



MICREOS

European Ombudsman
Médiateur européen
1 avenue du Président Robert Schuman
CS 30403
F-67001 Strasbourg Cedex

Wageningen, 27 November 2018

Madam the Ombudsman,
Dear Mrs. O'Reilly,

Micreos (www.micreos.com), a small/medium sized Enterprise established in 2005 with 70 employees, develops endolysin- and phage technology that enables targeted killing of only unwanted bacteria. As a privately-owned company, we run our own production and R&D center for endolysins in Bilthoven (Human Health) and for phages (food safety) in Wageningen. The company works together with ETH Zurich and numerous medical and technology centers, including Erasmus MC (Rotterdam), Public Health Lab Kennemerland, the Dutch Burn Centers (Beverwijk) and many others.

Our company's continuous commitment to helping mankind with products that are effective, sustainable and affordable were rewarded in April 2018 when Micreos' 'sustainable alternative to antibiotics' was chosen as Europe's most relevant innovation, at the finals of the EU's Ideas from Europe competition. Ideas from Europe is a European initiative that facilitates sustainable innovations aimed at addressing global challenges.

Micreos Food Safety has developed Listex™ P100, a product based on the bacteriophage P100 which selectively targets *Listeria* bacteria. With a mortality rate of around 13%, *Listeria monocytogenes* accounts for the highest amount of human fatalities compared to other microbial food contaminants¹. Listex™ P100 provides a method to prevent contamination with this food pathogen, making it possible to decrease the number of listeriosis cases and save lives.

According to the EFSA evaluation published in 2016, the product Listex™ P100 is an entirely safe product and poses no risk to human health².

In 2007, we presented the use of Listex™ P100 on Ready-To-Eat (RTE) food to the European Commission to be recognized as a processing aid as legally defined in Regulation (EC) No 1333/2008 on food additives. The classification as a processing aid corresponds with the regulatory position of various non-EU countries, such as the USA, Canada, Australia, Switzerland and Israel.

In the EU Listex™ P100 can be used – and is in fact marketed – as processing aid on RTE food from fruit- or vegetable origin.

¹ The European Union Summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016, European Food Safety Authority, 2017, <https://www.efsa.europa.eu/en/efsajournal/pub/5077>

² Evaluation of the safety and efficacy of Listex™ P100 for reduction of pathogens on different ready-to-eat (RTE) food products. European Food Safety Authority, 2016, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4565>



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The Commission wrongly classified the use of Listex™ P100 on animal-derived RTE food as a 'decontaminant' referring to Article 3(2) of Regulation (EC) No 853/2004 stating a "*substance other than potable water to remove surface contamination from products of animal origin*" requires an approval by the Commission and Member States.

Based on the Commission's decision we submitted a file for approval of the use of the product as a 'decontaminant' in June 2015.

Much to our regret we wish to complain about maladministration by the European Commission, during and after the long-lasting approval procedure.

1) The requirement of lawfulness, principle of proportionality and the duty to refrain from abuse of power

The classification of the use of Listex™ P100 on animal-derived RTE food as a 'decontaminant' can only be explained by the potentially deliberate misinterpretation of the intended functionality of Listex™ P100 on RTE food, and not by a proper implementation of the EU legislation.

Harmful bacteria are a common cause for foodborne illnesses. Whether or not a harmful bacterium causes an illness depends – as with chemicals – on the amount ingested. Therefore, maximum tolerable levels for various types of bacteria in different foodstuffs have been laid down by EU law³. For instance, this law prescribes that RTE food⁴ should – at the moment of consumption – contain an 'acceptable level' of microorganisms of concern. One of the microorganisms of concern is *Listeria monocytogenes* (Listeria). This bacterium is a foodborne pathogen responsible for listeriosis, an increasingly fatal disease. According to the law, the maximum tolerable level of Listeria that is allowed in RTE food is 100 living cells (i.e. 'colony forming units') per gram of food. Higher numbers cause an 'unacceptable' level, which comes down to microbial 'contamination' of the food.

In order to prevent microbial contamination in general, the EU laid down strict hygiene rules for food production and for traceability of the final food⁵. However, well-documented practice shows that even the strict hygiene rules are insufficient to avoid contamination of initially safe foodstuffs, while the traceability rule only enables the *removal* of contaminated products from the market *after* the problem has already emerged. A clear example of food contamination which cannot be totally eliminated, despite strict hygienic measures, is the contamination with Listeria. This is illustrated by the fact that there has been a statistically significant increase in the number of listeriosis cases between 2008 and 2016⁶, leading to alarming rates of fatalities and industrial recalls.

RTE foodstuffs are amongst those that are regularly contaminated with Listeria. Even when the RTE foodstuff has been produced with the help of pasteurization, incidental Listeria cells from the environment or equipment may settle on the food during the final stages of the production process,

³ Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

⁴ 'ready-to-eat food' means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern (Regulation No 2073/2005)

⁵ Regulation (EC) No 178/2002 laying down the general principles and requirements of food law (General food law)

⁶ The European Union Summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016, European Food Safety Authority, 2017, <https://www.efsa.europa.eu/en/efsajournal/pub/5077>



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such as cutting, slicing and packaging. These cells may subsequently multiply further to an 'unacceptable' level (and thus contamination). In order to avoid this, RTE food can be treated with a natural bacteriophage which kills the incidental *Listeria* cells before any *outgrowth* to unacceptable levels can occur. Such a bacteriophage, which is present in the product Listex™ P100, works specifically on *Listeria* cells and poses no risk to human health⁷. As it does *not* kill other foodborne pathogens, strict hygiene measures nevertheless remain indispensable. This implies that Listex™ P100 cannot be used as an effective decontaminant, which kills all types of micro-organisms present.

The bacteriophages present in Listex™ P100 exert their effect during the final stages of food processing and its use may result in the unintentional presence of residues in the final foodstuff. These natural, harmless residues (amino acids and nucleotides naturally present in foodstuffs) do not have any technological effect on the final product. Listex™ P100 is about preventing a process, not about reversing a process or 'decontaminating'⁸.

Nevertheless, the perceived 'decontamination' effect of Listex™ P100 caused the Commission not only to jump to conclusions but recently to persevere in its initial position:

- The Commission decided to organize a public consultation on the draft Commission Regulation on the use of Listex™ P100 against *Listeria* on animal-derived RTE food products between 12 July and 9 August 2017⁹. Identical feedback of 2 respondents (consumer associations) showed within 24-28 hours their doubts as to the classification of the use of Listex™ P100 as a 'decontaminant' under Regulation (EC) No 853/2004 and believed it should be considered as food additive, resulting therefore in a negative response (as a decontaminant).

- In the letter of 26 February 2018 Micreos explained to the Commission – again – that the use of Listex™ P100 is intended not to remove contamination, but to prevent it. A statement of Prof. Devlieghere, professor at Ghent University in Food Microbiology and Food Preservation, was included¹⁰.

In its letter of 9 April 2018, the Commission never addressed this scientifically founded argument challenging the classification as a 'decontaminant' but instead kept referring to the legal framework that requires an authorization (as a 'decontaminant') under Regulation (EC) No 853/2004. The Commission claims that there is insufficient support from the stakeholders to authorize a 'decontaminant', without accepting the fact that this classification has been incorrect from the start.

- In their meeting of 17 May 2017, several members of the Standing Committee of Plants, Animals, Food and Feed (SCoPAFF)¹¹ doubted precisely whether the classification as a decontaminant was correct. In view of the increasing listeriosis risks, on 3 July 2018 members of the SCoPAFF asked questions related to the option to recognize the use of Listex™ P100 on animal-derived RTE food as a processing aid or food additive, outside the scope of Regulation (EC) No 853/2004. The Chair

⁷ Evaluation of the safety and efficacy of Listex™ P100 for reduction of pathogens on different ready-to-eat (RTE) food products. European Food Safety Authority, 2016, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4565>

⁸ Similar to the use of acidulated water on the surface of freshly cut apples to prevent the browning and not to bleach the already brown apple.

⁹ https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-3512172_en

¹⁰ See also article in Parliament Magazine by Prof. Devlieghere "EU must reconsider phage solution to *Listeria* threat" <http://library.myebook.com/the-parliament/the-parliament-magazine-issue-472-19-march-2018/2018/110/#page/24>

¹¹ https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_biosec_20170517_sum.pdf



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of the SCoPAFF subsequently concluded that the producer of Listex™ P100 should be requested to clarify how the use of Listex™ P100 on RTE food should be classified.

Following this SCoPAFF meeting, the Commission did not contact Micreos with this request but published in the minutes that the authorization procedure of Listex™ P100 under Regulation (EC) No 853/2004 was halted because of lack of support¹².

- On 20 July 2018 Mr. José Inácio Faria, Member of the European Parliament, has sent the Commission a letter inquiring about the authorization of the use of Phage P100 and expressing new concerns about the recent European outbreaks of *Listeria monocytogenes*.

Much to our surprise, the Commission now presents new epidemiological tools as a solution on how to put an end to outbreaks by linking human cases with the source of the contamination in food.

In its answer to MEP José Inácio Faria the Commission neglects to mention the possibility to prevent *Listeria* outbreaks by enabling the use of Listex™ P100 on animal-derived RTE food. Contrary to the conclusion of several Member States, the Commission holds on to the classification of the use of Phage P100 on animal-derived RTE food as a “decontaminant”.

In its letter of 7 August 2018, the Commission claims most stakeholders, consumers and the European Parliament challenge the principle of decontamination. They allegedly consider the use of it as a disincentive to invest in hygiene. The MEP José Inácio Faria was informed *“the Commission is attentive at examining all aspects when considering the authorisation of such decontaminants and collecting a large support, notably among Member States. However, this was not proven to be the case during discussions held on the application you are referring to.”*

Asked for clarification in the letter of 15 October 2018 on which stakeholders (consumer associations, Members of the European Parliament etc.) consider the use of Listex™ P100 on animal-derived RTE food to be a decontaminant and therefore refuse to authorize such use of the product, the Commission only referred to the legislative framework.

The Commission did not inform MEP José Inácio Faria about the discussion among Member States regarding the classification of the use of Listex™ P100 on animal-derived RTE food during the recent meeting of the SCoPAFF Committee on the Biological Safety of the Food Chain on 3 July 2018 nor did the Commission inform MEP José Inácio Faria about the feedback of the consumer associations during the public consultation showing the same concern as to the classification of the use of Listex™ P100 on animal-derived RTE food under Regulation (EC) No 853/2004.

Moreover the answer of the Commission to MEP José Inácio Faria is not compatible with the reaction of the Ministry of Rural Affairs in Estonia highlighting that the concerns expressed during the SCoPAFF meeting of 17 May 2017 were not intended to halt the procedure but that they hoped that *“the clarifications will be done shortly in order to be able to induce more efficient ways in combating Listeria in the food sector”*¹³ or with the written reactions of the Danish Minister for Environment and

¹² https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_biosec_20180703_sum.pdf

¹³ Letter of the Ministry of Rural Affairs in Estonia dd. 9 April 2018.



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Food Mr. Esben Lunde Larsen and the German Federal Minister of Food and Agriculture Ms. Julia Klöckner¹⁴.

Apart from the fact that the intended use of Listex™ P100 on animal-derived food is meant to *prevent* contamination, and not to decontaminate, was Article 3(2) of Regulation (EC) No 853/2004 not meant to cover products like RTE food, nor to remove contamination of microbial origin. Originally, Art. 3(2) was meant to clean dirt and blood from carcasses at the slaughterhouse and not to remove bacterial contamination (such as Listeria) with water, *as water merely increases such contamination*. Moreover, it is very uncommon for RTE food (such as cheese and sausages) to be treated with water to remove surface contamination, which makes any connection with Art. 3(2) somewhat outlandish.

In order to answer the questions raised by the members of the SCoPAFF Committee, Microeos decided to prepare a comprehensive response document for all Member States in which all questions and confusions around the use of Listex™ P100 on RTE food are answered and clarified.

The content of this document, however, has already been presented to the Commission on several occasions¹⁵. Ignoring the scientific arguments, the concerns of consumer associations and of several Member States, the Commission holds on to the classification of the use of Listex™P100 on animal-derived RTE food as a decontaminant, wrongly referring to the requirement to properly implement the EU-legislation.

In doing so the Commission is using her power for purposes which have no basis in the law and which are not motivated by any public interest¹⁶. Moreover, the refusal to even respond to the scientific arguments shows the Commission is restricting the rights of Microeos (imposing an approval), while those restrictions are not in a reasonable relation with the purpose of the action pursued (claimed requirement of lawfulness doubted by several stakeholders)¹⁷.

2) The requirement of impartiality and objectivity

The Summary Report of the recent meeting of the SCoPAFF Committee on the Biological Safety of the Food Chain on 3 July 2018 refers to the discussion among Member States regarding the authorization of the use of Listex™ P100 on animal-derived RTE food. The Report only describes a number of concerns of the Member States but does not mention any discussion on the classification of the use of the product. The report suggests that the authorization procedure of the use of Listex™ P100 on animal-derived RTE food has been terminated due to lack of support. In no way does the Commission admit that the lack of support may be caused by its unsupported and potentially incorrect decision to authorize the use of Listex™ P100 on animal-derived RTE food as decontaminant.

¹⁴ Letter of the Danish Minister for Environment and Food dd. 23 October 2017 and of the German Federal Minister of Food and Agriculture dd. 26 July 2018.

¹⁵ Letters from Microeos of 18 September 2017, 4 December 2017, 26 February 2018. Letters from PA International of 22 January 2018, 8 February 2018, 22 February 2018, 17 August 2018.

¹⁶ The European Code of Good Administrative Behaviour (2005), article 7

¹⁷ The European Code of Good Administrative Behaviour (2005), article 6



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From the report of several Member States attending this meeting, it can be concluded that the SCoPAFF Summary Report overlooks the following statements: (1) it was agreed that the classification of the use of Listex™ P100 on animal-derived RTE foods as a decontaminant under Regulation (EC) No 853/2004, as proposed by the Commission, was unsuitable and (2) that the company (i.e. the undersigned) should now decide whether to pursue classification of the use of Listex™ P100 as a food additive or a processing aid.

This incomplete report created the impression that Listex™ P100 cannot be marketed in the EU in the future at all, as was reported in several trade publications. These publications further damaged the position of an EU award winning small/medium sized EU Enterprise that tries to fulfil key policy targets of the European Union in terms of innovation and SME development.

In our letter sent 15 October 2018 we asked the Commissioner to clarify why there is a discrepancy between the Summary Report of the SCoPAFF Committee on the Biological Safety of the Food Chain held on 3 July 2018 released by the Commission and the comments on the meeting of individual Member States. November 5th, 2018 the Commission responded she only published minutes to briefly inform on the discussion held in that meeting and that these minutes are not intended to offer a record of the discussion.

Taking into account the importance of the classification of the use of Listex™ P100 on animal-derived RTE food, the Summary Report should have reported on all relevant factors and given each of them its proper weight, whilst excluding irrelevant elements¹⁸.

In order to avoid any further discussion on the classification of the use of Listex™ P100 on animal-derived RTE food, the Commission ignored the conclusion of its own SCoPAFF Chair and chose to report only briefly on the discussion holding back vital information about the questions and concerns of Member States. This reporting lacks impartiality¹⁹.

3) The requirement of transparency and openness

In our letter sent 15 October 2018 we asked the Commissioner for disclosure of the extensive meeting minutes as well as to provide us a copy of all the documents concerning the SCoPAFF meeting held on 3 July 2018.

The Commission did not even answer this question in her letter of 5 November 2018 and in ignoring our demand for disclosure she refused to give us the requested information²⁰.

4) The requirement of due process

- The Commission decided to organize a public consultation on the draft Commission Regulation on the use of Listex™ P100 against Listeria on animal-derived RTE food products between 12 July and 9 August 2017²¹. Micreos was not informed by the Commission.

¹⁸ The European Code of Good Administrative Behaviour (2005), article 9

¹⁹ The European Code of Good Administrative Behaviour (2005), article 8

²⁰ The European Code of Good Administrative Behaviour (2005), articles 22 to 24

²¹ https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-3512172_en



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Feedback of 2 respondents (consumer associations) showed the same concern as to the classification of the use of Listex™P100 on animal-derived RTE food as a 'decontaminant'. They doubted that this use of Listex™ P100 was correctly classified and believed it should be regarded as food additive, resulting therefore in a negative response (as a decontaminant).

From the 9 responses, 7 supported the authorization. On basis of the two negative responses and the claim that there was not enough support from the Member States, the Commission decided to halt the authorization procedure without making any effort to find a more correct way to legally classify the use of Listex™ P100 on animal-derived RTE food.

In a scientifically supported answer Microeos and PA International reacted to the negative responses of the consumer organization, but never received any substantive feedback²².

In our letter of 15 October 2018, we asked whether it is common practice not to inform the producer concerned about the public consultation and whether this practice and the lack of following up on the results of a public consultation in this stage of the decision-making process can be considered to fulfil the requirements of due process.

The Commission answered there is no obligation for the Commission to inform on the launch of such consultation nor to react to the feedback received.

After a Public Consultation resulting in a majority supporting the draft Regulation the Commission decided to halt the authorization procedure of the use of Listex™ P100 on animal-derived food without following up on the minority opinions and concerns and even without consulting the producer. This behaviour does not meet the legitimate expectations of Microeos²³, nor indeed of the largest Groups of the European Parliament, including Vice Chairmen of the ENVI Committee, concerned with the increased Listeria threat.

The decision to halt the authorization procedure referred to the public consultation and was defended in later correspondence²⁴ of the Commission by a lack of resources.

According to EFSA, Listex™ P100 offers a safe²⁵ solution to the increasing number of confirmed listeriosis cases in the EU.

Because of its importance for public health, the decision to halt the authorization procedure without enabling the use of Listex™ P100 on animal-derived RTE food was not supported by several Member States. The Ministry of Rural Affairs in Estonia highlighted that the concerns expressed during the SCoPAFF meeting were not intended to halt the procedure but that they hoped that *"the clarifications will be done shortly in order to be able to induce more efficient ways in combating Listeria in the food sector."*²⁶

²² Letter from Microeos to BEUC of 17 August 2017. Letters from PA International to BEUC of 27 April 2018 and 4 May 2018.

²³ The European Code of Good Administrative Behaviour (2005), article 10

²⁴ Letter of 21 December 2017.

²⁵ Evaluation of the safety and efficacy of Listex™ P100 for reduction of pathogens on different ready-to-eat (RTE) food products. European Food Safety Authority, 2016, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4565>

²⁶ Letter of the Ministry of Rural Affairs in Estonia dd. 9 April 2018.



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The Danish Minister for Environment and Food Mr. Esben Lunde Larsen reacted similarly after the Public Consultation, as did the German Federal Minister of Food and Agriculture Ms. Julia Klöckner after the SCoPAFF meeting²⁷.

The decision of the Commission to halt the authorization procedure as a decontaminant without any follow up on the reaction of the Member States urging for a solution of the Listeria problem and thus ignoring the importance for public health in combatting Listeria clearly did not meet the legitimate expectations of the European Parliament and other members of the public concerned with public health.

5) The right to be heard and to make statements

After the Public Consultation of the draft Regulation the Commission decided to halt the authorization procedure of the use of Listex™ P100 on animal-derived food without hearing Microeos. She refused to approach Microeos for clarification on the issues raised during the Public Consultation, before the SCoPAFF meeting of 3 July 2018 and after the SCoPAFF meeting about her intention whether to pursue classification of the use of Listex™ P100 on animal-derived RTE food as a food additive or a processing aid.

Even worse, Microeos tried to address all concerns expressed by the SCoPAFF members, but the Commission refused to hear us answering that they were clever enough to make the decision themselves: *“Ability of Member States’ experts to take informed positions raised to them by the Commission cannot be challenged”²⁸ !*

In doing so the Commission violated the rights of defence of Microeos at every stage in the decision-making procedure²⁹ and her rights to submit written comments and, when needed, to present oral observations before the decision is taken³⁰. The understanding of the Commission of its position in an open and rules-based democracy is further demonstrated in its answers to formal letters signed by majority Group Members in the European Parliament.

We regret having to ask You to investigate our complaints. Repeatedly, we contacted the Commission in order to obtain redress. Our latest comprehensive letter of 15 October 2018 included 27 questions which remained almost all unanswered in the response of the Commission on 5 November 2018.

Enclosed we send You the documents listed below, supporting our complaints and witnessing of our efforts in vain to convince the Commission to treat our case according to the principles of good administration.

²⁷ Letter of the Danish Minister for Environment and Food dd. 23 October 2017 and of the German Federal Minister of Food and Agriculture dd. 26 July 2018.

²⁸ Letter of the Commission to Microeos of 9 April 2018

²⁹ The European Code of Good Administrative Behaviour (2005), article 16 (1)

³⁰ The European Code of Good Administrative Behaviour (2005), article 16 (2)



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Our complaints about maladministration concern facts and behaviour of the Commission from less than two years ago. Based on recent information the Commission refuses to reconsider its initial position on the use of the product. The subject of our complaint has never been brought to court.

We ask for your intervention hoping to convince the Commission to follow up on the concerns recently expressed by the stakeholders and acknowledge that the intended use of Listex™ P100 on animal-derived RTE food should not be regarded as a decontaminant falling under Article 3(2) of Regulation 853/2004 (but as a processing aid preventing Listeria).

Your intervention can lead to a solution in giving Micreos, Member States, European citizens and the industry legal certainty about the use of an entirely safe product that can help save lives and prevent recalls, in line with the views of key Members of the largest Groups in the European Parliament.

We are at your disposal for any further clarification.

Yours sincerely,

Mr Mark Offerhaus
CEO

Enclosed:

1. Timeline.
2. Global regulatory overview.
3. Letter from Micreos to the Commission of 26 February 2018.
4. Answer from the Commission to Micreos of 9 April 2018.
5. Letter of MEP Mr. José Inácia Faria to the Commission of 20 July 2018.
6. Answer from the Commission to MEP Mr. José Inácia Faria of 7 August 2018.
7. Letter of the Ministry of Rural Affairs in Estonia of 9 April 2018.
8. Letter of the Danish Minister for Environment and Food of 23 October 2017.
9. Letter of the German Federal Minister of Food and Agriculture of 26 July 2018.
10. Comprehensive document about Listex™ P100.
11. Letters from Micreos to the Commission of 18 September 2017, 4 December 2017, 26 February 2018.
12. Letters from PA International to the Commission of 22 January 2018, 7 February 2018, 22 February 2018, 17 August 2018.
13. Letter of Micreos to the Commission of 15 October 2018.
14. Answer from the Commission of 5 November 2018.
15. Chronological overview and copy of the correspondence with the Commission and Member States.
16. Analytical overview of the various issues not addressed (correctly) by the European Commission.
17. Analytical overview regarding the Public Consultation.