Annex 6

Projection of D-tagatose intake by the dietary survey approach

Annex 7

Data requirements for the evaluation of D-tagatose according to Commission Recommendation 97/618/EC and UK-ACNFP decision tree

Company: Arla Foods Product: D-Tagatose

You have identified the novel food as belonging to:

Class 1.2 - a pure chemical or a simple mixture from non-GM sources where the source of the NF has no history of food use in the EU.

You therefore need to supply information to satisfy the following structured schemes:

I. Specification of the Novel Food
II. Effect of the production process applied to the NF
III. History of the organism used as the source of the NF
IX. Anticipated intake/extent of use of the NF
XI. Nutritional information on the NF
XII. Microbiological information on the NF
XIII. Toxicological information on the NF

Select OK to continue.

Company: Arla Foods Product: D-Tagatose

Scheme I - Specification of the NF

There is sufficient information from scheme I.

Detailed outcome:

Depending on the derivation and composition of the NF, is appropriate analytical information available on potentially toxic inherent constituents, external contaminants and nutrients?

YES

Is the information representative of the NF when produced on a commercial scale?

YES

Is there an appropriate specification (including species, taxon etc. for living organisms) to ensure that the NF marketed is the same as that evaluated?

YES

OUTCOME: All appropriate analytical information and the appropriate specification of the NF needs to be forwarded with your application.

Company: Arla Foods Product: D-Tagatose

Scheme II - Effect of the production process applied to the NF

The result of scheme II is:

There is sufficient information from scheme II

Detailed outcome:

Does the NF undergo a production process?

YES

Is there a history of use of the production process for the food?

NO

Does the process result in a significant change in the composition or structure of the NF compared to its traditional counterpart?

YES

Is information available to enable identification of the possible toxicological, nutritional and microbiological hazards arising from use of the process?

YES

Are the means identified for controlling the process to ensure that the NF complies with its specification?

YES

Has the process the potential to alter the levels in the NF of substances with an adverse effect on public health?

NO

After processing is the NF likely to contain microorganisms of adverse public health significance?

NO

OUTCOME: Provide all relevant information on the production process.

Company: Arla Foods Product: D-Tagatose

Scheme III - History of the organism used as the source of the NF

The outcome of scheme III is:

Sufficient information from scheme III.

Detailed outcome:

Is the NF obtained from a biological source, i.e. a plant, animal or microorganism?

NO

OUTCOME: No information needed under this scheme.

Company: Arla Foods Product: D-Tagatose

Scheme IX - Anticipated intake/extent of use of the NF

The result of scheme IX is:

There is sufficient information from scheme IX.

Detailed outcome:

Is there information on the anticipated used of the NF based on its properties?

YES

OUTCOME: You will need to provide all relevant information.

Company: Arla Foods Product: D-Tagatose

Scheme XI - Nutritional Information on the NF

The result of scheme XI is:

There is sufficient information from scheme XI.

Detailed outcome:

Is there information to show that the NF is nutritionally equivalent to existing foods that it might replace in the diet?

NO

Is there information to show that the NF does not affect the bioavailability of nutrients from the diet or have any adverse physiological effects?

YES

Is there information to allow an assessment to be made of the nutritional impact of the introduction of the NF?

YES

OUTCOME: You will need to provide all relevant information on the nutritional composition and physiological and nutritional effects of the NF, plus that on any nutritional impact of its introduction.

Company: Arla Foods Product: D-Tagatose

Scheme XII - Microbiological Information on the NF

The result of scheme XII is:

There is sufficient information from scheme XII.

Detailed outcome:

Is the presence of any microorganisms or their metabolites due to the novelty of the product/process?

YES

Is there information to show that the NF is unlikely to contain microorganisms and/or their metabolites of adverse public health significance?

YES

OUTCOME: You will need to provide all relevant information on these microorganisms and/or their metabolites.

Company: Arla Foods Product: D-Tagatose

Scheme XIII - Toxicological information on the NF

There is sufficient information from scheme XIII.

Detailed outcome:

XIII TOXICOLOGICAL INFORMATION ON THE NOVEL FOOD

Is there a traditional counterpart to the NF that can be used as a baseline to facilitate the toxicological assessment?

YES

Compared to the traditional counterpart, does the NF contain new toxicants or changed levels of existing toxicants?

NO

Is there information which suggests that the NF might pose an allergenic risk to humans?

NO

OUTCOME: There is a traditional counterpart to the NF that can be used as a baseline to facilitate the toxicological assessment, and compared to that baseline the NF does not contain new toxicants or changed levels of existing toxicants.

Any allergenic risk to humans from the NF should also be investigated, and the information presented. Controlled allergenicity trials may need to be undertaken where necessary.

All studies and any cited literature references which support the answers to the above questions to establish the toxicological safety of the NF should be forwarded with your application.

Annex 7

Data requirements for the evaluation of D-tagatose according to Commission Recommendation 97/618/EC and UK-ACNFP decision tree

Company: Arla Foods Product: D-Tagatose

You have identified the novel food as belonging to:

Class 1.2 - a pure chemical or a simple mixture from non-GM sources where the source of the NF has no history of food use in the EU.

You therefore need to supply information to satisfy the following structured schemes:

I. Specification of the Novel Food
II. Effect of the production process applied to the NF
III. History of the organism used as the source of the NF
IX. Anticipated intake/extent of use of the NF
XI. Nutritional information on the NF
XII. Microbiological information on the NF
XIII. Toxicological information on the NF

Select OK to continue.

Company: Arla Foods Product: D-Tagatose

Scheme I - Specification of the NF

There is sufficient information from scheme I.

Detailed outcome:

Depending on the derivation and composition of the NF, is appropriate analytical information available on potentially toxic inherent constituents, external contaminants and nutrients?

YES

Is the information representative of the NF when produced on a commercial scale?

YES

Is there an appropriate specification (including species, taxon etc. for living organisms) to ensure that the NF marketed is the same as that evaluated?

YES

OUTCOME: All appropriate analytical information and the appropriate specification of the NF needs to be forwarded with your application.

Company: Arla Foods Product: D-Tagatose

Scheme II - Effect of the production process applied to the NF

The result of scheme II is:

There is sufficient information from scheme II

Detailed outcome:

Does the NF undergo a production process?

YES

Is there a history of use of the production process for the food?

NO

Does the process result in a significant change in the composition or structure of the NF compared to its traditional counterpart?

YES

Is information available to enable identification of the possible toxicological, nutritional and microbiological hazards arising from use of the process?

YES

Are the means identified for controlling the process to ensure that the NF complies with its specification?

YES

Has the process the potential to alter the levels in the NF of substances with an adverse effect on public health?

NO

After processing is the NF likely to contain microorganisms of adverse public health significance?

NO

OUTCOME: Provide all relevant information on the production process.

Company: Arla Foods Product: D-Tagatose

Scheme III - History of the organism used as the source of the NF

The outcome of scheme III is:

Sufficient information from scheme III.

Detailed outcome:

Is the NF obtained from a biological source, i.e. a plant, animal or microorganism?

NO

OUTCOME: No information needed under this scheme.

Company: Arla Foods Product: D-Tagatose

Scheme IX - Anticipated intake/extent of use of the NF

The result of scheme IX is:

There is sufficient information from scheme IX.

Detailed outcome:

Is there information on the anticipated used of the NF based on its properties?

YES

OUTCOME: You will need to provide all relevant information.

Company: Arla Foods Product: D-Tagatose

Scheme XI - Nutritional Information on the NF

The result of scheme XI is:

There is sufficient information from scheme XI.

Detailed outcome:

Is there information to show that the NF is nutritionally equivalent to existing foods that it might replace in the diet?

NO

Is there information to show that the NF does not affect the bioavailability of nutrients from the diet or have any adverse physiological effects?

YES

Is there information to allow an assessment to be made of the nutritional impact of the introduction of the NF?

YES

OUTCOME: You will need to provide all relevant information on the nutritional composition and physiological and nutritional effects of the NF, plus that on any nutritional impact of its introduction.

Company: Arla Foods Product: D-Tagatose

Scheme XII - Microbiological Information on the NF

The result of scheme XII is:

There is sufficient information from scheme XII.

Detailed outcome:

Is the presence of any microorganisms or their metabolites due to the novelty of the product/process?

YES

Is there information to show that the NF is unlikely to contain microorganisms and/or their metabolites of adverse public health significance?

YES

OUTCOME: You will need to provide all relevant information on these microorganisms and/or their metabolites.

Company: Arla Foods Product: D-Tagatose

Scheme XIII - Toxicological information on the NF

There is sufficient information from scheme XIII.

Detailed outcome:

XIII TOXICOLOGICAL INFORMATION ON THE NOVEL FOOD

Is there a traditional counterpart to the NF that can be used as a baseline to facilitate the toxicological assessment?

YES

Compared to the traditional counterpart, does the NF contain new toxicants or changed levels of existing toxicants?

NO

Is there information which suggests that the NF might pose an allergenic risk to humans?

NO

OUTCOME: There is a traditional counterpart to the NF that can be used as a baseline to facilitate the toxicological assessment, and compared to that baseline the NF does not contain new toxicants or changed levels of existing toxicants.

Any allergenic risk to humans from the NF should also be investigated, and the information presented. Controlled allergenicity trials may need to be undertaken where necessary.

All studies and any cited literature references which support the answers to the above questions to establish the toxicological safety of the NF should be forwarded with your application.