

19 December 2000

Re: 1) EU Directive prohibiting animal sourced materials in **animal feed** from 1 January – 30 June 2001;
2) 100% Porcine Gelatin Capsules and Cellulose Capsules.

This letter is only for customers who sell animal health products for farm animals in the EU. It's purpose is to explain how the above EU Directive applies to gelatin capsules supplied by Torpac for veterinary medicinal and nutritional use. In addition, to outline our plan to introduce 100% porcine gelatin capsules immediately and cellulose capsules later in the year 2001. *Please consult your regulatory advisors and local officials before you make any marketing or financial decisions based on this letter.*

EU Regulations

EU Directive 2000/766/EC, valid for the period from 1 January – 30 June 2001 was issued on 4 December 2000 as a temporary emergency measure to prevent the spread of BSE within the EU. It prohibits use of a large variety of animal sourced materials including bovine gelatin when used in an "animal feed". Importantly, it excludes porcine gelatin used as a coating for additives used in animal feed and it does not regulate animal sourced materials used in veterinary medicinal products.

Medicinal Products:

EU Directive EMEA/CVMP/145/97R regulates gelatin for veterinary medicinal use and permits the use of both bovine and porcine gelatin in medicines. There is a separate EU regulation requiring all medicines containing bovine gelatin to have a "Certificate of Suitability" from the European Directorate of Medicines confirming compliance with Ph. Eu. IIIrd Ed., no 1483, 2000. Please contact us to obtain a copy of this certificate.

Nutritional Products:

Manufacturers of nutritional products are aware that European countries have varying interpretations of EU Directive 75/524 which is the primary directive regarding animal feed. If you are in an EU country that considers nutritional products to be covered by Directive 75/524 you will likely need to use capsules made from 100% porcine gelatin from the period 1 January to 30 June 2001. **We now have available 100% porcine gelatin capsules so that you can continue shipments to your customers during the period Directive 2000/766 is in effect.** To avoid problems during government audits, we recommend that you label all cases of capsules you have in stock now as "For Veterinary Medicinal Use Only" and keep them in a separate area from your regular inventory.

If you are in an EU country in which the status of nutritional products is considered a "grey" area you will need to consult local officials and consultants regarding the use of capsules you currently have in stock for the period 1 January – 30 June 2000.

It is expected that after Directive 2000/766 expires on 30 June 2001, the new regulations for gelatin in animal feed will be in line with the regulations for medicines i.e. permit the use of bovine gelatin if a Certificate of Suitability (see section on Medicinal Products) is available. Please contact us to obtain a copy.



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*Special Capsules * Capsule Machinery * Soluble Containers*

Torpac Capsules: 100% Porcine Gelatin Capsules

Torpac Capsules have never included gelatin from any country in which there is a certified occurrence of BSE by the OIE (Organization of International Epizooties in Switzerland), US or EU.

Effective 1 January 2001, Torpac Capsules in the veterinary sizes (Size Su7, 7, 10, 11, 12, 12el, 13, SE, 9 and any of these sizes with a letter suffix e.g. 12elR) will be made from 100% porcine gelatin produced in USA at US Dept. of Agriculture (USDA) inspected plants certified under ISO 9001 and HACCP compliant. There will be no price increase or surcharge for 100% porcine gelatin capsules. IF YOU REQUIRE 100% PORCINE CAPSULES, PLEASE STATE THIS ON ALL PURCHASE ORDERS as for the next several months we will have some stocks of capsules made with a blend of bovine and porcine gelatin which are legal for any use outside the EU and within the EU for the next 6 months only in medicines.

Torpac Capsules Non Gelatin Capsules

In March 2001, Torpac will be able to supply limited quantities of veterinary size capsules made from HPMC, a cellulose derived from plant materials (trees), for trials. HPMC (Hydroxy Propyl Methyl Cellulose) is widely used in the pharmaceutical industry as a binder, gelling agent and coating material. HPMC capsules in the smaller sizes for humans (Size 00 through 3) have been introduced in the past few years. HPMC capsules in veterinary sizes are a Torpac exclusive and the result of a major 5 year R&D program to make veterinary size capsules from a non-animal sourced material. We strongly urge all our customers to begin trials with our new cellulose capsules.

Torpac's View

As a supplier to the agricultural industry we fully understand that consumers are demanding zero safety risk in their food. While some may view the challenge faced by the agricultural industry with pessimism, we believe it presents an opportunity to transform food from commodities into branded products. This should mean higher profits for the farmer and ultimately new opportunities for growth and profits for our industry.

If you have any questions, please contact us. We will also be contacting all EU manufacturers during the next few weeks to answer any questions.

Best wishes for the holiday season and 2001.

R. V. Tahil
President

P.S. For your convenience the EU documents referred to above are available from the "Comments on EU Directive 2000/766/EC" link on the Bulletins page of www.torpac.com.