

Seeking regulatory approval for a claim new to regulatory science: This product reduces the use of antibiotics

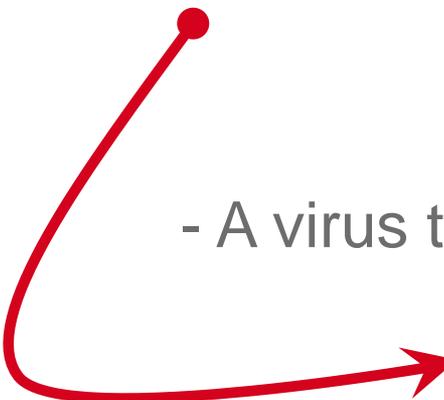
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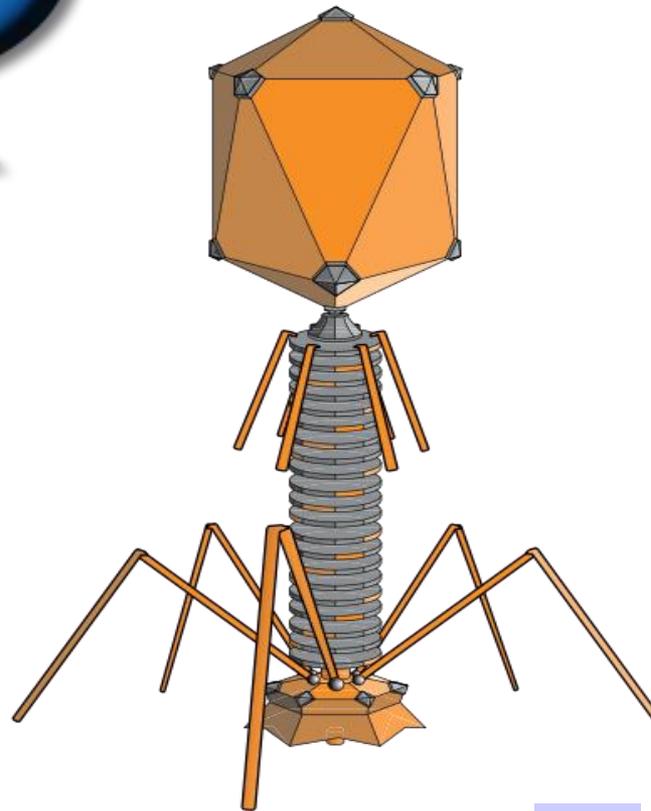
< Bacteriophages >

(ex. *Salmonella*, *Campylobacter*, *Listeria*, etc.)

What is a bacteriophage ?



- A virus that infects bacteria -



File:PhageExterior.svg
From Wikipedia, the free encyclopedia

Description	English: Artistic rendering of a T4 bacteriophage . The colours grey and orange do not signify anything, they are just used to illustrate structure. Created for Wikipedia Nederlands: De structuur van een bacteriofaag met 'staart'eiwitten.
Date	30 November 2009(2009-11-30)
Source	Own work
Author	Adenosine

What are the possible benefits of using bacteriophages ?



**But, ... what do I have to do to
put a phage into the market ???**



The first step is ...

... to know the final use (claims pursued)
according to the mode of action.

The main potential uses:

- 1) Application to surfaces.
- 2) Usage in foodstuff.
- 3) Administration to live animals.

Main legal framework in the EU:

Destination	Regulatory classification	Legal framework
1) Surfaces (facilities)	1) Biocide	Regulation (EU) No 528/2012
2) Carcasses and/or processed meat/fish (food)	2.1) Biocide (*)	Directive 98/8/EC (*)
	2.2) "Food decontaminant"	Regulation (EC) No 853/2004
	2.3) Food additive	Regulation (CE) No 1333/2008
	2.4) Processing aid (food)	EU National legislation
3) Animals (live)	3.1) Feed additive	Regulation (EC) No 1831/2003
	3.2) Processing aid (feed)	EU National legislation
	3.3) Veterinary medicine	Directive 2001/82/EC

(*) This option is no longer possible: This was foreseen in Directive 98/8/EC but now it has been repealed by Regulation (EU) 528/2012.

1) Surfaces (facilities):

1.1) Biocides



Regulation (EU) 528/2012

1) Surfaces (facilities):

1.1) Biocides → Regulation (EU) 528/2012

- **Definition:** Active substances (including viruses) intended to destroy any harmful organism by any means other than mere physical or mechanical action.

- **Main groups:**

- **Product-type 3:** Veterinary hygiene”:

For disinfecting material and surfaces associated with the housing or transportation of animals.

- **Product-type 4:** Food and feed area”:

For disinfecting of equipment, containers, surfaces, pipework, etc. associated with production, transport, storage, etc. of food or feed.

2) Carcasses and/or processed meat/fish (food):

[2.1) Biocides		Regulation (EU) 528/2012] *
2.2) Food decontaminants		Regulation (CE) 853/2004
2.3) Food additive		Directive 89/107/EEC
2.4) Food processing aid		EU National legislation

* This option is no longer possible: This was foreseen in Directive 98/8/EC but now this has been repealed by Regulation (EU) 528/2012.

2) Carcasses or processed meat/fish (food):

2.1) Biocides



Directive 98/8/EC (*)

- Main group:

- “Product-type 20: Preservatives for food or feedstock”:
Products used for the preservation of food or feedstock
by the control of harmful organism.

(*) Regulation (EU) 528/2012 repeals Directive 98/8/EC and explicitly justify the removal of this specific type of biocides.

2) Carcasses or processed meat/fish (food):

2.2) Food decontaminants Regulation (CE) 853/2004

- Definition:

- Strictly speaking “food decontaminant” itself does not appear in any regulation. But, indirectly:
- Only potable/(clean) water could be used to remove surface contamination. However other products could be authorised.

2) Carcasses or processed meat/fish (food):

2.3) Food additives Regulation (EC) 1333/2008

- **Definition:** Any substance (not ingredients) intentionally added to food for technological purposes which may result to become a component of such food.
- **Main group:** “Preservatives”: protect food against deterioration by micro-organisms and/or protect against growth of pathogenic micro-organisms.

2) Carcasses or processed meat/fish (food):

2.4) Food processing aids National EU legislation

- Definition:
- No harmonized EU law framework.
- Specifically out of the scope of food additives (Reg. 1333/2008).
- Any substance (not ingredients) intentionally used in the processing of raw materials/food/ingredients, to fulfil a certain technological purpose during treatment/processing which may result in the presence of harmless residues in food.

3) Live animals:

- 3.1) Feed additives  Regulation (EC) 1831/2003
- 3.2) Feed processing aids  EU National legislation
- 3.3) Veterinary medicines  Directive 2001/82/EC

3) Live animals:

3.1) Feed additives Regulation (EC) 1831/2003

- Definition:

- Feed additives have no correlation concerning definition and uses in comparison with food additives in EU.
- Any substance or microorganism (but not feed materials) intentionally added to feed or water in order to perform a favourable effect: animal products, animal production, welfare, etc.

3) Live animals:

3.1) Feed additives



Regulation (EC) 1831/2003

- Main categories and functional groups:

- <Technologicals>:

- “Preservatives”: Micro-organisms which protect feed against deterioration.

} **No**

- <Zootechnicals>:

- “Gut flora stabilizers”: micro-organisms which, when fed to animals have a positive effect on the gut flora.
- “Substances which favourably affect the environment”.
- “Other zootechnical additives”.

} **Unlikely**

} **Unlikely**

} **Possible**

- <Product quality additives>: *They do not exist (yet):*

- “Microbial contamination controllers”: to reduce the no. of zoonotic pathogens in animal food products.

} **Maybe in the future**

3) Live animals:

3.2) Feed processing aids National EU legislation

- Definition:
- No harmonized EU law framework.
- Specifically out of the scope of feed additives (Reg. 1831/2003).
- Any substance (not ingredients) intentionally used in the processing of feed raw materials/feedingstuffs, to fulfil a certain technological purpose during treatment/processing which may result in the presence of harmless residues in feed.

3) Live animals:

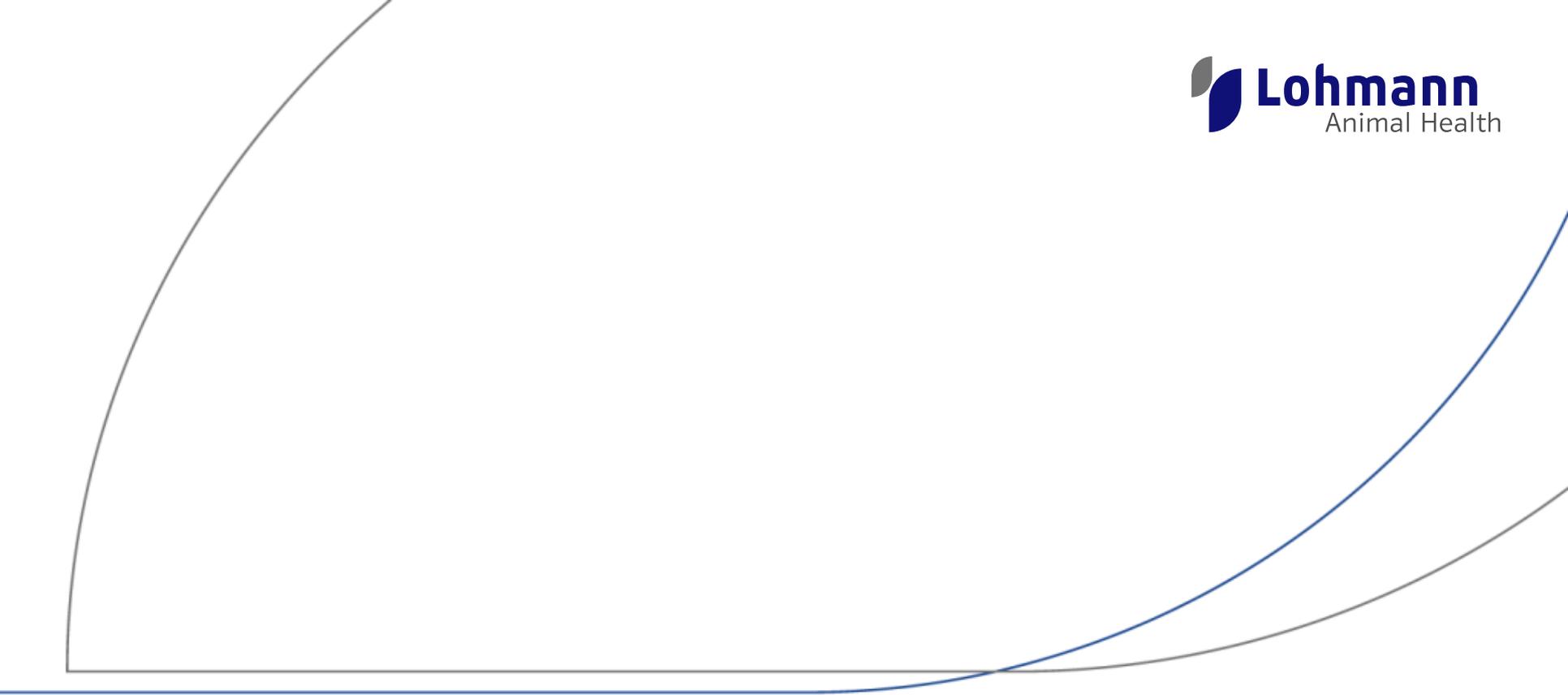
3.3) Veterinary medicines Directive 2001/82/EEC

- Definition:

- Any substance (including microorganisms) having properties for treating or preventing disease in animals, etc.

Overall conclusions:

- 1) Bacteriophages can reduce the use of antibiotics.
- 2) Bacteriophages are not explicitly defined in current EU legislation, nonetheless, there is legal framework to get an approval.
- 3) The legislation that can be applicable depend on the mode of action and use of bacteriophages. Therefore:
 - a) Surfaces: biocides.
 - b) Food: (biocides), food decontaminants, food additives or food technological aids.
 - c) Live animals: feed additives, feed technological aids or veterinary medicines.



Thank you very much!