COMMITTEE PAPER FOR DISCUSSION **ACNFP/132/02**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

HEAT-KILLED *MYCOBACTERIUM AURUM* AOGASHIMA

Issue

The Committee last reviewed the application from Solution Sciences Ltd. for their product Au+ (*M. aurum* Aogashima) at June 2016 meeting. Further information was requested on four outstanding areas. The applicant has now responded with an updated dossier. The Committee are asked to consider the newly updated dossier and what further recommendations they suggest for the novel food application.

Background

1. This application from Solution Sciences Ltd. is for authorisation of Au+ (produced from heat killed bacterium *M. aurum* Aogashima) as a novel food ingredient under EU Regulation 258/97. The novel ingredient is proposed to be added to a range of foods including milk and dairy products, breads, juice drinks and food supplements.

2. At the last meeting further questions were raised on:

    - Concept of the Novel food
    - Genetic Information
    - Specification of the novel food
    - Allergenicity

3. The letter providing feedback from the Committee's last consideration of the dossier is provided in **Annex A**. To inform the discussion, the applicant's updated dossier is provided at **Annex B** and the original dossier for comparison provided at **Annex C.** The Secretariat has also provided a summary of the issues considered by the Committee on Au+ (*M. aurum* Aogashima) to date in **Annex D.**

4. The applicant would welcome feedback from the Committee on the revised dossier and whether this provides the information needed for assessment.

Further information from the applicant

5. The applicant has commented on the on the concept of the novel food and the role they expect the novel food to play in the diet. This is put in the context of

the old friends hypothesis for bacteria and the suggestion from the applicant that exposing the gut to bacteria previously found in the microbiota may be beneficial for some people. The Committee is reminded that assessment of the efficacy of the product is outside the scope of the novel food regulation but has been raised with the applicant to assess whether the consumer would be misled by the novel food product.

6. The applicant has provided again the information on the taxonomic and genetic identification of the bacteria in the annex to the dossier. They have also revised the specification of the novel food and provided further data on the stability of the product under different conditions. The question of secondary metabolites raised by the Committee does not appear to have been addressed specifically in the revised novel food dossier.

7. The Committee also raised questions on the potential immunomodulatory effects of the bacteria. The applicant suggests that the bacteria being heat killed would ensure the bacteria do not proliferate and in the species is not considered pathogenic. The applicant reports that no allergic responses have been reported for this species despite this being a bacteria that previously has been prevalent in the environment.

Next steps

8. The dossier will be passing to the centralised risk assessment process from January. The table in Annex C is intended to summarise the discussion of the dossier to date to inform EFSA's consideration of the dossier. Members are invited to comment on whether the summary accurately reflects their views on the dossier.

Committee Action Required

- In light of the additional information provided by the applicant, the Committee is asked for its views and comments on the revised dossier.
- The Committee is also asked to indicate what feedback should be given to the applicant.
- Members are asked whether the table in Annex D outlining the Committee's consideration to date for the dossier provides an accurate summary of their views.

Secretariat
November 2017

Annexes Attached

Annex A – Letter providing feedback to the applicant from the meeting in June 2016

Annex B – Updated dossier from the applicant for the authorisation of *M.aurum*

Annex C – Original dossier for the authorisation of *M.aurum*

Annex D - Summary of concerns to date on Au+ (*M. aurum* Aogashima) and the information provided by the applicant in response**.**

ANNEX D

Summary of concerns to date on Au+ (*M. aurum* Aogashima) and the information provided by the applicant in response.

Concern raised	**Evidence presented**	
Concept of the Novel food The Committee sought to understand how the applicant would ensure that consumers will not be misled by the novel ingredient given the potential association with prebiotics. The Committee considered the rationale that use of the bacteria would be beneficial in all cases for all population groups was not supported by evidence. The Committee were keen to understand how the product would be targeted and how the applicant would ensure that non target groups did not consume the novel ingredient. The Committee asked whether non-viable *M. aurum* is present in treated drinking water systems to understand whether assumptions on the potential benefits of the novel ingredient were supported.	The applicant has provided more detail on the concept of the novel food and the background.	While it was recognised that the efficacy of the novel ingredient is outside the scope of the novel food assessment there were concerns that consumers could be misled by the novel ingredient depending on how it was presented for sale. It sought further information on the benefits of taking the novel ingredient. It also questioned which population groups would be targeted to consume the novel ingredient and how the applicant would make sure only the target population could obtain the product.
Genetic Information The Committee requested further information to characterise *the M. aurum* genome, including a full annotated genome sequence in order to look at the open reading frames (ORF's).	In the updated dossier the applicant has not provided information in this are or indicated any progress on this.	The Committee noted that further work was needed to fully characterise the novel food. For this purpose the Committee reiterated its request for an annotated genome sequence. This is a standard requirement

A detailed genome comparison of *M. aurum* Aogashima to both non-pathogenic and pathogenic mycobacteria species was requested. The Committee suggested the phylogenetic tree be revised to show relatedness of the species		of the Committee to enable it to carry out an evaluation of microorganisms as novel foods.
Specification of the novel food The Committee requested further characterisation of the red/orange colour of the final product as a result of the formation of a pigment from secondary metabolites. It was asked that the batch to batch variation in colour be characterised through use of a numerical value e.g. an optical density value using spectrometry. The Committee commented on the storage protection from light needed for the novel ingredient and if could be fulfilled through for all the food groups to which it would be added. Improvements on Annex 5 were requested so the term "Best match *M. aurum*" is replaced with a percentage to show the degree of the confirmed match. In addition that Annex 5 indicates the levels to which a contaminating organism would be considered "absent" and be provided in a footnote.	The applicant has provided a revised specification of the novel food.	The Committee was concerned about the colour of the pigment of the novel ingredient. It sought further information for the risk assessment on the chemical components of the product, and whether the pigment indicated the microorganism produced secondary metabolites. The Committee was also concerned about the stability of the product, particularly in relation to light and how this would be managed during the production process. The Committee questioned whether other organisms may be present in the novel ingredient with M aurum. It requested further information on whether the culture is mixed or an isolate where M aurum is dominant. It also sought information on whether there is a positive or negative immunological moderation in consumers after taking the novel ingredient as there are contradictions in the application
Allergenicity		

The Committee noted that mycobacteria's immunomodulation could be positive or negative and it was unclear from the information provided the nature of the impact in this case. The Committee questioned if there was possibility that *M. aurum* may have a negative effect or the capacity to cause sensitisation in some individuals and wished this to be explored in the dossier. The Committee questioned the biological response to the novel ingredient in individuals that may have potentially never been exposed but are exposed later in life. The long term impact of exposing those with a developing immune system to the bacteria was also raised.	The applicant has carried out an additional literature search and checked the Allergome database and found no allergenicity concerns related to the novel food.	