Which Path to go?

On how to find a Passage for Innovations through the Jungle of EU-Food Law – discussed by the Example of Bacteriophages

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I. Introduction

The basic principle of EU food law has remained unchanged by Regulation (EC) No. 178/2002: Any food operator is free to produce and sell foodstuffs in the EU without prior permission – provided the foodstuffs are safe[1]. Whether a foodstuff is safe must primarily be judged by the food operators themselves as Art. 17 (1) and Art. 19 (1) Regulation (EC) No. 178/2002 clearly point out.

However, the European legislator introduces an ever-growing number of authorisation procedures for specific legal categories of foodstuffs, such as the so-called "novel foods" or technological additives[2]. Thus, whenever an entrepreneur comes up with any kind of innovative foodstuff, ingredient or technology, the question must be asked: Which path to go? Is it possible to market the innovative product without prior permission? If not, which of the many authorisation procedures that are known today to EU-food law is to be chosen? Such practical demands seem to occur only rarely to the EU-legislator. The food business operators, the majority of them being small enterprises without the financial background of multi-national companies, and the local supervising authorities that have to deal with the every day application of EU-food law are basically left alone on vital questions about the marketability of innovative products[3].

Bacteriophages[4] or phages can serve as a good example to analyse the steps that have to be thought about before marketing an innovative food product in the EU. Phages are applied to attack and eliminate specific harmful bacteria during the production processes of sensitive foodstuffs such as meat or cheese[5]. While their application in the manufacturing of foodstuffs is rather new, there are multiple documentations of the basic safety and utility of certain phages, which are naturally present in many food products. However, from a legal perspective it has to be asked whether phages can be marketed without running through a prior authorisation process as there are a number of possible procedures under EU-law that come to mind when looking at the nature and functioning of these micro-organisms.

After introducing bacteriophages and their functions a bit further (II.) the attempt is undertaken in this article to briefly run through the scope of several authorisation procedures under EU law that could possibly apply to phages (III.). It will be seen in the end (IV.) that for bacteriophages – like for many other innovative substances or technologies – the authorisation procedures simply do not fit. Under such circumstances the legal analysis comes back to Art. 14 Regulation (EC) No. 178/2002, which serves as the necessary companion of the free marketability of foodstuffs in the EU: The concept of food safety.

II. Bacteriophages and their use in food production

Bacteriophages have long been in the focus of science[6]. They are viruses[7], which means micro-organisms that exist ubiquitously in our environ-

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1 Cf. further Gorny, Grundlagen des europäischen Lebensmittelrechts, marginal number 282 ff.

2 See Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (E.C. O.J. n° L 43 of 14/2/1997, p. 1) and Council Directive 1989/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for the use in foodstuffs intended for human consumption (O.J. 1989 L 40/27).

3 Cf. van der Meulen/Gregor, ZLR 2007, 265 with interesting results of a survey among food operators in the EU.

4 Parts of this article are based on an article about bacteriophages, which the authors published in ZLR 2007, 25.

5 See below II.

6 Cf. Loessner, BIOspektrum 2000, 452.

7 For this term cf. Römpp, Lexikon Lebensmittelchemie, 2. ed. 2006, 873 f.

ment[8] – including the human body and many foodstuffs. Viruses are defined as mobile genetic elements consisting of nucleic acids that can move outside of cells thanks to their protective protein coating[9]. They do not have their own metabolism, for their reproduction the micro-organisms need host cells whose biosynthetic activity they can use in order to reproduce[10]. The phage's genes encode proteins and thus influence the host cell's metabolic mechanism in a way that causes the host cell itself to die off[11].

The bacteriophages' characteristic lies in the fact that they attack specific bacteria: some phages attack a single bacterial genus, more often a specific species or a species' strain, whereas other bacteria are left unharmed[12]. By this means, phages can be specifically used on one or several kinds of unwanted bacteria without harming other – desirable – bacteria. In a space where different phages and bacteria interact, the phages keep on moving until they find corresponding bacteria whose surface they can "dock" on. There, they proliferate, kill the bacteria on they have used as host cells and through this release evolving viruses. The process of killing the host cell to release the viral offspring is also called "to lyse" or "lysis"[13]. When no more fitting bacteria are available, the bacteriophages gradually become inactive[14].

Due to the above-described working mechanisms bacteriophages can be used pointedly against unwanted bacteria in the production of foodstuffs[15]. Despite the high number of different pathogenic strains of bacteria some main trouble makers can be distinguished when looking at the illnesses that can be ascribed to the consumption of contaminated or otherwise negatively influenced foodstuffs: among those are campylobacter, salmonella and listeria, especially listeria monocytogenes[16]. The categories of foodstuffs that are affected most are especially fish, meat, poultry, products with raw eggs and raw milk, there especially cheese with raw milk[17]. Recently research about phages has been intensified in food technology[18], there are already solutions that are in practical use; in the USA the FDA has only last year approved a spray with bacteriophages to be applied on the surface of certain foods[19].

When bacteriophages that specifically attack salmonella or listeria are integrated into the production process of foodstuffs, a dangerous contamination with the bacteria can be avoided or at least lessened[20] due to the described biological mechanism. For this the respective phages have to be applied in the form of special cultures either on the surface or inside of the foodstuffs, the latter for example through integration into the process of maturation of cheese. Technically this can happen through the isolated addition of phages, or the phages are carried through non-pathogenic, i.e. harmless bacteria and thus integrated into the production process of foodstuffs. Bacteriophages that are pointedly used against harmful listeria monocytogenes can, for example, be combined with the similar but harmless listeria innocua and in this way be brought into the foodstuffs. In the respective space of interaction, e.g. in cheese, the phages coincide with the existing pathogenic bacteria, they reprogram the metabolism of these unwanted bacteria, reproduce and lyse the bacteria, killing the harmful contamination in the process of their reproduction[21].

However, contaminations can only be fought in a tight temporal connection with the application of phages, because the viruses become inactive and gradually eliminated when they cannot find a critical number of fitting bacteria to dock on to[22]. Thus, the conservation of foodstuffs for long periods of

8 Brüssow, Journal of Bacteriology 2004, 3678.

9 Cf. Römpp, Chemie Lexikon, 9. ed. 1992, vol. T-Z, 4928 for the term "Viren".

10 Römpp, Chemie Lexikon, 9. ed. 1992, vol. T-Z, 4928 for the term "Viren".

11 Römpp, Chemie Lexikon, 9. ed. 1992, vol. T-Z, 4928 f. for the term "Viren".

12 Graphically Loessner, BIOspektrum 2000, 452.

13 This expression originates from the term "lysis", with which the dissolution of cell membranes is described, cf. Römpp, Lexikon Biotechnologie 1992, 475 on the term "Lyse".

14 Noble, R. T., and J. A. Fuhrman, Virus Decay and Its Causes in Coastal Waters, Appl Environ Microbiol 63:77-83 (1997); Hurst, C. J., C. P. Gerba, I. Cech, Effects of environmental variables and soil characteristics on virus survival in soil., Appl Environ Microbiol 40:1067-79(1980).

15 Cf. e.g. Peek/Reddy, Gastroenterology 2006, 131: 1370.

16 Cf. Hartung, Journal für Verbraucherschutz und Lebensmittelsicherheit, vol. 1 Supplement 2 Dezember 2006, 196 ff.

17 Cf. Krämer in: Frede (ed.), Taschenbuch für Lebensmittelchemiker, 2006, 441 f.

18 Generally Werlein/Hildebrandt, Hygiene-Report 2006, 20.

19 Federal Register 2006, 71:47729-47732.

20 Peek/Reddy, Gastroenterology 2006, 131: 1370 on the FDA-approved spray in the USA.

21 Q.v. above II.

22 Loessner, BIOspektrum 2000, 452. Noble, R. T., J. A. Fuhrman, Appl Environ Microbiol 63:77-83 (1997); Hurst, C. J., C. P. Gerba, I. Cech, Appl Environ Microbiol 40:1067-79 (1980).

time of production, transport and storage is not possible through the singular application of phage cultures in the production process. For food safety and technology it is furthermore relevant what happens with possible remainders of bacteriophages that still exist when the consumer eats the treated foodstuffs. Only a few phages survive the passage through the stomach and the remaining ones are excreted. In fact, human excrements contain a high number of phages. If phages still manage to get into a person's bloodstream, i.e. through an injection, the phages will be fought and destroyed by the human body's defence cells as an intruding foreign object[23]. Furthermore, according to science, the phages themselves do not have an own pathogenic impact in the human body[24]. Actually, due to the ubiquitous existence in the environment they are already to be found in large numbers and have not yet attracted attention as being harmful for health[25]. Accordingly, the FDA in the USA has – after adequate examination – given permission for the marketing of a spray containing bacteriophages[26], another phage culture also received the so-called GRAS status, meaning it is "generally recognised as safe"[27].

After all, the use of bacteriophages in the production of foodstuffs appears to be an innovative method of fighting pathogenic bacteria[28]. The practical embedding into the different production processes is already advancing[29]. The addition of phages to starter cultures, as they are known from cheese and meat production, has become reality, and a study proves the potential usefulness of such cultures[30]. Thus, from a legal point of view, the question arises how the use of bacteriophages can be put into the context of food law.

III. The different legal pathways

Before an innovative food product can be lawfully marketed the responsible food operator has to both ask and answer whether the product is safe (1.) and whether it can be sold without going through a specific authorisation process (2.-5.). The EU legislator has introduced a number of authorisation procedures for foodstuffs during the past years and is planning to stipulate more in the future[31]. For food business operators this regulatory landscape demands an educated decision about how to proceed with the distribution of their products.

In the case of phages at least four authorisation procedures with completely different aspects having to be evaluated come to mind: The phages which are used to eliminate harmful bacteria during the production of sensitive foodstuffs could possibly be deemed decontaminants pursuant to EU-hygiene law (2.), they could be processing aids under EU-additives law (3.); being innovative means of fighting bacteria they may be characterised as "novel" by the Novel Food Regulation (4.) and, finally, bacteriophages could possibly be considered biocides pursuant to the EU-Biocide Directive for substances with a capacity to destroy micro-organisms (5.).

However, independent from any procedure of authorisation, the main issue to be dealt with before introducing innovative food products to the market in the EU remains the same: The final foodstuff has to be safe when it is consumed – accordingly this aspect is at the very heart of Regulation (EC) No. 178/2002 on general principles of food law and proceeds all other legal analysis.

1. The concept of food safety according to Art. 14 Reg. (EC) No. 178/2002

Pursuant to Art. 14 (1) Regulation (EC) No. 178/2002 foodstuffs which are unsafe shall not be placed on the market. The provision contains more than a simple prohibition clause; in conjunction with the further paragraphs of Art. 14 and with Art. 17 and Art. 19 on the food operator's primary responsibility for food safety it establishes one of the fundamental principles of European food law.

23 Loessner, BIOspektrum 2000, 452; Merril et al., Long-circulating bacteriophage as antibacterial agents, Proceedings of the National Academy of Science/USA/93, 3188-3193 (1992).

24 Loessner, BIOspektrum 2000, 45; Bruttin, A./Brussow, H., Human volunteers receiving Escherichia coli phage T4 orally: a safety test of phage therapy, Antimicrob Agents Chemother, 2005 Jul, 49 (7):2874-8.

25 Loessner, BIOspektrum 2000, 452.

26 Federal Register 2006, 71:47729-47732.

27 http://www.cfsan.fda.gov/~rdb/opa-g198.html.

28 Cf. also Werlein/Hildebrandt, Hygiene-Report 2006, 20.

29 With a practical example Peek/Reddy, Gastroenterology 2006, 131: 1370 on the FDA-approved spray in the USA.

30 This reports Loessner, BIOspektrum 2000, 452.

31 See for example the draft on new regulations for food additives, COM (2006) 428 final – 2006/145 (COD) -for further information on the draft cf. Hagenmeyer, EffL 2006, 295.

The entrepreneurial room to place innovative food products on the market in the EU outside the scope of specific authorisation procedures is limited primarily by the concept of food safety. Therefore, if foodstuffs are treated with bacteriophages, the foodstuffs will have to be safe when they are used by the consumer, independent of the actual application of phages.

Art 14 (2) Regulation (EC) No 178/2002 defines that foodstuffs are considered "unsafe" when they are "injurious to health" or when they are "unfit for human consumption". Pursuant to Art 14 (5) Regulation (EC) No 178/2002, "in determining whether any food is unfit for human consumption regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay"[32]. At first sight one might consider that the treatment of a foodstuff with phages – that belong to the category of viruses[33] – is a contamination of the foodstuff. However, Art 14 (2) lit. b Regulation (EC) No 178/2002 means the unintended contamination with harmful materials[34]. The phages are used specifically to fight unwanted contamination of foodstuffs with bacteria such as listeria and salmonella[35]. This is why their use can only fall under the first alternative of Art 14 (2).

Pursuant to Art 14 (2) lit. a Regulation (EC) No 178/2002, foodstuffs are considered not safe when they are injurious to health, with regard "not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations", as well as to any "probable cumulative toxic effects" and "any particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers" (cf. Art 14 (4)). A person who is legally responsible according to food law also has to assure himself that the respective products – including all ingredients in the specific matrix of the foodstuff – have no disadvantageous effects for the health of the consumer. According to Art 14 (7) of the regulation, this can be achieved by taking regress to the specific food law provisions for foodstuffs and their ingredients and by showing that these requirements are met in the specific case: "Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned." As there are no special provisions in respect to bacteriophages for the time being, a self-contained proof for the harmlessness for human health in the sense of Art 14 (2) and (4) Regulation (EC) No 178/2002 has to be brought forward by means of a scientific approach.

Adequate scientific proof of food safety can, for example, be achieved through studies, but also in any other scientific way[36]. It does not have to originate from a European source or even have been appraised by EFSA. Art 14 (2) Regulation (EC) No 178/2002 does not contain any further requirements in this respect; therefore it is sufficient to put forward any scientific proof for the safety, whose validity has to be revised by the authorities and courts – maybe with the help of an expert, in case of a controversy.

In this regard EFSA's QPS-programme ("Qualified Presumption of Safety")[37] appears to be a possibly advantageous tool for food business operators in order to produce convincing proof of safety of their foodstuff containing micro-organisms when it is doubted. The QPS-programme is meant to shorten and simplify the safety analysis for micro-organisms by EFSA. Without a product-specific case-to-case analysis, EFSA attempts to use existing scientific proof in evaluating the general safety of specific micro-organisms in regard to their consumption[38]. Taking the example of bacteriophages it seems therefore possible that EFSA – after reviewing scientific documentation – comes to the conclusion that the viruses are presumed safe for the use in the production of foodstuffs. With regard to the bilateral EU-US plans of simplifying regulatory

32 Meyer/Streinz-Meyer, Kommentar LFGB u. Basis-VO, Art. 14 Basis-VO, marginal number 31.

33 Q.v. above II.

34 Cf. Meyer/Streinz-Meyer, Kommentar LFGB u. Basis-VO, Art. 14 Basis-VO, marginal number 32.

35 Q.v. above II.

36 On the requirement of a scientific safeguarding cf. also Zipfel/Rathke, Lebensmittelrecht, C 101, Art. 14 Basis-VO marginal number 47 f.

37 See working paper DG Health & Consumer Protection on a generic approach to the safety assessment of micro-organisms used in feed/food and feed/food production, available on the EFSA website (www.efsa.europa.eu).

38 Cf. working paper DG Health & Consumer Protection (see above footnote 38), p.2.

approval procedures in cross-border commerce between the two economic areas, EFSA should also consider using prior evaluations of a food product by the FDA (e.g. the GRAS status) as a convincing indication for general food safety in the EU. However, the setting up of a new evaluation procedure such as EFSA's QPS-programme does not mean that a food product, which has not been run through the QPS-programme can automatically be considered unsafe pursuant to Art. 14 Regulation (EC) No. 178/2002. By no means does the addition of yet another EU-procedure change the general legal concept of food safety as pointed out above. Thus the QPS-programme can assist companies to provide evidence of food safety and it may support the EU-legislator through prior risk assessment in debating specific legislative steps. However, the QPS-programme by its factual and legal character does not establish any kind of a new authorisation procedure for micro-organisms or foodstuffs containing them.

Accordingly, the competent authorities and courts have the primary burden of proof if they have doubts about the safety of a specific food product[39]. They must base their activities against such products on sound scientific evidence. In case the food business operator can show proof of safety, e.g. by producing scientific documentation, the supervising authorities must overcome such evidence in order to be able to intervene against the marketing of the foodstuff[40]. Of course, when the proof of safety of a foodstuff is scientifically well founded, the counter-evidence has to be on a similar scientific basis in order to justify governmental interference with the private freedom of marketing. In case an enterprise can document the safety of its products through the attestation of a well-known scientific institution or even through an official appraisal like EFSA's QPS-documentation or the US-GRAS status, there have to be well-founded doubts about the scientific procedural methods to justify measures against the placing on the market of the foodstuff according to Art 14 Regulation (EC) No 178/2002[41].

Concerning bacteriophages the existing scientific findings indicate that consumption of possibly remaining phages together with the treated foodstuffs does not have disadvantageous effects on the health of the consumer. This is officially documented though the permission of a spray with phages in the US after a safety examination and the apportionment of the so-called GRAS status in another case of a culture of bacteriophages that is to be used in foodstuffs[42]. When they are used only in the process of production, in the final product at the time of consumption the phages will only be found in an inactive state or in very small numbers[43]. Another argument to back up the thesis that phages, which have remained after the consumption of a foodstuff develop no disadvantageous effects for the health of the consumer is the fact that they are already naturally existent in the human body and in many food products[44].

2. Hygiene-Regulation (EC) No. 853/2004: Are phages decontaminants?

The legal assessment of substances that are used in the production of foodstuffs largely depends on the question into which of the existing food law categories the substances have to be classified. This is due to the fact that the classification into one of the food law categories can lead to authorisation requirements. The described effects[45] of phages when fighting harmful bacteria may evoke the thought of them falling within the scope of hygiene law regulations. Against this background it will firstly be examined whether bacteriophages have to be considered "decontaminants"[46] pursuant to Regulation (EC) No. 853/2004.

According to Art 3 (2) 1st sentence Regulation (EC) No 853/2004, "food business operators shall not use any substance other than potable water or – when Regulation (EC) No 852/2004 or this Regulation permits its use, clean water – to remove surface contamination from products of animal origin, unless use of the substance has been approved in

39 Convincingly Meisterernst ZLR 2007, 2.

40 Cf. OVG Nordrhein-Westfalen, ZLR 2006, 302, 327 – Lactobact Omni FOS II.

41 On this also Zipfel/Rathke, Lebensmittelrecht, C 101, Art. 14 Basis-VO marginal number 47.

42 Q.v. above II.

43 See above II.

44 See above II.

45 Q.v. above II.

46 This term is not mentioned in Regulation (EC) No 853/2004, but follows from the objective that is put down in Art. 3 (2) of the directive, i.e. to remove contamination.

accordance with the procedure referred to in Article 12 (2)." The regulation therefore explicitly allows only potable water for surface cleaning and, under certain conditions, clean water without drinking quality. However, in the authorisation procedure of Art 12 of the Regulation, other products can be allowed as well. In this procedure, the European Commission is supported by the Standing Committee on the Food Chain and Animal Health pursuant to Art 12 (1) Regulation (EC) No 853/2004. This means that a scientific assessment of the quality and use of the substance takes place before it can be classified as a decontaminant in the sense of Art 3 (2) Regulation (EC) No 853/2004. Therefore it must be asked whether bacteriophages in their described specific ways of use against pathogenic bacteria actually underlie the authorisation requirements pursuant to Art 3 (2) in combination with Art 12 (1) Regulation (EC) No 853/2004.

In the case of bacteriophages the essential criteria of above mentioned definition are "surface contamination" and "remove". As a surface contamination according to the original meaning of the word one would have to consider staining of the surface area i.e. by dust and blood and the like. Those contaminations can usually be easily removed through water – like Art 3 (2) Regulation (EC) No 853/2004 provides for the normal cases. Whether the word "contamination" also includes contamination with pathogenic bacteria remains at least doubtful. The considerations upon which the regulation is based remain silent on that matter. Even though in the strict sense of the word, contaminations are also a kind of pollution, the fact that water is mentioned as the main means of decontamination indicates that the European legislator understands by contamination primarily the superficial soiling through substances like blood and dust that can easily be removed by water. Bacteria, however, can only very rarely be fought with water. The possibilities for obtaining an authorization via Art 12 of the Regulation correspond – according to this understanding of Art 3 (2) – to chemical or similar additives, which are added to the water that has been directly mentioned in the regulation to remove surface contaminations of blood and dust more effectively. This thesis is also reinforced by the word "removed". What is "removed" in the strict sense of the word is usually superficial dirt; bacteria however are "fought" or "killed".

Additionally, the phages do not always have to be applied on the surface of the foodstuff[47]. Bacteria will be found preferably, but not only, on the surface of contaminated foodstuffs[48]. Therefore it can also be sensible to let bacteriophage cultures work on the inside of foodstuffs, e.g. by adding a starter culture to the process of cheese production or directly to the milk or by injecting the phages deeper into meat and poultry. Art 3 (2) Regulation (EC) No 853/2004 obviously does not relate to such treatments of foodstuffs.

These considerations show that a classification of bacteriophages as decontaminants according to the regulation does not do justice to the functioning mode of the viruses. Bacteriophages are not tools with a hygienic focus that work mechanically or chemically to clean the surface of foodstuffs but rather constitute biologically effective micro-organisms that can more realistically be compared with the functioning of desirable bacteria in starter cultures of milk and meat products. The explicit permission of micro-organisms – including viruses – in Art 6 (2) German Act on Food and Feedstuffs (LFGB) also backs up this thesis[49]. The German legislator saw no need for further stipulations on the use of micro-organisms and for this reason generally allowed their use in the production of foodstuffs.

This result is confirmed by the efforts of the EC-Commission to regulate chemical decontaminants. Since 2004, there exists a draft regulation that specifically deals with certain chemicals that are meant to remove pathogenic bacteria exclusively from poultry[50]. These concrete regulations are embedded into a larger scale of regulatory endeavour, which is meant to cover all means of decontamination for surface contamination of foodstuffs with an animal origin[51]. However, the considerations on which the draft is based make it clear that the commission is concerned with the possible dangers of chemical changes in the affected foodstuffs[52]. To the present day, the object of the regu-

47 Cf. Loessner, BIOspektrum 2000, 453.

48 Q.v. above II.

49 Cf. Zipfel/Rathke, C 102, § 6 LFGB marginal number 29 and 31, in more detail q.v. below E. 5.

50 Draft Commission Regulation laying down specific conditions for the antimicrobial treatment of food of animal origin, SANCO/2111/2004 Rev. 1.

51 Cf. recital 5 and. Art. 1 of the Draft Regulation, loc.cit.

52 Cf. recital 8 of the Draft Regulation (loc.cit.) that speaks of "chemical changes".

lation is meant to be the use of artificially created decontaminants that chemically cause the removal of all surface bacteria with which they come into contact[53]. Those chemicals do not work specifically on one certain type of bacteria, but on the bacterial fauna of the product as a whole[54]. This is to say that the Commission wants to subject the effects of the destruction of the entire bacterial fauna to scientific control[55]. Bacteriophages, however, work biologically and not chemically[56], the viruses furthermore work specifically by attacking only the pathogenic bacteria for which they are destined[57]. The remaining bacterial fauna remains intact[58]. One will come to the conclusion that the need for regulation of phages cannot be compared with the need of regulation concerning chemicals – consequently bacteriophages neither at currently nor in future can be classified as means of decontamination, not even against the background of the new Draft Regulation.

Nevertheless, the European Commission's regulatory plans and activities for chemical cleaning agents show an important aspect concerning Regulation (EC) No 853/2004. Evidently, the Commission itself assumes that substances that are specifically used against bacterial contamination do not underlie the special authorisation procedure pursuant to Art 3 (2) and Art 12 of this Regulation. Otherwise, either this special admission procedure or the new provisions of the Draft Regulation would be superfluous. Therefore, the Draft Regulation also suggest that the authorisation requirements of Art 3 (2) Regulation (EC) No 853/2004 shall not comprise substances that work antibacterially and whose application on the surface of foodstuffs is not compulsory.

As a result, one can say that bacteriophages, which are used in the production of foodstuffs to fight targetedly pathogenic bacteria, are not subject to prior approval pursuant to Art 3 (2) Regulation (EC) No 853/2004.

3. The classification as technical additives or processing aids

The above-described ways in which bacteriophages are applied in food production are – in the broadest sense – technological ones. The question therefore arises whether these viruses or the inactive bacteria that are occupied with phages constitute an additive in the sense of the uniform European definition. Pursuant to the definition of Directive 89/107/EEC an additive is

> "any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods."

The Proposal of the European Commission for a regulation on food additives does not change the definition[59].

For the classification as an additive it is therefore of importance whether the phages themselves or their by-products or reaction products indirectly or directly become an ingredient of the foodstuff or at least could become such an ingredient. A technological function exists without doubt. However, a line has to be drawn between additives and processing aids[60] as is done in the applicable provisions. Pursuant to Art 1 (3) lit a, the Council Directive 89/107/EEC does not apply to processing aids. Pursuant to Article 2, No 2a of the aforementioned Draft Regulation on additives, processing aids also are not considered as additives.

Due to this negative definition, it has to be determined in a first step whether bacteriophages are to be considered as processing aids in the described ways of use.

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53 Annex 1 of the Regulation Draft (loc.cit.) contains four chemical substances that are supposed to be allowed. The Statement of the BfR on the Regulation Draft also relates only to chemical decontaminations, cf. BfR-Statement Nr. 016/2006 of 21.1.2006, available online on the BfR's website (www.bfr.de).

54 BfR-Statement Nr. 016/2006 of 21.1.2006, p. 1 and 4, available online on the BfR's website (www.bfr.de).

55 BfR-Statement Nr. 016/2006 of 21.1.2006, p. 1 f, available online on the BfR's website (www.bfr.de).

56 Q.v. above II.

57 Loessner, BIOspektrum 2000, 452.

58 Loessner, loc.cit.

59 COM (2006) 428 final – 2006/145 (COD); for further information on the draft cf. Hagenmeyer, EffL 2006, 295.

60 According to Zipfel/Rathke, C 102, § 2 LFGB marginal number 22, 85 this means that processing aids are no additives in the sense of the European definition.

According to the official annotations to Art 1 (3a) of Council Directive 89/107/EEC, a processing aid is defined as

> "any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product."

The definition of processing aids in Art 3 No 2 b of the Draft Regulation on food additives also takes up this definition contained in the directive.

The addition of isolated phages to foodstuffs as well as an addition via their non-pathogenic, i.e. already lysed host cells, which in turn can for example be part of starter cultures, happens for technological reasons, just as it is the case with additives. It is therefore of central importance whether the final product contains more than only
– unintended,
– technically unavoidable

residues of these substances or their derivates, and whether those residues
– are harmless for health and
– have no technological impact on the final product.

When only residues of a substance used in the production may be contained in the final product, this usually means that it is the added amount of substance in relation to the final product that has to be reduced to residues[61]. How this happens is irrelevant; therefore an active elimination of the substance is not required. However, the sole deactivation of the substance is not always considered to be sufficient[62].

For bacteriophages, these requirements would be met, when after completion of the production process there are only a small number of phages left in the foodstuff in comparison to the originally used number of phages. In their original, active form, the phages are no longer contained in the final product, however they might still be existent in an inactive, i.e. dead form. As long as the number of the inactive phages does not greatly differ from the original number of active phages, the question arises whether they can still be defined as residues in the sense of a processing aid. The Council Directive 89/107/EEC on additives and the Draft Regulation speak of "residues of the substance or its derivatives in the final product". The further requirements of the term "processing aid" suggest an equalisation of inactive substances with the active ones and therefore allow for a "numeric" interpretation of the term "residues". Those other requirements, e.g. the technical unavoidability, safety for health and a lack of technological functions in the final product would render the term "residues" useless, if those requirements were the only things that mattered. On the other hand, according to the intended purpose of the differentiation, the amount of residues cannot matter for the qualification of a substance. Processing aids are therefore not part of the definition of an additive, because they shall not be subject to an approval procedure. Such a procedure is considered to be necessary for additives as they are still effective in the final product and it therefore has to be determined whether they are safe for health. These two issues are entwined: every substance that is still active or at least could become active again might have an impact on the human metabolism and health so that a prior official examination of its addition to a foodstuff can be required. However, substances that for various reasons are no longer active in the final product and for which it can be assumed that they are no longer relevant under the aspect of safety, it is considered to be sufficient when the food operator him/herself is responsible for making sure that the use of these substances in the production of foodstuffs cannot lead to safety risks in the final product.

Taking into consideration the above described functioning of phages in the production of foodstuffs, and taking further into account the fact that these phages do not become inactive directly after their application in the manufacturing of foodstuffs, but instead depending on their surroundings become inactive only after a short delay, the question of when the production process is completed, is not only essential for the question whether the phages can be found only as a "re-

61 Cf. Zipfel/Rathke, C 102, § 2 LFGB, marginal number 88; Meyer/Streinz-Meyer, LFGB, § 2, marginal number 84.

62 Cf. Zipfel/Rathke, Meyer/Streinz-Meyer ibid.

sidue", but also for the fulfilment of the further requirements that lie in the definition of a processing aid. The completion of the production process means the moment at which a final product comes into existence in the sense of the official annotations to Art 1 (3a) of the Council Directive 89/107/EEC on additives or in the sense of the corresponding definition in the Draft Regulation for additives.

The term "final product" is also mentioned in the definition of a "food additive" in Art 1 (2) 89/107/EEC, however it remains undefined in the directive as well as it remains undefined elsewhere, e.g. in the Regulation (EC) No 178/2002. If one took into consideration only the strict sense of the word "final product", one might come to the conclusion that a "final product" would already exist at the moment at which the production process has been finished, i.e. when the producer of the foodstuff has ceased to influence the foodstuff in the sense of a treatment or anything similar. If that was the case, the latest possible moment for observation would be the one in which the foodstuff – in whose production bacteriophages had been used – is packaged.

However, this would not comply with the purposes of the provisions on processing aids on the one hand and additives on the other hand. According to the purposes of these provisions one has to take into account the moment in which the foodstuff is brought to use, i.e. when it is eaten by the consumer or at which it can be eaten by the consumer, and it has to be determined, whether residues are still existent at that time, whether these are technically unavoidable, and safe for health etc.

As a result one may say that inactive phages or bacteria constitute only residues in the sense of the definition of processing aids.

Further requirements, for example that the residues have to remain unintendedly in the final product, are technically unavoidable and have no technological impact on the product, are interdependent of each other. One cannot speak of an unwanted remainder of the residues when these have a technological impact on the final product[63]. The mere acquiescence of the existence in the final product does not change this, and it especially does not make them "intended" residues except for when the remaining of the residues is technically avoidable[64].

For several times it has been the topic of discussions which endeavours the manufacturer has to undertake to assure that the remaining of residues is considered as technically unavoidable. On the one hand, it is the best available technology that has to be considered, meaning that the residues cannot be entirely removed with all the methods available in technology to the present day. The possibilities, which the individual manufacturer has, are therefore not taken into account. On the other hand, the principle of proportionality that enjoys constitutional status, is respected as the costs for the removal have to be put into perspective with the manufacturing costs for the foodstuff, so that very expensive and time consuming measures are not demanded[65]. A removal of the inactive phages or the lysed bacteria is not possible in a physical way. One might only think of a chemical treatment, but this would be counterproductive for the foodstuff and its safety. Their presence in the final product would therefore be technically unavoidable. Moreover, as described above, a technological use in the final product, i.e. in the product that is to be eaten by the consumer, no longer exists. In particular, the inactive bacteria and phages do not have the impact that a preservative might have nor do they have any other technological effects.

Finally, the remaining residues have to "not present any health risk". The question of food safety in connection with the application of bacteriophages has already been discussed above in III. 1. The wording "do not present any health risk" is not identical with the term "injurious to health" in Art 14 of Regulation (EC) No 178/2002. However, a difference in content does not seem intended. Therefore it is the general opinion that a processing aid can only be considered a health risk when it is unsafe in the sense of Art 14 of Regulation (EC) No 178/2002.[66]

63 Cf. Zipfel/Rathke, C 102 § 2 LFGB marginal number 90.

64 Cf. Zipfel/Rathke, ibid.; Meyer/Streinz-Meyer, § 2 LFGB marginal number 84.

65 Cf. Zipfel/Rathke, loc.cit. marginal number 91; cf. also Bergmann, ZLR 2003, 628, 634 ff. for the comparable problem concerning § 31 LMBG.

66 Zipfel/Rathke, loc.cit., marginal number 92; Meyer/Streinz-Meyer, LFGB ibid.

Under the premise that they are safe for human health, bacteriophages can therefore be considered as processing aids.

4. Application of the Novel Food Regulation (EC) No. 258/97?

After having established that bacteriophages fall within the scope of the term "processing aid" further differentiations can be made in respect to possible food law categories. The first differentiation concerns the so-called "Novel-Food-Regulation" (EC) No 258/97.

The scope of application of the Novel Food Regulation is limited by Article 2 (1) lit. a of the Regulation. Accordingly, food additives in the sense of Directive 89/107/EEC shall not be comprised by the Novel Food Regulation. As processing aids bacteriophages are from a factual and legal point of view comparable to technological additives. The same reasons that lead to the expulsion of additives from the scope of the Novel Food Regulation point towards an exemption for processing aids as well.

Thus, phages have to be taken out of the scope of the Novel Food Regulation as they are in so far comparable with additives and are also defined in Directive 89/107/EEC.

5. Not to be forgotten: The Biocide Directive 98/8/EC

Through their elimination of harmful bacteria phages could secondly fall within the scope of Directive 98/8/EC concerning the placing of biocidal products on the market.

However, the Biocide Directive 98/8/EC likewise does not cover food additives according to its Article 1 (2) lit i. Therefore, it is for the same reasons as pointed out regarding the Novel Food Regulation that bacteriophages do not fall within the scope of the Biocide Directive.

6. The end of the journey

At the end of a journey through the scopes of application for several standing authorisation procedures under EU-food law the outcome is finally visible: Phages as micro-organisms for technological uses can presently benefit from the EU-legislator's relatively liberal stance towards micro-organisms and processing aids in food production. However, for bacteriophages, as for any other food product, the general principle of food safety pursuant to Art. 14 Regulation (EC) 178/2002 clearly formulates the requirements and the borderlines of their use.

IV. Conclusion

According to the basic principle of EU-food law, which has remained unchanged by Regulation (EC) No. 178/2002, food operators are free to produce and sell foodstuffs in the EU without prior permission – provided the foodstuffs are safe. Whether a foodstuff is safe must primarily be judged by the food operators themselves as Art. 17(1) and Art. 19 (1) Regulation (EC) No. 178/2002 clearly point out.

The EU-legislator constantly introduces new authorisation procedures for food products. However, the answer to the question "Which path to go?" is sometimes simpler than the route. It was shown here by the example of bacteriophages that even for products that appear very close to the scope of several different authorisation procedures, the basic principle of EU-food law applies. Art. 14 Regulation (EC) 178/2002 in such cases provides an effective tool to regulate innovative food products on the basis of their safety. In addition, the rather new QPS-procedure for micro-organisms managed by EFSA can assist both supervising authorities and food operators in evaluating the safety of a food product without delaying its marketing by a lengthy and expensive authorisation procedure for a specific product.