TORPAC®
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*Special Capsules * Capsule Machinery * Soluble Containers*

13 March 2013

A Review of European Union Regulations Permitting Torpac Porcine Gelatin Capsules To Be Used In Products For Food Producing Animals in the EU.

This note summarizes the key EU Regulations that permit Torpac Veterinary Size Porcine Gelatin Capsules to be used in Food Producing Animals (including ruminants) in the EU. There are separate regulations permitting use in **animal feeds including nutritional products** and in **registered veterinary medicines**.

Torpac Veterinary Size Porcine Gelatin Capsules are made only from porcine gelatin derived from the skin of pigs. There are no other animal derived ingredients in our capsules. The porcine gelatin we use is manufactured in the USA, Canada or European Union at government-inspected factories. Government veterinary officials certify every lot of gelatin we use and every batch of capsules we produce. We maintain full traceability from final product to raw materials in compliance with government regulations, ISO 9001, HACCP and GMP+.

Capsules For Animal Feeds including Nutritional Products

Regulation **575/2011** "the Catalogue of feed materials" lists gelatin as a permitted feed material and repeals the earlier catalogue included in 242/2010.

Part C, Section 9, lists Gelatin.

9.12.1	Gelatine ([15])	Natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals.	Crude protein Moisture if > 8 %

(15) The name shall be supplemented as appropriate by — the animal species, and/or — the part of the animal product, and/or — the animal species processed (e.g. porcine, ruminant, avian), and/or — the naming of the animal species not processed in respect of the ban on intra-species recycling (e.g. poultry-free), and/or — the material processed (e.g. bone, high or low ash) and/or the process used (e.g. defatted, refined).

Part A, para 2 states any feed material on the list used must comply with "relevant legislation of the Union…"

In Regulation **142/2011** "implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption" the conditions for gelatin to be used as a feed material are specified in Annex X, Section 5, Chapter 2. The gelatin we use is in full compliance with these requirements.

Capsules For Registered Veterinary Medicines.

Gelatin capsules for registered veterinary medicines may be put on the market under Directive 1069/2009 and 82/2011.

In Regulation **1069/2009** regulates "Animal products not for human consumption & repealing Regulation (EC) No 1774/2002." This directive includes the following statements:

Article 33 Placing on the market
Operators may place on the market the following derived products:
*(e) veterinary medicinal products as defined in Article 1(2) of Directive **82/2001**"*

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In Regulation **82/2001** "Community code relating to veterinary medicinal products"
Article 1 (2) defines veterinary medical products as:

> *Veterinary medicinal product: Any substance or combination of substances presented for treating or preventing disease in animals.*

On page Page L311/29 it defines the Dossier to be submitted for registration of a veterinary medicinal product:

> *A. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS*
> *The particulars and documents, which must accompany applications for marketing authorization, pursuant to Article 12(3)(c), shall be submitted in accordance with the following requirements.*
> *1. Qualitative particulars……*
> - *the active substance(s),*
> - *the constituent(s) of the excepients, whatever their nature or the quantity used, including colouring matter, preservatives, adjuvants, stabilisers, thickeners, emulsifiers, flavouring and aromatic substances, etc,*
> - ***the constituents, intended to be ingested or otherwise administered to animals, of the outer covering of the medicinal products-capsules, gelatine capsules, etc……***

This indicates Directive 82/2001 includes gelatin capsules as part of a veterinary medicinal product.

A detailed discussion of the regulations is available from Torpac on request.

We gratefully acknowledge the assistance of Dr. Uwe Seybold, Vice President for Regulatory Affairs at Gelita AG in Germany and Ms. Dominique Rolin, Manager Regulatory Affairs at PB Gelatin.

Please consult your regulatory advisors and local officials before you make any marketing or financial decisions based on this letter.

Questions or Comments email rajtahil@torpac.com