

Santé Canada

Health Products

Direction générale des produits and Food Branch de santé et des aliments

Bureau of Chemical Safety Food Directorate 251 Sir Frederick Banting Driveway Postal Locator: 2201C Ottawa, ON K1A 0K9

April 25, 2014

Our File: ADDPS10092404 Ref # 001

Mr. Gene Morgan Regulatory Affairs/QA Unit/Safety EnviroTech Chemical Services Inc. 500 Winmoore Way Modesto, CA 95358 **USA**

RE: HB₂

Dear Mr. Morgan:

This letter is in reply to your letter dated May 15, 2012, addressed to Mr. Bernard Dallaire of the Canadian Food Inspection Agency (CFIA), regarding a letter of no objection for "HB2". You have proposed that HB2 be used to generate a hypobromous acid solution that is to be used as an antimicrobial treatment on beef and pork carcasses. The CFIA has asked for Health Canada's comments on this matter and we are replying directly to you with copies to the CFIA. However, you may wish to follow up with the CFIA for guidance about appropriate labelling of your product.

It is our understanding from the information we have received from EnviroTech¹ that HB2 is hydrogen bromide, and that it is reacted in situ with sodium hypochlorite, potassium hypochlorite or calcium hypochlorite to generate hypobromous acid. EnviroTech has indicated that the reaction is carried out in an apparatus designed for this purpose, and that the other product of the reaction is sodium chloride, potassium chloride or calcium chloride. EnviroTech has further indicated that the resulting hypobromous acid is diluted with water to achieve the desired concentration of the use solution, which is up to 300 mg/L (ppm) for the solution to be used in a single application on pork carcasses and up to 900 mg/L (ppm) for the solution to be used in a single application on beef carcasses.

From a food safety perspective, we would have no objection to the use of HB2 to generate a hypobromous acid solution to be sprayed in a single application on pork carcasses for up to 30

¹Information was provided by you and by Dr. Jon Howarth, EnviroTech Technical Services (emails from Dr. Howarth dated January 15, 2014; December 19, 2013; October 8, 2013; August 15, 2013 and May 31, 2013).



seconds² at a concentration up to 300 mg/L, or to be sprayed on beef carcasses for up to 30 seconds at a concentration up to 900 mg/L, provided that:

- 1. There are no or negligible chemical residues³ remaining in or on the finished food as a result of such use of the hypobromous acid solution, including residues of reaction products that may form in or on the foods as a result of such use;
- 2. The HB2 used to generate the hypobromous acid is of acceptable food-grade quality and the water used to dilute the hypobromous acid and to make the use solution is potable;
- 3. HB2 is used in accordance with good manufacturing practices and as part of an acceptable quality control program wherein it is shown to be efficacious for its intended purpose and is considered necessary. In this regard, the conditions of use of hypobromous acid should be validated directly at the facility;
- 4. The use of an antimicrobial is considered necessary; the use of an antimicrobial treatment cannot replace good manufacturing practices and is meant to be an added safety measure where warranted;
- 5. The hypobromous acid use solution is not re-used on any food, including pork or beef carcasses, after its first application to carcasses (i.e., the hypobromous acid use solution is not to be recycled for use on food); and
- 6. We would expect that any plant using this product should include, as part of its quality assurance system, appropriate parameters for solution application (i.e., concentration, water temperature, minimum and maximum contact time) and indicators that validate the use of this antimicrobial as a processing aid (i.e., no or negligible residues, antimicrobial load reduction targets).

The user of HB2 should be advised to use sodium hypochlorite, potassium hypochlorite or calcium hypochlorite that is of acceptable food-grade quality to generate the hypobromous acid use solution.

As you are aware, the chemical residue study conducted on pork carcasses with HB2 applied at 300 mg/L (300 ppm) as available bromine, which was submitted for our review, demonstrated that the level of bromoform that may form on pork carcasses following the application of hypobromous acid at 300 ppm as available bromine resulted in lower levels of bromoform detected on pork carcasses than the levels detected on beef carcasses when applied at the same concentration as available bromine. The bromoform residue data that Envirotech had provided previously for beef carcasses sprayed with 300 ppm as available bromine was used as part of Envirotech's rationale to extrapolate a conservative level of bromoform that may form on beef carcasses when applied with HB2 at a higher use rate of 900 ppm as available bromine. Based on these assumptions used for this scientific rationale it was determined that the increased use rate up

² EnviroTech indicated a spray time of less than one minute. However, the data provided by EnviroTech do not address a spray time longer than 30 seconds.

³ Examples of chemical residues include residues of bromate, trihalomethanes such as bromoform, and of components of the treatment solution.

to 900 ppm as available bromine applied to beef carcasses during processing would not pose a health concern to an individual consuming this treated beef. Due to the fact there were no safety concerns raised with the amount of bromoform that may form on beef carcasses when applied with a single application of HB2 up to 900 ppm as available bromine, there is no reason to believe that higher levels of bromoform will form on pork carcasses compared to beef carcasses when applied with a concentration up to 900 ppm as available bromine based on the bromoform residue studies that Envirotech had submitted for beef carcasses and pork carcasses.

Based on this information, from a chemical safety perspective, we would have no objection to the use of HB2 to generate hypobromous acid solution to be sprayed for one application on pork carcasses for up to one minute at levels up to 900 mg/L. Please note, as always, the minimum amount of product should be used to achieve the technical effect.

Should any changes occur in the chemical formulation of this product or to the directions for use on its label (i.e., concentration, maximum contact time and intended meat products to be treated), which go beyond the conditions stated in this letter, then this letter of no objection will no longer be valid.

This letter is not an opinion regarding the acceptability of HB2 with respect to occupational health and safety which, in general, is subject to provincial and territorial oversight.

Sincerely,

Paul Loeven,

Scientific Evaluator,

Food Additives Section,

Chemical Health Hazard Assessment Division

Dr. René Patenaude, Meat Program, CFIA

cc:

Mr. Bashir Manji, Food Science Safety Directorate, CFIA