EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

Directorate B. Multilateral relations, quality policy
B.4. Organics

Expert Group for Technical Advice on Organic Production

EGTOP

Final Report on Cleaning and Disinfection

The EGTOP adopted this technical advice at the 12th plenary meeting of 14 – 15 December 2015 and submitted the final version on 11 January 2016.

About the setting up of an independent expert panel for technical advice

With the Communication from the Commission to the Council and to the European Parliament on a European action plan for organic food and farming adopted in June 2004, the Commission intended to assess the situation and to lay down the basis for policy development, thereby providing an overall strategic vision for the contribution of organic farming to the common agricultural policy. In particular, the European action plan for organic food and farming recommends, in action 11, establishing an independent expert panel for technical advice. The Commission may need technical advice to decide on the authorisation of the use of products, substances and techniques in organic farming and processing, to develop or improve organic production rules and, more in general, for any other matter relating to the area of organic production. By Commission Decision 2009/427/EC of 3 June 2009, the Commission set up the Expert Group for Technical Advice on Organic Production.

EGTOP

The Group shall provide technical advice on any matter relating to the area of organic production and in particular it must assist the Commission in evaluating products, substances and techniques which can be used in organic production, improving existing rules and developing new production rules and in bringing about an exchange of experience and good practices in the field of organic production.

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With regard to their declared interests, the following members did not participate in the adoption of conclusions on the substances mentioned below:

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All declarations of interest of Permanent Group members are available at the following webpage: www.organic-farming.europa.eu

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1. EXECUTIVE SUMMARY

The Expert Group for Technical Advice on Organic Production (thereafter called 'the Group') made the following recommendations:

The Group outlined an 'ecologically responsible approach to cleaning and disinfection', which aims at:

(i) achievement of a high level of microbial safety, including minimisation of the risk of micro-organisms building up resistance against control methods
(ii) minimisation of the use of disinfectants,
(iii) minimising operator safety and environmental impacts of disinfection and
(iv) achieving the lowest possible levels of residues in organic foods.

To achieve this aim:

- pathogenic microbial populations should be limited as much as possible with non-chemical methods,
- microbial risks should be reduced through conditions which do not favour growth of microbial species of concern,
- chemical disinfectants should be used only when other methods are not sufficient, surfaces should be carefully cleaned before disinfection to minimise the quantities of disinfectant needed, and
- the use of substances which cause unsafe working conditions, environmental concerns or residues in food should be avoided.

To implement this approach, a sufficient range of products for cleaning must be authorised. The Group recommends that ecolabelled cleaning products (minimum EU standard) should be used in preference, where possible. The Group proposes that ecolabelled products should be included in the basic lists, while non-ecolabelled cleaning products should be included in the restricted lists in the revised Annex VII of regulation 889/2008.

With respect to livestock production,

- the Group recommends that the current permission to use formaldehyde should be withdrawn unless there is clear evidence of need and no alternatives available. To determine these cases, the Group proposes a consultation of member states followed by a dossier review by EGTOP.
- The Group confirms that the use of sodium hydroxide in beekeeping is in line with current Annex VII and that this should not change.
- The Group confirmed that the addition of calcium oxide or calcium hydroxide to bedding materials is currently authorised, and the manure therefore has to be considered as coming from an organic farming system. Nevertheless, the Group underlines that such applications should be limited as much as possible and proposes further work in this area.
- For milking facilities, the substances listed explicitly in Annex VII should preferentially be used. In the short term, QACs should be prohibited. In the longer term, the use of cleaning and disinfection materials in milking facilities should be reconsidered.
- For disinfection of teats, the use of triclosan should be prohibited in the short term. In the longer term, disinfection of teats should be reconsidered.
- More work is recommended on footbaths and outdoor biosecurity mats

With respect to plant production,

- the Group recommends that sodium hydroxide, calcium hydroxide, sodium carbonate, organic acids, hypochlorites and oxidisers (hydrogen peroxide, peracetic acid) should be authorised for cleaning and disinfection of buildings and installations. The same substances plus alcohols (ethanol, propan-1-ol, propan-2-ol) should also be permitted for equipment.
- The Group does not propose to authorise benzoic acid at the moment, but invites submission of a dossier specifying its uses and the substances it could replace.
- More work is recommended on footbaths and outdoor biosecurity mats.
- The Group recommends that hydrogen peroxide, ozone, peracetic acid (for descaling and disinfection of irrigation systems) and other organic acids (for descaling of irrigation systems) may be used for cleaning and disinfection in irrigations systems.
- The Group underlines that the plant production sector needs sufficiently long transitional periods to ensure a smooth transition from the current regime to the proposals in this report.

With respect to food processing,

- the Group recommends that QACs and triclosan should not be used and that the use of chlorinated compounds should be restricted.
- It recommends further work on which compounds should be permitted for this area.

The Group confirmed earlier ideas for distinguishing between 'basic lists' and 'restricted lists' in Annex VII. A revised structure to Annex VII is proposed incorporating the recommendations above and suggesting improved terminology.

The Group reviewed four disinfection technologies.

- Electrolysed water was considered to be similar to sodium hypochlorite and that restrictions relevant to that compound should apply also to electrolysed water.
- UV light should be approved for use on product contact surfaces etc, but should not be used for product surface disinfection.
- Plasma gas should be approved for use on product contact surfaces etc. However, the Group cannot make a decision regarding the future of plasma gas technology in organic processing until the practical application is clarified. In the Group's opinion, a decision should be taken as soon as possible to create more certainty for investment decisions in the food industry.
- The Group found no objection to the use of bacteriophage for food disinfection providing the relevant food safety approvals are in place.

2. BACKGROUND

In recent years, several Member States have submitted dossiers under the second subparagraph of Article 21(2) of Council Regulation (EC) No 834/2007[1] concerning the possible inclusion, deletion or change of use conditions of a number of substances in Annex VII to Commission Regulation (EC) No 889/2008[2], or more generally, on their compliance with the above-mentioned legislation. In addition, questions have been raised regarding the applicability of the allowed cleaning agents for livestock production in the realms of plant production. Therefore, the

Group was requested to prepare a report with technical advice on the matters included in the terms of reference.

3. TERMS OF REFERENCE

In the light of the most recent technical and scientific information available to the experts, the Group was requested:

1. To review the substances listed in Annex VII section 1 of Regulation (EC) No 889/2008 on their appropriateness to be used for disinfection of buildings and installations for livestock as far as possible in the absence of dossiers. The Group is further asked to answer if the use of the **substances** listed below are in line with the objectives, criteria and principles as well as the general rules laid down in Council Regulation (EC) No 834/2007 and, hence, can be authorised for use in organic production under the EU organic farming legislation:

- SE dossier (2012): Sodium hydroxide (= caustic soda) for beekeeping
- Following up on its own recommendations in the Poultry Report, the Group was requested to review the use of formaldehyde for the disinfection of poultry houses, and to give consideration to alternative products (e.g. Virocid). In this respect it should be investigated whether the use of formaldehyde as disinfection agent is necessary for organic animal production.
- The Group was also requested to evaluate the suitability and advisability of Ecolabelled cleaning and disinfecting products for use in organic production (SE proposal)
- The Group was furthermore asked to consider if certain specific plant extracts should be included in the Annex, and to make an evaluation of such extracts in question (DK proposal)
- The Group was asked to evaluate whether bedding material in stables could also - besides being improved and enriched with any mineral product authorised as a fertiliser - be treated with a disinfectant, as for instant a calcium product from Annex VII, and still be considered as manure from an organic farming system (DK proposal).

2. According to Regulation (EC) No 834/2007, Art. 12(1)(j), products for cleaning and disinfection in plant production shall be used only if they have been authorised for use in organic production under Article 16. However, no substances have been approved for this purpose to date. The Commission has not received dossiers specifically for use in plant production. According to Article 95.6 of Regulation (EC) No. 889/2008, products authorised by the competent authorities may however be used.
Therefore, the Group was asked which of the substances currently listed in Annex VII to Regulation (EC) No 889/2008 for other purposes would be useful in plant production. The Group was further asked whether those substances would be sufficient to ensure disinfection in plant production, and to suggest further substances, if needed. The Group was also asked to consider the products that are currently approved on a national level.

3. The Group was asked to propose an ecologically responsible approach to cleaning and disinfection strategies within organic operations. This approach could apply to all fields of organic production (stables and livestock buildings, bee-keeping facilities, aquaculture, plant production, water irrigation systems, mushroom production, forcing of chicory, …). The Group was further asked to reflect to what extent such an approach could also be applied to post-harvest applications (storage, processing, transport) and to milking facilities. In this context, the Group

was requested to evaluate the suitability of the disinfectants used most frequently in non-organic production (such as Vircon), and to review the use of acids (such as citric acid) and hydrogen peroxide for disinfection and decalcification in irrigation systems and for water systems in animal production.

4. The Group was asked how residues of authorised disinfectants in organic foods could be minimised or avoided.

5. The Group was further asked to reflect on disinfection technologies (e.g. "electrolysed water" technology, UV light, ozone, plasma gas,…).
With respect to plasma gas the Group was asked to consider the following criteria:

- Organic principles: health, ecology, fairness, care
- Quality improvement: increase in yield and improvement of shelf life incl. reducing losses caused by fungi and bacteria
- Access to sufficient and nutritious food by reduction of food losses
- Innovation by using techniques that reflect natural processes.

4. CONSIDERATIONS AND CONCLUSIONS

Although this is the first EGTOP report dedicated to cleaning and disinfection, the Group has previously dealt with such aspects. (i) In the EGTOP report on poultry, the Group very briefly touched the substance chlorocresol, and it recommended reviewing the use of formaldehyde (chapters 3.6 and 3.7). (ii) In the EGTOP report on greenhouse production, the Group discussed cleaning and disinfection in greenhouses (chapter 3.4.5). (iii) In the EGTOP report on aquaculture (part B), the Group discussed cleaning and disinfection in aquaculture (chapter 4.5). This report is based on these previous discussions, but provides a more complete overview over the subject of cleaning and disinfection.

4.1 General considerations on hygiene management, cleaning and disinfection

The use of substances for cleaning and disinfection in organic production is regulated differently depending on the field of use. In the field of livestock production, it has been regulated already under the old organic regulation 2092/91, and the list of authorised substances has remained unchanged for many years. In the field of aquaculture, it was regulated much later, and the list has been revised recently. For the field of plant production, regulation was foreseen in 2007 when the new organic regulation was adopted, but at EU level, implementation is pending until now. However, several member states have adopted temporary national rules to fill this gap. For the field of processing, it is not regulated at the moment.

4.1.1. Terminology

Cleaning: Cleaning is the removal of 'dirt'. In the context of organic production, the primary aim is to remove micro-organisms themselves and substances which serve as substrates for microbial growth, or which provide protective environments for bacteria to survive subsequent disinfection.

Disinfection: According to the Codex Alimentarius 'General Principles of Food Hygiene', the term 'Disinfection' means "the reduction, by means of chemical agents and/or physical methods, of the number of micro-organisms in the environment, to a level that does not compromise food safety or suitability."

Note on cleaning/disinfection: cleaning and disinfection are closely related and difficult to separate. As a theoretical concept, cleaning acts by removal, while disinfection acts by killing. In practice, however, (i) many cleaning substances also have some toxic effect on micro-organisms, e.g. via high or low pH, or via surface activity against membranes. (ii) Some disinfecting substances also have a cleaning effect, e.g. strong oxidisers or alcohols.
In this document, the Group uses the following distinction: If a product contains at least one substance which is classified as a biocidal active ingredient, it is considered as a disinfectant. All other products are not considered as disinfectants. Cleaning compounds are not specifically regulated in the EU. They fall under REACH regulation (see below) regarding labelling.
In colloquial language and in trade, different terminology is sometimes used.

Descaling: is the removal of limescale from surfaces which are in contact with water (e.g. milking equipment, irrigation pipes) (=decalcination).

Decontamination: in the context of this report is the removal of specific harmful micro-organisms **from food** without necessarily achieving sterilisation.

Sterilisation in the context of this report is the procedure of making some object free of live bacteria and of other microorganisms for example by heat or chemical means.

Biocide: any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Active substance: means a substance or a micro-organism that has an action on or against harmful organisms.

Co-formulant: In the context of plant protection products, all components of plant protection products other than active substances are referred to as ‘co-formulants’. Co-formulants are sometimes also referred to as ‘formulating agents’ or as ‘inert ingredients’. The Group could not find a corresponding definition for biocidal products. In this report, it therefore uses the term co-formulants in the same way as normally used in plant protection products.

Residue: in the context of this paper, residue means a substance present in or on products of plant or animal origin, water resources, drinking water, food, feed or elsewhere in the environment and resulting from the use of a biocidal product, including such a substance’s metabolites, breakdown or reaction products.

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. REACH is governed by Reg. no. 1907/2006 of the European Parliament and of the Council.

IHO: The German association IHO (Industrieverband Hygiene und Oberflächenschutz für industrielle und institutionelle Anwendungen e.V.) has established a system for testing disinfectants, and publishes a list of disinfectants (called ‘IHO list’ below).

4.1.2 Outline of an ecologically responsible approach to cleaning and disinfection

The ‘ecologically responsible approach to cleaning and disinfection’ is about finding the right balance between the need for sufficient cleaning and disinfection and the requirement to strictly limit the use of synthetic inputs in organic production. Important elements of this approach are: (i) achievement of a high level of microbial safety, (ii) minimisation of the use of disinfectants, (iii) minimising environmental impacts of disinfection and (iv) achieving the lowest possible levels of residues in organic foods.
This chapter gives a brief outline of such an approach. However, the Group emphasises that there is not a single solution which fits all, and that such approaches need to be adapted to the specific conditions of individual operations in the context of an integrated hygiene plan, which must be implemented by sufficiently trained staff.

The overall aim: microbiological safety

The overall aim of this approach is microbiological safety. Microbiological safety relates both to humans, and also to livestock or crops. Long-term microbiological safety also includes minimisation of the risk of micro-organisms building up resistance against control methods.
To achieve this aim, it may often be necessary to kill micro-organisms. In addition, survival and growth of pathogenic and other undesired organisms must be controlled.

Role of non-chemical and chemical methods
There are numerous methods for reducing microbial populations that do not involve the use of chemical disinfectants (henceforth named 'non-chemical methods') such as easy-to-clean design of buildings and installations, appropriate organisation of processes and working schedules, tidy working habits, choice of high quality raw materials etc. Washing, cleaning and hot water/steam are of particular importance in most situations. Finally, such an approach is only successful, if it is implemented by well-trained staff. Physical disinfection technologies (see chapter 4.6) may complement this approach in some situations. Physical methods are the basis of good hygiene, and of primary importance for preventing contamination and limiting growth of microbial populations.
Non-chemical methods sometimes have complex modes of action. For example, well aerated soil in poultry ranges may reduce the levels of pathogens that are found in organic poultry houses, probably due to alterations of the soil microflora (biological mode of action mediated by management practices).
Chemical methods of disinfection should only be used as a complement to the non-chemical methods. The substances proposed for use in organic production are described in detail in chapters 4.2 – 4.5.

Management of microbial populations by influencing ambient conditions
It must be stressed that cleaning and disinfection are only parts of systems assuring food safety. Control of the factors affecting growth of micro-organisms is also important. Of these, temperature, pH (acidity) and water activity are the most relevant factors. These factors also determine which micro-organisms are best adapted and may predominate in the microbiome. Such micro-organisms can be harmless or even part of the desired flora on fermented foods. Cleaning and disinfection methods should always be more effective against pathogenic micro-organisms than against those micro-organisms involved in fermentations or in spoilage of the food (spoilage symptoms warn the consumer from eating food that could be hazardous as a consequence of e.g. temperature abuse).
There are many examples showing that colonisation of a biotope by harmless micro-organisms may also reduce the risk of growth of pathogenic contaminants. Examples are antagonists to *Listeria monocytogenes* present on the surface microbiome ('smear') of certain surface-ripened cheeses (especially those 'smeared' with a complex culture), human skin and large intestine where the autochthonous strains inhibit colonisation by pathogens, or compost with antagonistic effects on plant pathogens. These examples show that inappropriate disinfection may also have a negative effect on food safety & quality.

Methods to minimise residues in foods
This approach also aims at minimising the risk of residues or contaminants in food. This is described in more detail in chapter 4.1.9.

Summary of the ecologically responsible approach
1. Limit microbial populations as much as possible with non-chemical methods.
2. Reduce microbial risks through conditions which do not favour growth of microbial species of concern.

3. Use chemical disinfectants only when other methods are not sufficient.
4. Carefully clean before disinfection, to minimise the quantities of disinfectant needed.
5. Avoid using substances which cause environmental concerns or residues in food.
6. Ensure through training proper application of preventive measures, cleaning and disinfectants.

Note on the implementation of such approaches
The ecologically responsible approach to disinfection described here is a typical example of ‘good organic practice’. Good organic practice is primarily in the responsibility of each individual organic farmer or operator. In the field of agriculture, extension services can make a big contribution to the optimisation of farming practices, while for processing, no comparable services exist today.
It is difficult to *enforce* good organic practice through the regulatory system of organic legislation and inspection/certification. The old organic regulation (2092/91) made attempts in this direction, by authorising substances only under the condition ‘need recognised by the inspection body or inspection authority’. However, this provision was not successful, because it was implemented very heterogeneously from one certifier to the other, and was therefore discontinued. Nevertheless, it is possible to *encourage* good organic practice, by providing relevant support and information.
The promotion of good organic practice has the potential to improve the ecological performance of organic farming significantly. Good organic practice is not limited to disinfection, but applies to most farming and processing activities, and in the minimum to the use of all input categories. Good organic practice is part of the objectives and principles of organic production, as laid down in Reg. 834/2007. Nevertheless, the Group considers it worthwhile to reflect in which ways incentives leading to better organic practices can be strengthened. This will be a complex task, where the influences of the organic regulation will have to be considered in the context of general legislation, policy, support systems, market developments and the potential of research. The development of such an approach requires in the minimum a separate mandate to the Group, and possibly also an EU research project. The outcome might be a set of guidelines for different situations.

4.1.3 Aspects of biocide legislation relating to cleaning and disinfection

The use of active substances with disinfecting properties is subject to Reg. 528/2012. This regulation distinguishes between various ‘product-types’ of biocides. In the context of this report, the following product types (PT) are relevant:

- Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals (e.g. greenhouse installations, irrigation water)
- Product-type 3: Veterinary hygiene (Products used to disinfect the materials and surfaces associated with the housing or transportation of animals)
- Product-type 4: Food and feed area (e.g. food containers)

Most of the substances discussed in this report have been in use for many years (‘existing active substances’ according to Reg. 1451/2007). Such substances are subject to the EU’s biocide re-evaluation programme, but they may continue to be used under national authorisations until their re-evaluation at EU level is completed. The Group underlines that the advice given in this report is provisional, and might have to be reviewed once outcomes of the re-evaluation are published.
Substances which act as descalers or cleaning agents only are not subject to Reg. 528/2012.

4.1.4 Need for a range of authorised substances

The main targets of disinfection are fungi, bacteria, viruses, protozoa and algae, as well as certain parasites in the case of livestock production and aquaculture. Most disinfectants discussed here have a broad activity against these organisms. The choice of disinfectant therefore does not depend much on its species-specific activity, but mainly depends on whether the object to be treated tolerates the disinfectant. Substances with a disinfectant or descaling effect are reactive by nature. For example, alcohols are flammable and aggressive to certain plastics; acids and alkaline substances are caustic, hypochlorites and hydrogen peroxide are corrosive to certain materials, etc. Thus, many disinfectants, which would theoretically be effective, cannot be used in practical situations, because they would harm the installations, equipment, machinery or tools, or raise concern about occupational safety.
For this reason, organic operators need to have a choice of available disinfectants, which allows them to treat all materials in most situations.

4.1.5 Disinfection, descaling and cleaning

The substances listed in Annex VII serve three purposes: disinfection, descaling and cleaning. In this section, these three aspects are discussed separately, to allow a better understanding of the problems in various areas of organic production.
However, a number of substances from Annex VII serve multiple purposes (often to unequal degrees), so that it would be very impractical to list the substances which may be used for each purpose. The Group therefore recommends to keep the expression ‘cleaning and disinfection’ throughout Reg. 889/2008. Descaling does not need to be mentioned explicitly, because it is a special case of cleaning.

Disinfection
Disinfectants are by definition toxic to micro-organisms (and sometimes also other organisms), they are also the substances of major concern in organic production.
In the Group’s opinion, the highest priority is a clear regulation of active substances for as many uses as possible. Currently, Annex VII contains lists for livestock production and aquaculture; the extension to bee-keeping, crop production and food processing is discussed below.

Descaling
Descaling can be seen as a special case of cleaning, where the ‘dirt’ to be removed consists mainly of calcium carbonate. The presence of limescale may interfere with the functioning of tubes, pipes or taps, but they also facilitate the deposition of other dirt particles, with subsequent microbial growth. Thus, descaling is also important for microbial safety. Descaling is typically done with various acids. Some of the acids currently listed in Annex VII only serve as descaling agents, while others simultaneously have a descaling and an antimicrobial effect. Substances which only have a descaling effect are not subject to biocide legislation.
In the Group’s opinion, a clear regulation of descaling agents for as many uses as possible is desirable. Currently, Annex VII contains descaling agents in the lists for livestock production (including milking facilities) and for aquaculture; the extension to crop production and food processing is discussed below.

Cleaning
There is no agreement in the organic sector regarding the current regulatory state of cleaning, and the Group suspects that the practical implementation on what is allowed varies considerably between member states and/or certifiers.

Some actors argue that only water, steam, potassium and sodium soap are mentioned, and are therefore the only cleaning agents authorised. However, many certifiers interpret Annex VII as being only a list of authorised active substances for disinfection (analogous to Annex II), and tolerate the use of all cleaning agents. In the Group's opinion, a clarification is needed to achieve equal conditions for all operators.
In the Group's opinion, cleaning is an essential step in hygiene management, and good cleaning reduces the need for use of disinfectants. Water, steam, potassium and sodium soap are an extremely limited range of cleaning agents and are not sufficient to guarantee good cleaning under all conditions. The elaboration of a comprehensive list of cleaning agents is an extensive task which would at least require a separate sub-group with dedicated experts. Even though the Group agrees that cleaning is even more important for achieving microbial safety than disinfection, the Group focuses on disinfection and compounds not only removing, but also killing microorganisms, whether or not they are present only in disinfectants or (such as hypochlorite) in some cleaning agents, too. At the moment, the Group is not in a position to suggest a complete list of surfactants which would allow state-of-the-art cleaning. Nevertheless, it strongly recommends the use of substances which degrade rapidly and completely, and leave no residues. QAC and hypochlorite are widely used, but the Group has concerns that contamination incidents may be caused by this use, just as it may be by use of these compounds as disinfectants.
In all cases where food contact surfaces are disinfected, there is a general understanding amongst organic operators and certification bodies that, whatever cleaning substances are used, they must be rinsed off using potable water to minimise risk of the presence of these cleaning agents in the final product.
The Group suggests that the rules for cleaning should be further developed, possibly with a separate mandate.

4.1.6 Note on co-formulants of commercial products

'Co-formulants' (as defined in the section on terminology) improve characteristics such as the product's appearance, shelf-life, effectiveness or user-friendliness. For example, stabilisers are needed to increase shelf life, thickeners improve the adherence time to treated surfaces, foam suppressers are needed for use in high-pressure cleaners, buffers and sequestrants (chelating agents) reduce the corrosiveness towards surfaces and prevent deposition of scale.
Surfactants are particularly important. On one hand, they are the primary constituents of cleaning agents, which make particles such as oil and wax water soluble. On the other hand, they may be ingredients of disinfectant preparations where they lower the surface tension of water, which results in a better wetting of the surfaces and also of dirt particles and microorganisms.
In this way, the active substance can better target the micro-organisms, and its effectivity is increased. Finally, surfactants may have a negative impact on microbial cell membranes and may thus contribute to the reduction of micro-organisms. The composition of preparations is adapted to the intended use of each product. Co-formulants do not need to be declared on product labels, and are generally a secret of the manufacturer. It is therefore not possible for farmers, certifiers etc. to select products based on their co-formulants. Such ingredients are currently not regulated in other areas such as plant protection or fertilisation.
Therefore in the Group's opinion, the general regulation of co-formulants is a low priority, because it would require great efforts with limited environmental or other benefits. However, the Group could imagine specific measures to exclude a limited number of co-formulants with undesirable properties.

4.1.7 Note on ecolabelled cleaners

Introduction
The Group was requested to evaluate the suitability and advisability of ecolabelled cleaning and disinfection products.
The 'EU Ecolabel' provides detailed criteria for the voluntary labelling of various products, including certain types of cleaners. However, the ecolabel does not seem to apply to disinfectants. Detailed criteria for the labelling of certain types of cleaners are laid down by Commission Decision document no 4442 of 28 June 2011.

Reflections
The aim of the EU ecolabel, minimisation of the environmental impact, is in line with the objectives and principles of organic production. From an environmental point of view, it is thus advisable to use ecolabelled cleaners. The advantage is that operators can easily identify these products.
However, the Group is not certain whether ecolabelled products include a sufficiently broad range of substances to cover all cleaning needs of organic production. In addition, the ecolabel is granted at national level, and the Group does not know whether sufficient ecolabelled products would be available in all member states. The Group supports the use of ecolabelled products, but at the moment does not recommend an obligation to use only such products for cleaning.
If there should be a mandate on cleaning in the future, it will be worthwhile to consider the provisions of the ecolabel in more detail.

Conclusions
The Group recommends the use of ecolabelled products in preference to other products, where possible. In the new structure for Annex VII proposed by the Group, ecolabelled products should be included in the basic lists, while non-ecolabelled cleaning products should be included in the restricted lists.

4.1.8 Note on the use of plant extracts

Introduction
The Group was asked to consider if specific plant extracts should be included in Annex VII. Their use (disinfection, descaling, cleaning etc.) was not specified.

Reflections
Some plant extracts have been shown to have disinfectant properties, e.g. extracts of *Thymus vulgaris* or *Aloe vera* (Spentzouris, 2015), oregano and rosemary (de Medeiros Barbosaa et al. 2016), sumac and oregano (Gündüz et al. 2010) and Satureja extract (Amiri et al., 2013) and others (e.g. Nascimento et al. 2000; Silva et al. 2008), but additional research is needed before these extracts can be used in practice.
'Tea seed cake made of natural camelia seed' is the only plant-derived disinfectant authorised at the moment (see section 4.2.1 below). The Group is not aware of other plant extracts which can be used as active substances for disinfection today. If this is what the applicants intend, the Group recommends the submission of a dossier, which would allow the Group to carry out a proper evaluation. However, plant extracts can also be used as co-formulants of commercial

products (e.g. scents). This would be possible without listing in Annex VII according to the proposals made here.

4.1.9 Note on quaternary ammonium compounds (QACs)

Quaternary Ammonium Compounds (QACs) are a group of substances which are frequently used for cleaning and disinfection. They are applied in plant and animal production and in processing. The Group has not carried out a full evaluation, but as a preliminary opinion does not recommend their use for the following reasons: (i) many QACs are fairly persistent in the environment; (ii) some QACs cause residues in food, particularly if not fully rinsed; (iii) there is evidence that QACs can cause cross-resistance with antibiotics (Langsrud et al 2003). QACs are good cleaning agents but high water hardness and materials such as cotton and gauze pads may make them less microbiocidal because these materials absorb the active ingredients.

4.1.10 Practices to minimise / avoid contamination of organic foods

- All of the disinfectants listed in Chapter 4.5, except those mentioned below evaporate (alcohols) or decompose rapidly and completely, and therefore cause no concerns over residues.
- QACs are known to cause residues if not adequately rinsed, and are therefore not recommended for use by the Group.
- When hypochlorites come into contact with organic matter, they may react to produce various chlorinated compounds, collectively called 'disinfection by-products'. These may be present in foods as contaminants under certain situations. To minimise this risk, surfaces should first be cleaned thoroughly, and disinfected only afterwards, when as little organic matter as possible is present. This practice not only reduces residues, but also ensures good disinfection with low quantities of disinfectant. Hypochlorites may also be transformed into chlorate, which causes health concerns.

Note on implementation: It is obvious that traces of disinfectants or of disinfection by-products in organic foods (usually referred to as contaminants) are equally undesirable as pesticide residues. At the level of official food controls, however, there is a major difference in implementation. While for pesticide residues there is a comprehensive list of maximum residue levels for each possible food, there is no such system for all contaminants other than pesticides (e.g. residues of disinfectants). Thus, maximum tolerable levels have to be determined for each case on the basis of toxicological considerations and what is achievable by good food manufacturing practice. Where a substance is used as disinfectant and is used or has previously been used as pesticide, the system for pesticides applies. That is, the MRL for pesticide use applies, or if no specific MRL has been set, the 'default value' of 0.01 mg/kg applies. For example, the QAC benzalkonium chloride (BAC) is used as a disinfectant, but has been used as a fungicide in the past. Residues of BAC are thus considered as pesticide residues, even if it is more likely that they are caused by the use of a disinfectant. This can cause problems for risk management. As an example, there have been detections of QACs in organic products caused by cleaning agents (see EFSA, 2015). For an overview of QAC residues in various types of food, see EFSA (2013).
A further example of contaminations originating from disinfection today, but classified as pesticide residues because of past use as herbicide is chlorate (Zunker et al. 2015). Until 2008, use of chlorate as a herbicide was permitted. For pesticides which are not authorised any more,

Regulation (EC) No. 396/2005 (Chapter 3, Art. 18, 1b) specifies a maximum level of 0.01 mg/kg food. On the other hand, the WHO (2005) [Stand 2015-06-03] specified a preliminary maximum level of 0.7 mg chlorate/l in drinking water. Chlorate may be formed in solutions containing hypochlorite if their pH is too low, and the reaction is favoured by heat and UV light. Such solutions may be, within restrictions, used legally for drinking water disinfection. Hence, the maximum level of 0.01 mg/kg food may be exceeded if vegetables are washed with chlorinated drinking water, or if drinking water is used for irrigation.
It is the Group's impression that there is not equivalent treatment of pesticide residues and disinfectant contaminations with respect to organic food. More guidance in this area would be useful as issues of food quality and contamination are very critical for consumer trust in organic products. The Group therefore suggests that these aspects should be explored in detail.

4.2 Cleaning and disinfection agents in organic animal production

4.2.1 Overview of currently authorised substances

Introduction
In this chapter, an overview of all substances currently listed in Annex VII as substances allowed in animal husbandry (rev Art 23 (4) ECC Reg. 889/2008) is given. Substances are grouped according to their chemical properties and mode of action. The Group did not carry out a full evaluation of the substances, and has not thoroughly investigated whether each substance should remain listed.

Alcohols
There is a listing of 'alcohol' in Annex VII (1) and in Annex VII (2). This entry is ambiguous:

- In colloquial language, 'alcohol' refers to ethanol.
- In chemistry, an alcohol is an organic compound in which a hydroxyl functional group is bound to a carbon atom (e.g. methanol, ethanol, propanol etc.). In the context of disinfection, ethanol and 'isopropanol' (IPA) are most relevant, while n-propanol is used less frequently. Under EU biocides legislation, isopropanol is (correctly) referred to as 'propan-2-ol', and n-propanol as 'propan-1-ol'. For simplicity, propan-1-ol and propan-2-ol are collectively referred to as 'propanols' in this paragraph.

The Group could not find out which of the two meanings were originally intended. It is thus clear that ethanol is authorised, but it is unclear whether propanols are also authorised. The Group suspects that both interpretations occur among European certifiers, meaning that propanols are accepted by some certifiers, but not by all.
Alcohols are predominantly used for disinfection of surfaces, tools, hands etc. During this use the risk of explosion must be controlled for example by wiping rather than spraying, and ensuring that electrical devices are not switched on before 10 minutes after use.
In the absence of a dossier, the Group has not carried out a full evaluation of propanols. However, the Group has not identified relevant differences between ethanol and propanols other than boiling point, and therefore makes the preliminary recommendation that all these alcohols should be authorised.
None of these compounds represent risks of residues as they are all volatile. There are no MRLs set for either compound in food products.

Alkaline salts of calcium, sodium and potassium
Hydroxides are salts containing hydroxyl ions (OH). Their aqueous solutions are strongly alkaline. Under such conditions, proteins are modified and their removal from surfaces is

favoured, and fats may be partly saponified and can be removed more easily, too (Holah 2014; Marriott and Gravani 2006). Strong alkaline conditions also have some anti-microbial effect. The following hydroxides are currently listed:

- Sodium hydroxide is mentioned in Annex VII(1) and in Annex VII(2.1) under the common name 'caustic soda'. It is not listed in the EU biocides database.
- Potassium hydroxide is mentioned in Annex VII(1) under the common name 'caustic potash'. It is not listed in the EU biocides database.
- Calcium hydroxide is mentioned in Annex VII(1) under the common name 'milk of lime'. Strictly speaking, milk of lime refers to a suspension of calcium hydroxide particles in a solution of calcium hydroxide. Calcium hydroxide is also listed in Annex VII(2.1). Calcium hydroxide is under review as a disinfectant.

Calcium oxide (CaO) is mentioned in Annex VII(1) under the common name 'quicklime'. Calcium oxide is also mentioned in Annex VII(2.1). Calcium oxide is unstable. In contact with air, it converts to calcium carbonate. When it comes in contact with water, it reacts violently (heat production) and forms calcium hydroxide.

Carbonates are salts containing carbonate ions (CO_3^{2-}). Their aqueous solutions are alkaline. The following carbonates are currently listed:

- Calcium carbonate (common name: limestone) is mentioned in Annex VII(2.2). In addition, there is a listing of 'lime' in Annex VII(1). This term is ambiguous, but it probably refers to limestone. It is not listed in the EU biocides database. The Group is not aware of any use for cleaning or disinfection in the narrow sense. However, calcium carbonate is traditionally used for painting stable walls for hygiene purposes and to control stable flies.
- Calcium magnesium carbonate is listed in Annex VII(2.2) under the common name dolomite. It is not listed in the EU biocides database.
- Sodium carbonate is mentioned in Annex VII(1). This substance is also known as washing soda. Use as water softener and descaling agent (decalcification). It is not listed in the EU biocides database.

The Group has not carried out a full evaluation, but considers that all of these compounds should be added to the basic list of cleaning and disinfection compounds.
These compounds are considered ubiquitous in nature, so residues left as a result of their use are unlikely to be detectable over the normal background levels.

Organic acids
Organic acids are organic compounds with acidic properties. Because of their acidic properties, acids can potentially be used to remove limescales (descaling agents, decalcination agents). In addition, some acids also have disinfecting properties. The following organic acids are listed (Note: Peracetic acid and peroctanoic acid are considered below under oxidising agents)

- Acetic acid is listed in Annex VII(1) and in Annex VII(2.1). It can be used as descaling agent, but not as a disinfectant.
- Citric acid is listed in Annex VII(1) and in Annex VII(2.1). It can be used as descaling agent, but not as an agricultural disinfectant (the only use as disinfectant is for human hygiene).
- Formic acid is listed in Annex VII(1). It is under review as a disinfectant, under the biocide regulations.

- Lactic acid is listed in Annex VII(1) and in Annex VII(2.1). It occurs in two forms (called L and R, or plus and minus). The form L-(+)-lactic acid is under review as a disinfectant under the biocide regulations.
- Oxalic acid is listed in Annex VII(1). It can be used as descaling agent, but not as a disinfectant.

These compounds are considered ubiquitous in nature, so residues left as a result of their use are unlikely to be detectable over the normal background levels. Further many are volatile so will evaporate from the area or surfaces in which they are used.

The Group has not carried out a full evaluation, but considers that all of these compounds should be added to the basic list of cleaning and disinfection compounds.

Inorganic acids

Nitric acid and phosphoric acid are both listed in Annex VII(1), but their use is restricted to dairy equipment. Aqueous blends of nitric acid and phosphoric acid are commonly used for cleaning food and dairy equipment. They dissolve calcium and magnesium compounds, but they do not act as disinfectants.

Neither of these compounds present significant risks of residues as they are ubiquitous in nature and levels in foods would exceed those added by low level contamination from their use as cleaning compounds, particularly as they are readily rinsed. Therefore residues of their use as descalants are unlikely to be detectable over the normal background levels.

The Group has not carried out a full evaluation, but considers that these two compounds should remain authorised for milking facilities, and could possibly be authorised also for other uses except plant production, where there is a risk of dual use as a non-permitted fertiliser (see also chapter 4.3.4 below)

Hypochlorites

Hypochlorites cause broad microbial mortality by damaging the outer membrane, producing a loss of permeability control and eventual lysis of the cell. In addition, these compounds inhibit cellular enzymes and destroy DNA (Virto et al., 2005). Hypochlorites are also effective against bacterial spores but since these are more resistant than vegetative microorganisms, longer exposure times and/or higher concentrations of hypochlorite may be required (see e.g. Böhm 2002). Hypochlorites contain the hypochlorite anion (ClO^-), which is a strong oxidiser. The following hypochlorites are listed:

- Sodium hypochlorite is listed in Annex VII(1) and in Annex VII(2.1). It is under review as a disinfectant. Aqueous solutions of sodium hypochlorite are known as bleach.
- 'Calcium hypochlorite' is listed in Annex VII(2.1). It is under review as a disinfectant. Preparations containing calcium hypochlorite are distributed as powder or tablets, in which the hypochlorite is more stable. Hence, this compound is safer from the occupational health point of view and easier to handle.
- 'Mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid' are listed in Annex VII(2.1). Their use was discussed in the EGTOP report on aquaculture (part B), chapter 4.5.5. and they are now approved for use in aquaculture under the regulation.

The Group has some concerns over the use of hypochlorites. Firstly, disinfection with hypochlorites in the presence of organic matter leads to the formation of a great number of 'disinfection by-products'. (Hanberg 1996). Many of these chlorinated by-products are not readily biodegradable and/or toxic. They may thus pollute the environment, and in some cases they may even migrate into foods as contaminants. Secondly, the use of chlorine-based

disinfectants has been associated with the presence of chlorate contaminations in food (EFSA, (2015) (2). Finally, they pose a severe (potentially deadly) occupational health hazard, if they accidentally get into contact with acids.
Furthermore, if sodium hypochlorite is stored inappropriately the level of chlorine will drop and chlorate will raise, reducing the effectiveness of the disinfection while increasing the level of contamination with chlorate. Therefore operators must take care to ensure correct storage and to check active chlorine before use and adjust dosing accordingly. Further detailed control of their use including pH control, & chlorine content during cleaning could help to reduce these risks (Gil et al 2009).
On the other hand, the Group is aware of the current reliance of the food sector on these compounds, and does not consider it realistic to delete hypochlorites from Annex VII in the short term. Nevertheless, a substantial reduction or possibly a complete replacement of hypochlorites should be the long-term aim. This may necessitate some research into alternatives, and it also requires a more detailed evaluation, where necessity is considered separately for different fields of use. Precise information by member states on which uses are considered as essential would be the basis for a sound re-evaluation.

For the moment, the Group recommends that the listing of sodium hypochlorite in Annex VII remains unchanged. Calcium hypochlorite and mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid should be authorised for all uses for which sodium hypochlorite is authorised.

Peroxides and other oxidisers
Peroxides are compounds with an oxygen-oxygen single bond. Peroxides are unstable, and will easily split into reactive radicals. The following peroxides are listed:

- Hydrogen peroxide is listed in Annex VII(1) and in Annex VII(2.1). It is under review as a disinfectant.
- Ozone is listed in Annex VII(2.1). It is often considered separately from the peroxides, although it also contains oxygen-oxygen bonds. It is under review as a disinfectant according to biocide regulations.
- Sodium percarbonate is listed in Annex VII(2.2). This substance liberates hydrogen peroxide. Its use is discussed in the EGTOP report on aquaculture (part B), chapter 4.5.3. and has been approved for use in aquaculture under the regulation.
- Peracetic acid is listed in Annex VII(1) and in Annex VII(2.1). It is listed a second time in Annex VII(2.1) under the synonymous term ‘peroxyacetic acid’. It is under review as a disinfectant (mode of action: oxidiser).
- Peroxyoctanoic acid (octaneperoxoic acid) is listed in Annex VII(2.1) under its synonym ‘peroctanoic acid’. It is under review as a disinfectant (mode of action: oxidiser). The Group was not able to find evidence of significant use of this compound.

Of these compounds the risks of residues are low as the oxygen-oxygen bond breaks to leave elemental oxygen, which react to form $O_{2,}$ or ubiquitous oxidised compounds, with no significant toxicity. The only non ubiquitous residue may be octanoic acid from peroxyoctanoic acid, This is unlikely to be of significant toxicity and is readily biodegradeable
The Group has not carried out a full evaluation, but considers that all of these compounds should be added to the basic list of cleaning and disinfection compounds.

Miscellaneous substances in Annex VII(1)
‘Potassium and sodium soap’ are listed in Annex VII(1). They are not disinfectants, and their use is mainly as surfactants. However, they may have some impact on microbial cell membranes and

thus contribute to the reduction of micro-organisms. For a more detailed argumen on why surfactants should not currently be listed in Annex VII, see chapter 4.1.6.

‘Water and steam’ are listed in Annex VII(1). Water has no activity as a disinfectant, but it is a common component of commercial cleaners and disinfectants, and it is almost inevitably used in all cleaning and disinfection activities. However, water is used in all activities of organic plant production (irrigation), animal husbandry (drinking water), aquaculture and often also in food processing. Steam may also be used for cleaning, and its heat has a physical effect as disinfectant. In the Group’s opinion, water and steam may be used without being listed. Therefore, the Group recommends to delete water and steam from Annex VII.

‘Natural essences of plants’ are listed in Annex VII(1). The Group is not aware of any practical uses of these substances for cleaning or disinfection. The Group hypothesises that they were probably included to cover fragrances which might be added to some commercial products. For a more detailed discussion on whether fragrances, or more generally co-formulants, should be listed in Annex VII, see 4.1.6. For a short discussion about plant extracts see chapter 4.1.8.

Formaldehyde is currently listed in Annex VII(1). For a more detailed argumentation whether formaldehyde should be deleted from Annex VII, see chapter 4.2.3

‘Cleaning and disinfection products for teats and milking facilities’ are listed in Annex VII(1). This listing allows all substances for these purposes. For a more detailed discussion, see chapter 4.2.7

Miscellaneous substances in Annex VII(2)
Copper sulphate may only be used until 31 December 2015, and is therefore not further discussed here.

‘Tea seed cake made of natural camelia seed’ is listed in Annex VII(2.1). It is used as a disinfectant for empty ponds (fallowing procedure). Its use is currently restricted to shrimp production. The Group did not evaluate this entry.

Sodium chloride is listed in Annex VII(2.2). The use of sodium chloride is discussed in the EGTOP report on aquaculture (part B), chapter 4.5.6. and has been approved for use in aquaculture under the regulation

Iodophors are listed in Annex VII(2.2) with the restriction ‘only in the presence of eggs’. The Group has previously pointed out that there is a need for clarification regarding iodophors in Aquaculture (EGTOP report on aquaculture (part B), chapter 4.5.8).

Potassium permanganate is listed in Annex VII(2.1). The Group has previously pointed out that there is a need for clarification regarding this entry (EGTOP report on aquaculture (part B), chapter 4.5.8). Without knowing the precise use, the Group cannot perform a proper evaluation. The Group therefore suggests the following way ahead:

- The member states should be consulted whether potassium permanganate is still in use in their country, and a future decision must be taken regarding continued use depending upon the outcome of that survey.
- The Group recommends removal of this compound unless the survey above reveals specific and justifiable uses in aquaculture.

Humic acid is listed in Annex VII(2.1). Humic acids are a complex mixture of many different acids containing carboxyl and phenolate groups. They are a principal component of humic substances, and occur mainly in soil, peat and water bodies. They are not known to be disinfectants. The Group has previously pointed out that there is a need for clarification regarding this entry (EGTOP report on aquaculture (part B), chapter 4.5.8). Without knowing the precise use, the Group cannot perform a proper evaluation. The Group therefore suggests the same way ahead as for potassium permanganate.

4.2.2 Harmonised terminology for currently authorised substances

Some terms used in Annex VII are colloquial, outdated, ambiguous or inconsistent between Annex VII(1) and VII(2). The Group decided to use the nomenclature used by the European Chemicals Agency (ECHA) in the context of biocides legislation.
The Group suggests using the ECHA terminology also in Annex VII. For some substances, however, common names should be added in brackets as a help for organic operators. Table 1 shows the proposed new terms, together with the terms currently used in Annex VII.

Table 1: proposed new terminology for the substances currently listed in Annex VII. * no listing proposed (see discussion in text); ** listing depends on member state consultation (see discussion in text).

Proposed new terminology	**Current terminology in Annex VII(1)**	**Current terminology in Annex VII(2)**
Alcohols		
ethanol, propan-1-ol, propan-2-ol (alcohols)	alcohol	alcohol
alkaline salts of calcium, sodium and potassium		
sodium hydroxide (caustic soda)	caustic soda	caustic soda
potassium hydroxide (caustic potash)	caustic potash	-
calcium hydroxide (slaked lime)	milk of lime	calcium hydroxide
calcium oxide (quicklime)	quicklime	calcium oxide
calcium carbonate (limestone)	lime [?]	limestone (calcium carbonate)
calcium magnesium carbonate (dolomite)	-	Dolomite
sodium carbonate	sodium carbonate	-
organic acids		
acetic acid	acetic acid	acetic acid
citric acid	citric acid	citric acid
formic acid	formic acid	-
lactic acid	lactic acid	lactic acid
oxalic acid	oxalic acid	-
inorganic acids		
nitric acid	nitric acid	-
phosphoric acid	phosphoric acid	-
hypochlorites		
sodium hypochlorite (bleach)	sodium hypochlorite (e.g. as liquid bleach)	sodium hypochlorite
calcium hypochlorite	-	calcium hypochlorite
mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid	-	mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid
peroxides and other oxidisers		
hydrogen peroxide	hydrogen peroxide	hydrogen peroxide
Ozone	-	Ozone
Peracetic acid	peracetic acid	peracetic acid, peroxyacetic acid
Peroxyoctanoic acid	-	peroctanoic acid
Sodium percarbonate	-	sodium percarbonate
Miscellaneous substances in Annex VII(1)		
*	potassium and sodium soap	-
*	water and steam	-

Proposed new terminology	**Current terminology in Annex VII(1)**	**Current terminology in Annex VII(2)**
*	natural essences of plants	-
**	formaldehyde	-
Cleaning and disinfection products for teats, hands and milking facilities	cleaning and disinfection products for teats and milking facilities	-
Miscellaneous substances in Annex VII(2)		
*	-	copper sulphate
potassium permanganate **	-	potassium permanganate
tea seed cake made of natural camelia seed	-	tea seed cake made of natural camelia seed
sodium chloride (salt)	-	sodium chloride
humic acids **	-	humic acid
Iodophors	-	iodophores

4.2.3 Formaldehyde

Introduction, scope of this chapter
In the EGTOP report on poultry, the Group has suggested to re-evaluate the use of formaldehyde.

Authorisation in general agriculture and in organic farming
Under Biocide legislation, formaldehyde is considered as an 'existing substance', and its use remains authorised until its re-evaluation is completed. Its use for veterinary hygiene is currently under review.
The IHO list of disinfectants for animal husbandry and food processing in Germany contains only few preparations based on aldehydes, and these are predominantly based on glutaraldehyde rather than formaldehyde (IHO 2015). According to Böhm (2002), formaldehyde (1 – 3 %) is used for disinfection of animal housings. However, this publication dates from 2002 and the Group does not know to what extent this is still true today.

Agronomic use, technological or physiological functionality for the intended use
Formaldehyde is a broad-spectrum disinfectant. It is also a feed additive and a silage additive, but not in organic farming. These latter uses are not within the scope of this report.

Necessity for intended use, known alternatives
Formaldehyde is used in animal husbandry for disinfection of pig and poultry houses and in case of persistent hoof problems when animal welfare is at stake, it is occasionally used in footbaths for ruminants. In plant production, it is used in mushroom buildings for disinfection between crops. Formaldehyde has been permitted under Annex VII of the organic regulations but the Group does not have data on the current extent of its use by organic producers. Annex VII contains several other substances which could potentially replace formaldehyde.
Based on the IHO lists of tested disinfectants in Germany, the Group assumes that formaldehyde could be replaced with other disinfectants.
However, the Group understands that formaldehyde preparations are effective in disinfections of animal housings, especially in cases of transmittable animal diseases, e.g. caused by viruses

(Böhm, 2002; EFSA 2009b). In some cases, the veterinary authorities specify the disinfection methods to be used. The use of formaldehyde for such purposes is outside the scope of the organic regulations.

Origin of raw materials, methods of manufacture
Traces of formaldehyde are ubiquitous in nature. It is produced in the atmosphere by photo-oxidation. The material used for disinfection is usually manufactured by catalytic oxidation of methanol.

Environmental issues, use of resources, recycling
From the environmental point of view, formaldehyde raises no concerns. It is biodegradable and easily broken down by sunlight. Further, it is not persistent in the environment and does not bioaccumulate.

Animal welfare issues
The Group assumes similar effects as in humans. If used only in the absence of animals, effects can be avoided.

Human health issues
Formaldehyde is an irritant and potentially toxic. Irritation starts at about 1ppm. Formaldehyde is also an IARC Class 1 human carcinogen (based on oro-pharyngeal cancer incidence). The level required appears to be in the order of 10 – 100 ppm.
The odour detection threshold is below 1 ppm and the odour is unpleasant. This can help avoid exposure. Provided that the personnel are adequately trained and equipped, the risks of formaldehyde use can be managed. The main risks occur for inadequately equipped or trained personnel. However, organic regulations cannot guarantee safe use and given the potential health risks, the Group does not consider its use to be consistent with organic principles.

Food quality and authenticity
There are some indications in the literature that residues of formaldehyde can be detected in products such as milk (e.g. EFSA, 2014). These appear to be derived from the use of formaldehyde as a feed preservative. The EU has now prohibited the use of formaldehyde as a feed preservative, but this was not a permitted use in organic farming anyway.

Traditional use and precedents in organic production
It is traditionally authorised in EU organic farming.

Aspects of international harmonisation of organic farming standards
The Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced foods (revision 2013) do not contain provisions concerning disinfectants. Under USDA National Organic Standards, formaldehyde is not permitted (neither in plant nor in animal production). Under the IFOAM standard for organic production and processing (version 2014), formaldehyde is not included in the indicative list of equipment cleansers and equipment disinfectants (appendix 4 – table 2).

Other relevant issues
None.

Balancing of arguments in the light of organic production principles

The fact that formaldehyde breaks down rapidly and completely is positive from an environmental point of view. However, several other substances from Annex VII (e.g. peroxides, peracetic acid or ozone) also break down rapidly and completely. Also, its natural occurrence is in line with the principles of organic production.
From the occupational health point of view, formaldehyde is undesirable.
In the Group's opinion, the present, unlimited authorisation is clearly not adequate for this substance. However, given the existence of alternative products, the Group recommends withdrawing formaldehyde from Annex VII unless there is clear evidence of need for specific purposes where there are no alternatives.

Conclusions
Member states should be consulted on whether there is any evidence that there are specific uses for which formaldehyde is essential (i.e. there are no alternatives). Depending on the outcome of this consultation, formaldehyde should either be deleted from Annex VII, or its use should be strictly limited to clearly defined uses and for a limited period of time. In this case, a dossier demonstrating the need and specificity of use should be presented to EGTOP for evaluation.

4.2.4 Use of sodium hydroxide in beekeeping

Introduction, scope of this chapter
Sodium hydroxide (caustic soda, NaOH) is included in Annex VII(1) and in Annex VII(2.1). It may thus be used in livestock buildings and installations, and in aquaculture equipment and facilities.
The Group was asked whether its use should be extended to organic beekeeping.

Authorisation in general agriculture and in organic farming
Regarding the use under general legislation, the Group consulted a document issued by the Swiss authorities (BLV, BLW, BAG and Swissmedic 2013). According to this document, sodium hydroxide and sodium carbonate may be used to clean beehives after infestations with foulbrood. Sodium hydroxide is considered as a cleaning agent in this context, and not as a disinfectant. The Group could not find an entry of sodium hydroxide in the biocidal active substances database operated by ECHA.
At the moment, any instances of foulbrood must be reported to the authorities, who prescribe disinfection of the hives and define the methods and substances to be used. In this situation, the prescribed disinfection methods must be used by organic farmers. However, it is still useful to authorise such methods for organic production, to avoid problems with certification for the organic beekeeper.
It was not trivial for the Group to work out whether the organic regulation covers cleaning and disinfection in beekeeping. Annex VII(1) applies to 'livestock production' and refers to Art. 23(4), which refers to Art. 14(1)(f) of Reg. 834/2007. As Art. 14 of Reg. 834/2007 is entitled 'livestock production rules' and contains also rules on beekeeping, the Group concluded that the definition of 'livestock' includes bees. Therefore, Annex VII(1) applies also for beekeeping.

Agronomic use, technological or physiological functionality for the intended use
There are two types of foulbrood. 'American foulbrood' is caused by the bacterium *Paenibacillus larvae*, while 'European foulbrood' is caused by the bacterium *Paenibacillus alvei* or by *Melissococcus plutonius*. Both diseases are deadly for the infected hive. When such an infection has occurred, all frames and other equipment have to be cleaned thoroughly, before they are re-colonised with healthy bees, otherwise, the new bees will be re-infected by spores of

the bacteria. For cleaning, the equipment is submersed into a hot solution of sodium hydroxide for 15 minutes.

Necessity for intended use, known alternatives
An effective method for disinfection is clearly necessary. There are several methods for disinfecting, including sodium carbonate and sodium hydroxide. According to the dossier, sodium hydroxide is the most effective. The only non-chemical alternative would be to burn all infested equipment, but this is neither ecologically beneficial nor economically realistic.

Origin of raw materials, methods of manufacture
Sodium hydroxide is synthetic. It is industrially produced by the ‘chloralkali process’. In this process, chlorine and sodium hydroxide are produced by electrolysis of salt (sodium chloride) brine. The process requires high amounts of electrical energy.

Environmental issues, use of resources, recycling
The Group has no concerns.

Animal welfare issues
Rigid control of foulbrood is essential for the survival of bees.

Human health issues
Sodium hydroxide is potentially hazardous, but if it is correctly used and personal protective equipment is worn, the Group has no concerns.

Food quality and authenticity
No impact expected.

Traditional use and precedents in organic production
The old European organic regulation (2092/91) did cover cleaning and disinfection in beekeeping, and sodium hydroxide was explicitly authorised.

Aspects of international harmonisation of organic farming standards
The Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced foods (revision 2013) do not contain provisions concerning disinfectants. Under USDA National Organic Standards, sodium hydroxide has restricted applications in crop production and in food processing, but not in animal husbandry. Under the IFOAM standard for organic production and processing (version 2014), sodium hydroxide is included in the indicative list of equipment cleansers and equipment disinfectants (appendix 4 – table 2).

Other relevant issues
None.

Balancing of arguments in the light of organic production principles
The Group sees a need for this use of sodium hydroxide, and has no objections.

Conclusions
In the Group’s opinion, the use of sodium hydroxide in beekeeping is in line with the objectives and principles of organic production. This practice is authorised under the current organic regulation, because sodium hydroxide is listed in Annex VII(1), and this Annex also applies also for beekeeping. The Group therefore sees no need for amendments of Annex VII.

4.2.5 Note on the addition of disinfectants to bedding materials

Introduction, scope of this chapter
The Group was asked whether bedding material could be treated with a disinfectant, for example, a calcium product from Annex VII, and still be considered as manure from an organic farming system.
The use of calcium hydroxide (slaked lime) for this purpose is described by Gleeson (2013). Some companies also sell calcium oxide (quicklime) for this purpose. Depending on the animal husbandry system, manufacturers recommend weekly dosages between 100 and 500 g/m^2.

Reflections on the fate of calcium oxide
When calcium oxide is added to the bedding material, it will be converted to calcium hydroxide & subsequently to calcium salts, such as calcium carbonate. Calcium carbonate is authorised as a fertiliser, although only of natural origin.

Reflections on necessity and alternatives
In some regions, the addition of calcium oxide to bedding material seems to be quite a common practice. According to manufacturer's information, products based on calcium oxide inhibit the growth of pathogens like *Klebsiella*, *Pseudomonas* and *E. coli*, thus limiting the spread of udder and hoof infections via the bedding material. The effect is said to be associated with the raised pH in the bedding material. One independent study supports the finding of the reduction in pathogens by calcium hydroxide application to bedding (Gleeson 2013).
In some cases, especially if cattle cannot stay outside the housing for sufficient time, the addition of a disinfectant to the bedding material may help to prevent udder infections. However, alterations in the management system, and in particular the increased use of straw, would be an alternative, which is clearly preferred by the Group. In the Group's opinion, the addition of disinfectants to the bedding material should only be a last resort, if management practices alone do not have a sufficient effect.
In cases where the use of a disinfectant is necessary, the Group supports this practice for the sake of milk quality, and also for reasons of animal health and welfare. Also, the use of calcium hydroxide or calcium oxide may reduce the need of using antibiotics for animal therapy.

Reflections on the regulatory status and on good organic practice
Calcium hydroxide and calcium oxide are listed in Annex VII(1) without restrictions, and may therefore also be used in bedding materials.
However, even authorised substances can be used in better and in sub-optimal ways. In the Group's opinion, good organic practice in this particular case means that disinfectants are only added to the bedding material as a last resort, and for a limited time. By contrast, the routine addition of calcium hydroxide or oxide to the bedding material is a suboptimal organic practice. A more general discussion on the promotion of good organic practice can be found in section 4.1.2.

Reflections on the organic quality of manure

Because (i) the bedding material and manure is of organic quality, (ii) calcium hydroxide and calcium oxide are listed in Annex VII (1) without limitations and (iii) the resulting calcium carbonate is authorised as a fertiliser according to Annex IIA, the Group concludes that manure/

bedding material treated with calcium hydroxide or calcium oxide can be considered of organic quality.
If there should be an intention to limit or prohibit the addition of calcium hydroxide or oxide to bedding material, this should be done in the context of the rules on animal husbandry.

Conclusions
The addition of calcium oxide or calcium hydroxide to bedding materials is currently authorised and the manure therefore has to be considered as coming from an organic farming system.
Nevertheless, the Group underlines that such applications should be limited as much as possible, and should not be a routine practice. The Group suggests to explore how good organic practice can be further promoted, in this particular case as well as in many others, possibly through a separate mandate to the Group, and/or an EU research project.

4.2.6 Cleaning and disinfection agents for milking facilities

Introduction, scope of this chapter
The Group was asked to reflect to what extent an ecologically responsible approach to cleaning and disinfection could also be extended to milking facilities, and to evaluate the suitability of the most frequently used products. Because the cleaning of dairy equipment on farm is identical to and inseparable from cleaning of dairy equipment in processing plants for dairy products, the considerations in this chapter are also relevant for the dairy industry (see chapter 4.4).

Preventive measures
Disinfection in milking facilities starts with the general hygiene of the building, floors, external surfaces etc, and with precautions such as foot baths etc. Cleaning and disinfection of teats is also important, but this is discussed in a separate chapter below (4.2.7).

Frequently used substances
Cleaning and disinfection of milking facilities is done according to a hygiene plan, which defines a sequence of substances to be used. It usually contains acidic, alkaline and peroxo compounds, together with various cleaning agents.
Among the substances listed in Annex VII, peracetic acid, sodium hydroxide and sodium hypochlorite, nitric and phosphoric acids and iodophores are regularly used. However, the use of other substances is currently also permitted. The Group's attention was drawn to a product based on a mixture of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid. The Group was previously asked to evaluate this product in the context of aquaculture. The Group does not evaluate commercial products, but generic substances such as the active ingredients of commercial products. The evaluation can be found in the EGTOP report on aquaculture (part B), chapter 4.5.5. As the Group proposes above (see 4.2.1) to include mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid in the restricted list of Annex VII(1.2), it would also be authorised for use in milking facilities.

Reflections
The substances listed explicitly in Annex VII should preferentially be used in milking facilities. The use of other substances is only justified if these substances cannot be used. The current practice on organic dairy farms deviates considerably from this approach.
From the technical point of view, the Group sees the possibility to carry out most (but not all) disinfections with the substances explicitly listed in Annex VII. The Group identified the following obstacles for implementation: (i) currently, the organic regulation does not

communicate such a priority; (ii) some manufacturers of milking facilities prescribe which products must be used, and limit their product liability, if other products are used; (iii) automated milking facilities have in-built programmes for cleaning and disinfection, and the dairy farmer has no control over the substances used.
If the priority for explicitly listed substances would be better communicated, substantial progress might be made by organic dairy farmers on a voluntary basis (see discussion on 'good organic practice' above (4.1.2).
For further-reaching progress, joint efforts by organic dairy farmers, manufacturers on cleaning and disinfection products and manufacturers of milking facilities are required.
For the moment, the Group sees no possibility to restrict the use of products. However, it sees the possibility to communicate that explicitly mentioned substances should be used in preference.
The problems caused by QACs are described in section 4.1.9. There are significant moves in the dairy sector in some MS to restrict or remove QACs, due to (i) the concerns over residues of QACs and (ii) possible effects on cheese production due to their selective activity against Gram positive bacteria such as starter cultures for cheese & yoghurt and (iii) concerns over cross resistance with antibiotics. At the moment this development appears to be driven by retailers. The Group supports this removal of QACs from the list of permitted disinfectants in dairies. As QACs are currently still widely used, the organic sector should be careful not to prevent use of a range of other cleaning agents and disinfectants at a time when the industry is under such change.

Conclusions
The substances listed explicitly in Annex VII should preferentially be used in milking facilities.
In the short term, consistent with the recommendations in Sections 4.1.9 and 4.1.10, the use of quaternary ammonium compounds (QACs) for cleaning and disinfection of milking facilities should be prohibited.
In the longer term, the use of cleaning and disinfection materials in milking facilities should be reconsidered, and regulated more precisely.

4.2.7 Cleaning and disinfection agents for teats

Disinfection in the milking parlour will include teat cleaning using surfactants to clean the teats to reduce soil and bacterial numbers, followed by disinfection. Similar products may also be used after milking to reduce risk of mastitis. All products used on animals for mastitis control are classed as veterinary drugs and are thus outside the scope of the organic regulation. Products used for milk hygiene are classed as disinfectants (under biocide legislation), and are thus in the scope of Annex VII. The distinction is made on the basis of the claims on the product label.
At the moment, all substances are authorised for cleaning and disinfection of teats.

Frequently used substances
A wide range of active substances are currently used, for example iodine, iodophores, chlorhexidine, chlorhexidine digluconate and triclosan. Teat cleaners or disinfectants are frequently formulated with emollients such as glycerine or allantoin and with pH adjusters such as lactic acid. As stated above (4.1.6), co-formulants are outside the scope of Annex VII.
The Group is concerned about the use of triclosan, because there is a large and increasing literature on its toxicity. For example both thyroid hormone and estrogen hormone disruption has been reported (Stoker et al 2013). Although the authors quote a margin of safety, there is no threshold for receptor-based mechanisms in the Group's opinion. Additionally, triclosan is

lipophilic and bioaccumuates. It is found widely in human serum and, more worryingly, in human breast milk.

Reflections
The group of teat cleaners and disinfectants comprises some substances of concern such as triclosan, which should not be used in organic production.
The Group therefore sees the need to amend the current permission concerning teats.

Conclusion
In the short term, the use of triclosan should no longer be permitted.
In the longer term, the current permission concerning teats should be revised, with the aim to remove all substances of unacceptable toxicological concern.

4.3 Cleaning and disinfection agents in plant production

When Reg. (EC) 834/2007 was adopted, a clear intention to regulate the use of disinfectants in crop production was expressed in its Art. 12(1)(j). Until now, however, no disinfectants have been authorised for this purpose at the EU level. Some Member States (e.g. Austria) have filled this gap with national legislation (see below). In this chapter, the Group proposes how the use of disinfectants in plant production could be regulated.
In the EGTOP report on greenhouse production (chapter 3.4.5), the Group has previously discussed many aspects of disinfection in plant production. For an easy understanding by the reader, the major considerations and conclusions are repeated here.

4.3.1 General approach taken by the Group

The substances listed in Annex VII(1) have been authorised for organic production for a long time. In the Group's opinion, there is a broad consensus that these substances (with few exceptions discussed in 4.2.1 above) are in line with the objectives and principles of organic production.
As a starting point, the Group has therefore assumed that these substances might also be authorised for plant production. The following sections discuss whether this would be feasible in organic plant production.
France has taken a similar approach. All disinfectants listed in Annex VII(1) with the exception of formaldehyde may be used in plant production.
Also the Netherlands authorised most disinfectants listed in Annex VII(1) for plant production with the exception of phosphoric acid and with the addition of tosylchloramide or N-chloro tosylamide sodium salt (sold as chloramine-T), sulfite (only for the cleaning of picking tools and storage rooms for grapes) and fluoride based agents (only for the cleaning of the glass from greenhouses). The use of formaldehyde is only allowed for the disinfection of inoculation rooms for the mushroom production. In case of infection with quarantine organisms, also disinfectants that are prescribed by the legal authority as obligatory for the cleaning of production locations are allowed.

Austria has provisionally adopted a list of substances authorised for plant production. This list is similar to Annex VII(1), but lacks formaldehyde and sodium hypochlorite. On the other hand, it additionally contains chlorine dioxide, stone meals, micro-organisms and benzoic acid. The Group has not performed a full evaluation of these substances. As a preliminary opinion, the Group is not in favour of using chlorine dioxide (see section 4.3.4), and sceptical about the use of benzoic acid (see below). By contrast, the Group would not object to the use of stone meals and micro-organisms, but has doubts whether these have a use in cleaning or disinfection. Besides France and Austria, the Group assumes that many organic operators and certifiers restrict themselves to the substances in Annex VII(1) on a voluntary basis.

4.3.2 Cleaning and disinfection of buildings and installations

Necessity for cleaning and disinfecting greenhouses and their installations
Greenhouses (structure, glass and plastic covers) and their installations (benches, tables etc.) must be cleaned regularly, to remove algae, dirt, pests, diseases and weeds. Removal of algae and dirt is important to maintain the transparency of the glass or plastic and thus the amount of sunlight available to the crops. Removal of pests, diseases and weeds is important for prevention of phytosanitary problems. In some cases, there may also be a need to remove lime scales (e.g. on greenhouse tables).
Algae may easily inactivate disinfectants such as peracetic acid and hydrogen peroxide, due to their comparatively high active biomass and ability to deactivate free radicals. In conventional production, they are therefore normally removed by QACs. The Group does not recommend the use of QACs in organic production (see 4.1.9). However, if algae are regularly removed by cleaning, they will be present only in small amounts, and inactivation of disinfectants is not a major issue, and the Group sees no need to use QACs.

Necessity for cleaning and disinfecting other buildings and installations
Other buildings and installations used for indoor production (mushroom culture, forcing of chicory etc.) must be cleaned regularly, and sometimes also disinfected, in order to prevent phytosanitary problems, and also to guarantee the hygiene of the food. Buildings and installations used for storage of the harvest must be cleaned regularly, and sometimes also disinfected, for reasons of food hygiene.

Substances necessary for these purposes
In the Group's opinion, the disinfection of buildings and installations raises very similar demands, regardless whether the buildings are used for plant or for animal production. The Group recommends to authorise the following substances for these uses:

- sodium hydroxide, calcium hydroxide.
- sodium carbonate
- organic acids
- hypochlorites
- oxidisers (hydrogen peroxide, peracetic acid)

In greenhouse production, the following substances are also frequently used:

- quaternary ammonium compounds (QACs)
- benzoic acid
- phenols
- cresols
- glutaraldehyde

The reasons why the Group does not recommend authorising QACs are given in section 4.1.9.

Benzoic acid (provisionally authorised in Austria for organic production) is sometimes used in greenhouses. It is approved as a disinfectant for food contact areas and for veterinary hygiene. It

is also approved under plant protection legislation, again for the purpose of disinfecting buildings, installations, equipment and tools. According to product labels, it is active against fungi, bacteria, viruses. The uses include also footbaths (see 4.3.3). Finally, benzoic acid also has a use as food preservative (E210), but this use is not authorised for organic food. Therefore, benzoate residues in food originating from the application of benzoic acid might be interpreted as unauthorised use of a food preservative.
Benzoic acid occurs in nature. Some health concerns have been expressed, relating to foetal toxicity, skin irritation and pseudo-allergic reactions, hyperactivity and to the formation of small quantities of benzene. The Group has not evaluated whether these concerns are relevant in the context of the envisaged uses, or whether they only apply to the use for food preservation.
The Group was unable to find benzoic acid in any list of disinfectants tested according to standard (e. g. DIN, DVG, DLG, VAH in Germany). However, the Group could not exclude the possibility that use of benzoic acid has specific effects against certain plant pathogens and would therefore be eligible for inclusion in Annex II. The Group invites submission of a dossier for benzoic acid, specifying its uses and the substances it could replace, and clarifying in which Annex it should be included.

The Group has not carried out an evaluation of phenols, cresols and glutaraldehyde. In the absence of an evaluation, the Group does not recommend authorising these substances, especially cresols and other phenolics that contain covalently bonded chlorine such as chlorocresol.

4.3.3 Cleaning and disinfection of equipment, machinery and tools

Necessity for cleaning and disinfecting equipment and machinery
If equipment such as trays, containers, pots etc., is to be re-used, it must be thoroughly cleaned. Otherwise, soil-transmitted diseases will build up over time. Disinfection is necessary only occasionally.

Necessity for cleaning and disinfecting tools
Disinfection is particularly important in all cutting tools such as scissors and saws. Especially in areas where fire-blight occurs, all tools used for pruning apple trees must be disinfected regularly. Otherwise the disease may be spread from one infected tree to the whole orchard. Also in vegetable crops, scissors are regularly disinfected. Where seed potatoes are cut before planting, the blades must also be disinfected regularly.

Necessity for cleaning and disinfecting shoes, clothes and hands
Where crops are threatened by epidemics or invading diseases, farm workers' shoes and/or clothes and/or hands are sometimes also disinfected to prevent the introduction of such diseases from other farms or from other regions, or to prevent the spread between fields or greenhouses. (This is also relevant to animal production.)

Necessity for cleaning and disinfecting equipment for transportation and storage of the harvest
Equipment used for transportation and storage of the harvest such as crates, storage rooms and fridges must be kept clean and disinfected as appropriate. The aim is to guarantee food safety and crop health.

Substances necessary for these purposes

The Group recommends authorising the same substances as in the previous chapter, but additionally also:

- alcohols (ethanol, propan-1-ol, propan-2-ol)

The substances not recommended for authorisation are the same as in the previous chapter. with the possible exception of footbaths (see below).

Footbaths and outdoor biosecurity mats
Sometimes, disinfectant solutions are used in footbaths, to ensure that persons entering a building do not carry pathogens inside. The recommendations about which substances to use in footbaths vary widely, and comprise most substances also used for surface disinfection. For example, Strauch and Böhm (2002) recommend 2 – 4 % sodium hydroxide. The changing of shoes at the 'hygiene lock' is a non-chemical alternative to footbaths.
The issue of footbaths and outdoor biosecurity mats should be considered in more detail, if there is a further mandate on disinfection.

4.3.4 Cleaning and disinfection of irrigation systems & irrigation water

Although the irrigation system is part of the installations, it is discussed separately here, because it poses different challenges for cleaning and disinfection.

Types of irrigation systems
The systems vary considerably. Stationary distribution systems are permanently installed in the soil. In partially stationary systems, mobile irrigation pipes connect the irrigation device to a hydrant or well. Mobile distribution systems are entirely above ground and consist of single irrigation tube units that can be altered upon demand during the cropping season. All three modes occur in outdoor cropping systems, while, under indoor conditions, stationary distribution systems are the norm.
Irrigation systems are used intermittently and are often not subject to constant pressure. This means that there is standing water and that there might be reflux within the system. Standing water leads to settling of organic material in the pipelines and concomitantly to microbial growth, biofilm and limescale formation.
Apart from obstruction of the pipeline, clogging of the emitters is a common problem in drip irrigation systems. It is a multifactorial problem caused by chemical precipitation, microbial profileration and consequently biofilm formation, biofouling and suspended matter (B. Alnarius, personal communication).

Types of water used for irrigation
The quality of available water varies greatly. Available water may be (i) potable or municipal water, (ii) ground or surface water or harvested rainwater, (iii) wastewater, or (iv) recollected water. The level of microbial contamination and the load of total organic carbon varies considerably between these different sources.
Far from all growers use potable or municipal water for irrigation, as many farms are not connected to the municipal system. Furthermore, use of municipal water may be extremely expensive in some regions.
Water extracted through ground water wells is one frequent option; others are use of surface water or rainharvesting and use of rain water. Some farmers use mixtures of sources.
Wastewater can be of different origins, such as (i) wastewater from human wastes ('blackwater') or septic tank discharge, (ii) washing water ('greywater'), (iii) industrial drainage and process

water incl. cooling water and toxic wastes, (iv) drainage water such as urban run-off, highway drainage or storm drainage water. Wastewater may be regenerated through wastewater treatment in a four-step approach (Bitton, 2011).
Re-collection of irrigation water occurs only in indoor cropping systems. Such water can be reconditioned by passage through wetlands (Gruyer et al. 2013). In many countries, e.g. Germany, there are hygienic requirements for water which is used for irrigation of vegetables or fruit (Pfleger 2010).

Need for water disinfection
The need for cleaning and disinfection depends on the irrigation system and on the quality of the available water (see above).
Irrigation water may be a vehicle for dispersal of plant pathogens as well as human pathogens. In this context it needs to be emphasised that human pathogens may be internalised into the plant tissue, thus posing a risk for consumers. Hydrogen peroxide and ozone do not always fully destroy enteric human pathogens, and the surviving ones may be more aggressive when entering the consumer's body. In situations where the water source might be contaminated with human pathogens, adequate disinfection is therefore important.

Non-chemical methods
There are some non-chemical methods of water disinfection in plant production (Ehret et al. 2001; Newman 2004), such as slow filtration, photocatalysis, membrane technology, UV light and heat treatment, but there are technical and practical limitations to their use. Slow sand filtration is still the key method in purification to achieve potable water. However, it needs access to surfaces to install such filters and to reservoirs in which the filtered water may be stored. Filtration through wetlands has also shown positive results with respect to plant and human pathogens.
Photocatalysis may counteract enteric bacteria. In this case, no storage tanks for treated water are necessary, but this technology requires absence of coarse particles. Therefore, a prefilter of 70µm filter units needs to be installed prior to the photocatalytic unit. However, rigid pigmented spores of some fungi are too tough for this measure which might make it difficult in greenhouse operations. In field operations, where dispersal of human pathogens is a concern, this technique works very well.
Ultraviolet light may also be used to disinfect water. This is only effective if water is sufficiently clear, for example after filtration. (Newman 2004). Plant extracts habe also been tested for disinfection of water, but this method is not yet developed for practical application (Kirui et al. 2015).

Chemical disinfection
There are chemical methods for disinfection of water & water systems (Newman 2004). However, chemical disinfection of irrigation water is always incomplete. The by-products of disinfection are a readily available energy source for those micro-organisms which survive disinfection, resulting in massive population build-ups. Therefore removal of organic material and scale etc should be done prior to and separate from disinfection.

The Group recommends authorising the following substances for disinfection of irrigation water and irrigation systems:

- hydrogen peroxide
- ozone
- peracetic acid (for descaling and disinfection of irrigation systems)
- other organic acids (for descaling of irrigation systems)

Ozone can be used for disinfection of irrigation water (Newman 2004). However, generation of ozone is resource-intensive and expensive, which probably excluded its wider use. It was previously discussed in the EGTOP report in Food (III). In that report, the Group expressed concerns over its use for decontamination of food, but not over other uses.

Nitric and phosphoric acid are authorised for use in milking equipment, and would likely be useful also in irrigation systems. However, deterioration of the equipment through addition of strong acids needs to be considered carefully. Also, nitric acid is a source of synthetic nitrate, and phosphoric acid is a source of synthetic phosphate. The Group sees a potential for misusing these substances because of the nutrients they provide, and therefore recommends that nitric and phosphoric acid should not be authorised for irrigation systems.

The Group has concerns over the use of active chlorine for the following reasons: (i) sodium hypochlorite may damage roots and thereby create openings, through which plant pathogens can invade the plants, thus causing secondary plant damage. It has also been observed that human pathogens may invade the plant tissue passively through such primary injuries. (ii) The use of chlorine-based disinfectants has been associated with the presence of chlorate contaminations in food (EFSA, 2015). (iii) The use of chlorine-based disinfectants leads to the formation of a range of 'disinfection by-products' which may raise environmental concerns and may also be present in food as contaminants.
Therefore, the Group does not recommend the use of sodium or calcium hypochlorite, chlorine gas or chlorine dioxide for this purpose.
Having said that, the Group is aware that chlorine is often present in municipal water. Recent research shows that municipal water may contain chlorate, and that the use of such water may lead to substantial chlorate residues is crops (Zunker et al. 2015). Despite these concerns, the use of potable water, however achieved, must be permitted for all purposes.

If treatment of water is necessary for use in irrigation, biological and physical methods should preferably be used. If chemical disinfection is necessary, the Group has little concern about using peroxides as disinfectants. The use of preparations containing 'active chlorine' (such as hypochlorites) should be minimised, and operators must take care to ensure correct storage and to check active chlorine before use and adjust dosing accordingly. Preparations should be preferred the use of which minimises the generation of chlorinated by-products and other negative effects on plant growth and health.

4.3.5 Note on cleaning and disinfection of seeds and vegetative material

Use of disinfectants on seeds or vegetative material falls under plant protection product legislation. Therefore, the Group recommends that substances used for this purpose should be included in Annex II rather than Annex VII. For example, see the use of sodium hypochlorite on seeds, discussed in the EGTOP report 3/2011 on plant protection products. These uses are therefore not further discussed here.

4.3.6 Transitional measures for plant production

Reliable disinfection is important to ensure continued production and a high standard of food hygiene. To ensure a smooth transition from the current regime to the proposals in this chapter, the plant production sector needs sufficiently long transitional periods. The Group highlights the following aspects:

- Although the Group is confident that the substances proposed in chapter 4.5 are sufficient for the vast majority of all disinfections in plant production, it cannot exclude the possibility of a few special situations, where the substances proposed here are not sufficient.
- Many disinfections occur only once in the growing cycle (e.g. after a growing cycle is completed and the greenhouse emptied). In these cases, it may take considerable time to verify whether the disinfection needs can be covered with the proposed substances.
- The Group cannot verify whether for all substances which it proposes to authorise in plant production, there are commercial products available in each EU member state. If not, input manufacturers will need some time to develop disinfectants, prepare registration dossiers and have the products registered.
- While some organic operators will be able to adapt to these proposals very easily, others might need to re-design their hygiene plans. Re-design of hygiene plans is much more than just the replacement of one substance by another. It may involve revisions of the cleaning regime (frequency and products used), selection of new disinfection products, adaptations of the disinfection plan and training of the staff.
- The proposed changes affect the entire field of cleaning and disinfection, and the replacement of one substance may necessitate adaptations in other substances.

4.4 Cleaning and disinfection agents in food processing, storage and transportation

Introduction, scope of this chapter
Cleaning and disinfection in the food industry is required for food contact surfaces such as tanks, machinery, conveyors and for storage areas, for rooms, for packaging materials and for transport including tankers and bulk lorries. Cleaning and disinfection in food processing is wide and varied, and ranges from situations where brushing and vacuum cleaning are sufficient (e.g. mills) to situations which require specialised and detailed cleaning and disinfection protocols (e.g. dairy industry).
At the moment, the organic regulation makes no recommendations or requirements concerning cleaning and disinfection in food processing, storage and transportation.

Frequently used substances
The following substances are frequently used for cleaning and disinfection in food processing (non-exhaustive list):

- nitric*, phosphoric*, sulphamic and methanesulphamic acid
- sodium hydroxide*
- alkyl benzene sulphonic acid, sodium benzene sulphonate
- peracetic* and other peroxy acids such as peroctanoic* acid
- sodium hypochlorite*
- iodine, iodophores*
- biguanides
- chlorhexidine, chlorhexidine digluconate
- QACs such as alkyl dimethyl benzyl ammonium chloride, dodecyl dimethyl ammonium chloride
- Triclosan (chlorinated phenolic compound)
- glutaraldehyde

- N- (3-aminopropyl) -N-1.3-diamine
- EDTA, amino trimethylene phosphonic acid pentasodium salt

Substances marked with * are currently listed in Annex VII. The Group has not evaluated all of these substances. Concerns over the use of triclosan are expressed in chapter 4.2.7, and concerns over use of QACs are expressed in chapter 4.1.9. These concerns apply also to their use in processing.

Cleaning and disinfection of installations
Conveyors etc are cleaned using pressure washing and/or foam cleaning. The foaming properties of surfactants are used to hold in place and provide agitation for cleaning agents and/or disinfectants. In most cases sanitiser is left in contact with plant after the clean and is rinsed off at the start of production with potable water. However, in some applications products such as peracetic acid or hydrogen peroxide may be used in non-rinse applications, as they break down spontaneously.
Organic certification bodies generally require rinsing of these compounds, which can lead to conflict with operators and regulators such as environmental health who have concerns over reintroduction of pathogens in rinse water. Problems may arise if the surfaces are not sufficiently dried, as the resulting moisture favours the growth of recontaminants from the processing environment.

Cleaning in place (CIP) systems
Cleaning in plants processing liquids such as, juice, milk, beer etc is normally done using ‘Cleaning in place’ (CIP) systems, which work in several phases. Typically used substances are: warm water; sodium hydroxide; sodium hypochlorite; heat and/or chemical sterilisation; descaling with nitric, phosphoric, sulphamic, or methanesulphonic acid.

Disinfection of rooms and external surfaces
Rooms and facilities for aseptic filling, and for storage of foods, may need to be sterilised. This is commonly done with ozone or hydrogen peroxide. To ensure safe access after sterilisation, these substances can be dissociated using UV light.

Disinfection of small surfaces with sterilising wipes
Small surfaces and equipment such as knives etc are frequently cleaned using sterilising wipes. These come in two main types. The first type is based solely on alcohols (ethanol and/or isopropanol). As these evaporate after use and leave no residue, they are not considered a residue hazard in organic production and there should be no restriction on their use.
The second type of wipes is designed for residual activity on the treated surface. These wipes contain various surfactants and/or disinfectants in addition to or instead of the alcohols. To achieve the residual activity, they leave residues on the treated surface after use. In the Group’s opinion, this second type of wipes should only be used in situations where the treated surfaces are later rinsed, to avoid residue risks.

Disinfection of packaging material
Some packaging materials such as new plastic or glass bottles may contain sufficiently low microbial counts to not require sterilisation, or to be subject only to rinsing with sterile water prior to packaging. Other packaging material which is to be aseptically filled must be sterilised before use. Sterilisation may be by heat, UV light, radiation, or by chemical means. Widely used chemical techniques include chlorine dioxide, ozone, and hydrogen peroxide. The latter two can be dissociated with UV light after the treatment.

The use of ionising radiation on food or feed is prohibited by the organic regulation. As packaging material is outside the scope of this regulation, its use is formally allowed for packaging materials. However, the Group recommends considering this issue in more detail, if there should be a future mandate on cleaning and disinfection in processing.

Cleaning and disinfection in transport

Cleaning and disinfection in transport can be separated into several areas. (i) Liquid tankers, such as those used for beer, milk etc are usually subject to CIP as described above. (ii) Bulk lorries for handling dry goods such as grain etc are normally swept and vacuumed, and usually do not need sterilisation. Most accredited transport operations require clear recording of the last three loads carried and of any precautions and cleaning carried out. They also list prohibited loads which may not be carried in trailers used to carry food products. (iii) Other organic products are carried bagged or boxed.

In the Group's opinion, no special provisions or considerations are necessary for transport.

Food decontamination

For food products, the differentiation between post-harvest treatments and further processing is an artificial one. For raw material and ingredients, chemical decontamination is rarely used. However, there are specific areas such as fresh salads, seeds for sprouting or smoked fish where microbial risks such as salmonellae or pathogenic *E. coli* (for fresh salads and sprouts) and *Listeria monocytogenes* (e.g. for smoked fish and prepackaged fresh salads) have recently been highlighted. Chemical decontamination is considered and sometimes used in conventional production. This may involve substances like hypochlorite, chlorine dioxide, ozone, peroxyacetic acid, hydrogen peroxide or sulphur dioxide.

As these uses are prohibited in organic production, organic producers may be at a disadvantage compared with non-organic operators. For example, the recent requirement that Shiga toxin forming *Escherichia coli* must be absent from seeds for sprouting (Regulation (EU) No 209/2013) has resulted in organic operators dropping out of the market. This use is separate from the use on seeds for sowing, which is discussed in chapter 4.3.5.

In some areas such as salad washing there is an unclear line between providing chlorinated water for rinsing these products and carrying out surface decontamination of the product itself. World Health Organisation guidelines for potable water no longer contain suggested maximum levels for chlorine dioxide or ozone, so it is difficult for operators and certification bodies to differentiate between the use of disinfected water for rinsing or for decontamination of the product surface. Treatment with chlorinated water during food processing was identified as a major source of chlorate residues (EFSA 2015, Zunker et al. 2015).

Conclusions

Cleaning and disinfection in processing, storage and transportation is a complex field. The Group has no objections to the use of compounds listed in Annex VII. However, it is clear that these substances are not sufficient to meet all the cleaning and disinfection needs in food processing, so that other substances will need to be authorised specifically for use in processing. At the moment, the Group is not in a position to suggest a full positive list of substances for use in organic food processing. A research project on disinfection in the organic food industry is currently ongoing in Germany. This might provide further insights. For the moment, the Group recommends the following:

- The use of triclosan should be avoided.
- The use of QACs should be avoided.

- The use of chlorinated compounds should be minimised. Where their use is necessary, preparations containing compounds generating active chlorine should be appropriately stored. Their active chlorine contents should be monitored before use, and the dosage adjusted accordingly.
- Set up an EGTOP mandate for the topic cleaning and disinfection strategies and substances in organic storage and processing operations

4.5 New structure of Annex VII

4.5.1 Concept of a 'basic list' of generally authorised substances

The Group has previously developed the concept of a 'basic toolbox' or 'basic list' of substances generally approved for disinfection. EGTOP Food Report I is introducing the concept. The full rationale is given in the EGTOP report on Aquaculture (part B), chapter 4.6.1, where the concept has been applied to the substances used in the context of aquaculture. In the Group's opinion, the concept can be equally applied to livestock and plant production.
According to this concept, the basic lists contain substances for which there is a broad consensus that they may be used in organic farming. The limited lists contain substances where this consensus is lacking, but which are considered to be necessary for certain, specific applications. The basic list is always given first, and then the limited list. Annex VII(1) is split into Annex VII(1.1) and VII(1.2). For formal consistency, Annex VII(2.2) is re-named into Annex VII(2), and Annex VII(2.1) is re-named into Annex VII(3).
Calcium carbonate (limestone) and calcium magnesium carbonate (dolomite) are two exceptions. These two substances are currently listed with additional text which resembles a restriction for use. However, these 'restrictions' are merely descriptions of where the substance is typically used. A true restriction would limit possible uses, with the aim to manage a potential concern. The Group considers these two substances to be of very low concern, and therefore recommends including them in the basic list. The current restrictions are not considered necessary, and the Group proposes deleting them.

4.5.2 Proposed new structure of Annex VII

ANNEX VII

Products for cleaning and disinfection

1. Products for use in buildings and installations for livestock production referred to in Article 23(4), and in buildings and installations for crop production as referred to in art 12 j)

1.1 Basic list of substances for cleaning and disinfection, which may be used for all purposes authorised under general legislation:

- ethanol, propan-2-ol (alcohols)
- sodium hydroxide (caustic soda), potassium hydroxide (caustic potash), calcium hydroxide (slaked lime)
- calcium oxide (quicklime)
- calcium carbonate (limestone)
- sodium carbonate
- acetic, citric, formic, lactic, oxalic acids
- Peroxo compounds: hydrogen peroxide, peracetic acid, sodium percarbonate.
- Ecolabelled (at least to EU standard) cleaning products

1.2 List of substances for cleaning and disinfection, which may be used for limited purposes indicated here (only if other substances listed in chapter 1.1 of this Annex cannot be used):

- nitric and phosphoric acid (only for dairy equipment)
- cleaning and disinfection products for teats, hands and milking facilities, except QACs and triclosan
- sodium hypochlorite (bleach), calcium hypochlorite, mixtures of potassium peroxomonosulfate and sodium chloride, producing hypochlorous acid. (in situ) (use only, if chlorine-free products are not sufficiently effective; not to be used in irrigation systems or irrigation water)
- ozone (irrigation water & irrigation systems)
- products for use in footbaths and outdoor biosecurity mats
- cleaning products which are not ecolabelled, only if there are no suitable ecolabelled products

Formaldehyde has been excluded, but can be reinserted in Section 1.2 should specific needs be determined following review.

2. Products for use in aquaculture, both in the presence or absence of animals

2.1 Basic list of substances for cleaning and disinfection and for the management of aquatic ecosystems, which may be used for all purposes authorised under general legislation:

- sodium percarbonate
- acetic, lactic and citric acid
- hydrogen peroxide
- peracetic and peroxyoctanoic acid
- humic acids [listing depends on member state consultation]
- sodium chloride (salt)
- calcium carbonate (limestone) [no restriction proposed]

- calcium magnesium carbonate (dolomite) [no restriction proposed]
- cleaning products which do not contain active disinfectant substances
- Ecolabelled (at least to EU standard) cleaning products

2.2 List of substances for cleaning and disinfection, which may be used for limited purposes indicated here (only if other substances listed in chapter 2.1 of this Annex cannot be used):

- iodophors (only in the presence of eggs)
- cleaning products which are not ecolabelled, only if there are no suitable ecolabelled products

3. Products for use in aquaculture, only in the absence of animals

3.1 Basic list of substances for cleaning and disinfection, which may be used for all purposes authorised under general legislation:

- ethanol, propan-2-ol (alcohols)
- sodium hydroxide (caustic soda), calcium hydroxide (slaked lime)
- calcium oxide (quicklime)
- sodium hypochlorite (bleach), calcium hypochlorite, mixtures of potassium peroxomonosulphate and sodium chloride producing hypochlorous acid
- ozone
- cleaning products which do not contain active disinfectant substances
- Ecolabelled (at least to EU standard) cleaning products

3.2 List of substances for cleaning and disinfection, which may be used for limited purposes indicated here (only if other substances listed in chapter 3.1 of this Annex cannot be used):

- potassium permanganate [listing depends on member state consultation]
- tea seed cake made of natural camelia seed (use restricted to shrimp production)
- cleaning products which are not ecolabelled, only if there are no suitable ecolabelled products

4.6 Disinfection technologies

Introduction, scope of this chapter

This chapter covers a few specific disinfection technologies that the Group was specifically asked to consider. There may be others which were not mentioned in the original mandate, which the Group is not aware of, which may be preferable to those discussed below.

4.6.1 'Electrolysed water'

Introduction, scope of this chapter

'Electrolysed water' is traded and known under many names. Other commonly used names are 'activated water' or 'electro-activated water'. Electrolysed water is produced locally from water containing chloride salts, using electrical current. A major difference is whether it is derived from the anion, from the cation or both. Water from the anion ('plus pole') is acid, and is therefore often called 'acid electrolysed water'. Water from the cation ('minus pole') is alkaline, and is therefore often called 'alkaline electrolysed water'. Acid electrolysed water has been used for disinfection for a long time, particularly in Japan. Alkaline electrolysed water is mainly used

for cleaning. The characteristics of electrolysed water depend on the construction and control system of the generator. There are a review articles on electrolysed water (Al-Haq et al., 2005; Hricova et al., 2008; Huang et al., 2008; Gunarathna et al., 2014; Tirpanalan et al., 2011; Colangelo et al. 2015).
Today, water containing chloride salts (usually sodium chloride) is generally used in the generators, so this is taken as a basis for evaluation by the Group. At least in theory, however, it would be possible to use aqueous solutions of other chlorides. For that case, the present evaluation is not necessarily valid.
The technology of generating electrolysed water is a method for obtaining hypochlorous acid in-situ. In aqueous solutions, hypochlorous acid and hypochlorite co-exist in a pH-dependent equilibrium. Similar solutions are normally obtained by dissolving industrially produced sodium hypochlorite in water. Sodium hypochlorite is already listed in Annex VII. In this chapter, the Group has *not* performed an evaluation of sodium hypochlorite as such, but only of this new production method. Concerns over the use of chlorinated compounds are expressed in chapter 4.2.1.

Authorisation in general agriculture and in organic farming
For a long time, generators of electrolysed water were not covered by biocide legislation. Today, however, in-situ generated substances are also covered by biocide legislation, and the electrolysis of sodium chloride forming hypochlorous acid is explicitly mentioned.

Agronomic use, technological or physiological functionality for the intended use
Electrolysed water can be applied in plant and animal production and in food processing. It is prepared immediately before use, and is usually applied undiluted. It has a broad anti-microbial activity, and has been used in many areas (Al-Haq et al., 2005; Huang et al., 2008). Existing and possible new applications include medicine and dentistry, crop production (greenhouses, irrigation systems, mushroom cultures, foliage, seeds and fruits prior to storage), animal production (drinking troughs, stables) and food processing (machines, tools, cut vegetables, milk processing, meat and fish industry).
Electrolysed water usually contains 20 – 60 mg/kg free chlorine (hypochlorite and hypochlorous acid, in a pH-dependent equilibrium). Some publications attribute at least part of its activity also to the low pH value and/or to the presence of free radicals, but the contributions of pH and radicals is not clear, and seems to vary from one situation to the other (Al-Haq et al., 2005; Huang et al., 2008; Gunarathna et al., 2014). In line with biocide legislation, the Group considers electrolysed water as a solution of hypochlorous acid.

Necessity for intended use, known alternatives
Very similar to sodium hypochlorite, and possibly other substances from Annex VII.

Origin of raw materials, methods of manufacture
The process for generating electrolysed water is more or less the same process with which sodium hypochlorite is industrially produced. The Group sees no major difference between the two processes, and considers both end-products as synthetic.

Environmental issues, use of resources, recycling
Similar to sodium hypochlorite. However, if the process is carefully controlled, the generation in situ may cause less concerns about formation of chlorinated by-products (Fong et al., 2014)

Animal welfare issues
Similar to sodium hypochlorite.

Human health issues
Similar to sodium hypochlorite. However, if the process is carefully controlled, the generation in situ may cause less concerns about occupational health.

Food quality and authenticity
Similar to sodium hypochlorite. However, if the process is carefully controlled, the generation in situ causes less concerns about formation of chlorinated by-products.

Traditional use and precedents in organic production
Sodium hypochlorite has traditionally been authorised for disinfection in the EU organic regulation, while electrolysed water is not mentioned until now. It is currently used in some applications in organic production, based on the incorrect assumption that this is a physical technology that may be freely used.

Aspects of international harmonisation of organic farming standards
The Codex Alimentarius guidelines for the production, processing, labelling and marketing of organically produced foods (revision 2013) do not contain provisions concerning disinfectants. In the USA the EPA (Environmental Protection Agency) has approved the use of electrolysed water in the food industry (Colangelo et al., 2015). A recent document from the USDA clarifies that electrolszed water is a type of chlorine material that is allowed in organic production and handling. (McEvoy, USDA policy memo 15-4). In the IFOAM standard for organic production and processing (version 2014), electrolysed water is not mentioned.

Other relevant issues
None.

Balancing of arguments in the light of organic production principles
The electrolysed water technology is used to generate solutions of hypochlorous acid, which are then applied as disinfectant. In the Group's opinion, this should be regulated identically to the use of sodium hypochlorite, because in both cases there is a pH-dependent equilibrium of hypochlorite and hypochlorous acid.
In the Group's opinion, the current listing of sodium hypochlorite in Annex VII covers *in-situ* generation as well as industrial production. However, it may be that the generation *in situ* creates less concern regarding production of by-products (Fong et al, 2014)

Conclusions
In the Group's opinion, the use of electrolysed water is similar to the use of sodium hypochlorite. It may therefore be used for all purposes for which sodium hypochlorite is authorised, but not for any other purposes.
For the time being the Group sees no need to mention electrolysed water explicitly. However, if there should be more data showing that this technology leads to significantly lower levels of chlorinated by-products, a difference could be made between use of hypochlorites as such and the use of electrolysed water in the future.

4.6.2 UV light

Introduction, scope of this chapter

The Group has previously discussed UV light, in the context of plant protection (see EGTOP report on plant protection products (2011), chapter 3.5). Here, only the specific aspects relating to disinfection are discussed.

Authorisation in general agriculture and in organic farming
Authorised in general agriculture and in organic farming. See EGTOP report on plant protection products (2011), chapter 3.5. for details.
In Germany, direct treatment by UV irradiation is only permitted for potable water, for the surface of fruit and vegetable products, and of hard cheese during storage (Lebensmittelbestrahlungs-Verordnung § 1 no. 4).

Agronomic use, technological or physiological functionality for the intended use
For general information, see EGTOP report on plant protection products (2011), chapter 3.5). UVC is effective against some viruses, bacteria and fungi, and can be used for sterilisation. There are two main limitations to its use: (i) it must be used in closed containments to avoid human exposure, and (ii) it is only effective on surfaces directly exposed to radiation, and does not penetrate into cracks or porous materials. This limits its application to hard materials with smooth surfaces, such as steel, glass etc.
The Group sees its application mainly in food processing (disinfection of smooth food contact surfaces) and for disinfection of irrigation water.
In certain specific situations UVC may be used for decontamination of air, provided that the design of the room and the air flow leads to uniform exposure of the air. However, the effect of UV light should not be overestimated, and a poorly designed treatment may cause a false feeling of security.

Necessity for intended use, known alternatives
UVC has the potential to reduce the use of chemical disinfectants, in some situations but cannot completely replace them. Where possible the Group considers the use of physical methods such as UVC preferable to chemical disinfectants.

Origin of raw materials, methods of manufacture
see EGTOP report on plant protection products (2011), chapter 3.5.

Environmental issues, use of resources, recycling
For details, see EGTOP report on plant protection products (2011), chapter 3.5. For the use in food processing and for disinfection of irrigation water, the Group has no concerns from this point of view. Sub-lethal doses of UVC might induce mutations in micro-organisms (Watanabe *et al.*, 2011), which might lead to unpredictable side-effects.

Animal welfare issues
For details, see EGTOP report on plant protection products (2011), chapter 3.5. If UVC is properly used, the Group has no concerns.

Human health issues
For details, see EGTOP report on plant protection products (2011), chapter 3.5. If UVC is properly used, the Group has no concerns.

Food quality and authenticity
see EGTOP report on plant protection products (2011), chapter 3.5.

The Group has concerns over use of UV light to decontaminate organic food, because it may affect lipid oxidation and create free radicals. Also, the Group questions its effectiveness for many foods.

Traditional use and precedents in organic production
see EGTOP report on plant protection products (2011), chapter 3.5.

Aspects of international harmonisation of organic farming standards
see EGTOP report on plant protection products (2011), chapter 3.5.

Other relevant issues
None.

Balancing of arguments in the light of organic production principles
For details, see EGTOP report on plant protection products (2011), chapter 3.5. The Group sees benefits from the use for disinfection as above, while it has seen very little benefits from the use in plant protection.

Conclusions
The use of UVC is not prohibited under the current organic regulation. In the Group's opinion, the use of UVC for disinfection is in line with the objectives and principles of organic production, when used in a food processing context, except for use on the surface of organic products.

4.6.3 Plasma gas

Introduction, scope of this chapter
In the mandate on Food (III), the Group was asked to reflect on the use of plasma gas in food processing. In this mandate, the Group was asked to reflect more generally on all possible uses of plasma gas.
The Group sees no need to re-assess its previous evaluation of food uses. However, this chapter gives some additional information and includes also uses outside the food industry.
In the mandate, the Group is asked to consider organic principles (health, ecology, fairness and care), quality improvement (increase in yield and improvement of shelf life including reducing losses caused by fungi and bacteria), access to sufficient and nutritious food by reduction of food losses and innovation by using techniques that reflect natural processes. These aspects are mentioned in the following sections.

Authorisation in general agriculture and in organic farming
Methods for processing, cleaning or disinfecting are not regularly subject to an authorisation process. Plasma gas is not mentioned in IFOAM organic norms or USDA NOP standards, therefore it is assumed by the Group to be permitted for water or equipment, but not for treatment of organic foods.

Agronomic use, technological or physiological functionality for the intended use
Plasma is a gas with free electrons, ions, neutral particles and reactive radicals. The non-thermic-plasma (cold plasma) is generated e.g. in a dielectric barrier charge (DBD). Plasma gas is known for its antimicrobial capacity. The main mode of action is generation of free radicals (reactive oxygen and nitrogen species in situ; SKLM 2012). Up to now it is mainly used for disinfection /

sterilisation of medical devices which are sensitive to heat, and is currently under research for use in the food industry. Further technical details are given in the EGTOP report on Food (III).
Uses in the food industry: As a disinfection method, plasma gas may be used in food operations. Possible applications include disinfection of packaging materials and other food contact surfaces. Due to the low temperature of application, the technology might also be applied for food decontamination, especially for food likely to be consumed raw (some vegetables, fruits, eggs and meats). As these applications are not yet fully developed, the Group is not in a position to make a final statement whether they should be allowed in organic production. Possible benefits could be reduction of food losses and/or the prolongation of shelf life (the latter is discussed in the section on food quality below).Uses in plant and animal production: Applications for use in plant and animal production are not yet developed to commercial applications. Therefore, the Group cannot evaluate these uses.

Necessity for intended use, known alternatives
There is much concern about the microbiological quality and safety of vegetables and fruits likely to be consumed raw (e.g. leafy vegetables for salads). A method for decontamination of these foods that does not alter the sensory and nutritional quality of the food and does not leave residues such as chlorine compounds would be useful.
Plasma gas may be preferable to chemical alternatives for treatment of packaging materials and other food contact surfaces.
For example it could be an alternative to ozone which is difficult to handle but has an extremely short reaction time against microorganisms.
On the other hand the use of water and organic acids is possible in organic production and is a given alternative.

Methods of manufacture
In the last ten years, the development of atmospheric plasma gas (‘cold plasma’) has made great progress. Different methods are described but there is a need for additional research. Plasma gas technology is different from naturally occurring processes.

Environmental issues, use of resources, recycling (including the principle of ecology)
Plasma gas will have negligible pollution impact on the environment compared with chemical treatments. The reduction of food losses would contribute to the conservation of resources. However, it is not possible at the present stage of development to evaluate energy use of comparable plasma and other methods including chemical disinfection, because plasma gas technology is in a very early developmental stage.

Animal health/welfare issues
Not relevant for current applications.

Human health issues
Plasma gas mainly works by generation of free radicals which create concerns for occupational health, so these effects must be assessed. This assessment depends greatly on construction features and is therefore not possible at the present stage of development. For a more specific health evaluation of plasma gas application, there is currently not enough scientific information available. Additional information is given in the EGTOP report on Food (III).

Food quality and authenticity

The Group has no concerns regarding using plasma gas for disinfection of food contact surfaces. This use could have positive effects on food quality by helping to avoid contaminations of food with chemical disinfectants.

By contrast, the possible use for food decontamination might affect food quality, due to the formation of free radicals. Thus, the influence of this use on food quality needs further investigation. Food decontamination might be used to prolong shelf life. This would have ambivalent impacts: on one hand, it could contribute to the reduction of food waste, on the other hand, it could mean that older food, which may have undergone other physiological changes, can be sold to consumers without this being evident.

Traditional use and precedents in organic production
None (new technology).

Aspects of international harmonisation of organic farming standards
Not explicitly mentioned in any organic production standards.

Other relevant issues (including the principle of fairness)
In the Group's opinion, a decision regarding which uses of plasma gas are authorised should be taken as soon as possible to create more certainty for investment decisions in the food industry.

Balancing of arguments in the light of organic production principles
In principle physical technologies are preferable to chemical treatments. However, because the Group lacks information on uses, effectiveness, food quality and occupational health, it was unable to fully assess this technique. In general, the organic regulation gives a priority toward physical methods instead of chemical processes (Art 6(d) EC Reg. 834/2007). The reduction of microorganisms has to be measured under practical conditions and the possible toxicological effects need to be studied, consistent with the 'principle of care' (see EGTOP report on Food (III)).

Conclusions
The Group confirms the provisional conclusions which it has previously made in the context of uses in the food industry, that (i) at present there is no restriction regarding the use of plasma gas, (ii) plasma gas might have positive possibilities, and (iii) it is not yet possible to make a final evaluation of plasma gas due to lack of knowledge. With respect to other uses, the same provisional conclusions apply, but the technology is in a much earlier developmental stage. In the Group's opinion, a decision should be taken as soon as research results are available, to create more certainty for investment decisions in the food industry.

4.6.4 Disinfection using bacteriophages

Introduction, scope of this chapter
Bacteriophages are viruses, which specifically attack a very limited range of host bacteria. They may selectively inactivate specific pathogens, thus improving microbiological safety. This is different from classical methods of disinfection which have a much broader spectrum of activity, and reduce microbial populations as a whole.
The approach of using bacteriophages for elimination of pathogens from food is new and still in an early developmental stage.
A separate line of research uses phage endolysins rather than phages (Yang et al. 2014; Hagens and Loessner 2014). This approach has the potential to widen the spectrum of target organisms.

However, this approach requires the use of genetic engineering, and is therefore not considered in this chapter.

Authorisation in general agriculture and in organic farming
USDA NOP standards include the following as permitted 'Microorganisms—any food grade bacteria, fungi, and other microorganism.' Therefore once approved for food use phage could be used in organic production in the US. Similarly IFOAM organic standards permit 'Preparations of micro-organisms and enzymes commonly used in food processing'. The definition of commonly in this context is unclear, but it is assumed that phage permitted for use in foods could be used.

Agronomic use, technological or physiological functionality for the intended use
Use of phages in food hygiene has principal limitations. Unlike disinfectants, phages are host-specific. So, there is an inherent possibility that a resistant microbiome develops. The data available so far (EFSA 2009a, 2012a), demonstrate only a limited affect in foods or food environments. Hence, their most likely use is limited to assist in the elimination of specific pathogens. However, they cannot be used as or instead of a 'general purpose disinfectant'.
At the moment, two phage products are on the market. One is active against Listeria, and the other against Salmonella (see below). In future is likely that other strains of phages will be developed, which are active against other pathogens.

Necessity for intended use, known alternatives
There is a need for better control of *Listeria monocytogenes* in ready-to-eat fish products (e.g. smoked salmon). The use of phages may be promising if they reliably attack all *Listeria monocytogenes* strains in the food matrix or on the food contact surfaces, and if there is no relevant risk for the development of resistant strains.
Phages attacking salmonellae may assist in eliminating salmonellae from poultry or pig herds, and from poultry carcasses after slaughter.
Other hygienic measures have been shown to be effective against these pathogens, too. Thus, phages can only function as an additional tool, but cannot replace other sanitation methods.

Origin of raw materials, methods of manufacture
The phages used currently are not GMOs, and it should be possible to produce phage preparation in fermenters without use of gene technology.
By contrast, phage enzymes (endolysins) can only be produced using GM technology.

Environmental issues, use of resources, recycling
For phages authorised under general legislation, the Group sees no environmental risks.

Animal welfare issues
For the phages currently available, the Group identified no animal health or welfare issues. However, there is a possibility that phage technology could be used for veterinary purposes in the future, with beneficial effects on animal health or welfare.

Human health issues
According to EFSA (2009a, 2012a), the two phages currently on the market do not consist a general public health hazard. In the USA, the two phages received GRAS status from the FDA.
In the opinion of the Group reduction in *Salmonella* in poultry carcasses and reduction of *Listeria* on fish products reduces infection risks for consumers.

Food quality and authenticity
No issues identified.

Traditional use and precedents in organic production
The technology of using phages is new, and therefore has no traditional use. The use of granulosis viruses in organic plant protection is a precedent.

Aspects of international harmonisation of organic farming standards
Not explicitly mentioned in any organic production standards.

Other relevant issues
None.

Balancing of arguments in the light of organic production principles
According to the principles of organic production, biological control methods are preferable to chemical methods. In the Group's opinion, this clearly also applies to phage technology, with the obvious exception of phage endolysins which are produced with GM technology. For phage products authorised in horizontal legislation the Group assumes that risks have been excluded. In this context, von Jagow and Teufer (2007) argued that no official (pre-market) approval of using bacteriophages for food decontamination is required.

Conclusions
In the Group's opinion, the technology of using phages is in line with the objectives and principles of organic production. For this reason, and since there is apparently no safety concern (EFSA 2009a, 2012a), phage technology should be authorised for organic production in situations where elimination of a specific pathogen is aimed at, and if there are no legal constraints in horizontal food legislation.

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6. ABBREVIATIONS / GLOSSARY

Important terms are explained at the beginning of the report in section 4.1.1.