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1. Executive summary

Organic livestock are primarily supplied by organically produced feed and ruminants are mainly fed forages. Organic production promotes high animal welfare standards, in particular by meeting the species-specific behavioural needs of animals. All these aspects contribute to a preventive approach that limits the use of external inputs in livestock production, either be it for animal health or nutrition.

The RELACS project aims at developing alternative products and tools to reduce the use of contentious inputs in livestock production, namely anthelmintics, antibiotics and vitamins. Two complementary techniques acting on different stage in the worm life cycle have been tested as alternatives to anthelmintics. For antibiotics, RELACS aimed to adapt preventive herd health management tools to local conditions and to develop new options for mastitis treatment using essential oils. Finally, two strategies to reduce use of B and E vitamins in livestock production have been explored in RELACS: updating data on vitamin requirements and developing competitive non-GM high-yield yeast production strains.

The results of RELACS on these alternatives were presented to relevant stakeholders of the organic sector and to EU policymakers, in order to assess their acceptability of the alternatives and to identify under which conditions they could be adopted. This multi-actor approach and fact-based dialogue allowed to develop a "European roadmap to reduce contentious inputs in organic livestock production", with the aim to propose fair, reliable and implementable rules to achieve an identified realistic reduction pathway of anthelmintics, antibiotics, and vitamins.

The results of the RELACS project show that reducing the use of anthelmintics is a possible future, under several conditions. The two alternatives evaluated present a lot of potential but should not be seen as new veterinary drugs that will strictly replace anthelmintics. As for antibiotics, it is not possible to envisage a phasing out in organic farming in the current state of knowledge, but preventive herd health management tools show a good potential to reduce their use in the short term. In the medium-term, antibiotic reduction strategies could be complemented by the use of essential oils or other herbal veterinary medicinal products. In both cases, a holistic strategy should be adopted, where immune response and nutrition will help towards achieving control of parasites and diseases.

According to the results of the RELACS project, there is big potential to reduce the use of vitamin E and vitamin B2 in organic livestock feeding. However it is clear that these vitamins cannot be completely phased out of the diets without significantly endangering animal health.

The RELACS project shows that reduction pathways for anthelmintics, antibiotics, and vitamins are possible in a near future, but their achievement will require a strong policy support in several fields. Where the alternatives are new inputs which will need to be approved at EU level, the registration procedure (be it as feed additive or veterinary medicinal product) is considered as a major obstacle for their availability in the short term. Additionally, policy support for continuous research is needed, to further develop promising alternatives and search for new ones. Farmers should also be supported in adopting alternatives, as this supposes higher product costs and/or a need for additional knowledge.

In the case of livestock production, farmers rely directly on other actors to cure or feed their animals, which is less the case for plant health. Indeed, medicines must be prescribed by a veterinarian (medication provided by the farmer is not allowed) and feed mills decide the level of vitamins in their premix. Therefore, it is key to involve these stakeholders when developing alternatives in livestock production, in order to facilitate their adoption.

Developing alternatives to reduce the use of anthelmintics and antibiotics is also relevant for conventional farmers, as they use these inputs as well. However, it is important to consider these alternatives as a tool in a systemic approach to animal health, where preventive measures play a key role. This is already the basis of organic farming, but by spreading this paradigm shift in animal health approach, it would then be possible to bring conventional farmers on board to reduce synthetic inputs in livestock production. Ultimately, this would contribute to the Farm-to-Fork target on the reduction of the sales of antimicrobials by 50% by 2030.

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2. Introduction

Organic agriculture is based on a system approach that sustains and enhances the health of plants, animals, ecosystems, people, and the balance between them. This is achieved through management of ecological processes, adapted to local conditions, and closed nutrient cycles that allow organic farmers to build resilient and self-sustaining production systems, with the lowest possible dependence on external inputs.

Animal husbandry is part of this approach. Organic livestock husbandry is based on the harmonious relationship between land, plants, animals and humans. The integration of livestock in organic farms contributes to the cultivation of organically grown feedstuffs and nutrient recycling on the farm. Organic livestock are primarily supplied by organically produced feed and ruminants are mainly fed forages. Organic production promotes high animal welfare standards, in particular by meeting the species-specific behavioural needs of animals. All these aspects contribute to a preventive approach that limits the use of external inputs in livestock production, either be it for animal health or nutrition.

The Organic Regulation (EU) 2018/848[1] states that to maintain animal health in livestock, emphasis should be given on breed selection and the application of animal husbandry practices which enhance the immune system and strengthen the natural defence against diseases. However, in the event of disease, the EU regulations stipulate that the animal should be treated immediately to avoid suffering. Chemically synthesised allopathic veterinary products, such as anthelmintics or antibiotics, may be used where necessary and under strict conditions when the use of phototherapeutic, homeopathic and other products is inappropriate. Some feed additives, such as vitamins, may also be allowed when feed rations are not sufficient to meet the physiological and behavioural needs of the animals, but they should be limited to substances of natural origin. In very specific cases where no alternatives are available, synthetically derived substances may be used exceptionally.

Because these synthetic inputs can be essential for animal health, they are allowed under strict conditions under the Organic Regulation (EU) 2018/848, but their production and/or use raises some serious conflicts with organic standards and consumer expectations. The organic sector has always been engaged in finding alternative methods or products to reduce the use of what is considered as contentious inputs in organic livestock production. This is even more important now that the European Commission has set a target of 25% organic land by 2030, in order to achieve a sustainable growth of the organic sector.

The RELACS project is part of this effort, taking up and further developing the research undertaken on alternatives to reduce the use of anthelmintics, antibiotics and synthetically produced vitamins.

This roadmap presents the main findings and next steps to make the reduction of contentious inputs in organic livestock systems possible.

3. Methods

RELACS is broken down into 6 research and development work packages (WPs1-6), in which scientists and farmers working closely together with industry partners have developed, explored and adapted innovative solutions and strategies to reduce the use of copper (WP1), mineral oil (WP2), contentious fertilisers and manures (WP3), anthelmintics (WP4), antibiotics (WP5) and synthetic vitamins (WP6); one work package dedicated to the science-practice dialogue to support the development of relevant EU policies (WP7); one for outreach and technology transfer (WP8); and one for consortium and project management (WP9). All WPs are strongly linked to and interacting with WP7, leading the development of three European roadmaps for the reduction of contentious inputs in organic production:

i. European roadmap for the reduction of contentious plant protection products: copper and mineral oil
ii. European roadmap for the reduction of contentious fertilisers and manures in plant nutrition
iii. European roadmap for the reduction of contentious inputs used in livestock production: antibiotics, anthelmintics and vitamins

[1] Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

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The aim of the RELACS European roadmaps is to propose fair, reliable and implementable rules to achieve an identified realistic reduction pathway for each of these six priority contentious inputs.

The roadmaps have been developed through a multi-actor approach and a fact-based dialogue. As a first step, workshops were organised at national level to present and discuss the alternatives developed within RELACS to relevant stakeholders of the organic sector. Then, the outcomes of the national workshops were presented and discussed during a European workshop. All the outcomes of these workshops provide the basis for the preparation of the three European roadmaps.

3.1 National workshops

21 national workshops were organised in 9 EU Member States (France, Italy, Spain, Bulgaria, Hungary, Germany, Denmark, Estonia, Belgium) and the United Kingdom, gathering practitioners, advisors, national authorities, and scientists (see Figure 3-1 and Annex I), to discuss the pros and cons of alternative tools and techniques developed by RELACS, explore the current acceptance level as well as identify necessary adaptations of current legislation to enable the uptake of these alternatives.

Each workshop focused on one contentious input and its alternatives. Depending on the national context, one or more workshops were organised (see Table 3-1).

The workshops to discuss alternatives to the use of synthetic vitamins could not be organised, because of difficulties in gathering the relevant participants. Unlike all the other workshops of which the main stakeholders are the farmers, the relevant stakeholders to discuss alternatives to synthetic vitamins are the feed mills, which supply both the conventional and organic sector. Too few of these actors showed interest in participating in a RELACS workshop. This could be explained by the fact that the national networks of feed mills are less developed than the organic farmers' networks, and the fact that they are operating in a competitive market which makes it difficult to create sufficient confidence.

Table 3-1 Overview of national workshops organised by RELACS

	Copper	Mineral Oils	Nutrients	Anthelmintics	Antibiotics	Vitamins
France					2020 & 2021	
UK	Aug. 2021			June 2021	June 2021	
Hungary	Sept. 2021		Sept. 2021			
Spain	June 2021	June 2021			July 2021	
Italy	May 2021	May 2021	May 2021			
Germany	Sept. 2021		April 2021	April 2021	April 2021	
Estonia			Sept. 2021		Sept. 2021	
Belgium	July 2021					
Denmark			Sept. 2021			
Bulgaria	June 2021					
TOTAL	**7**	**2**	**5**	**2**	**5**	**/**

Technical dossiers on each alternative input or method were prepared by the research and technology development (R&D) work packages (WPs 1-6) and shared with the participants before the workshop. Each dossier provides basic information on the alternative proposed: technical, chemical and physical properties, specification of use, side effects, regulatory status, price and compliance with organic principles.

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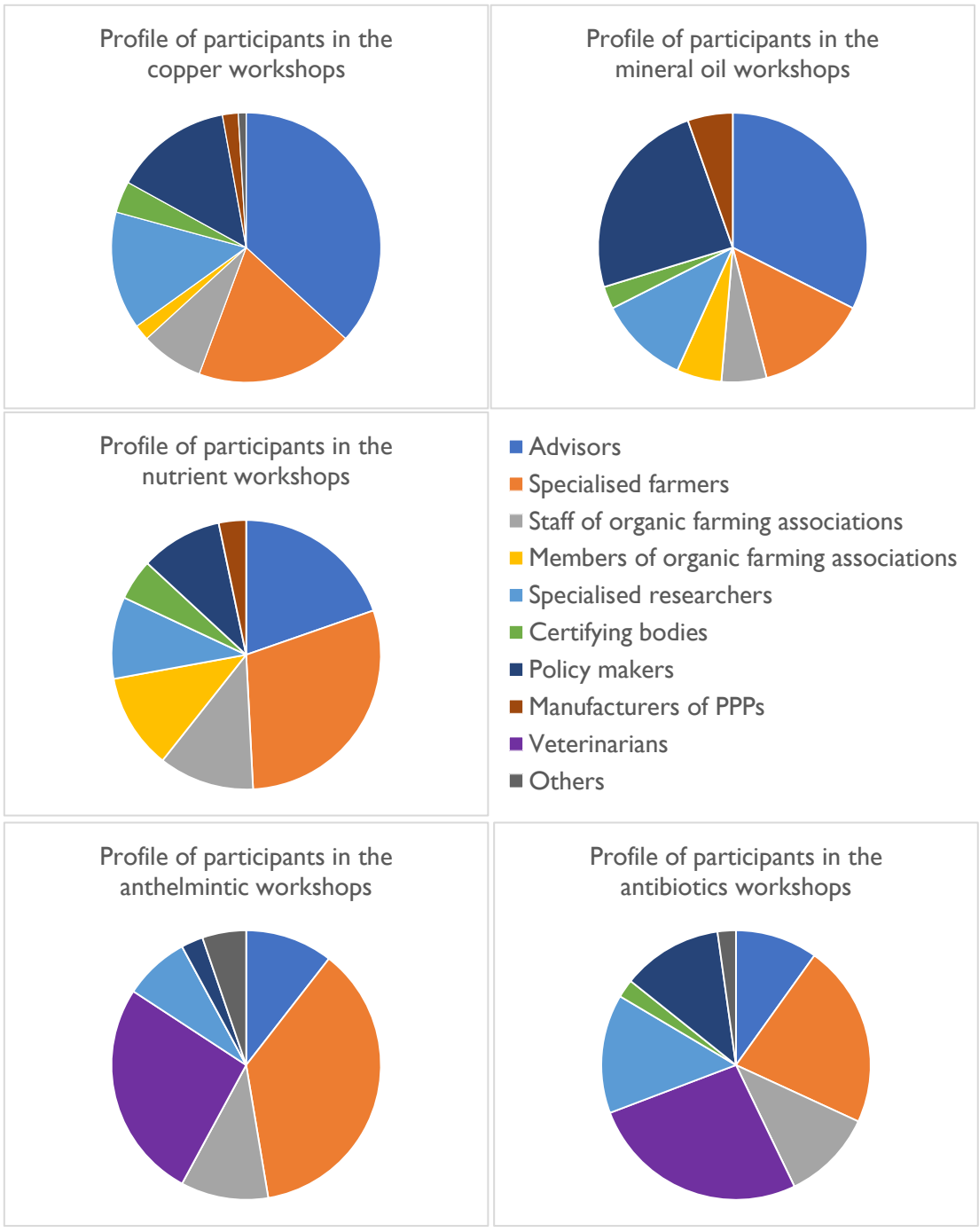
During the workshops, participants were invited to give their views on the acceptability of the alternatives presented regarding their efficacy, environmental impact, cost/benefit and practical obstacles to their uptake. They were also invited to identify knowledge and advisory needs to enable the uptake of the alternatives. Optionally, participants were also asked to identify regulatory and market aspects that might influence the adoption of the alternatives (registration, regulatory obstacles, scalability, supply chain).

Based on this assessment, the participants had to conclude for each alternative whether it could be accepted to reduce the use of the contentious inputs, and under which conditions. Participants were also asked to propose national recommendations and actions to reduce contentious inputs, elucidate bottlenecks and propose timelines for implementation. The outcomes of the national workshops are compiled in input-specific national roadmaps.

Figure 3-1 Overview of the profiles of the participants in the national workshops



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3.2 European workshop

A European workshop took place on the 2nd of December 2021, with the aim to share the conclusions of the national roadmaps and to discuss the actions needed at EU level to help reduce the use of contentious inputs and, more generally, to design fair, reliable and implementable EU rules on the use of inputs in organic production. The workshop was attended by about 50 people. Participants were mainly RELACS and Organic-PLUS partners; few participants were from the European Commission or industry.

A summary of the outcomes of the national workshops was presented to the participants, focusing on the level of acceptance of the alternatives by farmers and the main obstacles to their adoption that were identified. Then, the participants were divided into three working groups corresponding to the topics of the three RELACS European roadmaps (plant protection, nutrients, livestock). Based on the results of the national workshops, they brainstormed on potential solutions at EU level to facilitate the adoption of the alternatives developed by RELACS and considered acceptable by farmers.

The aim of the three RELACS European roadmaps – on the reduction of contentious plant protection products, nutrients, and inputs used in livestock production – is to provide recommendations for the reduction of contentious inputs in organic agriculture based on science and facts and in close discussion with relevant stakeholders through the RELACS national and European workshops.

4. Overview of the EU procedures for the authorisation of inputs in organic livestock

The Organic Regulation (EU) 2018/848 defines the principles and practices of EU organic agriculture, including the rules on the use of inputs. It establishes that the use of inputs should be limited to the minimum and defines clear criteria for the condition of their use. An input that is authorised in organic farming can only be used if it is first authorised by the relevant EU horizontal legislation.

4.1 Veterinary Medicinal Products

4.1.1 Authorisation under the EU horizontal legislation on Veterinary Medicinal Products

All veterinary medicinal products must receive a marketing authorisation before they can be sold and used in the EU. Marketing authorisation can be obtained through two ways:

- **Centralised procedure**: the European Medicines Agency (EMA) is responsible for the scientific evaluation of centralised marketing authorisation applications. Once granted by the European Commission, the centralised marketing authorisation is valid in all EU Member States, Iceland, Norway and Liechtenstein. This procedure is set by Regulation (EU) 2019/6 on Veterinary Medicinal Products (VMP).
- **National authorisation procedure**: individual Member States authorise the medicines for use in their own territory, after an evaluation by their National Authority. Mutual recognition of national marketing authorisations shall apply.

The paragraphs below detail the centralised procedure.

The Veterinary Medicinal Products (VMP) Regulation applies from 28 January 2022. It updated the rules on the authorisation and use of veterinary medicines in the EU, by amending the EU pharmaceutical legal framework set out by Regulation (EU) 726/2004 and creating a legal framework specific to veterinary products. Additionally, the VMP Regulation introduced the obligation for Member States to collect data on the sales and use of antimicrobials in animals.

The scientific evaluation of a market authorisation application is carried out by the Committee for Veterinary Medicinal Products (CVMP) of EMA, within 210 days of receipt of a valid application. The CVMP's assessments are based on a comprehensive scientific evaluation of data. They determine whether the medicine meets the necessary quality, safety and efficacy requirements and that is has a positive risk-benefit balance in favour of the animal population they are intended for. After the evaluation, the CVMP must issue a scientific opinion on whether the

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medicine may be authorised or not. The CVMP also recommends safe limits for residues of veterinary medicines used in food-producing animals and biocidal products used in animal husbandry, for the establishment of maximum residue limits by the European Commission. EMA sends this opinion to the European Commission, which delivers the marketing authorisation within 67 days. The Commission's decisions are published in the Community Register of medicinal products for veterinary use and EMA publishes a European public assessment report (EPAR).

Once authorised, any VMP for food-producing animals cannot be used without **veterinary prescription**. This means that medication supplied by the farmer is not allowed.

4.1.2 Use of veterinary medicinal products in organic farming

The Organic Regulation (EU) 2018/848 states that "Where animals become sick or injured despite preventive measures to ensure animal health, they shall be treated immediately". For veterinary treatments, it is specified that the use of phytotherapeutic, homeopathic and other products should be preferred to chemically synthesised allopathic veterinary medicinal products, including antibiotics. Unlike other inputs, such as PPPs, fertilisers, or feed additives, the organic regulation does not limit the veterinary products allowed to treat diseases. It rather establishes a hierarchy of approaches. The use of chemically synthesised allopathic veterinary drugs as a preventive measure, however, is prohibited.

The organic regulation set a withdrawal period between the last administration to an animal of a chemically synthesised allopathic veterinary medicinal product and the production of organically produced foodstuffs from that animal that is twice the withdrawal period for conventional farming, and at least 48 hours.

4.1.3 Discussions

Veterinary phytotherapy – or herbal veterinary medicine – is recently not regulated separately from other VMPs in the new VMP Regulation (EU) 2019/6. Therefore, phytotherapeutic products follows the same registration process than other VMPs. However, recital 12 and article 157 refer to "traditional herbal products used to treat animals". It is explained in recital 12 that "there is insufficient information to date on traditional herbal products used to treat animals in order to allow the setting up of a simplified system. Therefore, the possibility of introducing such a simplified system should be examined by the Commission based on the information provided by the Member States on the use of such products on their territory". Article 157 commits the Commission to submit a report on traditional herbal products used to treat animals to the European Parliament and to the Council by 29 January 2027. However, the Commission is free to decide whether it will make a legislative proposal to introduce a simplified registration system.

Medicinal plants are always complex mixtures of a broad spectrum of phytochemical substances. In the absence of an authorisation procedure adapted to the specific characteristics of herbal VMPs, it is feared that technical constraints will make it difficult or even impossible for new herbal VMPs to be authorised at EU level. Products that are authorised at national level through former simplified procedures could also be withdrawn from the market if compliance with the new VMP Regulation becomes technically – and economically – challenging. For instance, based on former existing simplified registration (at least in Germany and Austria), there are recently still about 20 registered traditional herbal VMPs on the German market and about 5 on the Austrian market.

Interestingly, about 60 medicinal plants are registered as active substances without withdrawal periods in Regulation (EU) 37/2010 on maximum residue limits for pharmacologically active substances[2].

[2] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

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4.2 Feed additives

4.2.1 Authorisation under the EU horizontal legislation on feed additives

Feed additives must be authorised at EU level before being put on the EU market. The Feed Additives Regulation (EC) No 1831/2003[3] establishes a common procedure for authorising feed additives and lays down rules for their placing on the market, labelling and use.

Applications for authorisation on the EU market are submitted to the Commission, alongside a technical dossier with information on the additive, its conditions of use, control methods and data demonstrating its safety and efficacy. The European Food Safety Agency (EFSA) is responsible for conducting the risk assessment based on the dossier submitted by the applicant. EFSA gives an opinion within 6 months of receipt of an application unless the Agency asks for further information and data to the applicant. If EFSA's opinion is favourable, the Commission prepares a draft regulation to authorise the additive. This is then discussed by Member States represented in the Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) – Section Animal Nutrition. The SCOPAFF decides by qualified majority to approve or reject the Commission's proposal. The result of the vote is binding for the Commission.

Authorisation is granted for specific animal species or categories and for specific conditions of use. Where appropriate, maximum residue limits are set in the relevant foodstuffs of animal origin.

4.2.2 Authorisation in organic production

Annex III, Part B, of the Implementing Regulation (EU) 2021/1165 establishes the list of authorised feed additives and processing aids used in animal nutrition in organic production, provided that the feed additives are authorised pursuant to Regulation (EC) No 1831/2003. To be included in this list, feed additives have to go through another evaluation process to ensure that they comply with the principles of organic farming.

It is the Commission that decides on the addition of a feed additives to Annex III, more precisely the "Organics" Unit of DG AGRI. Member States can submit to the Commission requests to do so.. Before taking its decision, the Commission receives advice from the expert group for technical advice on organic production (EGTOP), which is a permanent group of the Commission composed of independent scientists and other experts from EU countries with competences related to organic production.

The EGTOP assists the Commission by assessing for each substance the compliance of the following criteria with the objectives and principles of organic production:

- Necessity for intended use and known alternatives
- Origin of raw material and manufacturing process
- Environmental issues, use of resources, recycling
- Animal welfare issues
- Human health issues
- Food quality and authenticity
- Social, economic, and ethical concerns

Based on this technical evaluation, the EGTOP also provides non-binding recommendations on the authorisation of the substances for organic production. There is no pre-established logic for weighting the criteria against each other. The expert group follows a holistic approach and decides on a case-by-case basis.

The Commission generally follows the EGTOP's opinion. Any Commission's proposal concerning the authorisation of a new feed additive for organic production (meaning its inclusion in Annex III) is submitted for approval by the Committee on Organic Production, composed of representatives of EU Member States. The Commission's

[3] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition

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proposal may specify more restrictive conditions for the use of the substance in organic production than those established for the use in conventional farming – in the relevant horizontal legislation.

5. Reduction of anthelmintics

5.1 Problems associated with the use of anthelmintics

Anthelmintics represent a contentious input for organic farming. The synthetic residues can remain in the animal products for varying durations, depending on the class of anthelmintic used. Synthetic residues also can enter the environment through animal faeces and consequently leach into groundwater. The wide-spectrum activity of anthelmintic drugs carries eco-toxic implications for non-target organisms, including dung community composition, and for parasite biocontrol, pasture fertility and soil health (reviewed by Beynon, 2012).

There are currently no natural alternatives to anthelmintics that achieve the same level of efficacy. The value of anthelmintics to livestock health and welfare must therefore be balanced against the potential environmental and production costs through regulated use. Anthelmintics cannot be administered prophylactically in organic farming, and authorization must be given for their use to treat disease. Withdrawal periods for organic products are twice the legally required period for the conventional products. Evidence of disease prevention strategies such as high-quality feed, appropriate stocking density and appropriate housing conditions are a legal requirement based on the EU regulations (EU 2018/848). Conventional farming has no restrictions on the use of anthelmintics.

5.2 Tools and techniques assessed by RELACS

The aim of RELACS is to deliver two complementary techniques to reduce application of anthelmintics in livestock production.

The first technique assessed by RELACS is heather grazing for organic sheep. The works focused on quantifying the efficacy of bioactive grazing against ovine gastrointestinal nematodes, and validate it on farm.

The second alternative studied in RELACS is *Duddingtonia flagrans*, a biocontrol agent reducing infective gastrointestinal parasite loads in pastures. The use of this nematophagous ("nematode eating") fungus has been explored in previous research works and highly efficient fungal strains were identified (Saguees et al, 2011). A Swiss strain has been developed to Technology Readiness Level 7 (Oberhänsli and Heckendorn, 2017) and has been used in RELACS.

The main characteristics of the alternatives assessed by RELACS are presented in the following sections.

5.2.1 Heather

Description	Heather is a perennial plant, endemic in the countries of the Northern hemisphere.
Type of use	Heather as anthelmintic is tested against ovine parasite species. The aim is to get the animals to graze the heather. Heather is considered a bioactive forage, which means that its intake results in anti-parasitic activity
Mode of action	Heather contains condensed tannins that have been shown to have anthelmintic activity (direct antiparasitic effect, i.e. killing parasites). It also contains other compounds that can have a similar activity.
Efficacy	It is uncertain whether heather grazing can be used as stand-alone replacement of anthelmintic, it can however be used to reduce the use of anthelmintics in organic systems of production. As an alternative to anthelmintics, it will most likely be used to maintain parasite load at a low level, maybe replace some treatments and thus to reduce overall use of anthelmintics during the season.
Side effects	Excessive use may lead to a reduction in animal performance due to over consumption of condensed tannins.

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Historic of use & regulatory status	Grazing on forages rich in condensed tannins and other plant secondary metabolites has been tried and, in some cases, incorporated in parasite control strategies by organic farmers. No regulatory requirements for registration of heather grazing for parasite control.
Origin of raw material & production method	Heather grows naturally in Europe. It covers vast areas of moorland and is traditionally maintained by burning. In moorland and heatherland, heather is also one of the main feed crops for herbivores. Although the main body of the plant is tough and almost impossible to eat, the fresh tips that grow each year are eminently edible and are one of the main foods for deer, grouse, mountain hare, etc. Heather is particularly useful for animals as its tips retain their nutrients through winter and offer a source of food in the coldest of British climates.
Scalability	Heather grazing is limited by availability of heather, which is mainly found in uphill areas. This method is therefore restricted to uphill farms. Establishment of heather in other areas is possible if the climatic conditions as it is a robust plant. Particularly in areas that cannot be used for establishment of cereals and other crops for animal or human consumption. However, heather was tested here as a model plant; other plants with similar composition may be present in other parts of the world and could be used instead of heather.
Costs	If animals have access to heather grazing, the cost of grazing heather is lower than the cost of anthelmintics.

5.2.2 *Duddingtonia flagrans*

Description	Spores of the nematophagous fungus *Duddingtonia flagrans*
Type of use	*D. flagrans* may be used as anthelmintic against ovine, caprine and bovine parasite species, when added to daily feed ration.
Mode of action	The fungal spores survive the passage through the gastro-intestinal tract of animals and germinate only in the faeces. The fungus grows in dung pats and destroys infective helminth larvae, thus reducing pasture contamination and re-infection of grazing animals.
Efficacy	*D. flagrans* can reduce pasture contamination by infective larvae. It is uncertain whether *D. flagrans* can be used as stand-alone replacement of anthelmintic, it can however be used to reduce the use of anthelmintics in organic production systems. As an alternative to anthelmintics, it will most likely be used to maintain parasite load at a low level, maybe replace some treatments and thus to reduce overall use of anthelmintics during the grazing season.
Side effects	No adverse impact expected on animal health, human health, and environment, full evaluation pending
Historic of use & regulatory status	No traditional use of *D. flagrans*, but carriers are approved feedstuffs. In general, biological control of pathogens is a preferred control method in organic production. *D. flagrans* should be registered at EU level as feed additive under Regulation 1831/2003.
Origin of raw material & production method	*D flagrans* is a biocontrol organism. The nematophagous fungus is present in decaying organic materials. During fermentation on suitable media high numbers of robust Chlamydospores are produced. The *D. flagrans* additive is obtained via fermentation on food and/or feed grade raw materials. All materials can be obtained from certified organic origin.

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Scalability	Production of *D. flagrans* spores can be upscaled within less than 1 year. Several producers are able to ferment the fungus or have the capacity to build up new production.
Costs	The cost of feeding the *D. flagrans* additive is expected to be higher than the cost of anthelmintics. However, *D. flagrans* is effective irrespective of the resistance status of the helminths. It therefore presents an effective treatment for animals with otherwise untreatable resistant helminths.

5.3 Farmers' acceptance level of the alternatives proposed by RELACS

The acceptance level of farmers for the alternatives developed in RELACS to reduce the use of anthelmintics was assessed during the national workshops (see part 2.), which took place in Germany and in the United Kingdom.

The national workshops showed that there is strong interest amongst farmers in alternatives to anthelmintics to prevent or manage worm load in their animals. The main reasons given were concerns about anthelmintic resistance, animal welfare, environmental concerns and costs.

Farmers, advisors and veterinarians were very interested in the two alternatives, heather and *Duddingtonia flagrans*. Their complementarity is seen as a key aspect, as each alternative disrupts a different stage in the worm life cycle – heather disrupts the worm life cycle inside the animal, and fungi disrupts the worm life cycle on grass).

According to farmers, advisors and vets, both alternatives have a good potential to reduce the use of anthelmintics, but not to phase them out. They consider that further research is needed, both at lab and farm level, to substantiate the data on efficacy and environmental impact. They would only use these alternatives if they have been validated with solid scientific evidence and clearer explanation of mode of action. They would like that efficacy tests include information on sheep management costs associated to feeding heather or *Duddingtonia flagrans*. If solid evidence is provided, stakeholders are willing to use the alternative even at a slightly higher cost.

With regard to heather specifically, farmers would consider using this alternative as a preventive rather than a curative measure, as high concentrations are needed to treat animals effectively in case of infection. They think that the uptake of this alternative should not represent major increase of their workload, but the on-farm availability of heather will limit the access to this alternative. Farmers propose either to develop practical solutions easily accessible, such as heather pills, or to further investigate the anthelmintic potential of other bioactive forage, such as sainfoin or chicory. The potential impact of the introduction of heather cultivation on local biodiversity should be investigated at the request of farmers.

Regarding *Duddingtonia flagrans*, farmers have shown great interest in this alternative. They would like to have further information on the potential impact of the fungi on insects, as *Duddingtonia flagrans* is carried on grazing surfaces via animal faeces. The integration of *Duddingtonia flagrans* into farming practices is not easy, firstly because it is based on daily intake, which is not always feasible for animals that are not close by the farm. Secondly, because the fungus is used as a preventive measure, which implies a change in approach compared to anthelmintics, which are used as a curative measure. Farmers expressed interest in developing slow-release application alternatives. Finally, farmers, advisors and vets expect difficulties, or at least long and complex process, for *Duddingotnia flagrans* to be authorised under EU horizontal legislation, either as a veterinary product or as a feed additive.

The workshops also showed that engaging with vets and advisors in the process of scientific validation of the alternatives will be essential to encourage the uptake of the alternatives, as they will be involved in their dissemination to farmers.

5.4 Obstacles to the adoption of the alternatives

The two alternatives to anthelmintics may face various obstacles to their adoption, of different types.

First, as heather and *D. flagrans* are preventive measures, so their use involves a change of control strategy from curative to preventive. This paradigm shift needs to be accepted by vets, as it is likely to impact their current business model. If vets do not recognise the usefulness of these alternatives, their dissemination to farmers will be hampered.

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As things stand, there is not enough data to convince farmers, advisors and vets to use these products, despite their interest. The lack of data concerns efficacy, and practical management measures related to the use of these alternatives. Data demonstrating that these alternatives do not have a negative impact on the environment are available but have not been sufficiently presented to practitioners.

The inability to access or use the alternatives is a significant barrier to their adoption by farmers. On-farm availability of heather is limited to some geographic areas, and the impact of its introduction in local ecosystem is unknown. For *D. flagrans*, the daily intake of spores by animals is a serious logistical limitation.

Finally, the registration process of *D. flagrans* under the EU horizontal legislation for feed additives will be long and costly.

5.5 Strategies to overcome the obstacles: RELACS policy recommendations to support anthelmintic reduction

Heather and *D. flagrans* seem promising to lower the amount of synthetic anthelmintics used by organic farmers, but **scientific and practical knowledge on the two alternatives needs to be further developed**, mainly to substantiate the efficacy of the proposed products and to develop practical advice for including them into animal health strategies. Further research is also needed to identify more plants or active compounds to be developed as anthelmintic alternatives, in order to reduce the chance of depleting resources when upscaling organic production in view of the Farm to Fork target of achieving 25% organic farmland by 2030. This should include an exploration of grey literature as well as traditional and ecological knowledge on livestock management for better use of plant resources in pasturelands.

Involving vets in the validation process of the alternatives will be key to ensure a greater acceptability and adoption of the alternatives. Vets need to be demonstrated that the alternatives are effective against gastrointestinal parasites while not compromising animal health and welfare and food quality. The national workshops have shown that there is a growing interest among vets on alternatives to synthetic anthelmintics. Involving them in the product development phases can reinforce this interest and lead to greater knowledge. Additionally, including the alternatives into the curriculum and Continuing Professional Development (CPD) programmes of vets would ensure a better dissemination of alternative approaches and wider acceptance as well.

Technical and financial support should be offered to farmers who are committed to reducing anthelmintics. As part of the implementation of the new **CAP**, Member States should explore the possibilities to develop ecoschemes to reduce the use of anthelmintics and promote alternatives, or to adopt a change in animal health management strategy, from curative to preventive approach. To encourage preventive approaches, financial resources should be allocated to enable farmers to conduct free analyses to evaluate the parasite load and parasite species prevalent. Promoting on-farm and long-term trials will both support knowledge dissemination and facilitate acceptability.

Since the **registration process** of herbal products as feed additive or veterinary medicinal product is lengthy and costly, national governments and/or the EU should provide financial support for registration costs. This is relevant for *D. flagrans*, but also if alternatives based on tannin-rich plant extracts are developed. The EU horizontal legislation should also be better adapted to the specific characteristics of herbal products.

5.6 Reduction pathway for anthelmintics

The results of the RELACS project show that reducing the use of anthelmintics is a possible future, under several conditions.

Heather and *D. flagrans* have shown a lot of potential to reduce the use of anthelmintics but should not be seen as new veterinary drugs that will strictly replace anthelmintics. A change of approach to gastrointestinal parasites management must take place besides the adoption of the alternatives. A holistic strategy should be adopted, where immune response and nutrition will help towards achieving control of parasites. Alternatives must be used in a strategic manner to reduce pasture contamination. There is no need to aim for a 100% efficacy of the alternative inputs to anthelmintics, as they are only one element of the toolkit to control parasites.

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Further research will be necessary to complete the knowledge on the alternatives developed by RELACS and to explore other possibilities of alternatives to extend the toolkit for anthelmintic reduction. Although a few years are still necessary to have operational solutions ready to be placed on the market, the implementation of alternatives that contribute to parasite control can be done gradually. Indeed, some alternatives, e.g. management and feeding strategies, can be implemented earlier than other, e.g. the use of registered products.

While heather grazing is available immediately, authorisation of other alternatives at EU level will take time, whether to find the necessary financial resources – companies are generally reluctant to apply for authorisation of herbal products - to prepare the application dossier or to conduct the risk assessment. This means that some alternatives will only be available in the medium term.

Once authorised, financial and technical supports will be necessary for the adoption of the alternatives by farmers. If vets are taken on board, the adoption of the alternatives by farmers will go smoother.

6. Reduction of antibiotics

6.1 Problems associated with the use of antibiotics

Many classes of antibiotics that are important for human health are also used in livestock production, where excessive and improper use can drive antibiotic resistance. Transmission of resistant bacteria from livestock to humans has been documented via direct contact with animals and faeces, environmental contamination, and through the food supply chain resulting in serious public health concerns (The Organic Centre report, 2016). The additional ecological implications of antibiotics entering the environment and impacting microbe populations, and as chemical agents entering the food supply, make them contentious inputs for organic producers and consumers. Although the use of antibiotics is restricted in organic compared to conventional farming, mastitis is one of the main reasons for antibiotic treatments in both production systems (Landers et al., 2012).

The increasing incidence of antimicrobial resistant pathogenic bacteria, both in veterinary as well as in human medicine, underlines the necessity to reduce antibiotic input (Koch et al., 2017). According to the European Commission, antimicrobial resistance (AMR) is responsible for an estimated 33,000 deaths per year in the EU. Recent EU policy initiatives demonstrate that AMR is increasingly recognised as a major public health issue. In June 2017, the European Commission adopted the EU One Health Action Plan against AMR[4], as requested by Member States, with the aim to play a leading role in the fight against AMR. More recently, in the Farm to Fork Strategy adopted in May 2020, the European Commission set a target of reducing the overall sales of antimicrobials in the EU for farmed animals and in aquaculture by 50% by 2030.

6.2 Tools and techniques assessed by RELACS

RELACS aimed to deliver strategies to reduce antibiotic use in dairy production by adapting preventive herd health management tools to local conditions and by developing new options for mastitis treatment using essential oils. Although the use of antibiotics is restricted in organic compared to conventional farming, mastitis is one of the main reasons for antibiotic treatments in both production systems (Landers et al., 2012).

Animal health and welfare planning (AHWP, Vaarst et al., 2011) has been shown to be a useful tool, reducing antibiotic input significantly (Ivemeyer et al., 2012). RELACS has developed a protocol to adapt the AHWP method to various conditions in Europe. The RELACS protocol was built using the Scandinavian and Swish experience of AHWP, and previous projects dedicated to this tool (e.g. ANIPLAN). Mastitis has been used as an example to implement AHWP for the reduction of antibiotic use in organic dairy production.

Essential oils are well known to have a wide range of antimicrobial efficiency even in bacteria expressing multi drug resistance or as a possibility to inhibit quorum sensing. RELACS has built on two existing French farmer groups applying essential oils to treat clinical mastitis to evaluate their antibacterial effects.

[4] Communication from the Commission to the Council and the European Parliament - A European One Health Action Plan against Antimicrobial Resistance (AMR). COM(2017) 339 final

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The main characteristics of the alternatives assessed by RELACS are presented in the following sections.

6.2.1 Litsea essential oil

Description	Litsea citrate essential oil (EO) is a botanical extract from Litsea herbal (*Litsea cubeba*).
Type of use	Listea EO may be used for preventive and curative treatment of mastitis on dairy animals, by application to the udder and massage. It should be used on clinical mastitis "light to moderate" (without body temperature, blood in the milk, only with abnormal milk/redness/ hardness on quarters).
Mode of action	Litsea EO has anti-inflammatory effect. It reduces the development of main mastitis pathogens (*E. coli* , Staphylococcus and Streptococcus)
Efficacy	Preliminary outcomes positives but validation trials are needed.
Side effects	• Animal health: no negative effects as far as known, full evaluation pending • Food quality: full evaluation pending on potential impact on the natural acidification process of milk
Historic of use & regulatory status	Essential oils are widely used by French farmers for their antibacterial or anti-inflammatory effects, sometimes with advice of their veterinarians. Litsea EO must be registered under EU regulation 2019/6 on VMP and/or have an established MRL under EU regulation 37/2010.
Origin of raw material & production method	*Litsea cubeba* tree is native to Southern Chinese region. Litsea EO is extracted from the fruit. It is produced with a distillation process. Litsea EO is mainly produced in China, but also in other regions of Asia, in America and Oceania. It is and available in organic product.
Scalability	Easy to expand.
Costs	Litsea EO will be cheaper than antibiotics, but the use and application of EO requires more observation time than the application of antibiotics.

6.2.2 Oregano essential oil

Description	Oregano essential oil (EO) is a botanical extract from Oregano plant (*Origanum vulgare*).
Type of use	Oregano EO may be used for preventive and curative treatment of mastitis on dairy animals, by application to the udder and massage. It should be used on clinical mastitis "light to moderate" (without body temperature, blood in the milk, only with abnormal milk/redness/ hardness on quarters).
Mode of action	Oregano EO has anti-bacterial properties. It reduces the development of main mastitis pathogens (*E. coli* , Staphylococcus and Streptococcus)
Efficacy	Preliminary outcomes positives but validation trials are needed.
Side effects	Animal health: no negative effects as far as known, full evaluation pending Food quality: full evaluation pending on potential impact on the natural acidification process of milk
Historic of use & regulatory status	Essential oils are widely used by French farmers for their antibacterial or anti-inflammatory effects, sometimes with advice of their veterinarians.

	Oregano EO must be registered under EU regulation 2019/6 on VMP and/or have an established MRL under EU regulation 37/2010.
Origin of raw material & production method	*Origanum vulgare* native to the Mediterranean region, but widely naturalised elsewhere in the temperate Northern Hemisphere. Oregano EO is produced in Europe. Oregano EO is extracted from dried leaves or shoots of the plant, by steam distillation.
Scalability	Easy to expand.
Costs	Oregano EO will be cheaper than antibiotics, but the use and application of EO requires more observation time than the application of antibiotics.

6.2.3 Animal Health and Welfare Planning

Description	The Animal Health and Welfare Planning (AHWP) is an advisory tool
Type of use	In the RELACS project, the method is used in the context of antibiotic reduction for mastitis treatment, but it can be used for almost any health issue in farm animals (e.g. diarrhoea in calves, parasite control in laying hens etc.)
Method	The RELACS-AHWP Protocol aims to collect data on the health and welfare of dairy cows. Data are needed for (self-) reflecting of farmers, benchmarking between farms and for advisory reasons. Data collection has to be carried out in a highly precise manner and following the same protocol on each farm yearly, prior to the advising action. The Dataset comprises four parts: (I) Overall data of farm structure, (II) Milk recording data, fertility data, (III) Health and Treatment data and (IV) Health and Welfare data. The advising action within the RELACS AHWP protocol is the Farmer Field School approach (FFS), a specific form of facilitated farmer inter-collegial advisory. The ideal group size is 5 to 7 farmers which lead to one host and 4-6 advising guest farmers per meeting. The facilitator does not give any advice him- or herself but is responsible for the preparation and organization of the meeting, the moderation during the meeting as well as the writing up and distribution of the minutes to all participants after the meeting. One of the main important preparative activities is to circulate the Dataset described above of the host farm to all guest farmers as basis for discussion and inter-collegial advisory. A meeting comprises a farm walk (including demonstrating of at least one "success case") and a structured indoor discussion including two problem areas pointed out by the host farmer and subsequent inputs from each individual participant. The facilitator is responsible to guarantee that each guest farmer comments on the problem area and gives input how to solve it. Each problem area is closed by a conclusive statement of the host farmer about the next steps in this problem area to guarantee a high level of farmer ownership of the process.
Efficacy	The RELACS AHWP protocol improves animal monitoring, which allows to reduce the use of antibiotics while maintaining or improving health status. The dynamic planning process and inter-collegial experience based advising is perceived very positively by farmers.
Side effects	No side effects expected
Historic of use & regulatory status	Animal health plans exist in several European countries. They are mainly based on check lists ending up in a written plan, but such health plans don't necessary lead to an improvement in animal health situation on farms.

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	There is no requirement for registration of the AHWP at EU level. Protection of personal data should be ensured by compliance with the EU General Data Protection Regulation 2016/679.
Scalability	The method is scalable, provided that enough facilitators/moderators are available.
Costs	Labour costs mainly, related to data collection and participation in and/or facilitation of FFS. FFS require an effort of about one day annually per farmer (plus preparation time for the host farmer) and about 2 days annually per FFS participating farm for the facilitator (preparation, participation, taking notes).

6.3 Farmers' acceptance level of the alternatives proposed by RELACS

The acceptance level of farmers for the alternatives developed in RELACS to reduce the use of antibiotics was assessed during the national workshops (see section 3), taking place in Estonia, France, Germany, Spain and the United Kingdom.

National workshop showed that farmers are very interested in having access to alternatives to antibiotics, either to prevent mastitis, or to enhance udder care and healing as a complement to antibiotics in mild mastitis cases. There is also growing interest amongst advisors, veterinarians and researchers in learning about and using alternatives to antibiotics when treating and preventing mastitis. There was general agreement across the participants that antibiotics remain an important tool that is not yet ready to be totally phased out.

The **essential oils** were jointly assessed during the workshops, as they have similar characteristics and there is no difference in their mode of use. The general outcomes show that farmers, advisors and vets are rather reserved regarding the use of essential oils because of a lack of evidence on efficacy. In detail, the acceptance level is country-specific and depends on the traditional use of essential oils by farmers. France is a specific case, because organic farmers traditionally use essential oils to treat light mastitis. As a result, acceptability is higher amongst farmers, but vets are cautious and want more evidence on efficacy. The French authorities have been engaged in discussions with the agricultural sector on essential oils for several years, so the subject is somewhat better known than in other countries. In Germany, the use of essential oils is not legal and there is no real will to change the situation. In Spain, animal health professionals directly rejected essential oils. The health and welfare risks of mastitis are significant, which is why farmers, advisors and vets are not willing to accept essential oils until they have been scientifically proven to be as effective as antibiotics in treating mild to moderate mastitis. Vets would also need to have more data on their mode of action.

Unlike essential oils, the AHWP was widely accepted by farmers and acknowledged as a very effective tool to reduce antibiotics. Farmers who participated in Farmers Field Schools gave very positive feedback. Farmers Field Schools based on AHWP are seen as a successful knowledge exchange opportunity, where the proactive involvement of participants is appreciated. Although the process takes time, farmers feel that the benefits are worth the effort. However, implementing Farmer Field Schools require a higher availability of trained and funded facilitators, which is not the case everywhere. Advisors also estimate that lack of investment in exchange and training structures might be an obstacle to the dissemination of AHWP.

Finally, the workshops also showed that vets and advisors need to be involved in the process of scientific validation of essential oils and in the development of the AHWP, to ensure a greater acceptance of these alternatives.

6.4 Obstacles to the adoption of the alternatives

Essential oils are complex alternatives to assess. Proving their efficacy scientifically is complicated and requires more time and resources. Further research is also needed on the potential presence of essential oil residues in milk and the implications on food safety. In some countries, such as Germany, essential oils are not even authorised for use in on-farm trials for research purpose, which is an additional obstacle.

The EU registration process to authorise essential oils as VMP is lengthy and costly because it is not adapted to the specific characteristics of herbal veterinary medicinal products.

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Adapted advisory services and structures are necessary for a wider implementation of AHWP. This will require investments, especially to train advisors and finance their work, as the number of advisors will have to increase to effectively support the development of this tool.

At farm level, the implementation of the AHWP protocol is demanding in terms of time and involvement, as observation of animals is more time intensive. Additionally, a lot of data must be collected by farmers, in a very precise manner and following a well-defined protocol that they need to learn. Farmers must also have the ability to interpret the data, otherwise they will not see the value of this method. Finally, the implementation of the AHWP requires a change in the animal health strategy, towards more prevention. All these additional efforts may discourage farmers to adopt this tool.

The acceptance of alternatives by veterinarians has a significant influence on their adoption by farmers. AHWP demands a change in their business model which they might be reluctant to accept, while essential oils are not proven efficient and safe enough to most of them.

6.5 Strategies to overcome the obstacles: RELACS policy recommendations to support antibiotic reduction

AHWP is a promising and ready-to-implement tool for antibiotic reduction that is widely accepted among farmers. Changing vets and advisors teaching curricula will be key to widely disseminate this tool. This implies reviewing the content of their courses to include more preventive approaches, and changing their business models to ensure that their remuneration is not linked to the sale of veterinary medicines.

Farmers should also be trained to implementing AHWP, in such a way that it becomes a preventive tool to be used almost systematically. Advisory services will play a key role in this respect, therefore sufficient funding must be provided for these activities. The Common Agricultural Policy (CAP) can be used to financially strengthen advisory services.

In addition, Member States should explore the possibilities to propose CAP ecoschemes targeting antibiotic reduction strategies and the implementation of AHWP, in order to provide incentives for farmers and to compensate for the additional efforts associated with the new practices.

Finally, developing simple positive indicators for animal health should facilitate monitoring and disease prevention, and result in less frequent use of antibiotics. These indicators should be based on easily collectable health data. Developing positive indicators on the status of animal health would facilitate communication to the general public.

Essential oils are a complex topic. The lack of scientific evidence on their efficacy is a limiting factor, which needs to be overcome by further research on these aspects. However, the limited development of essential oils as alternatives to antibiotics is not only linked to research issues. Their development is also hindered by a lack of acceptance by veterinarians and the regulatory obstacles of the registration process.

To increase the level of acceptance of essential oils among veterinarians, knowledge about plants should be included in the veterinary curriculum. This would increase their awareness of the existence of herbal veterinary products and their traditional use.

The registration process of herbal veterinary medicinal products at EU level should be improved and a simplified registration process should be enabled. It is important to consider the specific characteristics of herbal products in comparison to synthetic drugs and to adopt a pragmatic approach for the risk assessment of herbal substances. Furthermore, it should be taken into account, that already about 60 medicinal plants are registered as active substances without withdrawal periods in Regulation (EU) 37/2010. With the Commission due to present a report on traditional herbal products used to treat animals in the EU by January 2027 (article 157 of Regulation (EU) 2019/6), there is an opportunity to establish an EU ad hoc expert group on this topic– managed by the Commission and including experts of animal health in organic farming systems.

6.6 Reduction pathway for antibiotics

The reduction of antibiotics in organic farming systems is possible under several conditions.

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AHWP shows a very good potential to reduce the use of antibiotics in mastitis treatments in the short term. This tool can be implemented on a large number of farms if advisors and veterinarians are trained to use this new tool and participate in its dissemination. This requires sufficient investment in advisory structures (both human and financial). Providing financial incentives to farmers implementing AHWP will further encourage the wide uptake of this tool. Developing tools to easily collect and monitor animal health data through simple and positive indicators will further support the adoption of this tool.

In the medium-term, antibiotic reduction strategies could be complemented by the use of essential oils or other herbal veterinary medicinal products, provided that research continues, and that a simplified EU registration process for traditional herbal veterinary medicinal products is put in place.

An increased involvement of veterinarians in the development of the alternatives will be an accelerating factor in their adoption, and ultimately in the reduction of antibiotics.

7. Reduction of synthetic vitamins

7.1 Problems associated with the use of synthetic vitamins

Healthy nutrition of livestock and poultry requires the addition of certain vitamins to the main plant-based feed components. Lipophilic and B- Vitamins occur naturally in plant-based feed. However, since livestock animals have a much higher metabolic rate than their wild relatives, their requirements for these substances are significantly higher.

Vitamin E is a group of fat-soluble molecules, tocopherols and tocotrienols. Vitamin E is essential for body functions such as growth, reproduction, and immunity for prevention of diseases and protection of tissues. Vitamin E is not synthesized in the rumen or the body, it needs to be supplied from feed. Fresh grass has a high concentration of vitamin E, mature crops and grain have low concentration, and preservation techniques with extensive wilting, like in haylage and hay making, reduce the vitamin E concentration strongly. Vitamin E supplementation is therefore often needed to meet the animal's requirement. This is particularly relevant during long indoor periods when preserved forages must be fed.

Vitamin B2 (Riboflavin) is an essential vitamin for all non-ruminant livestock animals. Poultry feed formulations need to contain riboflavin, in order to avoid disorders in energy metabolism, and to ensure oxidation protection of lipids, growth and neuronal control of the limbs. With increasing growth or laying performance of modern genotypes, these requirements raise due to higher metabolic turnover. This holds true also for organic poultry.

In organic systems, however, low inputs of artificial or isolated substances to animal feed are aspired. Given this background, vitamin supplements to organically managed animals should be as low as possible, yet keeping safe margins regarding animal health, welfare and productivity.

The production and use of vitamins E and B2 bears some serious conflicts with organic principles and, to a lesser extent, consumers' expectations. vitamin E is available in synthetic form and synthetic vitamins can be viewed as contentious inputs in organic agriculture. The synthetic vitamins are produced by use of strong solvents, which need special allowance under Regulation (EU) 2018/848.

Secondly, B-vitamins, which are mainly of microbiological origin, are now usually produced by genetically modified (GM) bacteria or yeast strains. However, in organic agriculture the use of genetically modified organisms (GMOs) is excluded in all levels of production by Regulation (EU) 2018/848. Organic production chains therefore rely on a limited number of alternative vitamin products. In recent years the availability of vitamin B2 produced with non-genetically modified micro-organisms has drastically reduced, increasing the risk of a supply gap for the organic sector. There is therefore an urgent need to develop separate lines for the microbial production of riboflavin without the help of GM bacteria or yeast. Such production lines are small-scale and use less efficient organisms, and thus are often more expensive.

Finally, it is worth mentioning that decisions on the nature of the vitamins and the levels of supplementation in premix and feedstuff are taken at feed industry level, not at farm level.

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7.2 Tools and techniques assessed by RELACS

Two strategies to reduce use of B and E vitamins in livestock production have been explored in RELACS. The first is the adaptation of diets based on updated data on vitamin requirements of today's organic livestock, and the second is the development of competitive non-GM high-yield yeast production strains.

Since specific recommendations for vitamin levels in organic systems do not exist, RELACS has investigated the potential to reduce the use of vitamins E and B2 in organic livestock. This was done based on the assumption that due to slightly lower growth rates and different feed formulations, lower vitamin levels than in conventional systems are feasible and do not compromise animal welfare nor productivity. Based on systematic literature review, RELACS has assessed vitamin E availability and demand in diets for organic dairy cows and reassessed recommendation for vitamin E supplementation. RELACS has also generated experimental evidence for safe lower levels of riboflavin supplementation to organic poultry feed formulations.

Finally, to increase the supply of vitamin B2 from acceptable sources, RELACS has selected high vitamin B2-producing non-GM yeast strains by established screening strategies (Kallbach et al., 2017).

The main characteristics of the alternatives assessed by RELACS are presented in the following sections.

7.2.1 Updated recommendations for vitamin E supplementation for dairy cows

RELACS has made a proposal for recommendation for cows in organic dairy production (see Table 7.2). These recommendations are based on a literature review, surveys of vitamin E status on organic dairy farms, experiments with vitamin E supplementation conducted in organic dairy farms, and the diet of major organic dairy farming types in Europe,

Table 7.2 - Comparison of Vitamin E supplementation recommendations for dairy cows in 3 dietary references (in IU/kg DMI)

	Pasture	Grass/legume silage	Other preserved forage*
Gestating, last 30 days	15/25/25	25/25/80	25/25/80
Lactating, <30 DIM	15/15/8	15/15/25	25/15/25
Lactating, <30 DIM	0/15/8	0/15/25	15/15/25

RELACS recommendations for cows in organic production
INRA feeding systems for ruminants, 2018
National Research Council, 2001

IU/kg DMI = International Units (IU) of vitamin E per kg total Dry Matter Intake (DMI)
DIM = Day in Milk

* Other conserved forages are hay, haylage, whole crop silages of grain and maize

According to RELACS recommendations, organically managed cows and heifers should receive vitam E supplements during a transition period, i.e. late gestation and early lactation. It is suggested that for dairy cows that are more than 30 days in lactation, where grazing pasture or grass clover silage is the main forage, no extra vitamin E supplementation is required. For grazing organically managed cows and heifers during the transition period, the supplementation can be reduced by about 50% relative to organic cows on preserved forages.

RELACS recommendations are the same as the recommendations given by the INRA feeding systems for ruminants published in 2018, except that:

- RELACS suggest supplementing cows in early lactation higher than the rest of the lactation, while INRA recommends the same level throughout the whole lactattion;

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- RELACS suggests less supplementation on pasture for cows during late gestation;
- RELACS suggests that supplementation is not needed to lactating cows on pasture and on high quality grass legume silages.

When grazing pasture or grass clover silage is the main forage, RELACS recommendations of vitamin E supplementation are between 75% an 95% lower than INRA 2018 and National Research Council 2001 recommendations when calculated over the whole production cycle, the period between one calving and the next. If other conserved forages are the main constituents of the diet, the RELACS recommendations are 5% lower than INRA 2018 and 50% lower than National Research Council 2001

7.2.2 Updated recommendations for vitamin B2 supplementation for chicken

Based on four different experimental approaches conducted by RELACS with organic broilers, parent hens and layers, it has been shown that vitamin B2 supplementation rates can be reduced in organic poultry systems, compared to common practices. In some cases, RELACS has defined lower safety thresholds.

	Recommended supplementation	Comparison with current recommendations for conventional poultry
Laying hens	3.0 mg Vit B2 / kg feed	66% of current recommendations
Breeding hens	4.0 mg Vit B2 / kg feed	Same level
Slow-growing broilers	4.0 mg Vit B2 / kg feed	Around 60% of current recommendations

This means that a safe reduction of up to 50% of vitamin B2 for EU countries compared to current formulations is possible. Such a reduction allows to significantly reduce the cost increase due to the use of vitamin B2 produced without the help of GMOs.

7.2.3 Alternative product: Ecovit R

Description	EcoVit R is a Riboflavin (Vitamin B2) not produced with the help of GMOs
Type of use	Riboflavin (Vitamin B2) supplementation to livestock and poultry feed.
Historic of use & regulatory status	Until 2018, certified GMO-free Riboflavin was imported to Europe from one single Chinese supplier. In order to reduce the risk of supply shortage, already since 2013, the development of an alternative yeast-based GMO-free Riboflavin product was started by a German organic food yeast producer (Agrano, Riegel, Germany). In 2018, the production in China was stopped and abruptly the availability of GMO-free feed riboflavin broke down. The development of the Agrano product was close to market at that time point, and the product (EcoVitR) is available since 2019.
Origin of raw material & production method	The product is a dried product from fermentation of the yeast *Ashbya gossypii* with organically certified sugar, potato protein, rice protein, sunflower oil and yeast extract. It contains 6g/kg riboflavin, produced by *Ashbya gossypii*.
Scalability	Small-scale production
Costs	Significantly higher

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7.3 Acceptability of the alternatives by the organic sector

As explained in section 3.1, the acceptability by organic stakeholders of the alternatives developed by RELACS to reduce the use of external vitamin E and B2 was not assessed during national workshops. However, it is still possible to analyse the main elements that could influence the acceptance of these alternatives by the sector. This is covered by this section, based on existing knowledge of the functioning of the feed industry in the organic sector.

First of all, it is important to remember that in the case of vitamins, the main stakeholders deciding on the use of alternatives are the feed and premix industries.

Regarding the revision of the requirements for vitamin supplementation, it can be expected that feed manufacturers will agree to update their formulations, provided that the recommendations are validated in scientific papers, that there is a demand from the organic livestock sector, and that their production costs do not increase (which seems unlikely since they can use less vitamins).

When it comes to new sources of non-GMO derivative vitamin B2, it is important to understand the availability of such products on the market before analysing the level of acceptance by the feed manufacturing industry. For the organic sector, the availability of vitamin B2 produced without the help of GMO is a highly important issue. The manufacturing process is technically and financially more demanding. Given that the organic farmers represent a smaller market than conventional farming, this can lead to dependence on a single supplier due to the lack of other producers on the market.

Indeed, before 2018, the European organic feed industry relied for several years on one single producer from China, which confirmed the non-GMO origin of its product via self-declaration certificates. In Autumn 2018, the Chinese producer stopped the supply on short notice, and after a few months, vitamin B2 not produced with the help of GMOs was not available anymore in Europe. Fortunately, at that time, another product, also not produced with the help of GMOs, was close to be available on the European market: the Agrano product Ecovit R. Indeed, given the unstable situation, the risk of a supply gap in vitamin B2 produced without the use of GMO had been anticipated for years by the organic sector: already in 2012 FiBL Germany and FiBL Switzerland started a project together with an organic producer of bakery yeast (Agrano GmbH & Co. KG, Riegel am Kaiserstuhl, Germany) to develop fermentation techniques for a riboflavin producing yeast strain (Ashbya gossypii). After a short supply gap in 2018-2019, the riboflavin-rich product "EcoVit R" from Agrano became available on the European market. Since March 2019, Ecovit R Powder is registered as feed material in the EU Feed Materials Register (ID Number: 008290-EN). Since it is produced according to organic standards, it is also certified organic.

Since 2020 a Dutch company Nutreco, in cooperation with a Chinese partner, is developing vitamin B2 that is produced with non-GM microorganisms. In 2021, a dossier for registration as feed additive was submitted to the European Commission. The risk assessment at EFSA is still ongoing (additional data have been requested). Given the length of the risk assessment process, the final decision for the approval of this product is not expected before mid-2023 at least.

In conclusion, it is not really relevant to analyse the potential acceptance of Ecovit R by feed manufacturers, when it is the only vitamin B2 product compatible with the organic rules currently available on the European market.

7.4 Obstacles to the adoption of the alternatives

No significant obstacles should prevent the implementation of the revised vitamin requirements for organic feed formulations. The scientific results of RELACS are promising, and adapting the manufacturing process to these new requirements should not be too demanding for feed mills.

The use of vitamin B2 produced without the help of GMOs is more challenging, for several reasons.

First, there is a lack of clarity regarding the regulatory status of Ecovit R at EU level. The Standing Committee on Plants, Animals, Food and Feed of the European Commission (SCOPAFF) suggested to treat Ecovit R as a feed additive, which would have required approval by EFSA. The producer was so far reluctant to start the approval procedure, due to economic and technical constraints, and claimed Ecovit R to be a feedstuff, a status which would not need EFSA approval. After repeated considerations by the SCOPAFF, the question of the legal status remains open. This situation has led to different approaches between Member States. In some cases, Ecovit R is considered

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as a feedstuff and is included in the national positive list for feedstuff, such as in Germany. In other cases, where Ecovit R is not recognised as a feedstuff, vitamin B2 supplementation can be provided by veterinary medicinal products containing GMO-derived vitamin B2 – which is permitted in organic farming, under veterinary advice. If uncertainty remains on the regulatory status of Ecovit R, the adoption of this product by the manufacturers of organic feed will be limited. Furthermore, the EU registration process for feed additives is lengthy and costly, which does not facilitate the clarification of the regulatory status, as the producer of Ecovit R would prefer avoiding such a lengthy process. The length of the registration process also hampers the availability of other new vitamin B2 compatible with organic production, as it was explained for the product developed by Nutreco (see section 7.3).

Another important obstacle to the use of Ecovit R is its price. Currently the market price of Ecovit R is 60€/kg. One kilogram is needed to reach the necessary concentration per ton of poultry feed. That results in extra cost (compared to conventional GMO-based riboflavin) of 20-30€ per ton of poultry feed, which is about 3-4% of the overall feed price. This higher price may discourage feed manufacturers from producing organic feed with non-GMO derived vitamin B2, as they are not sure that farmers would be willing to pay this price. Indeed, it is not clear to what extent organic farmers try to follow the vitamin recommendations for their animals, so the market is not reliable enough for feed mills.

7.5 Strategies to overcome the obstacles: RELACS policy recommendations

The case of vitamin supply to livestock shows that the field of micronutrients in organic animal feeding is little developed and supplementation levels rely on the large body of conventional feeding research, such as of national institutions (e.g., INRAe) or international industry associations such as the EU Association of Specialty Feed Ingredients. and their Mixtures (FEFANA) (Varga et al, 2022). It will therefore be necessary to target industry associations in order to promote the updated recommendations for vitamin E and B2 established by RELACS. A first step would be to disseminate scientific publications validating the results of the RELACS project, then to assess the need for further research to ensure that feed industries have sufficient evidence to implement these adaptations.

Research to determine native vitamin concentrations in raw materials in the organic diets should also be supported. It will help to refine vitamin supplementation and ultimately could allow to further reduce the use of synthetic vitamins. Currently, it is unknown to what extent a sufficient supply of vitamins is reached natively in organic diets. The European Commission announced in the EU Organic Action Plan[5] that it will support research and innovation under Horizon Europe on alternative sources of organic vitamins. This support is highly welcome. The evaluation of native vitamins concentration in organic livestock diets should be fully integrated in these research projects. Finally, diversifying the sources to produce vitamin B2 without the use of GMOs is necessary to secure the supply of feed in organic farming It will be important to integrate feed mills into the research projects, in order to facilitate the adoption of alternatives by the industry.

Integrating vitamin B2 produced without the use of GMOs in feed and premix will lead to an increase in the price per tonne of feed estimated at around 3-4%. This price increase can be limited by feed manufacturers by applying the reduced recommendations for vitamin B2 supplementation for organic poultry established by RELACS. Consultation and discussion between the different actors in the organic supply chain (feed mills, farmers, processors, retailers, consumers) could lead to a fair distribution of the cost increase among all stakeholders.

To avoid an insecure situation where the organic sector has only one supplier of vitamin B2, competing companies should be encouraged to produce organically certified vitamin B2. The specification of Ashbya gossypii (used by Agrano to produce Ecovit R) is published in a scientific publication, which make it accessible to any producer of yeast. Within RELACS, a further wild type of yeast strain, which has a riboflavin producing capacity comparable to Ashbya gossypii, has been characterized by the Thuenen Institute, which agreed to publish the specifications in a scientific publication. That means that there is not necessarily a monopoly of a single supplier, and that any yeast producer can start the production. In the medium term, this could help to improve the production process, increase the number of suppliers and lower the price of vitamin B2 produced without the use of GMOs.

[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee, and the Committee of the Regions on an action plan for the development of organic production, COM(2021) 141 final/2

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Advice and communication campaigns should be organised for organic farmers to make them aware of the vitamin needs of their animals. The use of vitamin supplementation in organic livestock can only be estimated – which was done by the RELACS project – and it is not clear if farmers are well aware of the necessity to provide vitamin supplements through feed in some cases. These campaigns would be beneficial for the animal health and welfare, and would also secure the market for vitamin B2 produced without the help of GMOs, which could encourage industries to produce it.

Finally, on the regulatory side, a clear decision in the SCOPAFF regarding the status of Ecovit R is needed. This would establish a more reliable environment for the use of Ecovit R, clarifying the situation for feed mills and harmonising the way it is used between Member States. This decision should not be based on economic reasons, but on the characteristics of the product, following the Commission's guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products (2011/25/EU). Furthermore, given the tight market situation due to the lack of alternative sources of vitamin B2 produced without the use of GMO, applications for such alternatives to be registered as feed additives at EU level should be prioritised by the Commission.

7.6 Pathway for a better adaptation of the vitamin supply to the needs of the animals in organic livestock

According to the results of the RELACS project, there is big potential to reduce the use of vitamin E and vitamin B2 in organic livestock feeding. However it is clear that these vitamins cannot be completely phased out of the diets without significantly endangering animal health.

Based on the recommendations updated by RELACS for animals raised under organic conditions, the potential reduction in vitamin E supplementation for dairy cows is estimated at around 50%, and in vitamin B2 supplementation for poultry at around 30%. These reductions could take place in the very short term, as soon as the updated recommendations are scientifically validated. It should be easy for feed mills to adopt them. There are no technical constraints for the feed industry to adapt their formulations for organic animals according to the new recommendations, nor financial obstacles since less vitamins are required, so costs should decrease. This would nevertheless require the dissemination of research results to industry.

In the long term, the use of synthetic vitamins in organic livestock production could be further reduced, by studying the level of native vitamins in the raw materials of organic animal diets. This would require support for research in this area.

The RELACS project has also shown that the supply from controlable European sources of vitamin B2 produced without the help of GMOs is possible and exists. However, the situation is still precarious as it is currently based on a single supplier (Agrano). It is therefore necessary to further develop the market of vitamin B2 produced without the help of GMOs to avoid any shortage and to ensure that there will be sufficient supply to support the growth of the organic sector. Research, economic and political actions are needed to achieve this in the coming years.

First, the European Commission has to take a clear decision on the regulatory status of products consisting of vitamin B2 produced without the help of GMOs, and it has to facilitate their registration at EU level when required, to make them available on the market in the short term. In parallel, feed manufacturers should be encouraged to produce and use vitamin B2 produced without the help of GMOs. Stimulating competition and reducing the vitamin B2 level in organic feed (according to updated recommendations) can result in a product at an acceptable price for farmers. At the same time, farmers need to be made aware of their animals' vitamin needs, which will stimulate demand for supplementation. The organic sector has a key role to play in all these actions in facilitating discussions between EU policymakers, feed manufacturers, and organic farmers.

8. Discussions

The RELACS project has shown that it is possible to reduce the use of contentious inputs used in organic livestock production, be it antibiotics, anthelmintics or external vitamins. However, a complete phase-out does not seem feasible, at least in the medium term.

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Research has developed alternative tools and methods that could quickly become available to producers, provided that clear political support is given in this direction.

First, several of the alternatives developed by RELACS are subject to a registration process at EU level, whether it is as VMP or feed additive (*Duddingtonia flagrans*, essential oils, new strain of vitamin B2). However, the specific characteristics of natural substances are hardly reconcilable with the data requirements of the EU registration procedures, which are more adapted to synthetic substances. As a result, alternatives to contentious inputs in organic farming are often blocked for years at the registration stage. Adapting the registration process to natural substances is therefore a key step to achieve a reduction in the use of contentious inputs.

Beyond the authorisation of the alternatives, there needs to be a change in the way alternatives are perceived, especially for antibiotics and anthelmintics. It seems reasonable to assume that the alternatives based on natural substances will not be as efficient as their synthetic counterparts. They should therefore be considered as a tool in a systemic approach to animal health, where immune response and nutrition will help achieving control of diseases and parasites. This is already the basis of organic farming, but by spreading this shift in animal health approach, it would then be possible to bring conventional farmers on board to reduce synthetic inputs in livestock production. Ultimately, this would contribute to the Farm-to-Fork target on the reduction of the sales of antimicrobials by 50% by 2030.

In the case of livestock production, farmers rely directly on other actors to cure or feed their animals, which is less the case for plant health. Indeed, medicines must be prescribed by a veterinarian (medication provided by the farmer is not allowed) and feed mills decide the level of vitamins in their premix. Therefore, it is key to involve these stakeholders when developing alternatives in livestock production, in order to facilitate their adoption.

For veterinarians, reducing the use of antibiotics and anthelmintics could also mean a reduction in their income, as they would sell fewer of these products. It is therefore necessary to consider how to change their business model to make it compatible with the reduction of antibiotics and anthelmintics.

Finally, research on improving the resilience of organic livestock systems is still quite scarce, and should be further supported.

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Annex I – Number and composition of participants in the national workshops

Number and composition of participants in the copper national workshops

	Belgium	Bulgaria	Hungary	Italy	Spain	UK
Advisors	2	20	3	6	4	4
Specialised farmers	5	4	3	3	3	2
Staff of organic farming associations	1	/	1	4	/	2
Members of organic farming associations	/	/	/	2	/	/
Specialised researchers	3	4	1	4	1	2
Certifying bodies	/	2	/	/	/	2
Policy makers	/	/	/	13	/	2
Manufacturers of PPPs	/	1	/	1	/	/
Others	/	/	/	/	1	/
TOTAL	**11**	**31**	**8**	**33**	**9**	**14**

Number and composition of participants in the mineral oil national workshops

	Spain	Italy
Advisors	4	8
Specialised farmers	1	4
Staff of organic farming associations	/	2
Members of organic farming associations	/	2
Specialised researchers	2	2
Certifying bodies	/	1
Policy makers	2	7
Manufacturers of PPPs	/	2
Others	/	/
TOTAL	**9**	**28**

Number and composition of participants in the nutrient national workshops

	Germany	Denmark	Hungary	Italy	Estonia
Advisors	2	2	4	4	NA
Specialised farmers	6	6	2	4	NA
Staff of organic farming associations	2	3	/	2	NA

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Members of organic farming associations	/	6	/	1	NA
Specialised researchers	2		2	2	NA
Certifying bodies		1	/	2	NA
Policy makers	1	1	/	4	NA
Manufacturers of fertilisers	/	/	/	2	NA
TOTAL	**13**	**19**	**8**	**21**	**NA**

Number and composition of participants in the anthelmintic national workshops

	Germany	UK
Advisors	2	2
Specialised farmers	4	10
Staff of organic farming associations	2	2
Veterinarians	2	8
Specialised researchers	1	2
Policy makers	1	/
Others	/	2
TOTAL	**12**	**26**

Number and composition of participants in the antibiotic national workshops

	Germany	UK	Spain	France
Advisors	2	2		5
Specialised farmers	4	10	2	4
Staff of organic farming associations	2	2	1	5
Veterinarians	2	8	4	10
Specialised researchers	1	2	5	5
Certifying bodies	/	/	/	2
Policy makers	1	/	/	10
Others	/	2	/	/
TOTAL	**12**	**26**	**12**	**41**