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Update on the EU Pathogen Reduction Treatment approval process

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Report Highlights:

After an EC proposal to approve Pathogen Reduction Treatments (PRTs) had been stalled in the EC interservices consultation process for eighteen months, on May 13, 2008, in the Transatlantic Economic Council, the EC promised to bring the proposal to the Standing Committee of the Food Chain and Animal Health (SCoFAH) for a vote. On May 28, 2008, the SCoFAH almost unanimously voted against the proposal and this was followed on June 16, 2008 by a Resolution from the European Parliament urging the European Council not to approve this PRT proposal.

Includes PSD Changes: No
Includes Trade Matrix: No
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Background

From the 1960s, the EU has shown a pattern of raising increasing impediments on U.S. poultry exports to the EU. For details see GAIN [E35166](#)¹.

In April 1997, U.S. poultry exports to the EU came to a halt when the EU issued [Council Directive 97/79/EC](#)² which banned the use of pathogen reduction treatments (PRTs) for decontaminating poultry carcasses. This Council Directive also ended the use of PRTs in the EU as the Commission initiated infraction proceedings³ against the UK for failing to abide by EU legislation since the UK continued to permit the use of chlorine in poultry processing plants. It was, however, not until 2003 that the UK verified it had banned the use of chlorine as a disinfectant for poultry and the Commission dropped the infringement proceeding.⁴

In 1998, the EU Scientific Committee on Veterinary measures related to Public Health (SCVPH) published a scientific report on the safety of using PRTs, titled the "[Benefits and Limitations of Antimicrobial Treatments for Poultry Carcasses](#)."⁵ The study provided criteria for assessing PRTs and noted that PRTs may be acceptable when used as part of an overall strategy for pathogen control throughout the whole production chain.

U.S.-EU Veterinary Equivalency Agreement and EU Hygiene Regulations

In 1999, the United States and the EU signed a [Veterinary Equivalency Agreement](#) (VEA)⁶. The concept of the equivalency agreement allows veterinary inspection requirements to differ between the U.S. and the EU but ensures the U.S.'s right to establish its own level of public health protection. For poultry, the VEA established the requirements necessary to establish equivalency of EU and U.S. sanitary regulations. In particular, Annex V of the Agreement outlines four requirements necessary to re-open the EU market to U.S. poultry exports. One of the requirements was an EC scientific review of PRTs.

In the May 2002 U.S.-EU Summit, the United States and the EU agreed to work together to resolve the technical issues inhibiting U.S. poultry exports to the EU. In December 2002, U.S. Government provided reports supporting the use of chlorine dioxide, trisodium phosphate, peroxyacids, and acidified sodium chlorite as pathogen reduction agents in poultry processing for scientific review by the European Food Safety Authority (EFSA). In April 2003, SCVPH issued their own [report](#)⁷ re-affirming that PRTs can be a useful method in reducing harmful pathogens in an integrated sanitary process. In December 2005, [EFSA](#)⁸ confirmed the safety of these four PRTs after a new scientific report from June 2004⁹ had suggested that the reaction products between chlorinated products and animal protein may produce semicarbazides, which are thought to be carcinogenic.

In the meantime, the EU had completed a major overhaul of its food safety system¹⁰. This overhaul resulted from the EU's [White Paper on food safety](#)¹¹ which outlined a radical revision

¹ <http://www.fas.usda.gov/gainfiles/200508/146130686.pdf>

² http://europa.eu.int/eur-lex/pri/en/oj/dat/1998/l_024/l_02419980130en00310032.pdf

³ <http://europa.eu.int/eur-lex/lex/LexUriServ/LexUriServ.do?uri=CELEX:52003DC0669:EN:HTML>

⁴ <http://europa.eu.int/eur-lex/en/com/rpt/2002/act0324en01/1.pdf>

⁵ http://europa.eu.int/comm/food/fs/sc/scv/out14_en.pdf

⁶ <http://forum.europa.eu.int/irc/sanco/vets/info/data/oj/98258ec.pdf>

⁷ http://europa.eu.int/comm/food/fs/sc/scv/out14_en.pdf

⁸ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620765475.htm

⁹ See: Hoenicke, K., R. Gatermann, L. Hartig, M. Mandix, and S. Otte. "Formation of semicarbazide (SEM) in food by hypochlorite treatment: is SEM a specific marker for nitrofurazone abuse?" *Food Additives and Contaminants*. Vol 21, No 6 (June 2004), pp. 526-537.

¹⁰ <http://useu.usmission.gov/agri/foodsafety.html>

of the EU's food safety rules. The "hygiene package" was approved with [Regulation 853/2004](#)¹² laying down hygiene rules for food of animal origin. This regulation legally provided the possibility for the use of PRTs in meat processing pending approval of individual PRTs for particular uses.

Implementation regulation for the approval of PRTs

In February 2006, the EC Directorate General for Health and Consumers (DG SANCO) submitted a proposal for poultry PRTs and circulated it within the inter-services level of the Commission. No consensus was however found on the proposal between the different DGs, with specifically DG Agri and DG Environment objecting to the proposal. A potential solution for DG Agri's objection was envisaged through a simultaneous amendment of the poultry marketing regulation, which would change the definition for poultrymeat to allow a PRT¹³. In September, 2007, the EC addressed DG Environment's concerns about the environmental impact of PRTs by ordering new scientific assessments of the individual PRTs. Two additional scientific reviews of the possible effect of poultry PRTs on antimicrobial resistance and their impact on the environment were conducted. On April 2, 2008, the European Food Safety Authority (EFSA) published the Scientific Opinion of the Biological Hazards Panel (BIOHAZ) "[Assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance](#)"¹⁴. On April 3, 2008, the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published their joint opinion on "[Environmental impact and effect on antimicrobial resistance of four substances used for the removal of microbial surface contamination of poultry carcasses](#)"¹⁵. Neither EFSA, nor the SCHER and SCENIHR found any prejudice against the use of PRTs, although a lack of data, especially on the effect of the disposal of for the environment, was highlighted. For more details see GAIN [E48040](#)¹⁶.

Transatlantic Economic Council

The EU-U.S. Transatlantic Economic Council was set up on the initiative of Chancellor Angela Merkel of Germany on her visit to Washington DC in January of 2007. In this initiative to tackle regulatory problems for trade between the U.S. and the EU, the poultry PRT approval issue was proposed in the agricultural/food domain. During the EU-U.S. Transatlantic Economic Council meetings, convened on 8 November, 2007, the United States raised the long-standing issue of PRTs for poultry. The EU agreed to press its scientific committees to finish their reviews by the next meeting in 2008. On May 13, 2008, the EC agreed to come forward with a PRT approval proposal for the Standing Committee on Food Chain and Animal Health (SCoFAH) to vote on.

Draft proposal approval procedure by the EU institutions

The EC presented a proposal setting strict conditions for allowing PRT treated poultry into the EU to the Standing Committee on Food Chain and Animal Health (SCoFAH)¹⁷. These five conditions are:

- A single PRT application only,

¹¹ http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf

¹² http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_139/l_13920040430en00550205.pdf

¹³ GAIN [E48066](#) - <http://www.fas.usda.gov/gainfiles/200806/146294952.pdf>

¹⁴ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178697425124.htm

¹⁵ http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_015.pdf

¹⁶ GAIN [E48040](#) - <http://www.fas.usda.gov/gainfiles/200804/146294207.pdf>

¹⁷ <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/819&format=HTML&aged=0&language=EN>

- No mixture of PRTs allowed,
- PRT treatment on whole carcasses only,
- PRT treatment followed by a mandatory water rinse,
- Labeling.

The U.S. voiced its opposition against these conditions, considering them unscientific and onerous. However, the original EU proposal was voted against almost unanimously in the SCoFCAH meeting of June 2, 2008¹⁸, with only the UK abstaining. On June 16, 2008, the European Parliament adopted a [Resolution](#)^{19, 20}, urging the European Council not to approve the use of PRTs. In late June of 2008 the EC informally declared its intention to forward its PRT proposal to the Council in line with EU regulatory procedures, but the proposal was not included on the agenda of the Ag Council of July 15, 2008, nor has it been scheduled for any Council meeting in July of 2008.

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E47039	EU opens poultry TRQ for the United States	05/25/2007
E35166	Analysis of US poultry meat trade with the EU: Past, present, future	08/29/2005
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These reports can be accessed through our website <http://useu.usmission.gov/agri/> or through the FAS website <http://www.fas.usda.gov/scriptsw/attacherep/default.asp>.

¹⁸ http://ec.europa.eu/food/committees/regulatory/scfcah/animal_health/add_0203062008_en.pdf

¹⁹ http://www.europarl.europa.eu/news/expert/infopress_page/067-32121-168-06-25-911-20080618IPR32120-16-06-2008-2008-false/default_en.htm

²⁰ GAIN E48067 -