

Report of EFSA

Report of the Public Consultation on the EFSA Draft Opinion on “*The use and mode of action of bacteriophages in food production*”

(Related to Question No EFSA-Q-2008-400)

Issued on 22 April 2009

Background

On the 22 January 2009, EFSA’s Panel on Biological Hazards (BIOHAZ) endorsed a draft scientific opinion on *The use and mode of action of bacteriophages in food production*. The draft opinion had been prepared by a BIOHAZ working group composed of external experts and members of the BIOHAZ Panel.

In line with EFSA’s policy on openness and transparency, and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engages in public consultations on key issues. The work on bacteriophages is such an issue, and on 30 January 2009 the draft opinion was published for public consultation until the 6 March 2009 (see Annex). EFSA has committed to publish the comments received as well as a short report on the outcome of the consultation.

Comments received

At the deadline, EFSA had received 24 submissions, from 15 interested parties (individuals, industry organisations and national and European assessment bodies). All comments received were scrutinized and subsequently tabulated with reference to the author(s) and the section of the draft opinion to which the comment referred. Comments submitted formally on behalf of an organization appear with the name of the organization. The table of all comments is published – without reference to individual names – as a separate document on the EFSA web site: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902525399.htm.

Screening and evaluation of comments received

General

Editorial comments were dealt with by EFSA’s secretariat. The remaining comments were discussed with the EFSA BIOHAZ working group that had drafted the original document, and presented to the BIOHAZ Panel.

Types of comments and Incorporation of comments in the opinion

EFSA is extremely grateful to the contributors for taking the time to send their comments, and these were well received by the WG and BIOHAZ Panel. A number of comments made reference to areas within the responsibility of the Risk Manager (European Commission) and

as such outside the remit of EFSA. The European Commission has clearly indicated in the background of the mandate supplied to EFSA, that bacteriophages when used on food of animal origin (including cheese) could be considered either as food additives or as substances for reducing surface contamination (and thereby requiring approval under regulation 853/2004). EFSA has directly answered to the ToR (1 and 2) in the mandate, and the decision to classify these agents under one or other regulatory frameworks belongs to the European Commission and is not within the remit of EFSA (Risk Assessment).

Also, several comments were focused on issues outside the Terms of Reference for this mandate, and as such outside the scope of this Opinion. In a number of received comments, personal views based on generalisations or assumptions, and unsupported by scientific data have been expressed, and as such the Panel considered that these could not be incorporated in the assessment. Finally, some comments have offered arguments for different interpretations of scientific information compared to the ones expressed in the draft opinion by the BIOHAZ Panel; these comments and arguments have been acknowledged and discussed. The draft opinion has been revised only where the BIOHAZ WG and Panel agreed with the argumentation.

In one instance, a new scientific publication has been pointed out to the WG, and this has been inserted in the text and list of references. Also a new conclusion has been added relating to the issue of bacteriophage insensitive mutants

The Opinion was subsequently presented to the BIOHAZ Panel and adopted at the plenary meeting on 22 April 2009.

ANNEX

The text below is from the EFSA website of the public consultation:

Public consultation on the draft Opinion on the use and mode of action of bacteriophages in food production

Deadline: 6 March 2009

The remit of EFSA’s Panel on Biological Hazards (BIOHAZ) is to provide scientific advice on questions on biological hazards relating to food safety and food-borne disease, including food-borne zoonoses and transmissible spongiform encephalopathies, microbiology, food hygiene and associated waste management. In 2008, the BIOHAZ Panel received a mandate from the European Commission (EC) (Question No EFSA-Q-2008-400), and appointed an expert group with the task to draft a Scientific Opinion on: “The use and mode of action of bacteriophages in food production”.

In this mandate, the EC is seeking technical assistance from EFSA on the way in which bacteriophages work. Specifically, they asked EFSA to describe the mode of action expected from the use of bacteriophage solutions on food of animal origin; and to advise whether the use of bacteriophages may lead to a continual functioning in the food (thereby protecting against recontamination), or whether the effect can be expected to be short lived (no continuing action in the final food). The EC at this stage is not seeking advice with regard to the safety in use of such bacteriophage solutions.

The draft opinion developed by the working group, and endorsed by the BIOHAZ Panel presents information on the state of the art on the areas mentioned in the terms of reference. In line with EFSA’s policy on openness and transparency, and in order to receive comments from the scientific community and stakeholders, EFSA has launched a public consultation on the draft opinion.

Interested parties are invited to submit written comments using the online form by 6 March 2009, 17:00 CET. Please exclusively use the electronic template provided with the documents to submit comments and refer to the line numbering.

Please note that comments submitted by e-mail or by post cannot be taken into account. It should be noted that a submission will not be considered if it:

- Is submitted after the deadline set out in the call
- Is presented in any form other than what is provided for in the instructions and template
- Is not related to the contents of the document
- Contains complaints against institutions, personal accusations, irrelevant or offensive statements or material

Comments complying with the criteria will be evaluated by EFSA’s Panel on Biological Hazards and taken into consideration where these will enhance the scientific quality or understanding of the document.

Publication date: 30 January 2009