



20 December 2011

Andre Prassinos  
BioBrew Ltd  
19 Rimu Street  
Kaka Point  
Balclutha  
9271

**ACVM Clearance Only. Biosecurity/ ERMA NZ  
clearance may still be required.**

Dear Andre,

## **CLASS DETERMINATION**

### **Biobrew**

The Agricultural Compounds and Veterinary Medicines Group have completed a class determination for the above named products based on the information provided by the applicant.

### **Determination**

This product is defined as an agricultural compound under the ACVM Act 1997. This product is exempt under the ACVM (Exemptions and Prohibited Substances) Regulations 2011 and Amendments and subject to the conditions of Schedule 2, Part B(25 & 26) for Oral nutritional compounds & oral gastro-intestinal acting microflora-enhancing compounds. These products do not require registration under the ACVM Act to be imported, marketed, distributed, sold or used in New Zealand.

### **Rationale**

This is an oral gastro-intestinal acting microflora-enhancing compound that does not make therapeutic or pharmacological claims to treat, prevent or cure any disease characterised by pain or distress in animals. All ingredients appear on the GRAS list.

### **Advice**

This determination has confirmed that the ingredients used in the product are nutrients or permitted non-nutrient substances only. An assessment of the fit for purpose status of the product has not been made. As per Regulations 7 – 13 of the Regulations, it remains the responsibility of the manufacturer to ensure that the product is fit for purpose and include appropriate use statements to ensure the product is used appropriately.

This determination applies to product that is supplied with both the outer tag and leaflet as this combination provides all legally required labelling information.

This determination is based on the information supplied as part of the application only. Promoting or selling this product in association with any other claims may alter the status of this product under the ACVM Act and Regulations.

The ACVM (Exemptions and Prohibited Substances) Regulations 2011 may be found on our website at <http://www.foodsafety.govt.nz/policy-law/food-regulation/nz-food-legislation/acvm-act-1997.htm>

Further information regarding the interpretation of the Regulations may be found in the 'Class Determination Rules' document that may be found on our website at

<http://www.foodsafety.govt.nz/elibrary/industry/class-determination-request-form/index.htm>

This class determination becomes invalid if:

1. This product is changed in any way.
2. This product is advertised using information different from that assessed in the process of this class determination.
3. **Three years** has elapsed since the date of this class determination.
4. You do not comply with the conditions stated in the ACVM Regulations 2001 and Amendments.

**If this product is being imported, this class determination letter (or copy) must be presented to MAF Biosecurity New Zealand in order for the product to be released under the ACVM Act. To avoid delays with the clearance of this product and incurring ACVM inspection costs, we strongly suggest a copy of this letter accompanies the declaration information clearly attached to the product.**

You may also have statutory obligations under the Hazardous Substances and New Organisms Act 1996 and Biosecurity Act 1993. Please refer to ERMA NZ and the MAF Biosecurity Division respectively at [www.ermanz.govt.nz](http://www.ermanz.govt.nz) or [www.maf.govt.nz/biosecurity](http://www.maf.govt.nz/biosecurity) for further information.

Yours sincerely



Emily Fairless  
Administrative Assistant (Operations)

**Official Receipt G.S.T 64-558-838**      DATE: 20/12/2011

Received From: H A Hughes

Being the class determination fee for:  
\$152.92

NZFSA General Ledger Code: 1-576-2101-355