestock farming: products for prevention and treatment of health issues, cleaning and disinfection, but also for example litter layers in stables. These products should be safe and effective, both for the animals and the consumer of animal products. While veterinary medicinal products are evaluated and registered by the Medicines Evaluation Board (CBG-MEB) and biocides by the Dutch Board for the Authorisation of Plant Protection Products (Ctgb), many of the available products fall outside the scope of these regulatory institutions. Some products contain registered feed additives (EU Regulation 1831/2003) or feed materials included in the EU Feed materials catalogue (Regulation (EC) No 68/2013, last amended by Regulation 2022/1104). These products should originate from GMP+ and SecureFeed certified suppliers. Whether or not a product falls in a certain category also depends on whether a claim is (consciously) communicated. Guidance on categorization can be found in:

- "*Nationaal Beoordelingskader Claims op Diervoeding*"
- "*Afbakening Biociden en (Dier)geneesmiddelen*"
- "*Leidraad voor bepaling van de grens tussen reinigingsmiddelen en desinfecteermiddelen*"

It is the responsibility of the manufacturer of the product to determine, based on the application and claim, which product category and which legislation, regulation and (external) supervision is applicable.

In this research, we focused on products that do not classify as a veterinary medicinal product, biocide or animal feed additives or materials and designated these as "grey zone" products. Examples are natural products for animal health, "green" biocidal products and microbial cleaners.

A workshop organized on the topic of grey zone products in 2019 showed that drivers for using these products in livestock production are diverse. Many of these products are aiming at increasing animal resilience, but products may also be used in relation to (costly) persistent health or hygienic problems at farms for which limited, expensive or no registered products are available. The emergence of new animal diseases and plagues and social pressure to reduce the use of synthetic chemicals may also lead to increased interest in 'green' alternatives to regular pharmaceuticals and biocides. The easy access of these products both online and on the international market is an appealing factor for their use.

As most of the grey zone products are placed on the market bypassing any official regulatory evaluation framework, many of these lack adequate specifications, quality criteria, proof of efficacy and safety evaluations. For manufacturers this can be profitable since it reduces costs for assessment, registration and supervision and less stringent requirements for the declaration of the ingredients. Products are for example sold as a cleaning agent, care product or animal feed, of which the claim in relation to the problem is deliberately or unintentionally omitted, in order to avoid registration as a veterinary medicine or biocide.

Aim of the research

The lack of overview and transparency related to the use of grey zone products creates potential risks to livestock exposed to these products and consumers eating animal derived products. Anticipating potential problems related to the use of unregulated products is a priority for The Netherlands Food and Consumer Product Safety Authority (NVWA).

The aim of this research was to gain more insight in the use of grey zone products on livestock farms and the farmers' motivation for their use. Furthermore, a chemical analysis strategy was developed to detect potential hazardous substances, which was applied to a selection of products. Since a wide range of grey zone products may be available on the market and not all of these products can be explored in detail, a strategy was developed to evaluate potential human health risks related to the use of grey zone products. Such a strategy allows for a classification of grey zone products into low to urgent priority for further actions. For time and budgetary reasons, it was decided to focus the research on one livestock species. Since for dairy farming some pre-existing information on the use of grey zone products was available, it was decided to start the research on this livestock production system.

2 Materials and Methods

2.1 Approach

In order to assess potential human health risks related to the use of grey zone products on Dutch dairy farms, the following tasks were performed in this project:

- Inventory of available grey zone products for dairy farming (section 2.3)
- Development of an analytical strategy to detect potential hazardous substances in grey zone products (section 2.4)
- Development of a risk classification method to evaluate the safety of grey zone products (section 2.5)

A schematic overview on the performed tasks in this project can be seen in Figure 1. One of the tasks in this figure, that is the development and testing of the risk classification method was performed by QRAAK in collaboration with and under the supervision of WFSR. QRAAK is a company that performs independent research on the livestock sector with expertise on risk assessment. WFSR performed the other activities as mentioned in this Figure.

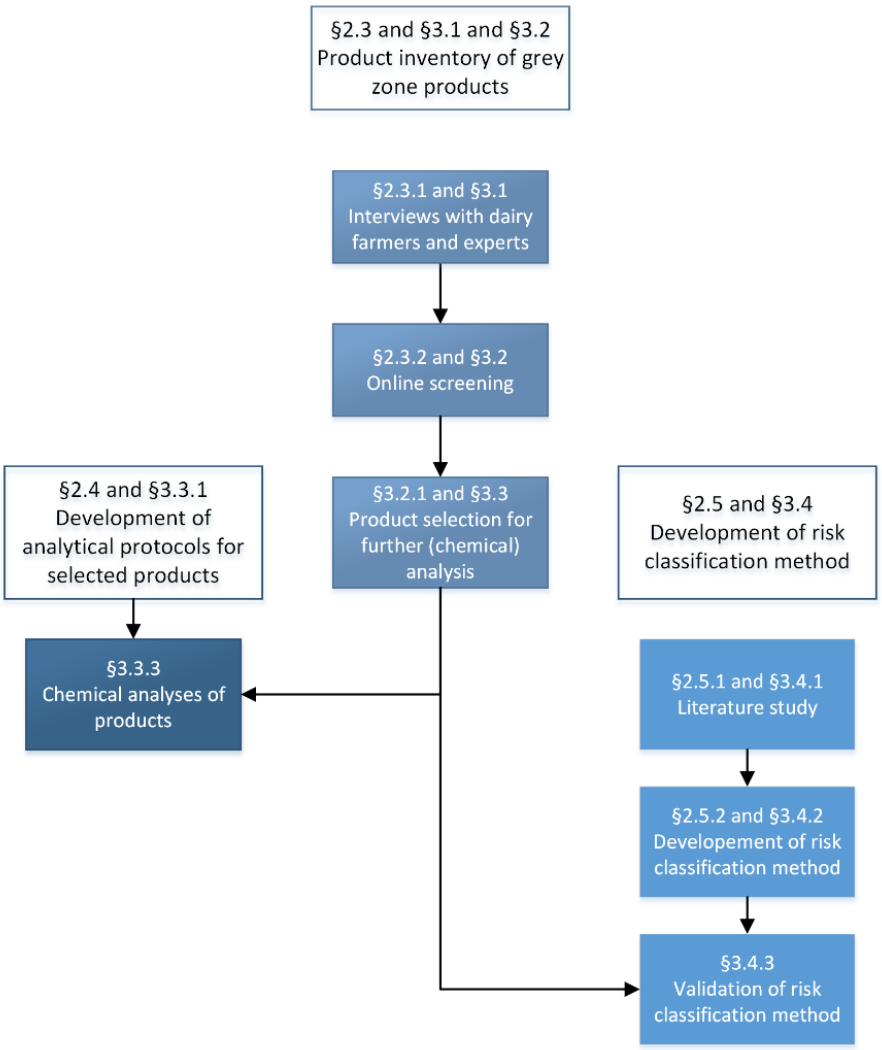

Figure 1 *Roadmap of the activities performed in this study with references to the paragraphs that describe the methods used (chapter 2) and the results of the activities (chapter 3)*

2.2 Demarcation

The focus of this research was on grey zone products for prevention and treatment of health issues in dairy cows and products applied for hygiene purposes. Previous research showed that grey zone products were mainly used for the treatment of udder and claw related problems (NZO, personal communication). Therefore, the focus of this research was on the use of grey zone products used for animal care or biocidal purposes on Dutch dairy farms. No distinction was made between conventional and organic farms and farms that also process the milk into dairy products.

2.3 Product inventory

2.3.1 Questionnaires and interviews

Predefined questionnaires were established to gain insight into the use of (grey zone) products on dairy farms. Separate questionnaires (in Dutch) were designed for: 1. Dairy farmers (Annex 1) and 2. Dairy experts (Annex 2). Experts were identified using Google with the following keywords: 'dierenarts' or 'dierenartspraktijk' or 'dierenkliniek' or 'rundveearts' or 'veearts' or 'beroepsorganisatie dierenartsen' or 'branchorganisatie melkveehouderij' or 'LTO' or 'ZuivelNL'. We@WUR was searched for experts based on the following expertise keywords: 'rundvee' or 'alternatieve landbouw' or 'biologische landbouw' or 'biologisch-dynamische landbouw' or 'melkkoeien' or 'melkvee' or 'melkveehouderij' or 'melkveevoeding' or 'uiergezondheid'. Contacts identified from the network of WUR researchers involved in related projects were approached as well. Moreover, relevant scientists from the faculty of Veterinary Medicine of Utrecht University were found using their organisational chart and the following keywords: 'bedrijfsdiergeneeskunde rund' or 'uiergezondheid rund' or 'gezondheidszorg landbouwhuisdieren met name herkauwers'.

To search for dairy farmers across the Netherlands, Google Maps and Stichting Demeter (Biodynamic Farmers Association) were consulted. The following keywords were used on Google Maps: 'melkveebedrijf' or 'melkveehouderij' in combination with the name of one of the twelve Dutch provinces: 'Friesland' or 'Groningen' or 'Drenthe' or 'Overijssel' or 'Utrecht' or 'Gelderland' or 'Noord-Brabant' or 'Limburg' or 'Noord-Holland' or 'Zuid-Holland' or 'Zeeland'.

Finally, experts and dairy farmers recommended during the interviews were subsequently approached to participate in the study.

Experts and dairy farmers were contacted by email in order to arrange an interview by phone or Microsoft Teams. In order to maximize the response rate, participation was rewarded with the chance to win a gift voucher. A week after the first invitation, a reminder was sent to invitees who did not respond. In total, 132 invitations for interviews were sent in February and March 2022, of which 50 invites to experts and 82 to dairy farms. Experts approached included researchers on the topic, veterinarians, members of branch organizations, NVWA inspectors, suppliers of dairy farm supplies, trade journalists and dairy companies. The goal was to interview ten experts and ten dairy farmers.

2.3.2 Online screening

Based on the results of the interviews as described above, an online screening was performed to gain insight in the availability of grey zone products available for dairy farming. Web shops selected were obtained from the answers given in the interviews and initial online searches for suppliers of animal care products. Only web shops offering products on the Dutch market were screened for their products. Products were selected based on their applicability in/on/to cattle. Moreover, products indicated by interviewees were searched for directly in web shops. Products were screened for the presence of clear and correct product descriptions, compositions, claims, authorisations and application manuals. The results were assembled in an Excel table.

Parallel to the online screening for products in web shops described above, an additional search was performed in Coosto, in collaboration with NVWA, to identify grey zone products mentioned on internet fora

or other social media platforms. Coosto is a content and social media marketing tool that can be used to monitor and improve content. Based on earlier searches and search terms used on a certain topic, a database is automatically built, which can be used to search for online content regarding the topic. The tool was used to search for potential use of grey zone products at the dairy farm using a combination of search terms from the following three groups:

Animal
'Rund' or 'Runderen' or 'Melkvee' or 'Melkgevend rund' or 'Melkkoe' or 'Koe' or 'Koeien' or 'Kalf' or 'Kalveren or 'Vaars'.

Health issue
'Gezondheid' or 'Ziek' or 'Energie' or 'Weerstand' or 'Immuunsysteem' or 'Eetlust' or 'Herstel' or 'Diarree' or 'Wormen' or 'Luchtweginfectie' or 'Longproblemen' or 'Droogzetten' or 'Mastitis' or 'Uierontsteking' or 'Uierverzorging' or 'Celgetal' or 'Afkalven' or 'Melkproductie' or 'Melkgift' or 'Klauwproblemen' or 'Klauwverzorging' or 'Klauwen' or 'Mortellaro' or 'Wond' or 'Ontsteking'.

Product characteristics
'Natuurlijk' or 'Bolus' or 'Kruiden' or 'Plantenextracten' or 'Homeopathisch' or 'Probiotica' or 'Prebiotica' or 'Biologisch' or 'Geen wachttijd' or 'Geen wachttermijn' or 'Alternatief'.

The search was conducted with a time range between June 23rd 2021 to June 23rd 2022.

2.4 Analytical strategy to identify potential hazards in grey zone products

A strategy was developed to analyse the potential presence of chemical hazards in grey zone products. The step-by step plan to develop this strategy is presented in Figure 2.

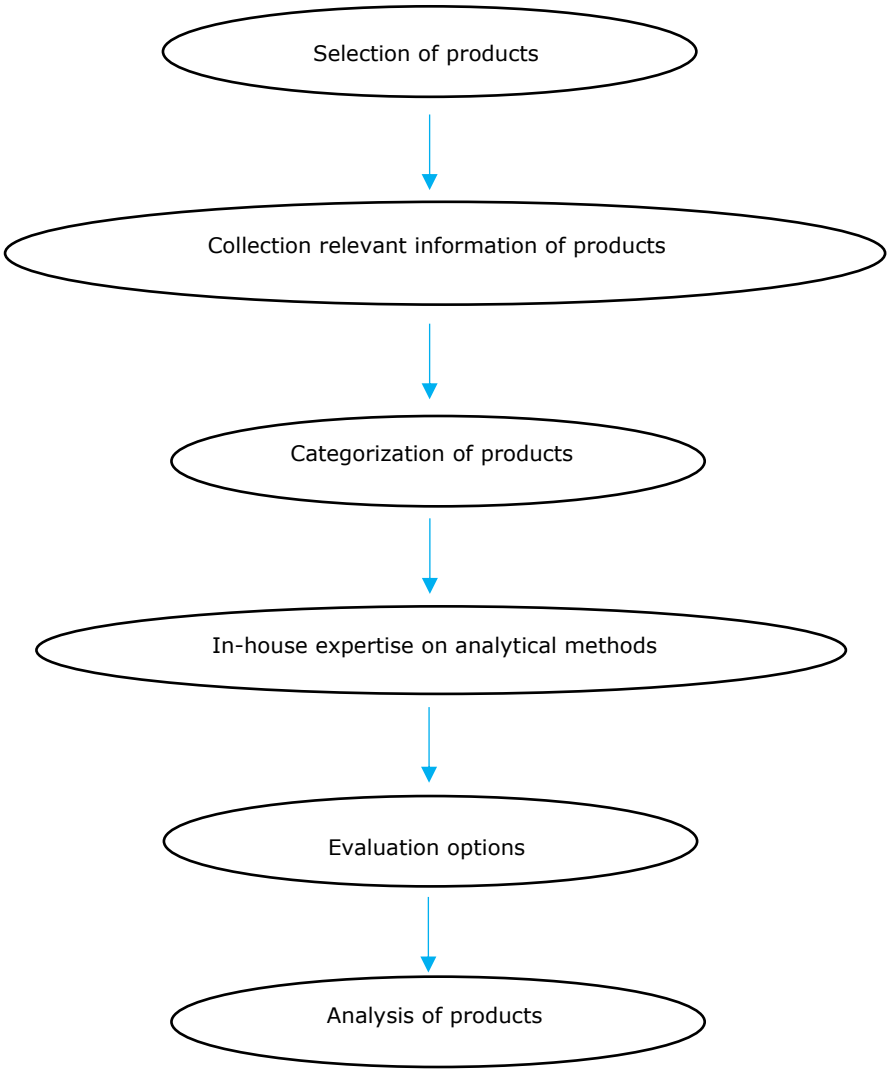

Figure 2 *Step-by-step plan to develop the strategy for analysing the products*

The procedure starts with selecting suspicious products based on expert judgment as was done in the online search (see section 2.3.2 and 3.2.1). These were categorized based on the identified issue. Relevant information for each of the products, such as compositional information on the label, was collected. Subsequently, several WFSR experts in the field of identification of unknown chemicals as well as of specific analytical techniques, such as bioassays, LC(HR)MS and GC(HR)MS were consulted to select the most appropriate analytical method(s). Based on this, a (specific) protocol for each product was developed and the products were analyzed according to the protocol.

2.5 Strategy development for risk classification of grey zone products

2.5.1 Literature review

A literature study was performed to evaluate methods available to rank potential health risks of grey zone products and biocides using Google Scholar and Scopus. The Advanced Search feature of Google Scholar was first used with the following keywords:

"Risk prioritization" OR "Risk ranking" OR "Risk classification" AND "Food safety hazards" AND "Animal care" OR "Care products" OR "Health impact" (search for terms in the whole article).

Furthermore, Scopus was consulted for additional articles on risk ranking methods using the following keywords:

TITLE-ABS-KEY TITLE (prioriti* OR rank* OR classif* OR "risk based" OR "risk-based") AND TITLE-ABS-KEY ("Food safety hazards" OR pollutant* OR "chemical hazard*" OR contaminant* OR toxin* OR "agricultural chemical*" OR agrochemical* OR "chemical compound*" OR "chemical substance*" OR residu* OR pharmaceutical* OR "vet* drug*" OR "vet* medic*" OR antibiotic* OR antimicrobial* OR antiparasitic* OR anti-parasitic* OR nsaid* OR sedative* OR hormone* OR steroid* OR "beta*agonist*") AND TITLE-ABS-KEY ("Animal care" OR "Care product*" OR "animal Health").

2.5.2 Strategy for evaluating grey zone products at the dairy farm

A semi-quantitative method based on scores was used to classify the risk of grey zone products. Fine (1971) and Kinney and Wiruth (1976) developed a method that is commonly used to evaluate risks in relation to health and safety (Fine, 1971; Kinney and Wiruth, 1976). The method helps to define the risk and appropriate actions by scoring the Severity, Probability and Exposure intensity. After determination of the severity (S), the intensity of exposure to the hazard (E) and the probability of the hazard to occur when exposed (P), the risk (R) can be estimated. The result of multiplying S x E x P defines the Risk index (R).

Due to the wide range of grey zone products available, which can be categorised in different applicable legislations and regulations depending on the application, it was necessary to develop a decision tree in order to estimate the severity (S) of the hazard. Various sources of information were used to answer the questions in the decision tree. In order to assess whether products or ingredients in the products were registered/authorised for use, Dutch and EU registrations for veterinary drugs and biocides were used as indicated at CBG-MEB, the EU veterinary medicines database, Ctgb and ECHA. Furthermore, relevant regulations, such as the EU regulation for placing feed on the market and for using feed ((EU) No 767/2009), the Animal Feed Catalogue (Regulation (EU) No 68/20130), the EU Register of Feed Additives (Regulation ((EC) No 1831/20030 and the list of feed intended for particular nutritional purposes (Regulation (EU) Nr 2020/354). Also guidelines published by CBG-MEB, Ctgb and the Dutch Ministry for Infrastructure and Environment were used, to assess claims and define the difference between the product categories veterinary medicines, biocidal products and feed.

3 Results and discussion

3.1 Results of interviews on products use on dairy farms

Of the 132 invitations sent out to participate in the research, 38% (i.e. 50 people) replied to the invitation. Of these replies, 52% (i.e. 26 replies) were rejections. Provided reasons for rejections included: 1. Irrelevancy for the company or expert to participate, 2. Lack of time (indicated by both experts and dairy farmers) due to non-specified reasons. Overall, the positive response rate was 18% (i.e. 24 replies). The aim was to interview 10 dairy farmers and 10 experts. Unfortunately, it was difficult to attract dairy farmers for this research. Ultimately, 13 experts and 4 dairy farmers were interviewed. The remaining 7 positive responders were not included for several reasons: no further response on time proposals, lack of time of the responder and the accomplishment of the aimed number of expert interviews. An overview of the response rate for the interviews can be found in Table 1.

Table 1 *Response rate for interviews*

Profession	Invitations sent	No response	Rejections	Interviewed
Dairy farmer	50	33	13	4
Expert	82	56	13	13
Total	**132**	**89**	**26**	**17**

The interviews were used to collect information on common health issues at the farm (section 3.1.1), commonly used grey zone products (section 3.1.2), incentives for the use of these products (section 3.1.3) and purchase channels (section 3.1.4).

3.1.1 Common health issues on dairy farms

The following health issues related to animal care on dairy farms were commonly reported during the interviews (between brackets the number of times reported): a. Udder problems including mastitis and (teat-)injuries (n=16), b. Claw problems including infections and problems with the joints and hooves (n=17), c. Metabolic disorders (n=10), d. Fertility-problems (n=6), e. Post-partum problems including uterine infections and ketosis (n=6), f. Gastro-intestinal problems (n=7), g. Diarrhoea among calves (n=6), h. Respiratory problems among older cows (n=7), i. Skin-problems including scabies and injuries (n=3), j. Stress (n=1) and k. Fever among young animals (n=1). An overview of the results on common health issues can be found in Table 2.

Common problems for which biocidal products are applied on animals or in their surrounding environment according to the interviewees included: a. Endo- and ectoparasites including flies, larvae, ticks, lice, liver flukes, lungworms and cryptosporidium (n=33), b. Pathogens (udder and claws) (n=1), c. Rota- and coronavirus among calves (n=2), d. Cleaning and disinfections of the stables (n=7), e. Cleaning and disinfection of the milking machines and milk tanks (n=12), f. Cleaning and disinfection of teats before and after milking (n=4), g. Cleaning and disinfection of milk processing sites (if applicable) (n=1) and h. Vermin (rats and mice) control (n=9). An overview of the results on common problems related to the use of biocidal products can be found in Table 3.

Other farm practices mentioned for which grey zone products potentially might be used were: during manure processing, ensilage, disinfecting animal drinking water and crop protection. These products do not directly target animal health but can cause potential risks.

Table 2 *Common health issues on dairy farms*

Profession	Claw problems	Udder problems	Metabolic disorders	Gastro-intestinal problems	Respiratory problems among older cows	Fertility problems	Post-partum problems	Diarrhea among calves	Skin problems	Stress	Fever among young animals
Dairy farmer 1	X	X	X		X	X	X	X			
Dairy farmer 2	X	X	X		X		X	X			
Dairy farmer 3	X	X	X								
Dairy farmer 4	X	X				X					X
Expert 1	X	X					X				
Expert 2	X	X							X		
Expert 3	X	X									
Expert 4	X	X	X	X	X	X	X	X			
Expert 5	X	X	X	X	X	X	X	X			
Expert 6	X	X	X			X			X		
Expert 7	X	X		X							
Expert 8	X	X	X	X	X	X	X	X		X	
Expert 9	X	X		X							
Expert 10	X	X	X	X					X		
Expert 11	X		X								
Expert 12	X	X		X	X						
Expert 13	X	X	X		X			X			
Total times mentioned	**17**	**16**	**10**	**7**	**7**	**6**	**6**	**6**	**3**	**1**	**1**

Table 3 *Common targets for biocidal/disinfection products on dairy farms*

Profession	Flies	Worms	Cleaning and disinfection of milking apparatus and milk tanks	Vermin	Cleaning and disinfections of sheds	Other endo- and ectoparasites	Cleaning and disinfection of teats before and after milking	Rota- and coronavirus among calves	Pathogens	Cleaning and disinfection of milk-processing sites
Dairy farmer 1	X	X	X			X	X			X
Dairy farmer 2	X	X	X	X						
Dairy farmer 3			X		X					
Dairy farmer 4	X	X	X		X					
Expert 1	X	X	X	X	X					
Expert 2	X		X	X		X	X		X	
Expert 3	X	X								
Expert 4	X	X		X	X	X		X		
Expert 5	X	X			X	X	X			
Expert 6		X	X	X						
Expert 7	X	X	X		X					
Expert 8	X	X	X			X				
Expert 9	X		X	X						
Expert 10	X	X		X		X				
Expert 11	X		X	X	X		X			
Expert 12	X	X		X						
Expert 13	X		X					X		
Total times mentioned	**15**	**12**	**12**	**9**	**7**	**6**	**4**	**2**	**1**	**1**

3.1.2 Commonly used grey zone products

Various commonly used health care products were mentioned by experts and dairy farmers including creams, oils, sprays, injectors, boluses, capsules, drinks with herbal preparations, mineral preparations, enzyme preparations and/or vitamin preparations. Among the reported products, seven homeopathic products were mentioned. Moreover, vaccines and other registered veterinary drugs were mentioned, but these obviously fall outside the definition of grey zone products.

Among frequently mentioned biocidal products were products containing acids, bases, chlorine, iodine, soda and copper sulphate in the form of sprays, baths, dips and pour-ons (products that are applied topically). Moreover, natural cleaning products, formaldehyde baths and general insecticides (e.g. VeeRust) were mentioned. The mentioned insecticides were all registered as veterinary drugs; hence they fall outside the definition of grey zone products.

3.1.3 Incentives to use grey zone products at dairy farms

Reasons for the application of grey zone products are diverse. The need to reduce or even omit the use of antibiotics was mentioned most frequently by both farmers and experts (n=12). This was followed by the need to find more effective alternatives for persistent problems like mastitis and Mortellaro (n=9). All farmers (n=4) and two experts mentioned that the focus on prevention and improving animal resilience is an important reason to minimize the use of 'synthetic' veterinary drugs by applying natural products for disease prevention. Reduction of costs was mentioned six times as a motivation for the use of grey zone products, although others (n=11) indicated that cost reduction is not a decisive reason to turn to alternatives. Other reasons for the use of grey zone products included: a. A better "feeling" associated with using non-pharmaceutical products (n=2), b. Organic farming system (n=5), c. Less harmful to the environment (n=4), d. Conventional products tend to get stricter monitoring of product-use (n=3), e. Bypassing the necessity to apply withdrawal periods after the use of conventional products (n=4), f. Avoiding (antimicrobial) resistance against conventional products (n=1), g. Lower occupational risks when applying the product (n=3).

3.1.4 Purchase channels

Grey zone products are obtained via various routes: via the veterinarian, from animal supply shops and wholesalers, equipment suppliers (mainly cleaning detergents and disinfectants), peddlers and online web shops, including those from pet shops and wholesalers, and the grey market. The interviews showed that livestock care products and potential grey zone products are often searched for on and obtained from the internet. This also includes the online web shops of animal supply shops, wholesalers and equipment suppliers. Products from veterinarians and peddlers are difficult to access for research purposes. Moreover, it is not expected to find unauthorised grey zone products offered by veterinarians. Therefore, it was decided to focus on the online availability of grey zone products.

Farmers can get acquainted with grey zone products through advice from veterinarians, especially on alternative products for treatment or prevention of persistent health problems. Also, dairy farmers share their user experiences of all kinds of products during study club gatherings and on online forums. Moreover, the handbook for natural animal health care is a source of and introduction to grey zone products for animal health (Groot et al., 2016a).

3.2 Online screening

3.2.1 Results online screening

From the interviews and online search on livestock farming supplies, 18 web shops were found to offer cattle care products: Macrovet, Vitafor, Agri Service Jeuken, VeeService Idac, Ritsema Dier & Tuin, MS Schippers, J. Slijkhuis, Melkvee.shop, De Boer, Welkoop, VITALstyle, VETstyle, Beforan, v.d. Belt Agri Service, Topro Animal Health, Zeinstra, Rinagro and AHV.

A brief scan of these web shops showed overlap between products offered by several web shops. Two web shops were mentioned as primary sources for farmers for online purchase of animal care products, i.e. Schippers and VITALstyle. These web shops were thus investigated in depth for grey zone products with potential hazards. Furthermore, additional smaller web shops were screened for potential grey zone products. An overview of the results is indicated below per web shop.

MS Schippers offers products from their own brand as well from other vendors of animal care products like VITALstyle. By expert judgement, an initial screening was performed which yielded 21 products that were subjected to a more elaborate analysis (i.e. looking into its composition). Products were selected based on indistinct product composition, obscure regulatory status (e.g. biocide or veterinary drug), suspicious (active) ingredients (e.g. unclear colouring agents) or unjustified claims (e.g. claims on disease treating properties). These products could be categorised into homeopathic veterinary drugs (n=2), biocidal products (n=2), supplementary feed (n=8), claw care products (n=2), skin care products (n=4) and a product for joints and muscles (n=1).

The VITALstyle web shop only offers products from their own brand. Their product assortment is larger than what is being offered by MS Schippers. All products are claimed to be based on natural ingredients like vegetables, fruits, grains and herbs. Nine products were selected for more detailed analysis comprising supplementary feeds (n=8) and one claw care product. These products were selected based on the indicated active ingredients (e.g. willow bark and seaweed) and unclear regulatory status.

The website of VITALstyle's sister company VETstyle, which offers additional products, was also evaluated. In total, four products (three supplementary feeds and one claw care product) were selected to be studied in more detail since the declared ingredients could not be matched with the claims on the label. It should be noted that the web shop also offers homeopathic veterinary drugs, which each have a REG NL code, indicating that they are permitted to be used in the Netherlands by the Medicines Evaluation Board (CBG-MEB). Since January 2022, homeopathic veterinary drugs need to be registered prior to marketing ((EU) Regulation 2019/6). These products may only be sold by a veterinarian or on veterinary prescription (UDA status). These products were, therefore, not further investigated.

Beforan was specifically mentioned by one of the interviewees as a supplier of grey zone products. Beforan offers boluses for cows and calves for various health care purposes including hooves care, milk quality (bacterial counts in milk) and claw and udder problems. Moreover, they offer an alternative to formaldehyde for treatment of Mortellaro based on pH changes. They also offer pills to support the immune system of calves and stimulate drinking when they suffer from diarrhoea. All products they offer for cattle care (n=4) lack clear descriptions of the product composition, hence they were studied in more detail.

Additional web shops mentioned in the interviews were: Agri Service Jeuken, Topro Animal Health, Sietse Jorna, Rinagro and AHV. Based on expert judgement, these were screened as well and resulted in six products which were studied in more detail: supplementary feed products (n=3), one skincare product, one udder care product and one homeopathic veterinary drug.

Results of the online screening are summarised in Table 4. Overall, most of the selected grey zone products were offered as supplementary feed. Based on availability (some products appeared difficult to purchase, only possible as a farmer or veterinarian), claims and ingredients, a specific selection of products was subjected to chemical analysis (in bold) as described in section 3.3. Vitalstyle K-Spirine and Topro PainCare bolus were selected because one of the main constituents is willow bark extract. This salicylic acid-rich ingredient could be substituted with cheaper synthetic salicylic acid. In that case, a veterinary medicine registration would be required. Melkstop B and LactaQuit are both products supporting drying off, claiming to reduce milk production, which could imply the presence of hormonal substances. The names of the products Klausan and Vet Violetspray both suggest these products to possibly contain gentian violet, which is a prohibited substance. Similarly, Anthrolan Hoef- en klauwenspray suggests the presence of anthralin, which is a pharmaceutical not authorized for food producing animals. BETA-LAC MS, Flexfeed Airo, and BronchiPlus were selected because of a rather explicit claim in combination with indistinct ingredients. These products were used as input to develop and test the analytical protocol for analyzing chemical hazards (section 3.3).

3.2.2 Results Coosto

The search on Coosto resulted in 478 hits. These were manually screened by evaluating the content of each hit based on expert judgement, resulting in ten hits containing potentially relevant information to the topic of this study: posts on news websites of the agricultural sector (n=5), trade magazines (n=2), an academic research institute (n=1), a news website on innovative developments (n=1) and a social media platform (n=1). Of the ten hits initially selected, only 4 were relevant with respect to grey zone products. Two posts contained information on grey zone products to be used in claw care, namely a formalin free claw bath and an alternative cleaning system to claw baths. Moreover, one post contained information on the use of boluses to prevent udder infections. Lastly, a list of products permitted to be used in organic farming was shared in a trade magazine for goat farms. This appeared to be an extract from the handbook of Groot et al. (2016b). None of the hits contained posts on internet forums related to dairy farm practices. From the Coosto search, three websites of the agricultural sector, namely melkveebedrijf.nl, melkvee.nl and vakbladelite.nl were identified as potentially interesting for the topic of this research. The newsfeed of these websites was screened to obtain potentially relevant information on the use of grey zone products. The Coosto search and the screening of the news sites did not retrieve new products that needed additional research.

Table 4 *Overview of interesting products from online screening (in bold the products selected for analytical analysis)*

Product	MS Schippers	VITALstyle	VETstyle	Beforan	Agri Service Jeuken	Topro Animal Health	Sietse Jorna	Rinagro	AHV
Homeopathic veterinary drugs	- Mamil Phyt Plus mastitis injector - Vitalstyle Pyrogenium compositum						**- Licoc**		
Biocides	- Cowipes 900 stuks - MS Formades								
Supplementary feed	- Vitalstyle Melkstop - Vitalstyle Panax knoflook bolus **- Vitalstyle K-Spirine** - Vitalstyle Transit knoflook bolus - Vitalstyle Energieplus bolus - MS Calmag Plus **- MS Flexfeed Airo** - MS Rumen Support	- K-Spirine bolus - Oervitaal Bio - Panax knoflook bolus - Transit knoflook bolus **- Melkstop B** - Bronch Arom F - Energieplus bolus - K-Spirine vloeibaar	**- LactaQuit** **- BronchiPlus** - DiarFlor		**- BETA LAC**	**- Topro PainCare bolus**		- Compost-O	
Claw care products	**- Anthrolan Hoef- en klauwenspray** - VITALstyle Klausan Violetspray	**- Klausan Violetspray**	**- Vet Violetspray**	- Healthy hooves ultimate plus					
Skin care products	- Vetericyn Utility gel - MS Blauwspray - Vitalstyle Calendula spray - MS Poederspray								- Qs Spray
Joints and muscle products	- Vitalstyle ProMotion spray								
Udder care				- Celgetal bolus & Biochar bolus					- AHV Aspi (also applied to support overall immune system of the animal)
Diarrhea among calves				- Dia-care pil					
Udder and claw care products				- Udder & Hoof combi bolus + Biochar bolus					

3.3 Strategy for analyzing chemical hazards

In order to assess the potential presence of chemical hazards in grey zone products, an analytical procedure was developed and tested on the eleven products selected from the online search (in bold from Table 4; see section 3.2.1). These products included skin care products (n=3), dry-off products (n=2), respiratory care products (n=2), immune system supporters (n=3) and one gastrointestinal product. Initially, relevant information on the reason for further investigation, the composition (if available) and the product characteristics (solid, liquid etc.) were collected. This information provided insights in the complexity of the product and gave directions to the analytical technique(s) that might be suitable for analysis. Next, the products were categorized based on the reason of usage and the suspected component (group), such as NSAIDs, hormones or dyes. The relevant information and categorization of the products are presented in Table 5.

3.3.1 Analytical procedure

In order to select the best strategy for analysis of the composition of the wide range of products selected, several WFSR experts were consulted. Various analytical techniques were considered as options, such as bioassays, microscopy and (un)targeted GC- and LC-(HR)MS analysis. The expert consultation resulted in information on the advantages or disadvantages of the technique and after evaluation, it was decided to analyze the products with LC-HRMS in untargeted mode. By using this technique and mode, comprehensive screening of compounds is possible, which is considered the most optimal for identification of unknown substances but also in case of particular suspicions. However, it should be noted that there are also limitations to this strategy, which is further explained in section 3.5.

The products were prepared for analysis according to a standard WFSR approach for identification of unknown chemical hazards. The first approach was based on dissolving the product in methanol. If this did not work, the alternative approach was to dissolve the product in water. For complex products that could not be dissolved in methanol, a liquid-liquid extraction was performed. A simple sample preparation is recommended for analysis of unknown compounds to prevent the loss of potential interesting substances. The LC-HRMS analysis was carried out using a standard method applied for the detection and identification of unknown compounds. In addition to the analysis of the products, three standard mixtures of NSAIDs, antibiotics and hormones were analyzed as positive control.

After the analysis of the products, the data was processed with Compound Discoverer. This software tool compares practical mass spectrometry data with online databases, such as mzCloud and Chemspider, as well as dedicated mass lists and predicted compositions. The output was a list of possible matches of compounds (>1000 matches) that could be present in the sample. The matches with large peak areas, several full matches with online databases, dedicated mass lists and predicted compositions, as well as interesting compounds potentially relevant related to the type of product were further selected. Finally, the chromatography of the selected matches was checked, and manually compared with the reference spectra.

The resulting list of matches for each product is presented in Table 5. The composition on the label was compared with the selected matches from the output list of Compound Discoverer. To confirm that a match is truly present in a sample, an additional targeted LC-MS/MS method including analytical standards should be performed. This final confirmation was however not applied in the current study as the products analyzed did not yield matches that justified a confirmatory analysis.

For some products, additionally, more targeted databases like Tracefinder were consulted to verify potential presence of added active substances such as painkillers, coccidiostats or hormonal substances. This was applied to the products Topro Care, Betalac, Melkstop B, Lactaquit and Licoc. The additional screening, however, did not reveal presence of any painkillers, coccidiostats or hormonal substances in these specific products. Among the analysed products were three products (Vet Violetspray, Klausan Violetspray and Anthrolan) that considering their appearance had to contain a distinct colorant. The prohibited substance gentian violet could not be found in the products with the analytical protocol used. Further analyses, i.e., paper chromatography and UV-VIS, were performed to try to determine which compound is causing the blue or black color, respectively. The results of the paper chromatography showed that Vet Violetspray and

Klausan Violet spray both contain two colorants, a blue and a yellow/orange color. Subsequently, UV-VIS spectra of the products Vet Violetspray and Klausan were recorded. Both UV-VIS spectra showed a maximum absorption at 630 nm which matches the reference spectra of patent blue. This indicates that the blue color in Vet Violetspray and Klausan Violetspray is most likely caused by patent blue and not by gentian violet which has a maximum absorption at 590 nm. The second, yellow/orange color possibly originates from the calendula that is declared as an ingredient on the label. The compound causing the black color of Anthrolan could not be eluted using the solvent in the paper chromatography experiment. The identity of the black colorant in the product Anthrolan could therefore not be established. To determine the identity of the black color further analysis with Raman spectroscopy could be performed to establish whether the black color is caused by e.g., carbon black or black iron oxide, which are commonly used additives in, amongst others, plastics, coatings, inks, paints and rubber.

Table 5 *Relevant information, categorization and results of the products analysed*

Product	Supplier	Content	Reason for further investigation	Form	Composition on label	Selected matches Compound Discoverer	Conclusion on ingredients
K-spirine vloeibaar	VITALstyle	250 mL	willow bark-> salicylic acid	liquid	CaCl Monopropylene glycol Glyceryl polyethylene glycol ricinoleate Boswellia 237 mg/kg aromatic substances, including willow bark and curcuma	Not analysed with LC-(HR)MS and therefore not processed with Compound Discoverer. Targeted LC-MS/MS analysis showed 170 mg/kg salicylic acid.	Unlikely that synthetic salicylic acid is added due to the relatively low concentration found in the product compared to an effective level of salicylic acid present in drugs for human application. The study regarding natural/synthetic salicylic acid will be continued.
Topro PainCare bolus	Topro Animal Health	12 x 100 g	Synthetic painkiller?	bolus	Salix alba (salicin, gallotannin) Propolis (essential oils, flavonoids, proteins, sugars, vitamins) Ascorbic acid (Vit C) Citrus extract Calcium stearate Total sugars as sacharose Ca, Mg, P, Na	D- (-)-Salicin D- (-)-Fructose D- (-)-Maltose Naringenin (flavonoid) Formononetin (isoflavone) Daidzein (isoflavone) Chrysin (flavone)	Based on the analytical protocol used, no suspicious results on NSAIDs were found. Matches found coincide with composition on the label.
BETALAC	ASJeuken	5 L	betaglucan (sugars) for disease control?	liquid (oil)	Thiamine-HCL (Vit B1) Riboflavin (Vit B2) Pantothenate (Vit B5) Pyridoxine (Vit B6) Cyanocobalamin (Vit B12) Vit E Vit A Betaglucan Monopropylene glycol Ca, Mg, P, Na, K, Co, Mn, Se 79% moisture 17.5% crude ash 0.39% crude fat	Pyridoxine (Vit B6) Thiamine (Vit B1) Riboflavin (Vit B2) Thiochrome (oxythiamine) Pantothenic acid (Vit B5) Nicotinic acid (Vit B3)	Betaglucans were not detected since these molecules are too large for the analytical method applied. Based on the analytical protocol used, no suspicious results on NSAIDs were found. Matches found coincide with composition on the label.

Product	Supplier	Content	Reason for further investigation	Form	Composition on label	Selected matches Compound Discoverer	Conclusion on ingredients
Melkstop B	VITALstyle	500 mL	unclear active substance; hormonal activity?	liquid	NaCl, MgCl 9000 mg of aromatic substances 25 mg citric acid monohydrate 93% moisture 2% crude ash 1% crude protein 1% crude fat 1% crude fiber 1% Na	Citric acid 2-furoic acid (aroma)	Based on the analytical protocol used, no suspicious results on hormones were found. Matches found coincide with composition on the label.
LactaQuit	Vetstyle	1 L	unclear active substance; hormonal activity?	liquid	NaCl, MgCl Artichoke extract 12.5 mg (Caffeoyl-quinic acid, chlorogenic acid, cynaropicrin and cynarin) Vitex Agnus-castus extract 10 mg (Monk's pepper: diterpenes, iridoid glycosides, flavonoids, alkaloids, essential oils) 0.1% crude protein 0.1% crude fat 0.1% crude ash 0.1% Na	D-(-)-Quinic acid	Based on the analytical protocol used, no suspicious results on hormones were found. Matches found coincide with composition on the label.
MS Flexfeed Airo	Schippers	1 L	unknown composition; bromhexine?	liquid (oil)	NaCl Propylene glycol 200 mg eucalyptus oil 18% moisture 9.3% crude oils 0.1% crude ash 0.05% Na	Eucalyptol Pulegone Citral	Based on the analytical protocol used and a specific mass search in the raw data, no bromhexine was found. Matches found coincide with composition on the label.
BronchiPlus	Vetstyle	800 g	unclear composition; bromhexine?	solid	NaCl Glucose 75 mg essential oils 100 mg clinoptilolite (mineral) 1% crude protein 1% crude fat 1.75% crude fiber 24% crude ash 15% hydrochloric acid insoluble ash 4% Na	D-(+)-glucose	Based on the analytical protocol used and a specific mass search in the raw data, no bromhexine was found. Match found coincides with composition on the label.

Product	Supplier	Content	Reason for further investigation	Form	Composition on label	Selected matches Compound Discoverer	Conclusion on ingredients
Klausan Violetspray	VITALstyle	200 mL	pigment-> gentian violet?	spray (blue)	Chamomile blossom (apigenin, alpha-bisabolol and chamazulene, coumarins (umbelliferone, herniarin), choline, mucilages, tannins, salicylates, fatty acids, amino acids and polysaccharides) Calendula (triterpene, saponinen en flavonoïden) Perubalsam (benzyl benzoate, cinnamaldehyde and other cinnamates) Oak bark (tannins) Larch resin (essential oils and resin acids)	Abietic acid (resin acid)	Based on the analytical protocol used and a specific mass search in the raw data, no gentian violet was found. Match found coincides with composition on the label. Further analysis with paper chromatography and UV-VIS showed that the visible blue color is most likely from patent blue. Furthermore, the product contains a yellow/orange color, which is probably from a mix of compounds of calendula.
Vet Violetspray	Vetstyle	200 mL	pigment-> gentian violet?	spray (blue)	Chamomillae flos (apigenin, alpha-bisabolol and chamazulene, coumarins (umbelliferone, herniarin), choline, mucilages, tannins, salicylates, fatty acids, amino acids and polysaccharides Calendulae flos (triterpene, saponinen en flavonoïden) Perubalsam (benzyl benzoate, cinnamaldehyde and other cinnamates) Oak bark (tannins) Larch resin (essential oils and resin acids) Isopropanol Acetonium Patent blue	Abietic acid (resin acid)	Based on the analytical protocol used and a specific mass search in the raw data, no gentian violet was found. Match found coincides with composition on the label. Patent blue was probably not found since the molecule is too large for the LC-HRMS analysis performed. Further analysis with paper chromatography and UV-VIS showed that the visible blue color is most likely from patent blue. Furthermore, the product contains a yellow/orange color, which is probably from a mix of compounds of calendula
Anthrolan	Schippers	200 mL	unknown composition-> anthralin?	spray (black)	No composition specified on the label	Citroflex A-4 (plasticizer) Abietic acid (resin acid)	Based on the analytical protocol used and a specific mass search in the raw data, no anthralin was found. The black colour could be from carbon black or black iron oxide. Further analysis using Raman spectroscopy is needed to clarify this.

Product	Supplier	Content	Reason for further investigation	Form	Composition on label	Selected matches Compound Discoverer	Conclusion on ingredients
Licoc anticocci-diosemiddel	Sietse Jorna	500 mL	homeopathic product for coccidiosis -> coccidiostats?	liquid	Homeopathic dilutions of Acidum muriaticum D8 Acidum phosphoricum D8 Allium cepa D44 Allium sativum D4 Arsenicum album D8 Cantharis vesicatoria D8 Tanacetum vulgare D4 Cina maritima D4 Colibacillinum D12 Ipecacuanha D5 Kalium bichromicum D8 Kalium iodatum D6 Kalium sulphuricum D7 Mercurius corrosivus D10 Sabadilla D4 Phytolacca decandra D6 Spigelia anthelmia D4 Staphylococcinum D10 Streptococcinum D12 Acidum formicicum D6 Potentilla erecta D4 in alcohol or water	No relevant matches	Based on the analytical protocol used and an additional Tracefinder search, no suspicious results on coccidiostats were found.

Immune system problems
Dry-off
Lung problems
Skin problems
Intestinal problems

3.3.2 Analysis of K-spirine

This product was analyzed for the presence of salicylic acid as part of the project Expertise Management DBM. Targeted LC-MS/MS analysis showed that K-spirine contains approximately 170 mg/kg salicylic acid. This level is relatively low considering the levels in human drugs, making the presence of synthetic salicylic acid less likely. However, at this point it is not possible to determine whether the salicylic acid is from natural origin (from the willow bark, one of the main components of K-spirine) or has been added in a synthetic form.

The project *Expertise Management DBM* is currently investigating whether a distinction between natural and synthetic salicylic acid is possible. The approach is to identify intermediates from biosynthesis and metabolites in plants, as well as impurities from aspirin synthesis. A targeted LC-MS/MS method will be developed and can be applied to K-spirine. This should provide a specific marker or a ratio between markers allowing discrimination between natural and synthetic salicylic acid. Subsequently, it can be determined whether the levels of salicylic acid in K-spirine can be explained based on the composition as stated on the label. This study will be continued in 2023 and thus no further results could be provided in this report.

3.4 Risk classification strategy

Since many grey zone products are available to be used at the dairy farm, a classification is needed to identify products that may lead to potential human health risks. Therefore, a risk classification strategy was developed that allows for a prioritization of products, distinguishing products that are expected to be safe for use from products that require further attention. A literature review was performed to find available risk ranking methods for this purpose (section 3.4.1) and a method was developed that can be used to prioritize grey zone products (section 3.4.2). This method was tested on a selection of grey zone products (section 3.4.3).

3.4.1 Results literature review

A literature study was performed to identify methods that can be used to rank grey zone products for potential human health risks. The search on Google Scholar resulted in 105 hits. Titles and abstracts were screened for their relevance within the scope of this study. Overall, publications were found describing methods to rank chemicals or foodborne pathogens within food, animals, (care) products or environments. These methods were mostly (semi) quantitative, including multicriteria decisions analyses, (comparative) risk assessments and scoring methods. Two reviews were found describing risk ranking methods for the prioritization of food and feed related hazards (Manning and Soon, 2013; Van der Fels-Klerx et al., 2018a). The search in Scopus resulted in 82 hits. Based on the titles and abstracts, 23 publications described risk ranking methods of pathogens, chemicals from products (e.g. personal care products, pharmaceuticals) and pollutants in the environment. Methods included machine learning algorithms, modelling, surveys and ranking systems based on set criteria. Five articles described risk ranking methods of (veterinary) pharmaceuticals and personal care products (PPCPs) and were read in more detail (Kumar and Xagoraraki, 2010a; Klaschka, 2012; Ortiz de García et al., 2013; Lyu et al., 2019; Su and Cui, 2020). Three articles described more quantitative methods to prioritize risks. Lyu et al. (2019) used model simulations (HYDRUS-1D model and an exposure model) to rank PPCPs in groundwater, soil and air based on distribution and toxicity data which were weight and scored. Moreover, a quantitative study of Structure-Activity Relationships (Q)SAR) can be used to determine adverse effects of PPCPs and metabolites (Ortiz de García et al., 2013). This method can be used to estimate the severity of the hazard. Since detailed information on the ingredients used in grey zone products is usually lacking, this method is less appropriate for ranking these products. Lastly, Kumar and Xagoraraki (2010b) developed a ranking system for PPCPs and endocrine disrupting chemicals in water based on 4 criteria: occurrence, treatment in drinking water treatment plants, ecological effects, and health effects. As all three methods were developed to rank hazards in environmental systems, it was less suitable to be used as a risk ranking method with regards to public health.

3.4.2 Developed strategy

None of the methods found in the literature review focused on the risk ranking of products for potential human health risks. Therefore, the methods could only be used as a base for the development of a risk ranking strategy for products. From the evaluated methods in the review of Van der Fels-Klerx et al. (2018a), a scoring method seemed applicable for this study. The Fine & Kinney model (Fine, 1971; Kinney and Wiruth, 1976) was used as a basis for developing a risk evaluation to classify grey zone products. This method scores the severity (S), the probability of exposure (P) and the exposure intensity (E) of a product. Severity in this case includes the potential human health risk after consumption of animal products derived from exposed animals and includes both the transfer to animal products and the toxicity of chemical hazards. Due to the wide range of grey zone products that may be encountered at the farm, it was decided to establish a decision tree as input for ranking the severity in step 1 (see Figure 3). The definitions as used in the Fine & Kinney model were adapted to the dairy sector. These additions to the definitions were further specified, as a result of testing the decision tree on a number of products.

Apart from establishing the severity, the decision tree also pinpoints potential legal issues that need to be further explored. An example is the presence of a claim implying the function of a veterinary drug, e.g. stating it helps against diarrhea, on a product that is not authorised as veterinary drug. Such discrepancies between a claim and product registrations are flagged in the decision tree as 'check Dutch legislation' (see the yellow blocks in Figure 3).

After determination of S in Step 1, P is determined in Step 2 and E in Step 3. The risk of the grey zone product is finally established by multiplying S, P and E. This risk classification method is meant as a guide in determining the need for further actions.

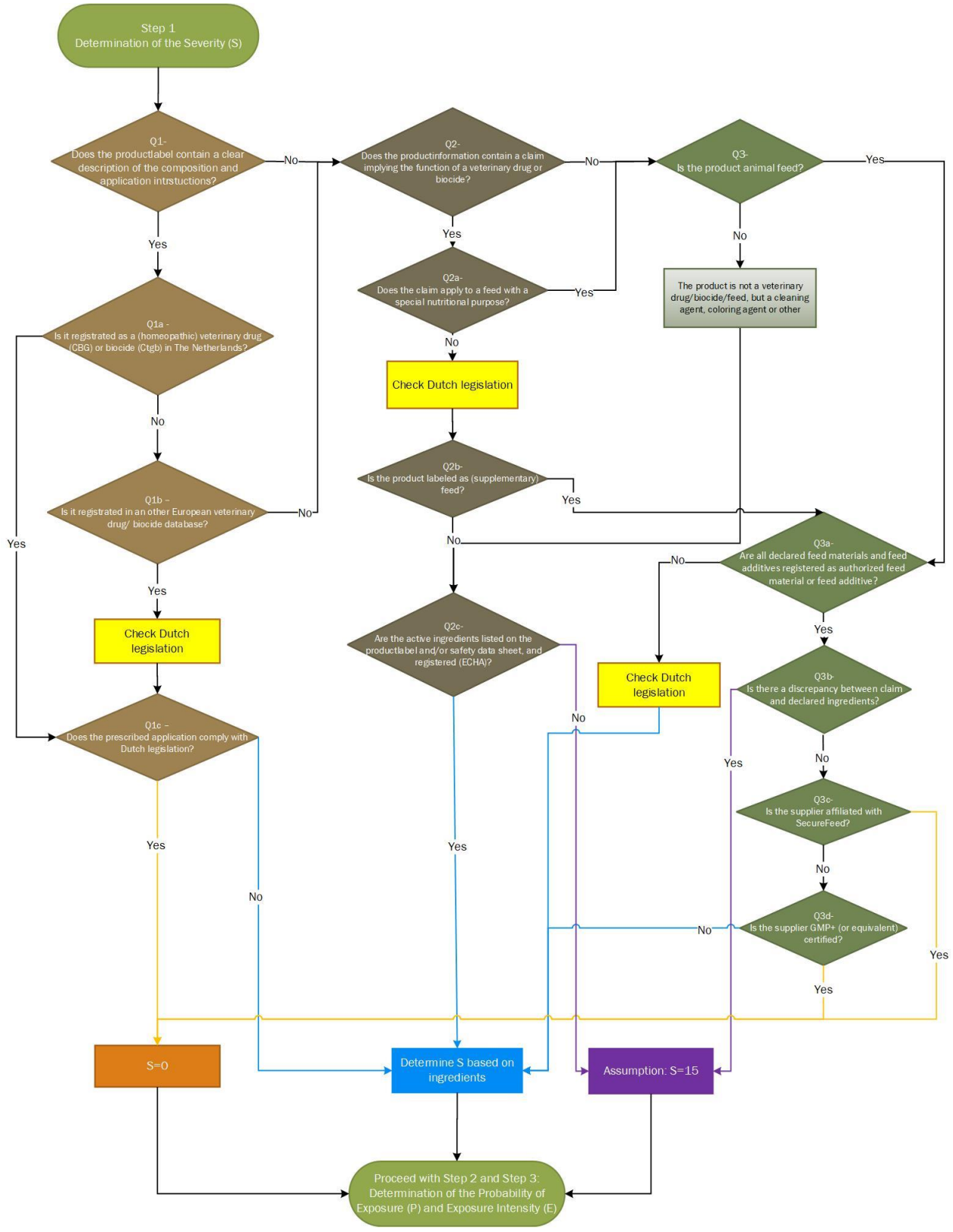

Figure 3 *Decision tree to determine the severity of the use of grey zone products*

Step 1 Determination of the Severity (S)

The first part of the risk classification is estimating the severity (S) of the hazard on a scale from 0 to 100. The decision tree (Figure 3) helps to determine whether the severity is low (S=0), unknown (assumption: S=15) or should be established based on the ingredients of the products. When the ingredients are known, the toxicity of these ingredients can be established and the potential transfer to animal products can be assessed. The severity factor is classified according to the definitions stated in Table 6.

Table 6 *Severity factor determination*

Severity	**S =**
Catastrophic, many fatal casualties. Residues which can lead to death.	100
Disaster, multiple fatal casualties. Residues which can lead to cancer.	40
Very Severe, a fatal casualty. Residues in dairy or meat products are possible and may lead to cancer. Or lack of prove on which a severity can be determined (for example because the ingredients are unknown or because of a possible discrepancy between the ingredients and a claim).	15
Severe. Possibly residues in dairy or meat products. Active ingredients are known, but do not lead to serious damage or negative effects or only after exposure to an extreme high dose over a long period of time.	7
Damage. Harmful for all productive animals, limited to a specific farm. Residues in limited quantity of dairy or meat products and/or with limited impact on health, and of passing nature. Manifests in a limited group of people.	3
Small damage. Harmful for the exposed animal and of passing nature. Limited level of residues in minor quantity of dairy or meat, and/or with minor symptoms of illness that hardly manifest themselves.	1
No damage, no residues in dairy or meat or effects are controllable	0

In order to classify the severity of the grey zone products, a decision tree was developed (Figure 3). The questions (Q) in the decision tree are explained below.

Q1		Does the product have a clear label with the ingredients and clear instructions covering the purpose, application and dose?
Q1a		Is the product a registered veterinary medicine (to be recognised by "(homeopatisch) diergeneesmiddel", a REG NL (H) Number and registered at CBG-MEB www.diergeneesmiddeleninformatiebank.nl or Is the product an authorised biocidal product (to be recognised by NL-1234567-0000 / SA-1234567-0000 / EU-1234567-0000 / 12345N) and registered at Ctgb: Ctgb Toelatingen?
Q1b		Check whether the product is registered as a veterinary medicine in another (European) country: Home | UPD (europa.eu). Or in case of a biocidal product: does the product have a European authorisation: Toelating van biociden - ECHA (europa.eu)?
	Q1b = yes	Check whether the product is allowed / authorised to be used in the Netherlands for this goal, by consulting the Dutch legislations
Q1c		Check the communicated application (on website or label) against the Dutch legislation
		Explanation: *Veterinary medicine: is it plausible that the product is applied according to the authorised application e.g. with respect to the "cascade" legislation:* Cascade | College ter Beoordeling van Geneesmiddelen (cbg-meb.nl)*?* *Biocidal product: does the communicated application and dose comply with the Dutch (Ctgb) or European Authorisation:* Toelating van biociden - ECHA (europa.eu)*?*
	Q1c = yes	Conclusion: Risks are controlled by authorisations or certified systems -> Low Risk.
	Q1c = no	Conclusion: Application may lead to hazards. Severity needs to be determined by the dossiers in relation to the active substances. Are the active substances known and to what extent may they lead to damage for animals / dairy and meat products / humans / environment? Severity needs to be determined according to Table 6. -> Proceed to Step 2.

Q2		Does the product information (label, promotion material, product specifications, website or other communication) contain a claim implying the function of a veterinary medicine or a biocide? *Explanation:* *Dutch links to explanations about claims in relation to (veterinary) medicines, biocides, or animal feed:* • Nationaal Beoordelingskader Claims op Diervoeding • Afbakening Biociden en (Dier)geneesmiddelen • Leidraad voor bepaling van de grens tussen reinigingsmiddelen en desinfecteermiddelen • Code voor Aanprijzing van Gezondheidsproducten - Keuringsraad KOAGKAG *Explanation claims:* • A health claim is a claim which states, gives the impression or implies that there is a connection between the product or a component thereof and health. • A disease risk reduction claim is a claim that states, suggests or implies that the application or ingestion of the product or any component thereof significantly reduces a risk factor for the development of a disease. *Is the impression created that the product:* • prevents, treats or cures a disease? With the exception of coccidiostats and histomonostats, as permitted under Regulation (EC) No 1831/2003; however, this point does not apply to claims concerning nutritional imbalances, provided they are not associated with any disease symptoms • has a special nutritional purpose? 'The purpose of meeting the specific nutritional requirements of certain categories of animals whose digestive or absorption mechanisms or metabolism has been temporarily or irreversibly impaired or may be temporarily or irreversibly impaired, and which may therefore benefit from the intake of a feed adapted to their condition'. • destroys, deters, renders harmless, prevents the effects of, or counteracts a harmful organism by any means other than purely physical or mechanical? • stimulates, increases, improves, strengthens a certain physiological function? • is a medicine, by word usage such as veterinary, veterinarian?
Q2a		Is the claim applicable to a feed with a special nutritional purpose? Explanation: check whether there is one of the described special nutritional purposes applicable according to Regulation (EU) 2020/354 and the associated characteristics and provisions. For exact conditions, see: Link to Vo (EU) 2020/354 *Included special nutritional goals in relation to dairy / cattle:* • Support preparation for oestrus and reproduction • Support the regeneration of hooves, feet and skin • Support for nutritional imbalances during nutritional transition • Weaning support • Support for the repair of the skin and skin appendages • Stabilization of water and electrolyte balance to support physiological digestion • Reducing the risk of tetany (hypomagnesaemia or head disease) • Reduction in the risk of acidosis • Reduction in the risk of bladder and/or kidney stones • Long-term release of trace elements and/or vitamins to pastured cattle • Reducing the risk of milk fever and subclinical hypocalcemia • Reducing the risk of ketosis • Compensation for iron deficiency after birth • Stabilization of physiological digestion
	Q2a = yes	The product is a diet feed -> Proceed to Q3
	Q2a = no	Check the product against the Dutch legislation: based on the communicated claim, the product should be registered or authorised as a medicine or a biocide, but is not registered.
Q2b		Is the product labeled as (complementary) feed?
Q2c		Are the active substances mentioned on the label and/or the SDS? And are they registered on the ECHA website For active substances, see: Information on biocides - ECHA (europa.eu) or Regulation (EC) 2017/698 or as an active substance in veterinary medicines?
	Q2c = yes	Determine severity factor according to Table 6 based on the active ingredients.
	Q2c = no	Severity determination is not possible according to Table 6 -> Assumption: S = 15 -> proceed to step 2

Q3		Is the product a feed product?
		Explanation: *'Animal feed': all substances and products, including additives, processed, partially processed or unprocessed, which are intended to be used for oral feeding to animals. Recognizable by, among other things, the words "feed material, (complete or complementary) animal feed, mineral feed, milk replacer, additive, premix or premix".*
	Q3 = no	The product is categorized as another product: such as cleaning agent, care product or other product category other than veterinary medicinal products, biocide, animal feed. Is an SDS available and does it contain the mandatory information? VIB-check
Q3a		Are all declared feed materials and feed additives registered as authorized feed material or feed additive?
		Explanation: • *EU Animal Feed Catalogue. Regulation (EU) No 68/2013: link* • *Authorized feed additives can be found in the EU Register of Feed Additives link* • *In case of doubt about the classification of feed, see also: GMP+ decision tree feed material*
	Q3a = yes	Product complies with animal feed legislation and regulations provided there is no possible discrepancy between a claim and the declared ingredients (Q2). Proceed with Q3b.
	Q3a = no	Check the product against Dutch legislation, because the product does not comply with animal feed legislation and regulations. Severity determination based on the declared ingredients according to Table 6.
Q3b		Is there a discrepancy between the claim and the declared ingredients?
	Q3b = yes	Claim: S = 15 because of a possible discrepancy between the composition and the claim
Q3c		Is the supplier a SecureFeed participant? See: Deelnemerslijst | SecureFeed
	Q3c = yes	Food safety risks are sufficiently controlled -> S = 0 -> Low risk
Q3d		Is the supplier GMP+ or equivalently certified? (Check whether the company is registered on GMP+: Database certified companies or equivalent system: GMP+ mutual recognition
	Q3d = yes	risks are controlled --> S = 0. When products are not certified, the likelihood of potential issues is estimated to be larger since there is no certified system which independently checks whether the supplier has implemented a well based HACCP risk assessment, suitable control measurements and a monitoring system, which is the basis to be GMP+ certified. a
	Q3d = no	Determine severity factor according to Table 6 based on the active ingredients.

Step 2 Determination of the Probability of Exposure (P)

Once the Severity has been determined, the probability (Factor P) that people will be exposed to the hazard needs to be determined on a scale of 0.5 to 10. For this, the possibility of ingestion by the animal or contact with dairy products needs to be established with the underlying assumption that the higher the probability the animal is exposed, the higher the likelihood that active ingredients of the product are transferred to animal derived products such as milk or meat. In order to do this, the product's use needs to be assessed based on the product information or descriptions on the website or advertisements. Consider the following questions:

- Is it applied on the skin or on the claws?
- Is it applied on the udder / on the teats or injected?
- If used or applied on or near the animal: is there a chance of oral ingestion (e.g., by licking)?
- Does oral intake take place through feed or via drinking water or is the product applied in the room or atomized? If so, are the animals (possibly) present in the same room? Can absorption take place by inhalation or licking?

The probability of exposure can then be determined according to Table 7.

Table 7 *Probability determination*

Probability	P =
Can be expected, almost certain (oral, nasal or (sub)cutaneous intake)	10
Quite possible (application takes place near animals or milk, where contact with the animal or the milk is possible)	6
Unusual, but possible (application takes place near animals or milk, where exposure does not normally occur when applied correctly, although it cannot be excluded)	3
Only possible in the long term (application takes place near animals or milk, where long-term exposure is possible, for example because the product remains in the environment)	2
Very unlikely (exposure is unlikely but cannot be completely excluded)	1
Virtually impossible (examples: addition to manure or on parts that animals or milk cannot come into contact with)	0.5

Step 3 Determination of the Exposure Intensity (E)
After the severity and probability factor have been determined, the exposure intensity can be determined (Factor E) on a scale of 0.5 to 10. The duration of exposure and the number of animals treated at the same time are relevant for this. To do this, the frequency of product application, individual or group treatment and the duration of application need to be assessed based on the product information or descriptions on the website or advertisements.

Consider the following questions:
- How often is the product applied:
  - Constantly
  - Daily, for several hours
  - Weekly or occasionally
  - Monthly
  - Several times a year
  - Very rare
- How many animals are exposed at the same time?
  - How many milk-producing animals are exposed at the same time?
  - How many non-dairy producing animals are exposed at the same time?
- During what period of time does the exposure take place?

The exposure intensity factor (Factor E) is then determined according to Table 8.

Table 8 *Exposure intensity determination*

Exposure Intensity	E =
Continuous, including by the substances remaining persistent in the environment after a single application, or exposure of the entire flock regardless of the duration of exposure	10
Daily, during a few hours or exposure of the majority of the flock regardless of the duration of exposure	6
Weekly or occasional or exposure of a minority of the herd irrespective of the duration of exposure or all non-dairy producing animals	3
Monthly or exposure of 1 to 5 dairy animals for several days per year or majority of non-dairy animals	2
Several times a year or 1 to 5 milk-producing animals per year for a maximum of 1 day or a minority of non-dairy-producing animals (including animals in the dry period)	1
Very rarely or 1 to 5 non-dairy producing animals per year	0.5

If in the communication-means overdosage is recommended compared to any legally permitted dose, the exposure intensity as primary assessed can be increased as follows:
- Overdosage by a factor 1 – 2 -> Scale E 1 step higher
- Overdosage by a factor 2 – 5 -> Scale E 2 steps higher
- Overdosage by a factor of 5-10 -> Scale E 3 steps higher
- Overdosage by a factor > 10 -> Scale E 4 steps higher

NB: overdosage compared to the legally permitted doses are not permitted!

Step 4 Risk classification (R)
Based on the conclusions from Step 1, 2 and 3, the risk of human health problems can be estimated by multiplying the factors S, P and E according to the formula R = S x P x E (Fine, 1971; Kinney and Wiruth, 1976). Based on the product, the risk classification can be determined according to Table 9. Contrary to the original risk classification in the method of Fine & Kinney, the subdivision between Moderate (20 < R <=40) and Medium (40 < R <= 200), has been merged into one Medium category (20 < R <=200). This combination does more justice to the urgency and associated proposed actions in relation to grey zone products. The various combinations of risk outcomes depending on S, P and E are indicated in Annex 4.

The mentioned actions in Table 9 need to be interpreted as proposed and possible actions, in relation to the urgency of the risk category.

Table 9 *Risk classification and proposed actions per risk category*

Risk score	Classification	
R <= 20	Low	No actions required
20 < R <= 200	Medium	Measures required
200 < R <= 400	High	Immediate attention required
R > 400	Urgent	Highest priority

In order to give guidance to the corresponding actions following from the determined urgencies Low, Medium, High and Urgent, various actions can be taken. When a product is classified as low risk, no further actions are needed. For the other risk classes, the higher the risk score, the higher the urgency for further actions. It is up to the risk manager to decide which further actions are needed.

We recommend the following:
- When a product receives a medium score, desk studies may be performed to determine possible transfer and residues in dairy and meat. Furthermore, it is recommended to re-evaluate the product's application on a frequent basis (e.g., every year). When the product usage patterns change over time, the probability of exposure (P) may change and when the product is applied at a different frequency, the exposure intensity (E) may change as well. This will impact the final risk classification.
- When a grey zone product is classified as high risk, it requires immediate attention, for example by analyzing animal products derived from exposed animals for the potential presence of residues.
- When a grey zone product receives a risk score above 400, the probability of exposure and exposure intensity are high and combined with a high severity this could lead to human health risks. These products should get the highest priority and further actions are recommended to prevent human exposure to food safety hazards. Actions could entail the (temporary) withdrawal of products from the market and the investigation of substances in the grey zone product and residues in dairy and meat products.

The described guidelines above, are related to the situations in which the risk classifications are a result of a well based severity assessment, following the assessed ingredients of a product. In case the risk classification is based on a lack of information, in which S is assumed to be 15, the first step would be to contact the producer and request for the full composition, which can be followed by performing a risk assessment on the actual and complete composition and proceed with the new outcome of the risk assessment.

Additionally, analysis for possible non-declared substances in the product that can explain a claim, could be considered. When probability of exposure and exposure intensity are high resulting in a risk classification above 900, even a more urgent action can be considered like (temporarily) withdrawal from the market and to start investigating possible residues in dairy and milk.

A proviso (#) is added to the risk classifications when it is based on such a worst-case assumption (see also Table 10). This is to differentiate risk classifications based on identified health risks from those based on assumptions since compositions are unclear.

3.4.3 Testing the risk method

The risk classification method was validated and finetuned using the products obtained through the online screening. The validation of each product can be found in Annex 3. The summary of the results can be found in Table 10. Testing the different products showed that most tested products resulted in a check against the rules and regulations, because of a claim in combination with a lack of a registration or authorization as a veterinary medicine or biocidal product. This also implies a possible discrepancy between the communicated composition and the claim.

Two products were tested by three persons to validate the methodology. All three persons reached the same conclusions with respect to severity and probability, but the intensity of the exposure (E) was evaluated differently. After discussing the results, a common E-factor was set for dry-off products. Overall, the product testing showed that the method was capable of classifying the products into low, medium, high and urgent risks, which indicates the urgency for further actions.

Table 10 *Summary of results from testing the risk classification method*

	Decision tree Severity classification (S)					Probability (P)	Exposure Intensity (E)	Risk (R)[1]
Product	**Q1**	**Q2**	**Q3**	**Check against regulation applicable?**	**Severity (S)**			
Klausan Violetspray	Q1: Yes, clear label Q1a: No, no veterinary / biocide registration Q1b: no, no registrations outside NL	Q2: Yes, several claims in relation to veterinary medicine/biocide Q2a:No, no feed application Q2b: No, no feed declaration Q2c: Yes, active substances are known	N.a.	Yes: no registrations. But claims related to animal health / disinfection are made.	S = 15, based on discrepancy between composition according to label and claim.	P = 10, product is applied on the skin	E = 2, application for several days on a small part of the flock	R = 15 x 10 x 2 = 300 -> High#
LactaQuit	Q1:Yes, clear specification. Q1a: No, no veterinary / biocide registration Q1b: no, no registrations outside NL	Q2: Yes, several claims in relation to veterinary medicine/biocide. Q2a: No, no claims in relation to diet feed Q2b: Yes, product is labelled as complementary feed	Q3a; Yes, all ingredients are approved as feed. Q3b: Yes, claim is applicable	Yes: No registrations. But claims related to animal health / disinfection are made.	S = 15, based on discrepancy between composition according to label and claim.	P = 10. Product is applied as feed (oral intake).	E = 1. One-time application starting the dry period for cows	R = 15 x 10 x 1 = 150 -> Medium#
MS Flexfeed Airo	Q1: Yes, clear info. Q1a: No, no veterinary / biocide registration Q1b: no, no registrations outside NL	Q2: No, no claims.	Q3: Yes, complementary feed. Q3a; Yes, all ingredients are approved as feed. Q3b: No Q3c: Yes, supplier is SecureFeed.	Yes: Complies with feed legislations, but check is needed in order to check whether spraying application is authorized for feed.	S = 0. All risks for feed / food safety are controlled sufficiently.	P =10. Application as feed (oral intake) and spraying (nasal intake)	E = 10. Application on the complete flock, during several days.	R = 0 x 10 x 10 = 0 -> Low

	Decision tree Severity classification (S)					Probability (P)	Exposure Intensity (E)	Risk (R)[1]
Product	**Q1**	**Q2**	**Q3**	**Check against regulation applicable?**	**Severity (S)**			
Compost-O	Q1. No. Limited information available.	Q2: Yes, claim in relation to veterinary medicine/biocide. Q2a: No, no claims in relation to diet feed Q2b. No, no feed declaration. Q2c. Composition / ingredients unknown.	N.a.	Yes: No registrations. But claims related to animal health / disinfection are made.	S = 15, because of lack of information regarding the composition, severity classification is not possible	P = 10. Application as feed (oral intake)	E = 10 Application on the complete flock, during multiple days.	R = 15 x 10 x 10 = 1500 -> Urgent#
Topro Paincare Bolus	Q1:Yes, clear specification. Q1a: No, no veterinary / biocide registration Q1b: no, no registrations outside NL	Q2: Yes, claim in relation to veterinary medicine/biocide. Q2a: No, no claims in relation to diet feed Q2b: Yes, product is labelled as complementary feed	Q3a No, not all ingredients are clear.	Yes: No registrations. But claims related to animal health / disinfection are made. Also check is needed against feed legislation.	S = 15, based on discrepancy between composition according to label and claim. Also because of unclarity regarding the ingredients	P = 10. Application as feed (oral intake)	E = 3 Application on some producing animals, during several days.	R = 15 x 10 x 3 = 450 -> Urgent#
Licoc	Q1 No. No label.	Q2: Yes, several claims i.r.t. veterinary medicine/biocide. Q2a: No, no claims in relation to diet feed Q2b. No. No label. Q2c No, Active substances unknown.	N.a.	Yes: No registrations. But claims related to animal health / disinfection are made.	S = 15, No information regarding the composition. Claims are applicable.	P = 10. Oral application.	E = 10. Preventive treatment of complete herd is possible.	R = 15 x 10 x 10 = 1500 -> Urgent#

	Decision tree Severity classification (S)					Probability (P)	Exposure Intensity (E)	Risk (R)[1]
Product	**Q1**	**Q2**	**Q3**	**Check against regulation applicable?**	**Severity (S)**			
Cowipes	Q1: Yes, clear info. Q1a: No, no veterinary / biocide registration Q1b: no, no registrations outside NL	Q2: Yes, several claims in relation to veterinary medicine/biocide. Q2a: No, no claims in relation to diet feed Q2b. No, no feed declaration. Q2c Yes, active substances are known.	N.a.	Yes: No registrations. But claims related to animal health / disinfection are made.	S = 1 Known ingredients, no reason to expect major damage.	P = 10. Application on udder and teats (cutaneous). Contact with milk is possible.	E = 10. Daily application on all milk producing cows.	R = 1 x 10 x 10 = 100 -> Medium
MS Formades	Q1 Yes, clear information. Q1a. Yes, product is registered as biocide. Q1c. Yes. Application according to authorisation.	N.a.	N.a.	N.a.	S = 0. Product is controlled as biocide.	P = 10. Application on hoofs.	E = 10. Application on complete herd, for multiple days.	R = 0 x 10 x 10 -> Low
Melkstop B	Q1: Yes, clear info. Q1a: No, no veterinary / biocide registration Q1b: no, no registrations outside NL	Q2: Yes, several claims i.r.t. veterinary medicine/biocide. Q2a: No, no claims in relation to diet feed Q2b: Yes, product is labelled as complementary feed	Q3a; Yes, all ingredients are approved as feed. Q3b: Yes, claim is applicable.	Yes: No registrations. But claims related to animal health / disinfection are made.	S = 15, based on discrepancy between composition according to label and claim.	P = 10. Application as feed (oral intake)	B = 1. One-time application starting the dry period for cows	R = 15 x 10 x 1 = 150 -> Medium#
Diaflor	Q1: Yes, clear info. Q1a: No, no veterinary / biocide registration Q1b: no, no registrations outside NL	Q2: Yes, several claims i.r.t. veterinary medicine/biocide. Q2a No, product is a diet feed, but not all claims are linked to diet feed. Q2b Yes, product is labelled as complementary feed	Q3a; Yes, all ingredients are approved as feed. Q3b: Yes, claim is applicable.	Yes: No registrations. But claims related to animal health / disinfection are made.	S = 15, based on discrepancy between composition according to label and claim.	P = 10. Application as feed (oral intake)	B = 0,5. Application on some calves, during risk on diarrhea	R = 15 x 10 x 0,5 = 75 -> Medium#

1 In case the severity is based on unclear compositions or discrepancies between claim and ingredient declarations, S is assumed to be 15. This is indicated in the risk classification with a proviso #

3.5 Discussion

The low positive response rate of dairy farmers to the interview invitations limited the amount of information gained on daily practices with regards to the care of their livestock. The promised reward of a gift voucher apparently did not help in recruiting more farmers. Only organic dairy farmers agreed on an interview. This may be explained by the fact that they are more used to explaining and promoting their alternative way of dairy farming. Additional workshops organized together with branch organizations like LTO could help to attract other dairy farmers to have a joined discussion about the use of grey zone products.

Although farmers could obtain grey zone products from veterinarians, peddlers and physical shops, the screening for grey zone products was limited to the web shops identified from interviews and initial internet search. It was expected that veterinarians would not provide farmers with unauthorized products, and that the product inventory of physical shops is the same as of their online web shops. However, it cannot be excluded that other smaller and/or less prominent web shops and peddlers may offer additional grey zone products. Another limitation to the current study is that only Dutch web shops were screened. The current ease of online shopping expands the possibilities of dairy farmers to obtain grey zone products from foreign web shops, which obviously generates additional risks.

Untargeted LC-HRMS combined with Compound Discoverer was used as an initial analytical strategy for the analysis of illegal or undeclared substances in the selected products, since it allows for comprehensive screening of (unknown) compounds. One should realize however that this approach has its limitations. Compounds present in a product may remain undetected (as was exemplified by the failure to identify the colorant in the stained dermal care products). Reasons for this relate to choices that had to be made with respect to sample preparation, type of chromatography, detection method, mass range (100-1000 m/z) and data processing (e.g., filters and databases). All of these aspects inevitably cause the loss of compounds or matches, but they cannot be avoided. For instance, the product Anthrolan could hardly be dissolved in organic solvent or water. It is therefore unlikely that all compounds present in the product could be extracted during sample preparation. In addition, some hormonal substances for example, can only be detected using gas chromatography (GC-HRMS). As a consequence of the chosen analytical strategy, it cannot be excluded that hormonal substances potentially present in for example the products for dry-off, Melkstop B and LactaQuit may remain unnoticed. Another limitation is the possible mass range of the standard LC-HRMS method used, which implies that large molecules, such as betaglucans in Betalac and patent blue in Vet Violetspray cannot be detected. Also, the type of databases used in the workflow of Compound Discoverer will influence the exact hits that are obtained. For this study, only large databases of mzCloud and Chemspider were used. The application of available smaller, specific databases may yield additional hits. In addition, the output in Compound Discoverer is very large, which could leave lower signals of potentially interesting compounds unnoticed and influence the final selection of compounds that are observed as match by the data processor. This also summarizes the reasons why not all the compounds that were present on the label of a product were retrieved as a hit using the applied approach. Despite these limitations, LC-HRMS potentially provides a lot of information about a wide range of possible components potentially present in suspect products. Therefore, overall, the strategy used is considered a good basis for identifying unknown substances. Depending on the type of product or the claim, additional analysis could be recommendable for further examination of the potential presence of harmful chemical substances in a product. This includes, for example, the use of GC-HRMS for products with suspected or claimed hormonal activity. Due to limited time and resources, the additional analysis applied on the current set of products remained limited to the evaluation of the spectra against a defined set of standards comprising painkillers, hormones and coccidiostats, which did not yield any notable hits.

For the risk classification, a combination of a scoring method and a decision tree was used. Various methods are available for risk ranking of chemical hazards. These range from quantitative methods, such as full risk assessment, to qualitative methods, such as expert elicitation. In between these methods are the semi-quantitative methods that may be based on scores (van der Fels-Klerx et al., 2018b). Depending on time, budget and data availability, an appropriate method can be selected (van der Fels-Klerx et al., 2015). Although a wide range of methods are available for ranking food safety hazards, no methods were found for classifying products. Nevertheless, it was assumed that the available hazard ranking methods may also be used for ranking products. Because of the wide range of products found, a semi-quantitative method was

selected using scores as the basis for the risk classification method. Additionally, a decision tree was developed to provide input for the severity of the product. Such decision trees have successfully been applied for ranking hazards as input for risk-based monitoring (see e.g. (Pikkemaat et al., 2022)). The combination of scores and the decision tree for severity as applied in the current research allowed the classification of grey zone products, which indicates the level of attention required. In case the classification is based on uncertainties (S=15), further information from the producer is needed in order to evaluate the severity of the product.

4 Conclusions and recommendations

4.1 Conclusions

The aim of this study was to gain more insight in the use of grey zone products at dairy farms, the potential presence of illegal substances and, when these grey zone products are used, the potential human health risks as a result of subsequent residues in dairy products. The research showed that it was difficult to attract dairy farmers to be interviewed. The results are thus primarily based on expert elicitation and online search on web shops. This showed that the most common and persistent health problems on dairy farms are related to udder and claw care of cattle. Additionally, the presence of flies and parasites (in particular worms) was identified as a major reason for product use, but this primarily concerned registered biocides and veterinary drugs (Table 2 and Table 3). In total, 42 grey zone products were retrieved from the interviews and via an online search. The majority of these products were supplementary feed. In total, 11 of the 42 products were selected for further chemical analysis. The products selected for further evaluation showed discrepancies between composition, claims and regulatory status. Often a description of the composition was unclear or missing.

A chemical analysis strategy was developed to detect the presence of illegal or undeclared substances, which was applied to the selected 11 grey zone products. The applied analytical strategy depends on the type of product (composition, physical state) as well as the reason for the investigation (suspicion of particular types of substances). All products were initially analysed using LC-HRMS and the data was processed using Compound Discoverer. For a selection of products, additional dedicated analyses, such as UV measurements and chromatography to identify illegal dyes, were performed. The analyses performed on the investigated products did not show illicit or undeclared substances.

Since a wide range of grey zone products may be available on the market and not all of these products can be explored in detail, a strategy was developed to evaluate potential human health risks related to the use of grey zone products. A literature review revealed that there are currently no existing risk ranking strategies that can be used to prioritize products based on potential human health risks. Therefore, a risk classification method was developed based on scoring severity of the product with respect to huma health, probability of exposure and exposure intensity. A decision tree was developed to guide in establishing the severity of the product. Discrepancies, e.g. between a claim and authorisations, were flagged in the decision tree with the advice to check the Dutch legislation. The established strategy was tested on several products showing the method was capable of classifying products into low, medium, high and urgency for further actions.

4.2 Recommendations

- The broad availability, easy access, incentives for use and the lack of organized monitoring of grey zone products poses a potential risk for animal and human health. Food safety authorities can use the established strategy for ranking grey zone products that are used at the farm so that follow up actions can be taken to prevent food safety risks.
- The current study focused on availability of grey zone products on Dutch web shops. However, products may also be bought from other web shops outside the Netherlands. It is, therefore, recommended to expand the search to international web shops such as Alibaba.com or Ebay.com.
- It is recommended to check the regulatory status for products in which a discrepancy between claim and registration was identified or for which the ingredient declaration is unclear.
- It is recommended to screen for possible non-declared substances in the product in case of discrepancies between the composition on the label and the claim, especially for products that are classified as high or urgent. For this purpose, LC-HRMS can be used as a starting point. Additional targeted analysis may be needed to further determine the substances present in the product.

- This study only focused on the use of grey zone products at cattle dairy farms. It is expected that at other livestock farms also grey zone products are used for the same and/or other issues. It is thus recommended to evaluate the use of grey zone products in other livestock species. This will clarify differences and similarities between species and allows for a validation of the proposed methodology for both the analytical screening and the risk classification.

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Annex 1 Questionnaire interview with dairy farmers

Vragenlijst telefonische enquête: Melkveehouders

Dierbehandelingsmiddelen/-verzorgingsmiddelen: middelen die worden ingezet om de gezondheid van melkvee te verbeteren of te behouden

1) Met welke gezondheidsproblemen wordt u geconfronteerd bij uw melkvee? (Zoals uierontsteking, klauwontsteking, maag-darmproblemen)
2) Welke middelen gebruikt u/heeft u wel eens gebruikt voor deze gezondheidsproblemen?
   a) Waarvoor heeft u deze verzorgingsmiddelen gebruikt?
   b) Hoe past u deze middelen toe? (Is het een zalf, bolus, via voer...?)
   c) Gebruikt u wel eens alternatieve middelen (middelen die niet door dierenarts zijn voorgeschreven?
      i) Wat is de reden dat u voor een alternatief middel gekozen heeft? (Werkt het beter, is het goedkoper,....?)
      ii) Via welk kanaal komt u aan deze middelen? (Dierenarts, op een beurs, via voerleverancier, internetaanbieder etc.)
      iii) Hoe kwam u in aanraking met deze middelen?
      iv) Zoekt u wel eens op internet naar middelen? Zo ja, waar?
3) Welke andere verzorgingsmiddelen worden (door andere melkveehouders of vroeger) ook wel gebruikt om genoemde problemen aan te pakken? (Homeopathische middelen/kruiden)
   a) Waarom specifiek deze middelen?

Biociden (desinfectiemiddelen)

1) Met welke problemen wordt u geconfronteerd m.b.t. de bestrijding van schadelijke organismen in de melkveehouderij? (Zoals pathogenen, maar ook ongedierte in de stalomgeving, reinigen melkinstallaties)
2) Welke biociden gebruikt u/heeft u wel eens gebruikt? (Zoals ontsmettingsmiddelen, insecticiden, muizengif, houtbeschermingsmiddelen en afweermiddelen)
   a) Waarvoor heeft u deze biociden gebruikt?
   b) Hoe past u deze biociden toe?
   c) Gebruikt u wel eens alternatieve biociden?
      i) Wat is de reden dat u voor een alternatief middel gekozen heeft? (Werkt het beter, is het goedkoper, ...?)
      ii) Waar heeft u deze alternatieve biociden gekocht?
      iii) Hoe kwam u in aanraking met deze biocide(n)?
      iv) Zoekt u wel eens op internet naar middelen? Zo ja, waar?
3) Welke andere biociden worden (door andere melkveehouders) ook wel gebruikt om genoemde problemen aan te pakken?
   a) Waarom specifiek deze biociden?

Overige middelen

1) Zijn er naast de verzorging van melkvee en bestrijding van pathogenen en ongedierte, andere (veel)voorkomende problemen of situaties?
2) Welke middelen gebruikt u/heeft u wel eens gebruikt? (Zoals mycotoxinebinders, toevoegingsmiddelen bij inkuilen)
   a) Waarvoor heeft u deze middelen gebruikt?
   b) Hoe past u deze middelen toe? (Is het een zalf, bolus, via voer...?)
   c) Gebruikt u wel eens alternatieve middelen voor deze problemen?
      i) Wat is de reden dat u voor een alternatief middel gekozen heeft? (Werkt het beter of is het goedkoper?)
      ii) Waar zijn deze middelen verkrijgbaar?
      iii) Hoe kwam u in aanraking met deze middelen?
      iv) Zoekt u wel eens op internet naar middelen? Zo ja, waar?

3) Welke andere producten worden ook wel gebruikt om genoemde problemen aan te pakken?
   a) Waarom specifiek deze middelen?

Afsluiting

1) Heeft u contacten die we ook zouden kunnen benaderen voor ons onderzoek?

Annex 2 Questionnaire interview with experts

Vragenlijst telefonische enquête: Experts

Dierbehandelingsmiddelen/-verzorgingsmiddelen: middelen die worden ingezet om de gezondheid van melkvee te verbeteren of te behouden

1) Weet u welke problemen er spelen bij de verzorging van melkvee? (Zoals uierontsteking, klauwontsteking, maag-darmproblemen, etc.)
2) Weet u welke middelen hiervoor wel eens gebruikt worden?
    a) Waarvoor worden deze middelen gebruikt?
    b) Hoe worden deze middelen toegepast? (Is het een zalf, bolus, of via voer...?)
    c) Weet u of er wel eens alternatieve middelen gebruikt worden die niet gereguleerd zijn?
    d) Weet u waarom melkveehouders wel eens alternatieve, niet gereguleerde middelen gebruiken?
    e) Waar zijn deze middelen verkrijgbaar?
        i) Kent u websites die deze middelen aanbieden?
        ii) Hoe kent u deze middelen?
3) Welke andere verzorgingsmiddelen worden ook wel gebruikt om genoemde problemen aan te pakken?
    a) Waarom specifiek deze middelen?

Biociden (desinfectiemiddelen)

1) Weet u welke problemen er spelen bij de bestrijding van schadelijke organismen in de melkveehouderij? (Zoals pathogenen, maar ook ongedierte)
2) Weet u welke biociden wel eens gebruikt worden?
    a) Waarvoor worden deze middelen gebruikt?
    b) Hoe worden deze middelen toegepast? (Is het een zalf, bolus, of via voer...?)
    c) Weet u of er wel eens alternatieve middelen gebruikt worden die niet gereguleerd zijn?
    d) Weet u waarom melkveehouders wel eens alternatieve, niet gereguleerde biociden gebruiken?
    e) Waar worden deze biociden verkocht?
        i) Kent u websites die deze biociden aanbieden?
        ii) Hoe kent u deze biociden?
3) Welke andere biociden worden ook wel gebruikt om genoemde problemen aan te pakken?
    a) Waarom specifiek deze biociden?

Overige middelen

1) Zijn er naast problemen met de verzorging van melkvee en bestrijding van pathogenen en ongedierte, andere (veel)voorkomende problemen/situaties op de boerderij?
2) Weet u welke andere producten wel eens gebruikt worden? (Zoals mycotoxinebinders, toevoegingsmiddelen bij inkuilen)
    a) Waarvoor worden deze middelen gebruikt?
    b) Hoe worden deze middelen toegepast? (Is het een zalf, bolus, of via voer...?)
    c) Weet u of er wel eens alternatieve middelen gebruikt worden die niet gereguleerd zijn?
    d) Weet u waarom melkveehouders wel eens alternatieve, niet gereguleerde middelen gebruiken?
    e) Waar zijn deze middelen verkrijgbaar?
        i) Hoe kent u deze middelen?
3) Welke andere middelen worden ook wel gebruikt om genoemde problemen aan te pakken?
    a) Waarom specifiek deze middelen?

Afsluiting

1) Heeft u contacten die we ook zouden kunnen benaderen voor ons onderzoek?

Annex 3 Resultaten test risicoclassificatie aan de hand van enkele producten

A3.1 Klausan Violetspray

Verzamelde informatie:
VITALstyle Klausan Violet Spray 200ml - Agradi.nl
Vitalstyle Klausan Violet spray, 200 ml - Verzorgingsproducten (schippers.nl)
Koop uw Klausan Violetspray | VITALstyle
Klausan violet spray EcoStyle 200ml | Diergeneesmiddelen | Macrovet.nl
ECOstyle Klausan violetspray | Verzorging van hoeven (medpets.nl)
2905439_NL_MSDS_02102014.pdf (schippers.nl)
Product sheet_N0330BBMMLL0217_X_X_nl_2905439_20180425.pdf (schippers.nl)

Doorlopen beslisboom:

Deel 1 Ernst bepaling

Q1: JA: via de verschillende websites is een zichtbaar label, specificatie/bijsluiter en MSDS beschikbaar.

Q1a: NEE: Er is geen registratienummer vermeld op de informatiedragers. Ook gecontroleerd op toelatingen databank Ctgb / CBG: product is niet bekend.

Q1b: NEE: geen registratienummer buiten NL bekend.

Q2: JA: de volgende claims in relatie tot diergeneesmiddelen en biociden zijn terug te vinden op de bijsluiter en websites:

- De werkzame stof Larikshars vormt een luchtdoorlatende film die vervuiling tegen gaat. Goudsbloembloesem stimuleert de vorming van nieuw weefsel en Perubalsem werkt conserverend. Klausan violetspray kan ook als nabehandeling bij onthoornen worden toegepast.
- bevordert het natuurlijke herstel van hoef en klauw ook voor navelbehandeling.
- Directe werking
  - Antibacteriële en ontstekingsremmende eigenschappen
  - Samenstelling (werkzame stoffen)
  - Kamillebloesem: zuiverend en reinigend
  - Goudsbloembloesem: voor een gezonde huid en ondersteunt het natuurlijke huidherstel
  - Eikenschors: werkt drogend op de huid
  - Perubalsem: ondersteunt de aanmaak van nieuwe huidcellen
  - Larikshars: vormt een beschermende en luchtdoorlatende laag tegen vuil
    - Op website van Marcovet wordt gesproken over wachttijden:

Specificaties Klausan violet spray EcoStyle 200ml

Sorteer	Veehouderij
Artikelnummer	100263
EAN Code	8711731002608
Fabrikant	Ecostyle
Toelating	n.v.t.
Kanalisering	VRIJ
Doeldier	Rund, Schaap, Geit, Varken, Paard
Indicatie	Hoefverzorging
Toedieningsvorm	Dermaal - op de huid
Wachttijd Melk	geen
Wachttijd vlees	geen
goedkeuring verkoop geneesmiddelen	

Q2a: NEE: Product toepassing is sprayen. Het wordt niet oraal opgenomen – geen diervoeder toepassing.

Conclusie: product is een biocide of diergeneesmiddel, maar niet als zodanig geregistreerd.

Q2b JA. Samenstelling: Chamomillae flos, Calendulae flos, Decoctum Cortex Quercus, Terebintha Laricina, Balsam Peruvianum, Alcohol isopropylicus, Acetonium, Patentblauw (E 131).
Ernst bepaling dient te worden uitgevoerd op basis van bovenstaande stoffen. Betreffen met name homeopathische producten. Vanwege discrepantie tussen de samenstelling en de claim – **worst case: S = 15.**

Deel 2 Kans op blootstelling
Product wordt toegepast op de klauwen, de huid na onthoornen of via de navel (kalveren). Kans dat product wordt opgenomen door het dier is bijna zeker. **P = 10.**

Deel 3 Blootstellingsintensiteit
Beschreven gebruik
- Hoeven en klauwen: De aangetaste delen zorgvuldig reinigen, drogen en royaal met ECOstyle Klausan violetspray behandelen.
- Navelbehandeling: Navel royaal aan alle kanten behandelen.
- Voor uitwendig gebruik, behandeling indien nodig dagelijks herhalen.
- Gebruik bij Mortellaro bij koeien: de aangetaste huid schoon en droog maken, sprayen en 20 seconde laten drogen. Hierna nogmaals sprayen. Vervolgens leg je een gaasje over de plek en tape je de klauw in. Na 3 dagen verwijder je het verband. Dit herhaal je zolang het nodig is.

Inschatting: afhankelijk van de gezondheidsstatus van een koppel, kan de toepassing gedurende enkele dagen plaatsvinden op een klein aandeel van het koppel. Of er sprake is van overdosering, is niet vast te stellen omdat de dosering niet verder gekwantificeerd wordt. **E = 2**

Deel 4 Risicoclassificatie
Risicoclassificatie R = S x P x E = 15 x 10 x 2 = 300.

R = 300 = HOOG#.

Opmerking: indien de ernst bepaling op basis van de ingrediënten serieus wordt opgepakt, zal deze naar alle waarschijnlijkheid lager uitvallen. Uitkomst bij Factor E= 7 à R=140 en Factor E = 3 à R = 60. Beiden komen uit op R = MIDDEN risico.

Opvallend: Klausan staat vermeld op de Groene lijst van Bionext voor de toepassing in de Biologische melkveehouderij!

A3.2 LactaQuit

Verzamelde informatie:
Lactaquit Vetstyle 1 liter - Veeapotheek.nl
Koop uw LactaQuit | VETstyle
VETstyle_LactaQuit_Stappenschema_A4.indd
D3B6915DD6D6.pdf (vetstyle.nl)
LactaQuit - Webshop A7 Noord dierenartsen
Covetrus - Dierenarts benodigd heden, Catalogus VPK veterinaire producten

Gerefereerde leveranciers:
- veeapotheek.nl Handelstraat 17 5961 PV Horst aan de Maas
- Vetstyle Ecomunitypark 1, 8430 AC Oosterwolde
- A7 Noord Dierenartsen Nipkowlaan 17 9207 JA Drachten / Elingsloane 18 9251 MN Burgum
- Covetrus Beversestraat 23 | 5431 SL | Cuijk

VOEDERADVIES:

Direct achterin de bek toedienen na de laatste melkbeurt voor droogzetten:

Koeien	Dagproductie vanaf 12 liter	eenmalig 100 ml
	Dagproductie vanaf 20 liter	eenmalig 150 ml
Schapen	Direct na het spenen	eenmalig 50 ml
Geiten	Dagproductie vanaf 2,5 liter	eenmalig 50 ml

Let op: Schudden voor gebruik. Voorkom stimuleren, door bijvoorbeeld aanraken, van de uier na het toedienen van LactaQuit, om het vrijkomen van hormonen die de melkproductie stimuleren te vermijden.

Samenstelling (volgens productinformatie – geen label beschikbaar):

Aanvullend diervoeder voor lacterende koeien, schapen en geiten:
- Natriumchloride, magnesiumchloride
- Vitex agnus-castus extract (monnikspeper) - Vitex Agnus-castus extract 10.000 mg.
- Cynara Scolymus extract (artisjok) - Artichoke extract 12.500 mg,

Product GMP 050587 – SecureFeed deelnemer ECO002. Betreft EuroStyle

Doorlopen beslisboom:

Deel 1 Ernst bepaling

Q1: JA: niet direct een label van de verpakking, maar wel een uitgebreide productfolder (pdf) via Vetstyle beschikbaar door in te loggen als dierenarts of veehouder, met op pagina 7 de etikettering. Via verschillende webshops van dierenartsen terug te vinden.

Q1a: NEE: Er is geen registratienummer vermeld op de informatiedragers. Ook gecontroleerd op toelatingen databank Ctgb / CBG: product is niet bekend.

Q1b: NEE: geen registratienummer buiten NL bekend.

Q2: JA: de volgende claims in relatie tot diergeneesmiddelen zijn terug te vinden op de websites en productinformatie:

- Ondersteunt het droogzetten van koeien, schapen en geiten
- LactaQuit beïnvloedt de melkdrang. Hierdoor verlaagt de melkstroom en de druk in de uier neemt af.
- LactaQuit ondersteunt een goede uiergezondheid.
- LactaQuit bestaat uit een complex van o.a. Artisjok extract (Cynara scolymus) en Monnikspeper (Vitex Agnus Castus), die de hormonen die betrokken zijn bij de melkproductie beïnvloeden.
- De kruidenextracten in LactaQuit hebben een anti-galactagene werking. Galactogenen zijn stoffen die de melkproductie initiëren, onderhouden en vergroten. De toegevoegde kruidenextracten in LactaQuit hebben juist het tegenovergestelde effect op de melkproductie. Ze werken als dopamine-agonist en verlagen zo de productie van prolactine, met als gevolg een verlaging van de melkproductie.
- Minder lactose, minder bacteriën: Door het ontbreken van melk in de uier is er minder lactose beschikbaar voor bacteriële ontwikkeling. Dit verkleint het risico op het ontwikkelen van mastitis en helpt het gebruik van antibiotica te voorkomen.
- Klinische studies hebben de effectiviteit aangetoond van medicatie geproduceerd uit het plantenextract bij de behandeling van premenstrueel syndroom (PMS) en cyclische mastalgie. Het werkingsmechanisme verloopt via dopaminerge effecten die resulteren in veranderingen in de prolactinesecretie uit de hypofysevoorkwab. Bij lage dosis blokkeert het de activering van D2-receptoren in de hersenen door competitieve binding, waardoor de afgifte van prolactine licht toeneemt. In hogere concentraties is de bindingsactiviteit voldoende om de afgifte van prolactine te verminderen. Monnikspeper vertoont centrale dopaminerge activiteit in vitro en in vivo. Dit dopaminerge effect remt de door basale en thyrotropine afgevende hormoon gestimuleerde afgifte van prolactine. Vanwege het dopaminerge effect kan Agnus castus daarom worden beschouwd als een efficiënt alternatief fytotherapeutisch geneesmiddel bij de behandeling van lichte hyperprolactinemie (zie Onderzoek: Sliutz et al., 1993)
- Cynara Scolymus is rijk aan flavonoïden met een antioxidantwerking, o.a. Luteoline. Luteoline, in combinatie met de andere flavonoïden in het extract, heeft een indirect effect op de productie van dopamine. Luteoline is een krachtige fosfodiësterase (PDE4)-remmer. Het remmen van PDE4 verhoogt de effectiviteit van de dopamine productie en de werking van dopamine receptoren. (via een cascade met cyclisch AMP).
- Voor de gezondheid van het dier is het bevorderend dat er geen antibiotica gebruikt wordt bij het droogzetten van de koeien, er geen residuen bij vroegtijdig afkalven worden achtergelaten en dat de spenen zo gezond mogelijk blijven. Economisch gezien worden er minder kosten in rekening gebracht bij deze alternatieve methode van droogzetten, mede door de nul dagen wachttijd op de melk.
- Een alternatief voor het traditioneel droogzetten van gezonde koeien. Het risico op mastitis kan worden verlaagd door het verlagen van de druk in de uier en de beperking op de melkafgifte.

Q2a: NEE: Betreft een aanvullend diervoeder. De term dieetvoeder wordt niet gevoerd. Ook zijn bovenstaande claims, niet opgenomen in de lijst met toegelaten bijzondere voedingsdoelen voor dieetvoeders.

Conclusie: diervoeder zou op basis van de claims geregistreerd moeten zijn als diergeneesmiddel, maar is niet als zodanig geregistreerd.

Q2b JA: Samenstelling: Natriumchloride, magnesiumchloride, Vitex agnus-castus extract (monnikspeper) - Vitex Agnus-castus extract 10.000 mg. Cynara Scolymus extract (artisjok) - Artichoke extract 12.500 mg,

Q3a JA: natriumchloride, magnesiumchloride zijn toegelaten diervoedergrondstoffen. Vitex Agnus-castus extract en Cynara Scolymus extract (artisjok) zijn geregistreerd als 2b natural products – botanically defined in EU Register of Feed Additives.

Q3b JA: er is sprake van een mogelijke discrepantie tussen de samenstelling en een claim. **S = 15**

Q3c Aanvullend doorlopen: Verschillende leveranciers.
JA: Vetstyle: Product wordt verkocht door Eurostyle BV. Eurostyle BV is leverancier (handelaar): GMP+ gecertificeerd GMP050587 én SecureFeed deelnemer

Q3d: Veeapotheek.nl, A7 Noord Dierenartsen en Covetrus zijn noch SecureFeed deelnemer, noch GMP+ gecertificeerd.
Ernst bepaling op basis van Risicoclassificatie SecureFeed https://securefeed.eu/system/files/2022-04/D-13%20Risicoclassificatie%202022%20-%20versie%2014%20-%20april%202022_0.xlsx: (Mengvoeder voor rundvee, Aromatische stof): Laag Risico.
Worst Case: ondanks dat volgens het label, de vermelde ingrediënten laag risico zijn, is een discrepantie van toepassing in relatie tot een claim. S = 15

Deel 2 Kans op blootstelling
Product wordt toegepast als diervoeder bij droogstaande koeien: éénmalige dosering na laatste melkbeurt. **P = 10**

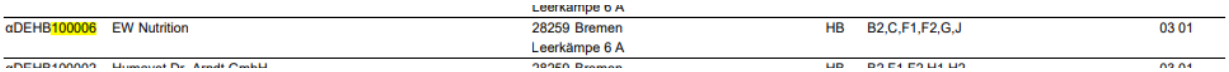
Deel 3 Blootstellingsintensiteit
Wordt éénmalig toegepast bij koeien die droog worden gezet. Dosering wordt duidelijk aangegeven. Geen signaal voor overdosering. **B = 1**

Deel 4
Risicoclassificatie (worst case). R = S x P x E = 15 x 10 x 1 = 150.
R = 150 = MIDDEL#.

A3.3 MS Flexfeed Airo

Verzamelde informatie:
MS Flexfeed Airo - Voedingssupplementen (schippers.nl)
Produkt-Nr (schippers.nl): MSDS
Label_N0440BBMMLL0217_X_X_nlendefresitda_2901980_20190529.pdf (schippers.nl) Label
Certificate_N0350BBMMLL0217_X_X_en_1704420__1705013__1705321__2701095__2901980__2901981__3709810_20210129.pdf (schippers.nl) Verklaring GMO vrij
Leverancier: GMP030499 Schippers Bladel BV (SecureFeed deelnemer)

Labelvermelding:
- Producent: DE HB 10006 EW Nutrition - GMP014019



- GMP028601 Schippers Europe BV, Hapert

Aanvullend diervoeder voor varkens en pluimvee

Samenstelling volgens label:
- Propyleenglycol, Natriumchloride
- Aromatische stoffen: Eucalyptus olie 200.000 mg

Aanvullende informatie op website:
MS Flexfeed Airo is een natuur zuivere kruidenolie op basis van zorgvuldig geselecteerde plantenextracten en is rijk aan etherische oliën. Samenstelling: Bevat onder andere eucalyptus-olie en munt. *(opmerking: dit lijkt erop dat niet alle ingrediënten worden gedeclareerd. In het geval van aromatische stoffen is dit volgens de diervoeder wetgeving niet verplicht)*

Toepassing:

Dosering:
- Drinkwater (bij voorkeur vernevelen): Varkens en pluimvee: 200 - 300 ml per 1000 liter water / Rundvee: 15 - 20 ml per 10 liter water / Kalveren: 10 ml per 100 liter melk / Melkgeiten: 15 - 20 ml per 10 liter water / Lammeren: 10 ml per 100 liter melk of water
- Stallucht: regelmatig vernevelen of sprayen met grove druppel en bij voorkeur onverdund gebruiken. Bij kalveren onverdund vernevelen. Bij slachtkuikens tot 3 weken oud, 500 ml oplossen in 10 liter water (10 liter oplossing is voldoende voor ongeveer 20.000 slachtkuikens) --> *Is hier de warenwet van toepassing? Volgens MSDS is toepassing diervoeder.*
- Individueel: dagelijks, gedurende 2 tot 4 dagen, muil en neus sprayen. Bij kleinere dieren volstaat het plaatsen van een bevochtigde doek in mand of hok --> *Is hier de warenwet van toepassing? Volgens MSDS is toepassing diervoeder.*
- Wachttijd: niet van toepassing.

Doorlopen beslisboom:

Deel 1 Ernst bepaling

Q1: JA: label, veiligheidsblad en toepassing via website MS Schippers beschikbaar.

Q1a: NEE: Er is geen registratienummer vermeld op de informatiedragers. Ook gecontroleerd op toelatingen databank Ctgb / CBG: product is niet bekend.

Q1b: NEE: geen registratienummer buiten NL bekend.

Q2: NEE. Geen claims zichtbaar op website of productinformatie

Q3: JA, product wordt gedeclareerd als aanvullend diervoeder.

Q3a JA: Propyleenglycol, Natriumchloride zijn toegelaten voedermiddelen. Eucalyptus olie en muntolie is geregistreerd onder 2b natural products – botanically defined op Vo EU 1831/2003. Op basis van de tekst "MS Flexfeed Airo is een natuur zuivere kruidenolie op basis van zorgvuldig geselecteerde plantenextracten en is rijk aan etherische oliën" lijkt het erop dat niet alle ingrediënten worden gedeclareerd. In het geval van aromatische stoffen is dit volgens de diervoeder wetgeving niet verplicht.

Conclusie: product voldoet aan de diervoederwetgeving. Er worden echter meer toepassingen vermeld zoals verneveling en sprayen in de neus. Zijn deze toepassingen toegelaten?

Q3b: NEE: er is geen sprake van een claim.

Q3c: JA, Schippers Bladel is SecureFeed deelnemer. Conclusie: risico's voor voedselveiligheid zijn voldoende geborgd. **S = 0**

Deel 2 Kans op blootstelling

Product wordt toegepast als diervoeder, door toepassing via het drinkwater. Daarnaast kan het verneveld worden of als spray worden toegepast. **P = 10**

Deel 3 Blootstellingsintensiteit

Wordt via het drinkwater toegepast of via het vernevelen in de stal. Dus voor het volledige koppel. Bij individuele toepassing staat: dagelijks, gedurende 2 tot 4 dagen vermeld. Dosering wordt duidelijk aangegeven. Geen signaal voor overdosering. **E = 10**

Deel 4

Risicoclassificatie (worst case) R = S x P x E = 0 x 10 x 10 = 0.
R = 0 = LAAG.

A3.4 Compost-O

Verzamelde informatie:
Salmonella bestrijden met Compost-O - Rinagro (rinagro-smart-farming.nl)
Compost-O - Rinagro (rinagro-smart-farming.nl)
Compost-O 10 Liter • Composteren
Flyer_CO_webtuin.pdf (composteren.nl)
Compost-O | BoerBeter
Compost-O – RMV Hardenberg (rmv-hardenberg.nl)
Beschrijving (bron: www.composteren.nl/product/compost-o-10-liter/)

Label:

Samenstelling
Compost-O is een gepatenteerde en wettelijk beschermde formule.
Deze vloeistof bevat een hoge concentratie aan mineralen en niet genetisch gemodificeerde aërobe micro-organismen, die vrij in de natuur voorkomen.

Composteren zonder te beluchten met Compost-O
Met de compostverbeteraar Compost-O kunt u composteren zonder te beluchten. De mest/compost krijgt op die manier een zeer hoge eindkwaliteit, wat uiteindelijk ook de kwaliteit van het eindproduct zal bevorderen. Rinagro Smart Farming biedt u daarmee de oplossing voor het composteren van organisch materiaal. Voor zowel potgrond/tuinaarde als landbouwgrond.

Koekvorming (mestkelder, mestsilo, mestzak)
Doordat Compost-O de afbraak van het organische materiaal stimuleert is deze zeer geschikt om in te zetten tegen koekvorming. Zo haalt u bijvoorbeeld gemakkelijk de put van het jongvee maar ook de mestsilo helemaal leeg.

De voordelen genoemd bij AgriMestMix zijn ook hierop van toepassing.

Waarom Compost-O?
Het is belangrijk dat compost van goede kwaliteit is om de kwaliteit van het eindproduct tevens te waarborgen. Daarnaast is het wel zo prettig als dit niet al te veel tijd in beslag neemt. **Composteren versnellen** kan met Compost-O van Rinagro Smart Farming. In plaats van 9 maanden heeft u dankzij Compost-O al na zo'n 6 maanden perfect bruikbare compost. Ideaal in bijvoorbeeld de varkenssector. De ammoniumstikstof die gebonden blijft heeft de voorkeur.

Dit om de volgende redenen:
- Het spoelt minder uit;
- Het wordt in de wortel al omgezet in bouwstoffen voor celdeling;
- Het wordt niet afgemaaid voordat het benut is;
- Het werkt al bij lage temperatuur en lage lichtintensiteit;
- Het versterkt wortelgroei;
- Het bevordert betere uitstoeling en groei in de breedte;
- Het versterkt de opname van andere veelal vastgestelde (micro-) nutriënten;
- Het geeft compactere en sterkere celstructuur in blad, waardoor een hoger weerstand tegen ziektes wordt bereikt.

Dosering van Compost-O
Gebruik 5 liter per 100 m³. Leng de Compost-O aan met water om het te verdelen. Let wel: gecomposteerd product dient voldoende vocht te bevatten voor optimale werking.

Salmonella bestrijden met Compost-O

Claim Rinagro
Een melkveehouder die een aantal jaren Compost-O gebruikte voor het mineraliseren van zijn mest, kreeg te maken met een salmonellabesmetting in zijn bedrijf. Hij verdiepte zich in de omstandigheden van de salmonella besmetting en kwam erachter dat dit een bacterie is die in zuurstofloze omstandigheden leeft (anaeroob). Door het verkregen octrooi op de producten van Rinagro, ging hij zich verdiepen in de werking van Compost-O. Door het bestuderen van de documentatie van Rinagro, wist hij dat de techniek van het werkingsprincipe binnen een week de anaerobe omstandigheden naar aerobe omstandigheden omzette.
De melkveehouder diende de Compost-O toe aan het ruwvoer.

Door het uitproberen kwam hij tot de conclusie dat 500ml gemengd met 10L water geschikt was voor 50 GVE. Hij heeft dit vervolgens 20 dagen toegepast. De gezondheidsdienst heeft 14 dagen later een melkmonster geanalyseerd (reguliere controle). Hieruit bleek dat de besmetting niet meer meetbaar was. Het bedrijf zat op niveau 3. Na controles in april, juni en december zat het bedrijf weer op niveau 1. Afgelopen februari is het bedrijf officieel 'salmonellavrij' verklaard! Opmerkelijk is dat hierbij de dragers gebleven zijn.

Doorlopen beslisboom:

Deel 1 Ernst bepaling
Q1 NEE, het label is beschikbaar, maar bevat geen concrete samenstelling. Tekst in relatie tot de samenstelling: Compost-O is een gepatenteerde en wettelijk beschermde formule.
Deze vloeistof bevat een hoge concentratie aan mineralen en niet genetisch gemodificeerde aërobe micro-organismen, die vrij in de natuur voorkomen. Op het label staan meerdere gebruiksaanwijzingen / doseringen vermeld per toepassing.
Op de website staat beschreven dat een melkveehouder het succesvol heeft toegevoegd aan het ruwvoer, om Salmonella besmetting van het melkvee te bestrijden. Een dosering en periode van toepassing staat beschreven: 500 ml Compost-O in 10 liter water, gedurende 20 dagen toegevoegd aan het ruwvoer voor 50 GVE. Deze toepassing en dosering staat niet vermeld op het label.
Er is geen veiligheidsblad beschikbaar.
Q2 JA: Claim wordt geuit in relatie tot bestrijding van Salmonella op een melkveebedrijf.

Q2a NEE: geen claim in relatie tot dieetvoeder. Op basis van de claim Salmonella bestrijding, zou het product geregistreerd moeten zijn als diergeneesmiddel of biocide. Compost-O is niet geregistreerd op de CBG of Ctgb databank.

Conclusie: product is een biocide of diergeneesmiddel, maar niet als zodanig geregistreerd.

Q2b NEE: product is niet gedeclareerd als diervoeder additief of conserveringsproduct voor ruwvoer, terwijl het wel als diervoederadditief wordt toegepast.

Conclusie: product voldoet niet aan de wet- en regelgeving.

Q2c NEE: samenstelling is niet concreet. Het betreft een gepatenteerde en wettelijk beschermde formule. De vloeistof bevat een hoge concentratie aan mineralen en niet genetisch gemodificeerde aërobe micro-organismen, die vrij in de natuur voorkomen. En er is sprake van een discrepantie tussen de samenstelling en de claim. **S = 15**

Deel 2 Kans op blootstelling
Product kan worden toegepast door toevoeging aan stalmest. In dit geval is de kans op opname door het dier en/of kans op contact met zuivelproducten nihil. **P = 0.5**

Bij de toepassing ter bestrijding van Salmonella, wordt het toegepast als toevoeging aan het ruwvoer en vindt opname plaats. **P = 10**

Deel 3 Blootstellingsintensiteit
In relatie tot de toevoeging aan stalmest, is de blootstellingsintensiteit verwaarloosbaar. **E = 0,5**
In de beschreven toepassing ter bestrijding van Salmonella, wordt het product toegepast door toevoeging aan het diervoeder voor alle aanwezige dieren, gedurende 20 dagen. **E = 10**

Deel 4 Risicoclassificatie
Risicoclassificatie (worst case) R = S x P x E = 15 x 10 x 10 = 1500.
R = 1500 = URGENT#.
(Ter informatie – indien enkel de toepassing volgens het etiket wordt beoordeeld is de Risicoclassificatie:
R = S x P x E = 15 x 0,5 x 0,5 = 3,75. R = 3,75 = LAAG)

A3.5 Topro PainCare Bolus

Verzamelde informatie:
https://www.topro.nl/product/klauwgezondheid-rund/rundvee-klauwgezondheid/topro-paincare-bolus/ - Via deze site zijn ook het etiket en de productspecificatie te downloaden.

Leveranciers:
- Topro Animal Health, Sluiskolk 3, Vroomshoop
- Topro Animal Health is niet als zodanig bekend als SecureFeed deelnemer of GMP+ gecertificeerd bedrijf. Bio Enterprise BV is wel bekend als SecureFeed deelnemer en GMP+ gecertificeerd als handelaar onder PDV103322
- Volgens KVK is Topro een handelsnaam van Bio Enterprise BV

- Bio Enterprice BV https://www.bio-enterprise.nl/8713296100393
- De Boer Drachten, Jade 34, Drachten https://www.deboerdrachten.nl/bio110039-topro-paincare-bolus-12x100g/3 SecureFeed deelnemer
- Happy Farmer.nl Lieveld 6, Oirschot https://happyfarmer.nl/paincarebolus Geen GMP+ certificaat, geen SecureFeed deelnemer
- Kuipers Agrishop, Botaniaweg 2a, Marrum https://www.kuipersagrishop.nl/bolussen-voor-koeien-en-kalveren/10744-topro-paincare-bolus-bi110039-topro-paincare-bolus-is-eenbolus-voor-koeien-voor-orale-toediening-ter-ondersteuning-van-comfort-e-8713296100393.html Geen GMP+ of SecureFeed deelnemer
- AgriVos, Theo van Doesburgstraat 47, Drachten https://agrivos.nl/product/topro-paincare-bolus-12-x-100-gram/ https://www.kuipersagrishop.nl/bolussen-voor-koeien-en-kalveren/10744-topro-paincare-bolus-bi110039-topro-paincare-bolus-is-eenbolus-voor-koeien-voor-orale-toediening-ter-ondersteuning-van-comfort-e-8713296100393.html Geen GMP+ of SecureFeed deelnemer

Producent: Mojac Technologies 102 AV Marceaui Feyry 24100 Bergerac (F) αFR24037002

MINISTÈRE DE L'AGRICULTURE ET DE L'ALIMENTATION

Liste des établissements agréés au titre du Règlement (CE) n°183/2005 / List of approved feed establishments (Reg 183/2005)

15/10/20

Numéro agrément / Approval number	Date de l'agrément / Approval date	Nom / Name (Raison SOCIALE)	SIRET	Coordonnées / Contact details (adresse postale code postal bureau distributeur téléphone fax mail site web)	Type activité	Observations / Remarks	Destination	Fab. add. PM
α FR22389016	11/06/2012	COMPAGNIE REGIONALE D'ALIMENTS	40096680000023	ZONE ARTISANALE DE 16 RUE ZA L'ECLUSE 22120 YFFINIAC qualite@coreal.fr	Intermédiaire d'aliments pour animaux			Additifs
α FR22389017	11/06/2012	SA HINAULT	49728052900015	L'ECLUSE RUE D ARMORIQUE 22120 YFFINIAC qualite@coreal.fr	Fabrication d'aliments pour animaux		Animaux de rente	
α FR22389018	26/01/2015	DELTAVIT - TONIBIO	31329655000111	23 RUE SAINT AUBIN 22120 YFFINIAC	Intermédiaire d'aliments pour animaux			Additifs Pré mélange
α FR23149001	15/05/2001	COOPALIM	43275315000023	LA GARE 23140 PARSAC-RIMONDEIX	Fabrication d'aliments pour animaux		Animaux de rente	
α FR24037002	**28/12/2017**	**MOJAC TECHNOLOGIES**	**41456712300065**	**102 AV MARCEAU FEYRY 24100 BERGERAC**	**Fabrication d'aliments pour animaux**			

Doorlopen beslisboom:

Deel 1 Ernst bepaling

Q1 JA. Product heeft een duidelijk label en productspecificatie. Deze zijn te downloaden via de websites van Topro en Bio Enterprise BV.

Q1a NEE. Product wordt gedeclareerd als mineraalvoeder. Heeft geen REG NL Nummer of Biocide nummer. Product staat ook niet vermeld op website van CBG of Ctgb.

Q1b NEE. geen registratienummer buiten NL bekend.

Q2: JA. Claims zijn benoemd op websites en productspecificatie:

Zo bevat de PainCare bolus Salix Alba wat afkomstig is van de schietwilg met als functie dat het ontstekingsremmend, pijnstillend en koortsverlagend werkt. Daarnaast is Vitamine C toegevoegd wat werkt als antioxidant en wat **pijnverlichting** geeft.
Ook is citrusextract toegevoegd wat een ontstekingsremmend en vochtafdrijvend effect heeft en het stimuleert de spijsvertering. Daarnaast is propolis toegevoegd, dit heeft als functie dat het een antibacteriële en ontstekingsremmende werking heeft en het versterkt.
Aangeraden wordt om vóór gebruik of vóór verlenging van de gebruiksduur een dierenarts te raadplegen.

Q2a: NEE. Geen claims in relatie tot dieetvoeder. Ook de term dieetvoeder wordt niet gevoerd.

Conclusie: diervoeder zou op basis van de claims geregistreerd moeten zijn als diergeneesmiddel, maar is niet als zodanig geregistreerd.

Q2b: JA: product wordt gedeclareerd als mineraalvoeder in de vorm van een bolus

Q3a: NEE. Voor de volledige toetsing of de vermelde diervoedergrondstoffen zijn toegelaten, is aanvullende informatie nodig. Nog enkele onduidelijkheden m.b.t. plantaardig vet uit koolzaad, calciumstearaat en propolis.
Samenstelling volgens label met Nr EU 68/2013 diervoedercatalogus / GMP FSP Nr:

- Magnesiumoxide 11.2.1 Magnesiumoxide / GMP 11.521 Akkoord.
- Plantaardig vet uit koolzaad 2.20.1 Plantaardige oliën en vetten. Toelichting: De benaming „plantaardige oliën en vetten" kan worden vervangen door de term „plantaardige olie" of „plantaardig vet", naargelang het geval. Bij de benaming moeten ook de plantensoorten en in voorkomend geval het deel van de plant worden vermeld. Er moet worden aangegeven of de olie (oliën) en/of het vet (de vetten) ruw of geraffineerd is (zijn). Dit staat niet vermeld op het label. Niet volledig / duidelijk gedeclareerd
- Citrus extract Citrus Extract staat niet als zodanig geregistreerd als diervoedergrondstof in EU diervoedercatalogus. Mogelijk betreft het 5.27.1 Pectine: Pectine wordt door extractie met water verkregen uit (natuurlijk voorkomend) geschikt plantaardig materiaal, doorgaans citrusvruchten of appelen. Er mogen geen andere organische neerslagmiddelen dan methanol, ethanol en propaan-2-ol worden gebruikt. Het gehalte aan methanol, ethanol en propaan-2-ol samen mag ten hoogste 1% bedragen, uitgaande van de watervrije stof. Pectine bestaat hoofdzakelijk uit de partiële methylesters van polygalacturonzuur en de ammonium-, natrium-, kalium- en calciumzouten daarvan. Citrus Extract GMP 5.012. Akkoord.
- Propolis 9.3.1 Bijproducten van de bijenteelt. Honing, bijenwas, koninginnengelei, propolis, stuifmeel, bewerkt of onbewerkt. De naam wordt in voorkomend geval vervangen door de naam van het specifieke product. Niet geregistreerd op SFP lijst GMP.
- Calciumstearaat Niet onder deze naam geregistreerd als diervoedergrondstof in EU Diervoedercatalogus. Niet geregistreerd op SFP lijst GMP. Mogelijk geregistreerd als 13.6.4 Vetzuurzouten: product verkregen door de reactie van vetzuren met minstens vier koolstofatomen met calcium-, magnesium-, natrium- of kaliumhydroxide, -oxide of –zouten. GMP 2.092: Calciumzout van plantaardige vetzuren.
- Stearinezuur: **Stearinezuur** of ***n*-octadecaanzuur** is een lange keten verzadigd vetzuur. Het komt met name in dierlijke vetten voor, maar sommige plantaardige vetten en oliën bevatten ook wat stearinezuur. De zouten en esters worden stearaten genoemd. Stearinezuur is een vettige vaste stof. De vetzuurcode bedraagt C18:0. Het eerste getal (18) geeft het aantal koolstofatomen aan, het tweede het aantal dubbele bindingen, in dit geval nul.
- Voor juiste conclusie m.b.t. etikettering en toegelaten diervoedergrondstof is aanvullende informatie nodig.
- 3a300 ascorbinezuur (vitamine C) - Toegelaten als diervoederadditief voor alle diersoorten, geen min/max
- E551b Colloïdale silica Toegelaten als diervoederadditief voor alle diersoorten, geen min/max
- Sensorische toevoegingen: Salix alba Toegelaten als diervoederadditief voor alle diersoorten, geen min/max als 2b Natural products – botanically defined

Ernst bepaling: Samenstelling is niet volledig te toetsen ten opzichte van de diervoederwet- en regelgeving, daarnaast bestaat er een discrepantie tussen de gedeclareerde samenstelling en de claim. **S = 15**

Deel 2 Kans op blootstelling
Product wordt toegepast als bolus (1 bolus per keer per koe). Kan indien nodig na 1 of 2 dagen worden herhaald. Geleidelijke afgifte gedurende 2 dagen. Wordt toegepast op runderen boven de 400 kg. **P = 10**

Deel 3 Blootstellingsintensiteit
In de beschreven toepassing wordt het product toegepast op één of enkele dieren per keer (bij het afkalven, bekappen van de klauwen, klauwgezondheid, uiergezondheid, koeien die niet fit zijn). Afgifte is geleidelijk gedurende 2 dagen. Toediening kan na 1 of 2 dagen herhaald worden. **E =3**

Deel 4 Risicoclassificatie
Risicoclassificatie (worst case) R = S x P x E = 15 x 10 x 3 = 450
R = 450 = URGENT#.

A3.6 Licoc anticoccidiosemiddel

Verzamelde informatie:
https://www.sietsejorna.nl/winkel/diergezondheid/kalververzorging/licoc-anticoccidiosismiddel-500ml/www
(NB De informatie via deze link is niet meer beschikbaar d.d. 15-10-2022)
https://prolako.nl/producten.php?catid=11&gid=3#163
https://www.medpets.nl/excellent-licoc/
https://www.euro-joe.com/NL/product/Licoc-REG-NL-VRIJ

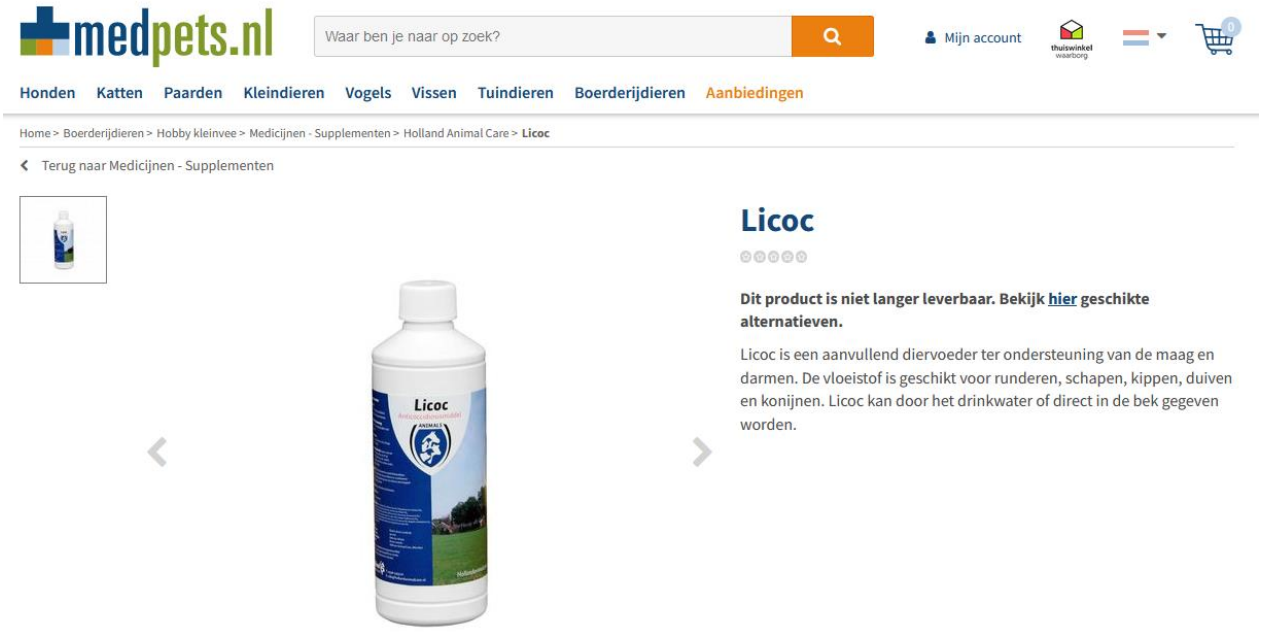
Informatie op website Prolako:
LICOC bestrijdt coccidiosis en andere darmstoornissen.
Toediening / dosering:
Bij de eerste verschijnselen van coccidiosis;
Oraal in de bek: Lam 15ml, big 4ml, kalf 30 (1 maal daags gedurende 3 dagen)
Wachttijden: geen.
Inhoud flacon: 500 ml.
Te gebruiken bij: rund en schaap.
Licoc uitsluitend curatief behandelen. Om een verdere uitbraak van coccidiosis te voorkomen raden wij u aan bij signalering van coccidiosis een koppelbehandeling toe te passen.

Registratie:
Homeopatisch diergeneesmiddel.

Informatie op website Euro joe
Homeopatisch diergeneesmiddel vrijgesteld van registratie.
Ter bestrijding van coccidiosis en andere darmstoornissen bij schaap, lam, rund, kalf, kip, duif en konijn.
Bevat een combinatie van: homeopatische grondstoffen.
Toediening / dosering
Bij de eerste verschijnselen van coccidiosis;
Oraal in de bek: lam 15 ml, big 5 ml, kalf 30 ml (1 maal per dag gedurende 3 dagen)
Opmerking
Licoc uitsluitend curatief behandelen.
Om een verdere uitbraak van coccidiosis te voorkomen raden wij u aan bij signalering van coccidiosis een koppelbehandeling toe te passen.
Toediening
Oraal of door het drinkwater.
Door het drinkwater bij kippen, duiven en konijnen
1e en 2e dag: 100 ml op 35 l water;
3e t/m de 5e dag: 100 ml op 75 l water.
Direct in de bek d.m.v. een drench spuit bij
Rund, schaap, kalf en lam.

Wachttijden
Geen.
Registratie
Homeopathisch diergeneesmiddel vrijgesteld.

Informatie MEDPETS.nl:



Dit product is niet langer leverbaar. Bekijk hier geschikte alternatieven.
Licoc is een aanvullend diervoeder ter ondersteuning van de maag en darmen. De vloeistof is geschikt voor runderen, schapen, kippen, duiven en konijnen. Licoc kan door het drinkwater of direct in de bek gegeven worden.

Doorlopen beslisboom:

Deel 1 Ernst bepaling
Q1 NEE. Geen label beschikbaar. Daarnaast tegenstrijdige informatie over productcategorie: homeopathisch diergeneesmiddel of aanvullend diervoeder.
Q2 JA. Claim met betrekking tot behandeling coccidiose.
Licoc uitsluitend curatief behandelen. Om een verdere uitbraak van coccidiosis te voorkomen raden wij u aan bij signalering van coccidiosis een koppelbehandeling toe te passen.
Q2a NEE. Geen claim op basis van de beschreven bijzondere voedingsdoelen.
Product is niet geregistreerd als homeopathisch diergeneesmiddel.

Conclusie: Product zou op basis van de claim geregistreerd moeten zijn als (homeopatisch) diergeneesmiddel. Dit is niet het geval.

Q2b NEE. Geen etiket beschikbaar. Volgens website Medpets zou het wel een aanvullend diervoeder betreffen, maar dit is niet te verifiëren.
Q2c NEE. Werkzame stoffen zijn niet bekend. Ernst bepaling niet mogelijk, bovendien is er sprake van een claim. **S = 15**

Deel 2 Kans op blootstelling
Product wordt toegepast als orale dosering (1 maal daags gedurende 3 dagen). **P = 10**

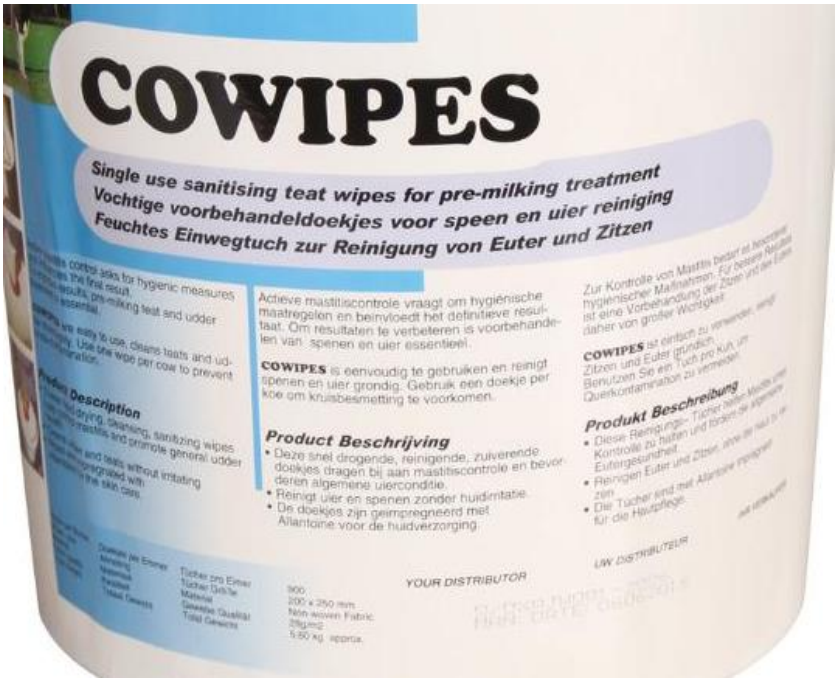
Deel 3 Blootstellingsintensiteit
In de beschreven toepassing wordt het product curatief toegepast op één of enkele dieren 1 maal daags gedurende 3 dagen. Ter voorkoming van verdere uitbraak, wordt ook een koppelbehandeling geadviseerd. **Worst case E = 10.** (NB bij enkel curatieve toepassing B = 2)

Deel 4 Risicoclassificatie
Risicoclassificatie (worst case) R = S x P x E = 15 x 10 x 10 = 1500
R = 1500 = URGENT#.
(Bij enkel curatieve toepassing R = 15 x 10 x 2 = 300. R = 300 = HOOG. Direct actie vereist)

A3.7 Cowipes

Verzamelde informatie:
https://www.schippers.nl/cowipes-900-stuks-emmer-1909926.html -

Veiligheidsblad en etiket zichtbaar via website



https://www.kuipersagrishop.nl/bolussen-voor-koeien-en-kalveren/10744-topro-paincare-bolus-bi110039-topro-paincare-bolus-is-eenbolus-voor-koeien-voor-orale-toediening-ter-ondersteuning-van-comfort-e-8713296100393.html

Cowipes zijn snel drogende, reinigende, zuiverende, doekjes dragen bij aan mastitiscontrole en bevorderen de algemene uierconditie. Reinigt uier en spenen zonder huidirritatie. De doekjes zijn geïmpregneerd met Allantoïne voor de huidverzorging.

De Cowipes worden geleverd in een emmer met daarin 1 rol à 900 stuks
- Goed drogend
- Reinigend
- Er blijven geen residuen achter
- Elk dier haar eigen doekje om kruisbesmetting te voorkomen
- Verzorgend, géén huidirritatie
- Uierdoekje

Gebruikerstips:
- Actieve mastitiscontrole vraagt om hygiënische maatregelen en beïnvloedt het definitieve resultaat. Om resultaten te verbeteren is voor behandelen van spenen en uier essentieel. Cowipes is eenvoudig te gebruiken en reinigt spenen en uier grondig. Gebruik een doekje per koe om kruisbesmetting te voorkomen.

Productafmetingen:
- Individueel doekje: 25 x 20 cm

Materiaal eigenschappen:
- Doekjes: non-woven (polipropyleen en viscose)
- Geïmpregneerd met chloorhexedine, allantoïne en alcohol oplossing

https://www.agridiscounter.nl/cowipes-vochtige-uierdoekjes-emmer-900-vellen.html
https://www.deboerdrachten.nl/397290-cowipes-chloorhexedine-doekjes-900-stuks/3

Samenstelling (Bron: MSDS)
- Food grade alcohol (CAS 64-17-5)
- Propylene glycol (CAS 57-55-6)
- Chlorhesidine (CAS 55-56-1)
- Alantoin (CAS 97-59-6)
- EDTA (CAS 60-00-4)
- Methylparaben (CAS 99-76-3)

Doorlopen beslisboom:

Deel 1 Ernst bepaling

Q1 JA. Label is zichtbaar op de websites van de aanbieders. Tevens een MSDS beschikbaar met daarop de werkzame stoffen.

Q1a NEE. Product is niet geregistreerd als Biocide of als diergeneesmiddel. Er is geen registratienummer vermeld. Product staat niet vermeld op de CTGB en CBG websites.

Q1b NEE. Geen registratienummers bekend buiten Nederland.

Q2 JA. Claim is niet vermeld op label of website MS Schippers. Op de volgende bronnen staat wel een claim vermeld:
Vermelding website De Boer Drachten:
Cowipes wegwerpdoekjes zijn eenvoudig te gebruiken en reinigen de spenen en uier (alsook de handen van de melker) grondig, en dit zonder huidirritatie. De doekjes zijn gemaakt van polyviscose en geïmpregneerd met Chloorhexidine, Allantoine en Alcohol. Ze zijn snel drogend, reinigend, zuiverend en desinfecterend. Een voorbehandeling op deze manier zorgt dus voor een grote tijdsbesparing. Gebruik een doekje per koe, zo wordt kruisbesmetting voorkomen.
MSDS Schippers: These rapid drying, cleansing, sanitizing wipes
Zie ook in de MSDS onder hoofdstuk 2. Applications:
- Food Grade Alcohol. Disinfection, good effective for disinfecting bacteria, germ or fungus
- Chlorhesidine. Good effective for disinfecting Gram-negative bacteria, Gram positive bacteria, some fungi, and some virus. high anti bacteria ratio
- Alantoin. Improving cell growth, accelerating wound healing. Softening keratin
- Methylparaben. Preservatives. Effective for disinfecting bacteria, some fungi, and some virus

Q2a NEE, Geen claims in relatie tot dieetvoeder.

Conclusie: op basis van de claims zou het product als biocide of diergeneesmiddel geregistreerd moeten zijn. Dit is niet het geval.

Q2b: NEE. Geen vermelding diervoeder.

Q2c: JA. Werkzame stoffen zijn bekend.
Methode: Toetsing van de werkzame stoffen ten opzichte van de ECHA lijst toegelaten actieve stoffen voor gebruik als biocide: via Search for Chemicals - ECHA (europa.eu)

- Food grade alcohol (CAS 64-17-5) Toegelaten als actieve stof
- Propylene glycol (CAS 57-55-6) Bekend product, geen registratie als actieve stof. Info bij Hazard classification & labelling:
  According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified. According to the majority of notifications provided by companies to ECHA in CLP notifications no hazards have been classified.
  This substance is used in the following products: anti-freeze products. Other release to the environment of this substance is likely to occur from: outdoor use, indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners), indoor use in close systems with minimal release (e.g. cooling liquids in refrigerators, oil-based electric heaters) and outdoor use in close systems with minimal release (e.g. hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids).
- Chlorhesidine (CAS 55-56-1) Bekend product, geen registratie als actieve stof. Info bij Hazard classification & labelling: D*anger! According to the classification provided by companies to ECHA in REACH registrations this substance is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and causes serious eye damage. Additionally, the classification provided by companies to ECHA in CLP notifications identifies that this substance is harmful if swallowed, may cause damage to organs through prolonged or repeated exposure, causes skin irritation, may cause allergy or asthma symptoms or breathing difficulties if inhaled and may cause respiratory irritation. Cosmetic Products Regulation, Annex V - Allowed Preservatives.* Wikipedia: Chloorhexidine – Wikipedia\
- Allantoin (CAS 97-59-6) Bekend product, geen registratie als actieve stof. Info bij Hazard classification & labelling: *According to the notifications provided by companies to ECHA in REACH registrations no hazards have been classified. This substance is used in the following products: pharmaceuticals and cosmetics and personal care products.*
- EDTA (CAS 60-00-4) Bekend product, geen registratie als actieve stof. Info bij Hazard classification & labelling: *Warning! According to the harmonised classification and labelling (ATP01) approved by the European Union, this substance causes serious eye irritation. Additionally, the classification provided by companies to ECHA in REACH registrations identifies that this substance is harmful if inhaled and may cause damage to organs through prolonged or repeated exposure. Detergents Regulation - Content Labelling This substance is used in the following products: washing & cleaning products, coating products, polishes and waxes, biocides (e.g. disinfectants, pest control products), adhesives and sealants, fillers, putties, plasters, modelling clay, non-metal-surface treatment products, photo-chemicals, air care products, metal surface treatment products and textile treatment products and dyes.*
- Methylparaben (CAS 99-76-3) Bekend product, geen registratie als actieve stof. nfo bij Hazard classification & labelling: *According to the classification provided by companies to ECHA in REACH registrations this substance is toxic to aquatic life with long lasting effects. Additionally, the classification provided by companies to ECHA in CLP notifications identifies that this substance causes serious eye irritation, is harmful to aquatic life with long lasting effects, causes skin irritation and may cause respiratory irritation. Under assessment as Endocrine Disrupting (ED list). This substance is used in the following products: cosmetics and personal care products, plant protection products and perfumes and fragrances. Other, Cosmetic Products Regulation, Annex V - Allowed Preservatives*

Alle ingrediënten zijn bekend onder een CAS Nr, met bekende toepassing als actief ingrediënt voor biocide, voor gebruik in reinigingsmiddelen of cosmetica. Methylparaben staat onder beoordeling vanwege "Endocrine Disrupting".

Op basis van deze informatie, zijn de volgende conclusies aannemelijk:
- Claim kan in relatie gebracht worden met de ingrediënten
- Ingrediënten zijn bekende stoffen voor gebruik in biociden, reinigingsmiddelen of cosmetica. Er is geen aanleiding om aan te nemen dat het gebruik leidt tot grote schade of residuen of schade voor alle productieve dieren. **S = 1**

Deel 2 Kans op blootstelling
Product wordt toegepast als voorbehandeling, reiniging / desinfectie van het uier en spenen. Opname via de huid is in theorie mogelijk. Daarnaast kunnen residuen in contact komen met de zuivel, tijdens het melken.
P = **10**

Deel 3 Blootstellingsintensiteit
In de beschreven toepassing wordt het product dagelijks toegepast op alle melkgevende dieren. **E = 10**

Deel 4 Risicoclassificatie
R = S x P x E = 1 x 10 x 10 = 100
R = 100 = MIDDEL

A3.8 MS Formades

CTGB Toelating: MS Formades
MS Formades - Desinfectiemiddelen (schippers.nl)

Uitstekend middel voor het ontsmetten van uw stal.
- Zorgt voor een zeer sterke desinfecterende werking
- Wordt in de veehouderij ook veel gebruikt in voetbaden
- Zorgt voor harde klauwen
- Wordt preventief gebruikt tegen Mortellaro

Dosering:
- Ontsmetting van stallen: ± 3 liter Formades toevoegen aan 100 liter water
- In een voetbad: ± 3-4 liter Formades toevoegen aan 100 liter water

Toepassing:
- Een goede behandeling duurt 3-5 dagen en wordt in de stalperiode eenmaal in de 2-3 weken herhaald
- Eventueel kan ook een individuele behandeling plaatsvinden met een rugspuit, direct op de klauwspleet van de poten

Toelatingsnummer:
- NL: 13612N
- BE: 3718B

Wetgeving:
- Gebruik biociden veilig. Lees vóór gebruik eerst het etiket en de productinformatie
- Label, productspecificatie en Veiligheidsblad (MSDS) beschikbaar via website Schippers.

Inhoudstoffen:
Formaldehyde (CAS 50-00-0)
Methanol (CAS 67-56-1)

Doorlopen beslisboom:

Deel 1 Ernst bepaling
Q1 JA. Label, productspecificatie en Veiligheidsblad (MSDS) beschikbaar via website Schippers.
Q1a JA. Product is geregistreerd als Biocide NL 13612N (exp date 1-2-2023).
Q1c JA. Toelating voor: Ter bestrijding van bacteriën (incl. mycobacteriën, maar excl. bacteriesporen), gisten, schimmels en virussen door middel van vernevelen, zoals beschreven in de gebruiksaanwijzing, in dierverblijfplaatsen met bijbehorende stallen en materialen (machines en gereedschappen) Desinfectie door middel van vernevelen mag uitsluitend worden uitgevoerd door professionals, die een opleiding voor ruimtedesinfectie hebben gevolgd.

Ter bestrijding van bacteriën (incl. mycobacteriën, maar excl. bacteriesporen) op hoeven van rundvee en schapen door middel van hoefbaden

Conclusie: S = 0

Deel 2 Kans op blootstelling
Product wordt toegepast als voetbad voor volledige koppel. Opname via de klauwen / huid is in theorie mogelijk. **P** = **10**

Deel 3 Blootstellingsintensiteit
In de beschreven toepassing wordt het product meerdere dagen toegepast op het volledige koppel. **E = 10**

Deel 4 Risicoclassificatie
Risicoclassificatie (worst case) R = S x P x E = 0 x 10 x 10 = 0
R = 0 = LAAG.

A3.9 Melkstop B

Verzamelde informatie:
VITALstyle MelkStop B | droogzetten koe/ geit | 10 x 500ml (btndehaas.nl)
Koop uw MelkStop B | VITALstyle
VITALstyle MelkStop 500 ml - Agridiscounter
VITALstyle MelkStop B Bolus 6x95g - Agradi.nl
Ecostyle MelkStop 500 ml-Melkvee.shop

Productinformatie: https://melkvee.shop/index.php?controller=attachment&id_attachment=554

Label: https://melkvee.shop/index.php?controller=attachment&id_attachment=555

Uitingen op websites / productspecificatie:
- Het bevat een mengsel van natuurlijke aromatische stoffen uit kruiden die de melkdrang beïnvloeden. De melkstroom wordt verlaagt en de druk in het uier neemt af.
- Droogzetten zonder antibiotica.
- MelkStop B is een aanvullend diervoeder die geschikt is voor hoogproductieve dieren. Waarschijnlijk kende u MelkStop al, maar de samenstelling van dit product is verbeterd zodat het nu ook in de biologische veehouderij gebruikt mag worden. Vandaar dus de 'B'. Tevens is dit product door de veranderde samenstelling ook geschikt geworden voor geiten en schapen. MelkStop B zorgt ervoor dat de melkgift wordt verlaagd. Hierdoor neemt ook de druk in de uier af wat ervoor zorgt dat melk uitliggen (en dus mogelijke infecties) wordt voorkomen.

Inhoudstoffen (Agridiscounter)
- Peterselie extract: Heeft invloed op de afgifte van prolactine waardoor de melkproductie vermindert.
- Rozemarijnolie: Beïnvloedt de aanmaak van dopamine. Dopamine remt de afgifte van prolactine en beïnvloedt daardoor de melkproductie.

Voordelen van het droogstandsconcept (NB heeft van toepassing op combinatie van Transit Knoflookbolus en MelkStop):
- Minder kans op een verminderde uiergezondheid
- Minder uitliggen van de melk
- Langdurig een goede uierondersteuning tijdens transitie
- Kan het antibioticagebruik rond de droogstand verminderen

Specificaties:
- Geschikt voor: hoogproductieve koeien en geiten
- Te gebruiken bij: verlagen van de melkgift voor de droogstandsperiode

- Functies: melkstroom verlagen en druk in de uier afnemen
- Geen wachttijd
- Gemakkelijk toe te dienen
- Snel minder melkdrang
- Natuurlijk product
- Toegestaan in de biologische melkveehouderij

Toediening:
- Koe: dien MelkStop B na de laatste melkbeurt voor het droogzetten achterin de bek toe. Bij een dagproductie vanaf 12 liter is het voldoende om eenmalig 500 ml toe te dienen. Indien nodig kan dezelfde toediening na 48 uur nog eenmaal worden herhaald.
- Geit: dien dit product direct toe na de laatste melkbeurt voor het droogzetten achterin de bek. Bij een dagproductie vanaf 2 á 3 liter is het voldoende om eenmalig 50-75 ml in te geven.

Gerefereerde leveranciers:
- Melkvee.shop, Kantooradres: Ruurloseweg 21, 7251 LA Vorden
- BTN de Haas B.V., Osloweg 139, 9723 BK Groningen
- VITALstyle is een handelsmerk van EUROstyle B.V., Ecomunitypark 1, 8430 AC Oosterwolde
- Ecostyle BV Postbus 127 8430 AC Oosterwolde. GMP030231
- Agridiscounter, Puttenstraat 15 8281 BP Genemuiden
- Agradi BV, Graaf van Solmsweg 52K, 5222 BP 's-Hertogenbosch

Producent (label): Producent: ɑ BE 100388

Doorlopen beslisboom

Deel 1 Ernst bepaling

Q1: Ja. Het product heeft een duidelijk label.

Q1a: Nee, het product is geen diergeneesmiddel of biocide.

Q1b: Nee, het product is niet geregistreerd als diergeneesmiddel of biocide buiten NL.

Q2: Ja. Uitingen in relatie tot een claim:
- Invloed op hormonen blijkt uit: Peterselie extract: Heeft invloed op de **afgifte van prolactine** waardoor de melkproductie vermindert. Rozemarijnolie: Beïnvloedt de **aanmaak van dopamine.** Dopamine remt de afgifte van prolactine en beïnvloedt daardoor de melkproductie.
- Dat melk uitliggen (en dus **mogelijke infecties**) wordt voorkomen. Droogzetten zonder **antibiotica.**

Q2a: Nee, claim heeft geen relatie met een dieetvoeder.

Conclusie: diervoeder zou op basis van de claims geregistreerd moeten zijn als diergeneesmiddel, maar is niet als zodanig geregistreerd.

Q2b: Ja, het product is geëtiketteerd als aanvullend diervoeder.

Q3a: Ja, gedeclareerde samenstelling bevat geregistreerde voedermiddelen en toevoegingsmiddelen.
Voedermiddelen volgens label:
- Sorbitol (EU Diervoedercatalogus Nr 13.5.5)
- Propyleenglycol (EU Diervoedercatalogus Nr 13.11.1)

Toevoegingsmiddelen:
Mengsel van Aromatische stoffen, o.a.
- Peterselie extract 2b Natural products – botanically defined. Parsley tincture.
- Rozemarijnolie 2b Natural products – botanically defined. Rosemary Oil.

Q3b JA: er is sprake van een mogelijke discrepantie tussen de samenstelling en een claim. E = 15

Q3c Aanvullend doorlopen: Leveranciers SecureFeed?
- NEE: Melkvee.shop, Kantooradres: Ruurloseweg 21, 7251 LA Vorden GMP002319 GB Dairy Products BV
- NEE: BTN de Haas B.V., Osloweg 139, 9723 BK Groningen. Geen GMP+
- JA: VITALstyle is een handelsmerk van EUROstyle B.V., Ecomunitypark 1, 8430 AC Oosterwolde. GMP050587

- NEE. Ecostyle BV Postbus 127 8430 AC Oosterwolde. GMP030231 Nr, wat is vermeld op label is niet terug te vinden op de GMP Plus website. EcoStlyle zou nu Eurostyle heten?
- JA: Agridiscounter, Puttenstraat 15 8281 BP Genemuiden. SecureFeed deelnemer onder de naam De Haan Palletindustrie BKTF BV h.o.n. de Haan Farmservice GMP017760
- NEE: Agradi BV, Graaf van Solmsweg 52K, 5222 BP 's-Hertogenbosch. Geen GMP+

Q3d Leveranciers GMP+?

- JA: Melkvee.shop, Kantooradres: Ruurloseweg 21, 7251 LA Vorden GMP002319 GB Dairy Products BV
- NEE: BTN de Haas B.V., Osloweg 139, 9723 BK Groningen. Geen GMP+
- NEE. Ecostyle BV Postbus 127 8430 AC Oosterwolde. GMP030231 Nr, wat is vermeld op label is niet terug te vinden op de GMP Plus website. EcoStlyle zou nu Eurostyle heten?
- NEE: Agradi BV, Graaf van Solmsweg 52K, 5222 BP 's-Hertogenbosch. Geen GMP+

Ernstbepaling: Vanwege discrepantie tussen samenstelling en claim **S = 15**

Deel 2 Kans op blootstelling
Opname via de bek. **P = 10**

Deel 3 Blootstellingsintensiteit
Na de laatste melkbeurt voor het droogzetten achterin de bek toe. Bij een dagproductie vanaf 12 liter is het voldoende om eenmalig 500 ml toe te dienen. Indien nodig kan dezelfde toediening na 48 uur nog eenmaal worden herhaald.

Product wordt dus toegepast op, per keer, een minderheid van de niet (meer) melk-producerende dieren.
E = 1

Deel 4 Risicoclassificatie
R = S x P x E = 15 x 10 x 1 = 150
R = 150 = MIDDEL#.

A3.10 Diaflor

Verzamelde informatie:
Koop uw DiarFlor | VETstyle
DiarFlor - Webshop A7 Noord dierenartsen

Productinformatie met label: https://www.vetstyle.nl/files/5C/F6/026FCFB825A7.pdf

Leveranciers:
- VETstyle is een handelsmerk van EUROstyle B.V., Ecomunitypark 1, 8430 AC Oosterwolde
- A7 Noord Dierenartsen Nipkowlaan 17 9207 JA Drachten / Elingsloane 18 9251 MN Burgum

A7 Noord Dierenartsen is noch SecureFeed deelnemer, noch GMP+ gecertificeerd.

Uitingen op websites / productspecificatie:
Aanvullend dieetvoeder voor kalveren bij diarree
- Stabiliseert de darmen
- Ondersteunt de fysiologische spijsvertering

DiarFlor is een aanvullend dieetvoeder voor kalveren ter stabilisatie van de water- en elektrolytenbalans en ter ondersteuning van de fysiologische spijsvertering. In het geval van risico op spijsverteringsstoornissen (diarree), tijdens en na die stoornissen.

Het bevat eipoeder met speciaal geselecteerde immunoglobulinen, die de darmwand beschermen en de weerstand van het kalf ondersteunen. De pre- en probiotica (darmflorastabilisatoren) in DiarFlor zijn

specifiek gericht op het stabiliseren van de darmflora en het behoud van een gezonde darmwerking. DiarFlor ondersteunt de spijsvertering en eetlust.

De elektrolyten en sporenelementen in DiarFlor vullen de verliezen van deze stoffen ten gevolge van diarree aan. Natriumbicarbonaat, natriumpropionaat en natriumcitraat herstellen het zuur-base evenwicht en gaan verzuring van bloed en pens tegen. DiarFlor bevat daarnaast een breed complex aan biologisch actieve stoffen die de spijsvertering en de darmflora stabiliseren en met directe en indirecte immunomodulerende eigenschappen. Het is samengesteld uit o.a. prebiotica (FOS, MOS), clinoptiloliet, probiotica (darmflorastabilisatoren) en immunoglobulinen.

VOEDERADVIES
De aanbevolen gebruiksduur is 1-7 dagen en ten hoogste 4 weken.
Aangeraden wordt om vóór gebruik of vóór verlenging van de gebruiksduur een dierenarts te raadplegen. Neem voor een advies gerust contact op met onze voedingsdeskundige.

Bij verhoogd risico op diarree, ondersteuning na anti-parasiet en/of antibioticabehandelingen: Vanaf 2e levensdag tot dag 10: 2x daags 25 g per voerbeurt. Mengen door normale melkvoeding.

Bij eerste symptomen diarree: 2x daags 50 g op 1 liter water (dieetdrank), mengen door normale melkvoeding, gedurende 3 dagen.

Bij acute diarree:
- Dag 1-2: Min. 4x daags 50 g op 1 liter water (dieetdrank), mengen door normale melkvoeding.
- Dag 3-5: Min. 2x daags 50 g op 1 liter water (dieetdrank), mengen door normale melkvoeding.

DiarFlor mengen bij temperatuur rond 40°C. Het kalf dient de gehele dag te beschikken over water tussen de voerbeurten door. 1 Afgestreken maatschepje bevat 100 g. De hoeveelheid DiarFlor mag niet meer bedragen dan 14,2% van het dagrantsoen (bij 88% droge stof).

SAMENSTELLING, TOEVOEGINGSMIDDELEN EN ANALYTISCHE BESTANDDELEN:
Samenstelling: Glucose, weipoeder, magere melkpoeder, natriumcitraat, natriumchloride, pectine, chicorei-inuline, kaliumchloride, natriumbicarbonaat 1,4%, eipoeder (1%) (rijk aan immunoglobulinen), gist.

Toevoegingsmiddelen per kg: Sensoriële toevoegingsmiddelen: 15.350 mg mengsel van aromatische stoffen.

Darmflorastabilisatoren: 2x 10^{10} KVE mengsel van Enterococcus faecium DSM 7134 en Lactobacillus rhamnosus DSM 7133 (4b1706).

Technologische toevoegingsmiddelen: 70.000 mg clinoptiloliet van sedimentaire oorsprong (1g568), natriumpropionaat.

Nutritionele toevoegingsmiddelen: Vitaminen: 200 mg vitamine E, 500 mg vitamine C, 20 mg vitamine B1, 50 mg vitamine B2, 20 mg vitamine B6/pyridoxine hydrochloride, 100 µg vitamine B12, 360 mg niacinamide, 120 mg calcium-D-pantothenaat, 5 mg foliumzuur, 20 mg vitamine K3.

Sporenelementen: 80 mg zink als zinkoxide (3b603), 15 mg koper als koper (II) sulfaat-pentahydraat (3b405), 150 mg ijzer als ijzer-(II)-sulfaat-monohydraat (3b103), 60 mg mangaan als mangaan(II)oxide (3b502), 1,2 mg jodium als calciumjodaat, watervrij (3b202), 0,3 mg selenium als natriumseleniet (3b801).

Analytische bestanddelen: Ruw eiwit 5,2%, ruw vet 0,3%, ruwe celstof 0,3%, ruwe as 24,7%, zoutzuur onoplosbare as 10%, calcium 0,3%, fosfor 0,2%, magnesium 0,1%, natrium 5,5%, kalium 2,2%, chloride 3,9%.

Doorlopen beslisboom

Deel 1 Ernst bepaling

Q1 JA, label beschikbaar via uitgebreide productfolder.

Q1a: NEE: het product is geen diergeneesmiddel of biocide.

Q1b: NEE, het product is niet geregistreerd als diergeneesmiddel of biocide buiten NL.

Q2: JA. Uitingen in relatie tot een claim:

- ter ondersteuning van de fysiologische spijsvertering. In het geval van risico op spijsverteringsstoornissen (diarree), tijdens en na die stoornissen.
- stabiliseren van de darmflora en het behoud van een gezonde darmwerking. DiarFlor ondersteunt de spijsvertering en eetlust.
- DiarFlor bevat daarnaast een breed complex aan biologisch actieve stoffen die de spijsvertering en de darmflora stabiliseren en met directe en indirecte immunomodulerende eigenschappen.

Q2a: Ja, product wordt gelabeld als dieetvoeder.

- Dieetvoeder claim Nr 72. Stabilisatie van de fysiologische spijsvertering. Essentiële voedingskenmerken: toevoegingsmiddelen voor diervoeding van de functionele groep "darmflorastabilisatoren" zoals bedoeld in Bijlage I bij verordening EG Nr 1831/2003.
- Dieetvoeder claim Nr 55. Stabilisatie van de water- en electrolytenbalans ter ondersteuning van de fysiologische spijsvertering. Essentiële voedingskenmerken: electrolyten Natrium, Kalium en chloride. Gemakkelijk verteerbare koolhydraten. Vermeldingen op etiket: Natrium, Kalium, Chloriden, Koolhydraatbronnen, Bicarbonaten en/of citraten.

Echter de claim in relatie tot immunomodulerende eigenschappen is niet opgenomen in de lijst van toegestane claims in relatie tot dieetvoeder.

Conclusie: diervoeder zou op basis van de claims geregistreerd moeten zijn als diergeneesmiddel, maar is niet als zodanig geregistreerd.

Q2b: JA, product is gelabeld als aanvullend dieetvoeder.

Q3a: JA, gedeclareerde samenstelling bevat geregistreerde voedermiddelen en toevoegingsmiddelen.
Samenstelling:

- Glucose (EU Diervoedercatalogus 13.2.2. Dextrose)
- Weipoeder (EU Diervoedercatalogus 8.17.1)
- magere melkpoeder (EU Diervoedercatalogus 8.11.1)
- natriumcitraat (EU Diervoedercatalogus 11.4.7 Natriumzout van organische zuren)
- natriumchloride (EU Diervoedercatalogus 11.4.1 Natriumchloride)
- pectine (EU Diervoedercatalogus 5.27.1)
- chicorei-inuline (EU Diervoedercatalogus 4.4.9)
- kaliumchloride (EU Diervoedercatalogus 11.5.1)
- natriumbicarbonaat 1,4%, (EU Diervoedercatalogus 11.4.2)
- eipoeder (1%) (rijk aan immunoglobulinen) (EU Diervoedercatalogus 9.15.3)
- gist (EU Diervoedercatalogus 12.1.5)

Toevoegingsmiddelen per kg:

- Sensoriële toevoegingsmiddelen: 15.350 mg mengsel van aromatische stoffen.
- Darmflorastabilisatoren: 2x 10^{10} KVE mengsel van Enterococcus faecium DSM 7134 en Lactobacillus rhamnosus DSM 7133 (4b1706). Toegelaten voor kalveren tot max 4 maanden leeftijd. Dosering minimaal 1 x 10^{9} CFU
- Technologische toevoegingsmiddelen: 70.000 mg clinoptiloliet van sedimentaire oorsprong (1g568) Toegelaten voor alle diersoorten, max 10.000 mg/kg compleet diervoeder 12% vocht.--> geborgd door max 14,2% van dagrantsoen, natriumpropionaat 1k281 Toegelaten voor herkauwers, geen min/max..
- Nutritionele toevoegingsmiddelen: Vitaminen: 200 mg vitamine E (3a700), 500 mg vitamine C (3a311/3a312), 20 mg vitamine B1 (3a820/3a821), 50 mg vitamine B2 (3a825/3a826), 20 mg vitamine B6/pyridoxine hydrochloride (3a831), 100 µg vitamine B12 (3a835), 360 mg niacinamide (3a315), 120 mg calcium-D-pantothenaat (3a841), 5 mg foliumzuur (3a316), 20 mg vitamine K3 (3a711).
- Sporenelementen: 80 mg zink als zinkoxide (3b603), 15 mg koper als koper (II) sulfaat-pentahydraat (3b405), 150 mg ijzer als ijzer-(II)-sulfaat-monohydraat (3b103), 60 mg mangaan

als mangaan(II)oxide (3b502), 1,2 mg jodium als calciumjodaat, watervrij (3b202), 0,3 mg selenium als natriumseleniet (3b801).

Q3b JA: er is sprake van een mogelijke discrepantie tussen de samenstelling en een claim. **S = 15**

Q3c Aanvullend doorlopen: JA: VETstyle is een handelsmerk van EUROstyle B.V., Ecomunitypark 1, 8430 AC Oosterwolde en SecureFeed deelnemer.
NEE: A7 Noord Dierenartsen Nipkowlaan 17 9207 JA Drachten / Elingsloane 18 9251 MN Burgum. is noch SecureFeed deelnemer, noch GMP+ gecertificeerd.

Q3d Vanwege een mogelijke discrepantie tussen de gedeclareerde samenstelling en de claim: **S=15**

Deel 2 Kans op blootstelling
Opname via de bek. **P = 10**

Deel 3 Blootstellingsintensiteit
De aanbevolen gebruiksduur is 1-7 dagen en ten hoogste 4 weken. Bestemd voor kalveren. Bij verhoogd risico op diarree, ondersteuning na anti-parasiet en/of antibioticabehandelingen: Vanaf 2e levensdag tot dag 10: 2x daags 25 g per voerbeurt. Mengen door normale melkvoeding.

Kortom: het product wordt specifiek toegepast bij probleemgevallen op kalveren, dus geen melk producerende dieren. Afhankelijk van de gezondheidsstatus van de rundveehouder, is B = 0,5 of B = 1 aannemelijk.

Worst case: E = 1

Deel 4 Risicoclassificatie
R = S x P x E = 15 x 10 x 1 = 150
R = 150 = MIDDEL#.

Annex 4 Detailed risk classification table

Table A4.1 *Different risk outcomes depending on S, P and E*

		Exposure (E)					
Severity (S)	**Probability (P)**	**0,5**	**1**	**2**	**3**	**6**	**10**
0	0,5	0	0	0	0	0	0
	1	0	0	0	0	0	0
	2	0	0	0	0	0	0
	3	0	0	0	0	0	0
	6	0	0	0	0	0	0
	10	0	0	0	0	0	0
1	0,5	0,25	0,5	1	1,5	3	5
	1	0,5	1	2	3	6	10
	2	1	2	4	6	12	20
	3	1,5	3	6	9	18	30
	6	3	6	12	18	36	60
	10	5	10	20	30	60	100
3	0,5	0,75	1,5	3	4,5	9	15
	1	1,5	3	6	9	18	30
	2	3	6	12	18	36	60
	3	4,5	9	18	27	54	90
	6	9	18	36	54	108	180
	10	15	30	60	90	180	300
7	0,5	1,75	3,5	7	10,5	21	35
	1	3,5	7	14	21	42	70
	2	7	14	28	42	84	140
	3	10,5	21	42	63	126	210
	6	21	42	84	126	252	420
	10	35	70	140	210	420	700
15	0,5	3,75	7,5	15	22,5	45	75
	1	7,5	15	30	45	90	150
	2	15	30	60	90	180	300
	3	22,5	45	90	135	270	450
	6	45	90	180	270	540	900
	10	75	150	300	450	900	1500
40	0,5	10	20	40	60	120	200
	1	20	40	80	120	240	400
	2	40	80	160	240	480	800
	3	60	120	240	360	720	1200
	6	120	240	480	720	1440	2400
	10	200	400	800	1200	2400	4000
100	0,5	25	50	100	150	300	500
	1	50	100	200	300	600	1000
	2	100	200	400	600	1200	2000
	3	150	300	600	900	1800	3000
	6	300	600	1200	1800	3600	6000
	10	500	1000	2000	3000	6000	10000

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