

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

NONI JUICE FROM Mi GMBH - ADDITIONAL INFORMATION

ISSUE

Mi GmbH has submitted additional information in response to the questions raised at the Committee's March 2005 meeting. Members are asked to consider these data and whether this product can be regarded as substantially equivalent to an existing Noni juice product.

Background

1. At the March 2005 meeting, the Committee considered an application from Mi GmbH Switzerland and Mi EU Ltd for an opinion on equivalence for their noni juice compared with the approved noni juice produced by Natures Products and marketed by GSE-Vertrieb (ACNFP/71/3).
2. Members asked for more detailed compositional analysis of the products. The Secretariat forwarded this request to the applicant on 15 April 2005 (see Annex 1).
3. The applicant has answered by providing compositional data of a number of different batches of Mi's noni juice and Natures Products noni juice (Annex 2). These data show a relatively high degree of comparability between the two sets of noni juice samples.

Committee Action Required

4. The Committee is asked whether it is satisfied with the latest set of compositional data on noni juice from Mi and Natures Products. If not, Members are asked to indicate what additional data would be required.
5. The Committee is also invited to consider and comment on the draft opinion for Mi's application (Annex 3). If Members conclude that the substantial equivalence has been demonstrated then, once their comments have been incorporated, the opinion for Mi's application will be published on the Agency's website for a short period of public consultation before being finalised and conveyed to the applicant.

**Secretariat
May 2005**

Annexes Attached

- **Annex 1:** Letter from the Secretariat to the applicant requesting further compositional data on Mi GmbH/EU Ltd and Natures Products noni juice.
- **Annex 2:** Additional compositional data supplied by Mi GmbH/EU Ltd. Table summarising results and certificates.
- **Annex 3:** Draft initial opinion of substantial equivalence for Mi GmbH/EU Ltd noni juice. **Restricted**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Letter from the secretariat to the applicant requesting further compositional data on Mi GmbH/EU Ltd and Natures products noni juice.

**Secretariat
May 2005**

Mr Garry Martin
MiGmbH
Rigistrasse 166
CH-6340 Baar
Switzerland

15th April 2005
By e-mail only

Reference: NFU 562

Noni – Application for an opinion on substantial equivalence

Dear Mr Martin,

The Advisory Committee on Novel Foods and Processes (ACNFP) considered your request for an opinion on the substantial equivalence of your noni juice products at its recent meeting on March 30th.

The committee noted that the application contained data on the compositional analysis of only a single sample for each of 2 noni juices (Swiss made noni juice and Natures Products/GSE Vertrieb noni juice). Therefore the Committee has delayed a decision on the equivalence of your product until they have seen more compositional data for these noni juice products. You should therefore repeat the studies described in Appendix 3 of your Dossier in order that the Committee is reassured that your samples are equivalent to those of Natures Products. Please note that a full compositional analysis, at least as detailed as that presented in Appendix 3 of your Dossier, is required.

Could you also confirm that you do not intend to market a juice that is solely ultrafiltrated to remove micro-organisms.

Yours Sincerely

Katherine Halliwell
Novel Foods, Additives, and Supplements Division

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Additional compositional data supplied by Mi GmbH/EU Ltd. Table summarising results and certificates.

**Secretariat
May 2005**

Table: A comparison of noni juice produced by Mi GMBH compared with Natures Products (all per 100ml)

Samples	Mi GMBH						Natures Product				
	05-00818-001 (March 05)	05-00818-03 (March 05)	05-05887-001 (Additional Data)	05-05887-002 (Additional Data)	05-05887-003 (Additional Data)	<i>Mean</i>	363996 (March 05)	05-05887-004 (Additional data)	05-05887-005 (Additional Data)	05-05887-006 (Additional data)	<i>Mean</i>
Parameters											
Minerals g per 100ml	0.53	0.45	0.45	0.41	0.44	0.46		0.49	0.64	0.60	0.58
Total Protein Nx6.25 g per 100ml	0.32	0.23	0.23	0.22	0.22	0.24	0.3	0.23	0.60	0.39	0.38
Alcohol Vol- %	0.2	0.4	0.3	0.2	0.2	0.26	0.37	0.3	0.4	0.2	0.31
Potassium mg per 100ml	227	175	175	176	184	187.4	220	223	278	263	246
Magnesium mg per 100ml	13.3	10.5	11.0	11.1	11.5	11.48	14	13.4	18.1	16.4	15.4
Sodium mg Per 100ml	6.14	10.6	11.4	14.7	12.3	11.02	8.3	12.1	13.3	15.1	12.2
L-(+)-Lactic Acid g per litre	Ndt	Ndt	0.34	1.78	1.11	0.64	-	1.35	1.64	2.14	1.71
D-(-)Lactic Acid g per litre	Ndt	Ndt	0.06	1.80	0.93g	0.55	-	1.15	1.33	2.07	1.51

Ndt – None determinable