ENVIRONMENTAL ASSESSMENT

1. Date: July 8, 2004

2. Name of Applicant/Petitioner: Albemarle Poultry Sciences, LLC

3. Address:

George M. Ricks, M.S., C.I.H.
Senior Industrial Chemist
Albemarle Corporation
451 Florida Street
Baton Rouge, LA 70801-1765.
Telephone: 225-388-7943
Fax: 225-388-7023
E-mail: george_ricks@albemarle.com

4. Description of Proposed Action:

The action requested in this notification is the establishment of a clearance to permit the general use of 1,3-dibromo-5,5-dimethylhydantoin (DBDMH) as an antimicrobial in water during poultry processing at a level not to exceed that needed to provide the equivalent of 100 ppm of available bromine in the water. The product will be introduced to process water and applied to poultry carcasses and their parts and organs to control the growth of pathogens.

In water, DBDMH breaks down to form hypobromous acid and 5,5-dimethylhydantion (DMH), as shown below:

DBDMH + H_2O = 2HOBr + DMH

Hypobromous acid is the active antimicrobial agent, while the DMH by-product serves no further function in the water. After undergoing chemical oxidation during use (disinfection), the hypobromous acid converts to bromide ion. DMH remains in the water and does not react further.

Based on the chemistry of DBDMH and the traditional usage of the term "available bromine" in the disinfection industry, the maximum available bromine level of 100 ppm corresponds to a maximum DBDMH addition level of approximately 90 ppm. The chemistry of DBDMH, including pertinent chemical reactions and calculations showing how the DBDMH level corresponds to equivalent available bromine, is further discussed in Attachment 4 of FCN No. 000334.

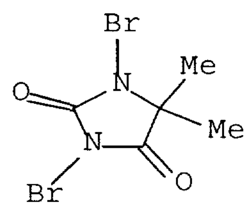
This product is proposed for general use in poultry processing plants that may be located throughout the United States. DBDMH will be introduced to plant process water at the levels described above and applied as an antimicrobial to control the growth of pathogens on poultry carcasses and their parts and organs. It is estimated that the poultry industry utilizes between 5 and 10 gallons of water per processed bird. This water ultimately runs into drains and enters either the "Offal" stream or the "Wastewater" stream. Generally, the Offal stream consists of all effluent prior to the chiller system(s). The Offal stream contains the waste solids (heads, intestines, fat, feathers) which are filtered and removed and sent to a rendering plant where they are further processed into poultry feed and litter. The remaining filtered water from the Offal stream is sent to the Dissolved Air Flotation Generator (DAF) where it may be chemically treated and filtered further. The resulting water is sent to the wastewater treatment plant. The chiller waters (overflow and end-of-day contents) empty to the Wastewater stream. The chiller waters contain fat and other solids which may be dislodged as the carcasses are agitated and pass through the chiller system. This stream may be chemically treated and filtered in the DAF area and sent to the wastewater treatment plant. Solids from the DAF area are also sent to the rendering plant. After the solids are removed, all wastewater are sent to the wastewater treatment plant where it is collected and treated by the facility prior to being discharged to a POTW, other receiving waters or land application. Only minor quantities are lost to evaporation into the air. The primary route of disposal for water that has been treated with DBDMH is through the processing plant wastewater treatment facility. A small amount of water containing these disinfectant by-products may be bound to Offal solids and carried over to the rendering plant. However, the level of by-products carried over to the rendering plant on the Offal solids and on poultry fat are considered insignificant since these compounds are water soluble and are expected to remain in the wastewater streams. Additionally, DMH is not considered fat soluble to any appreciable extent. There are three reasons that support this assertion. 1. DMH is very water soluble. 2. The partition coefficient (Log P) for DMH is –0.657.[1] The magnitude of this number indicates that DMH strongly prefers water over the oil phase. 3. A study was performed by Albemarle Poultry Sciences, LLC to determine if there is preferential uptake of DMH by poultry carcasses submerged in poultry chiller water treated with DBDMH. The data showed that poultry immersed for an extended time period into water containing a known amount of DMH did not result in a decrease of DMH from the water. The differential concentrations of DMH in the chiller water before and after submerging the carcasses was inconsequential to the extent that changes could be measured. The final report from the above study is attached to this Environmental Assessment as Appendix 1.

[1] Calculated using the ACD Software Solaris V4.67.

5. Identification of Substances that are the subject of the Proposed Action:

The substance that is the subject of this Notification is 1,3-dibromo-5,5-dimethyl hydantoin (DBDMH). The CAS Registry Number is 77-48-5. The FCS may also be identified as 1,3-dibromo-5,5-dimethyl-2,4-imidazolidinedione.

The molecular structure for DBDMH is given below. The molecular formula is $C_5H_6Br_2N_2O_2$, and the molecular weight is 286. DBDMH is a white, crystalline solid.



A confidential description of the product composition appears in Form 3480 of FCN No. 000334.

6. Introduction of Substances into the Environment:

a. Introduction of substances into the environment as a result of manufacture:

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated substances. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of DBDMH. Consequently, information on the manufacturing site and compliance with relevant emissions requirements are not provided here.

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b. Introduction of substances into the environment as a result of use/disposal:

DBDMH will be used at a level not to exceed that needed to provide the equivalent of 100 ppm available bromine in process water. As shown in Attachment 4 of FCN No. 000334,

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based on traditional industry usage of the term "available bromine," this corresponds to a maximum DBDMH addition level of 90 ppm. In water, the DBDMH breaks down into hypobromous acid and DMH. After disinfection, hypobromous acid converts to bromide ion. DMH remains in the water and does not react further.

Due to its instability in water, there will be no release of DBDMH, *per se*, as a result of its use as intended. Moreover, the hypobromous acid is highly reactive and is not expected to survive transit through the poultry processing system given the high organic content of the water following contact with poultry carcasses and after mixing with other aqueous waste streams. (The half-life of hypobromous acid in low-demand tap water has been estimated by EPA as 125 hours. The hypobromous acid will degrade far more rapidly in the aqueous systems present in the poultry plant.) Thus, it is fully expected that no hypobromous acid will be released from the poultry plant. For these reasons, this Environmental Assessment focuses on the DMH and bromide ion as the principal, and ultimate, byproducts that may be released as a result of use of the FCS.

As shown in Attachment 4 of FCN No. 000334 and described in the following paragraphs, addition of DBDMH at the maximum level of 90 ppm results in a maximum DMH concentration of 40 ppm and a maximum bromide ion ($Br^{(-)}$) concentration of 50 ppm in the dosed water.

Introduction of the decomposition products of DBDMH into the environment will take place primarily via release in wastewater treatment systems. The introduction of decomposition products to the environment from a rendering plant and downstream from a rendering plant is not considered a significant pathway. The decomposition products are water soluble and are expected to remain in the wastewater streams (See section 4 of this EA) and discharged either directly into the environment via a receiving body of water such as a river or stream or indirectly into the environment by way of a POTW. To determine the environmental introduction concentrations (EIC) of these by-products, we must first make an estimate of the DBDMH maximum use level. A typical poultry plant processes approximately 200,000 birds per day. It has been estimated that the poultry industry utilizes approximately 5 to 10 gallons of water per processed bird[2]. Assuming a worst-case water usage of 10 gallons per bird and DBDMH is added to all of this process water at the maximum approved level of 90 ppm (or 90 mg/kg), the total amount of DBDMH used is:

200,000 birds/day x 10 gal. water/bird = 2,000,000 gal. water/day containing DBDMH

2,000,000 gallons water/day x 3.785 L/gal. = 7.57×10^6 L/day = 7.57×10^6 kg water/day

7.57×10^6 kg water/day x 90 mg/kg x 1 kg/10^6 mg = 681.3 kg DBDMH per day

The amount of DMH that is produced as a result of the addition of this maximum amount of DBDMH may then be calculated. As shown in Attachment 4 in FCN No. 000334, the amount of DMH produced from a given amount of DBDMH is calculated using the ratio of the molecular weight of DMH (128.1) to that of DBDMH (286). Thus, the amount of DMH produced from the addition of a total of 681.3 kg of DBDMH is calculated as follows:

DMH formed = 681.3 kg DBDMH x (128.1 DMH ÷ 286 DBDMH) = 305.2 kg DMH

Similarly, the amount of $Br^{(-)}$ produced from the addition of 681.3 kg of DBDMH is calculated using the ratio of the weight of two bromide ions (159.8) to that of DBDMH, as follows:

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2 Kipper, Brian, 1991. A survey of wastewater practices in the broiler industry.

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Bromide ion formed = 681.3 kg DBDMH x (159.8 ÷ 286) = 380.7 kg $Br^{(-)}$ ion

Therefore, the maximum amounts of DMH and $Br^{(-)}$ ion that may be formed in poultry process water in a typical poultry processing plant from all uses of DBDMH are approximately 305.2 kg and 380.7 kg per day, respectively. These maximum calculated levels of DMH and $Br^{(-)}$ ion are based on worst-case assumptions. It must be pointed out that it is unrealistic that any poultry processor would add DBDMH at its maximum level to all process water. It would not be practical to do this and would be cost prohibitive.

An estimate of the environmental introduction concentrations (EIC) of DMH and $Br^{(-)}$ ion can now be calculated. As previously noted in section 4, there are two effluent streams associated with poultry processing (the Offal and the Wastewater Streams). Generally, the Offal stream consists of all effluent prior to the chiller system(s). The Offal stream contains the waste solids (heads, intestines, fat, feathers) which are filtered and removed from the water and sent to a rendering plant where they are further processed into poultry feed and litter. The remaining filtered water from the Offal stream is sent to the Dissolved Air Flotation Generator (DAF) where it may be chemically treated and filtered further. The resulting water is sent to the wastewater treatment plant. The chiller waters (overflow and end-of-day contents) empty to a separate wastewater stream which may also be chemically treated and filtered in the DAF area. The chiller waters contain fat and other solids which are dislodged from the carcasses as they are agitated and moved through the chiller system. All solids removed are sent to the rendering plant. After the solids are removed, all wastewater discharged from the DAF area are sent to the wastewater treatment plant where it is collected and treated by the facility prior to being discharged to a POTW, other receiving waters or land application. Only minor quantities are lost to evaporation into the air. The primary route of disposal for water that has been treated with

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DBDMH is through the processing plant wastewater treatment facility. A small amount of water containing disinfectant by-products is expected to be carried over to the rendering plant from the Offal and DAF generated solids. However, the level of by-products carried over to the rendering plant is expected to be insignificant since they are water soluble and will remain in the wastewater stream (See section 4 of this EA). Consequently, no environmental effects are expected by further processing poultry Offal into other usable products such as poultry feed.

To calculate the maximum concentration at which DMH and $Br^{(-)}$ ion may be introduced into the environment from the wastewater stream entering the wastewater treatment plant, we will assume that the entire quantities of these by-products will ultimately be discharged to the on-site wastewater treatment plant.

To calculate the concentration at which DMH and $Br^{(-)}$ ion may be present in poultry plant wastewater, it is necessary to consider the total volume of wastewater produced, which includes water from, *e.g.*, rinsing of the evisceration trough, viscera carriage flume, chiller water, Off-Line Reprocessing, Inside-Outside Bird Washers, and all other water sources.[3] For this purpose, we will assume a worst-case wastewater volume of 10 gallons per bird.[4] On this basis, the maximum DMH and $Br^{(-)}$ ion concentrations in the wastewater are calculated as follows:

10 gal./bird x 200,000 birds/day = 2,000,000 gal. waste water/day

3 Wesley, R.L. (1985). Water reuse and conservation in poultry processing. *Poultry Sci.* 64:476. The author identifies the primary sources of waste water in poultry processing as consisting of the scalder and chiller overflow; viscera carriage flume; handwash stations and evisceration trough rinse; and plant sanitation program.

4 Kipper, Brian, 1991. A survey of wastewater practices in the broiler industry.

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$2{,}000{,}000$ gal. x 3.785 L/gal. = 7.57×10^6 L/day = 7.57×10^6 kg waste water/day

305.2 kg DMH/day ÷ 7.57×10^6 kg waste water/day = 4.0×10^{-5} kg DMH/kg water

= 40 ppm DMH

380.7 kg $Br^{(-)}$/day ÷ 7.57×10^6 kg waste water/day = 5.0×10^{-5} kg $Br^{(-)}$/kg water

= 50 ppm $Br^{(-)}$ ion

Even assuming that none of the DMH were degraded in the on-site wastewater treatment facility, the level of DMH in the plant effluent would be significantly diluted upon being released to the publicly owned treatment works (POTW). Assuming a typical POTW with a daily flow of 25 million gallons per day, the maximum DMH concentration in water entering the POTW is calculated as follows:

25 million gal./day x 3.785 L/gal. = 9.46×10^7 L/day

40 ppm DMH x (7.57×10^6 L/day ÷ 9.46×10^7 L/day) = 3.2 ppm DMH

Similarly, the maximum concentration of $Br^{(-)}$ ion in water entering the POTW is calculated as follows:

50 ppm $Br^{(-)}$ ion x (7.57×10^6 L/day ÷ 9.46×10^7 L/day) = 4.0 ppm $Br^{(-)}$ ion

7. Fate of Emitted Components in the Environment:

According to the calculations detailed above, DMH and $Br^{(-)}$ ion may be present in wastewater received by POTWs at concentrations up to 3.2 ppm and 4.0 ppm, respectively. These also represent the maximum concentrations in effluent exiting POTWs assuming, very conservatively, that none of the DMH or bromide is lost during processing at the POTW. The actual concentrations at which the by-products may be present in receiving waters into which POTW effluent is discharged will be even lower due to the dilution effect of mixing effluent with

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the water flowing through the receiving river or other body. Assuming that the effluent concentrations are diluted by as little as 10-fold, the maximum concentrations of DMH and $Br^{(-)}$ ion in the receiving water will be 0.320 ppm (320 ppb) and 0.400 ppm (400 ppb), respectively.

Data previously submitted to FDA indicate that DMH is relatively stable in water, but that DMH degrades rapidly to yield carbon dioxide in activated sludge.[5] Therefore, the DMH produced as a byproduct of the addition of DBDMH to water is expected to be degraded by the biological treatment facility at the poultry processing plant. If any DMH remains in the effluent from the poultry plant, this residual is expected to be fully degraded at the POTW. Thus, DMH is not expected to be present in treated wastewater that is released from the POTW.

On the contrary, the $Br^{(-)}$ ion may remain in the treated wastewater released from the POTW unless special steps are taken to remove it from the POTW effluent. As demonstrated by the data discussed in Section 8 below, however, it is unlikely that a receiving POTW would need to put such special steps into place given the absence of any environmental concern regarding the possible aqueous release of bromide ion at the maximum level calculated.

The direct discharge of poultry process wastewater containing DMH and $Br^{(-)}$ into the environment represents a worst-case scenario and must be considered. As previously noted, a maximum DBDMH level of 90 ppm corresponds to maximum DMH and $Br^{(-)}$ levels of 40 and 50 ppm respectively. This represents the maximum levels of these by-products that would be directly discharged into a receiving body of water such as a river or stream. Using a conservative dilution factor of 20, the environmental effect concentration (EEC's) would be 2 ppm for DMH and 2.5 ppm for $Br^{(-)}$.

8. Environmental Effects of Released Substances:

[5] *See* EA for FAP 4B4418, id.

Testing previously provided to FDA indicates that DMH does not have a tendency to bioaccumulate in fish. A large volume of toxicological data on DMH in aquatic organisms also has been submitted. LC_{50} values reported for DMH range from 1300 mg/L in grass shrimp to 14,200 mg/L in the fathead minnow. Aquatic static bioassays of DMH indicate that DMH is not toxic at levels of 12,700 to 14,200 mg/L (sheepshead minnow, grass shrimp, oysters) and 1300 to 8100 mg/L (water flea).[5]

FDA previously established a toxic concentration criterion (TCC) for DMH of 29 ppm (29 mg/L) based on the lowest observed adverse effect level.[6] The maximum concentration at which DMH may be released into the environment via indirect discharge, assuming no degradation in biological waste water treatment systems, was calculated above to be 0.320 ppm, or 0.320 mg/L. This is approximately 2 orders of magnitude below the TCC. The maximum concentration at which DMH may be released into the environment via direct discharge, was calculated above to be 2 ppm, or 2 mg/L. This is approximately 1.5 orders of magnitude below the TCC. Thus, we respectfully submit that there will be no adverse effect on organisms in the environment as a result of the postulated release of DMH at the maximum level calculated.

Bromide ion also is of low toxicity to aquatic organisms. Attached to this Environmental Assessment, as Appendix 2, is a printout of the results of a search of an EPA ecotoxicity database for the compound sodium bromide.[7] (A search of the same database for "bromide ion," CAS Reg. No. 24959-67-9, did not yield any hits.) Since sodium bromide dissociates in water to

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6 *See* Finding of No Significant Impact (FONSI) for FAP 4B4418.

7 Specifically, the database searched was the Environmental Protection Agency's ECOTOX Ecotoxicology Database, located at http://www.epa.gov/ecotox/.

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yield the free sodium and bromide ions, the data on sodium bromide serve to provide useful information on the toxicity of the bromide ion, itself.

As indicated by the printout in Appendix 2, a large amount of data is available on the toxicity of sodium bromide to both fresh water and salt water organisms. The data include both LC_{50} values obtained from acute toxicity testing, as well as no-observed effect concentrations (NOECs) for a variety of toxicity endpoints from long-term exposures.

It should be noted from the outset that, although the search term used was "sodium bromide," the data outputted from the database include the results of certain studies that actually were designed to investigate the toxicity of hypobromous acid. In particular, these studies include three acute toxicity assays conducted by an industry task force to support a pesticide re-registration effort for sodium bromide used in the generation of hypobromous acid.[8] The studies in question report a 96-hour LC_{50} of 0.18 ppm for opossum shrimp, a 96-hour LC_{50} of 0.47 ppm for the Virginia oyster, and a 96-hour LC_{50} of 0.19 ppm for sheepshead minnow. The reference given in the ECOTOX database (reference 344) for all three studies is to an EPA Pesticide Ecotoxicity Database in the Environmental Fate and Effects Division of the Office of Pesticide Programs. The studies in question are not currently in the public domain. However, the Notifier, Albemarle Corporation, was a participant in the task force that carried out the studies and confirms that the actual test compound in the noted studies was hypobromous acid, as suggested by the titles of the studies provided in the footnote above. Specifically, the studies were

[8] Surprenant, D. (1988) *Acute Toxicity of Hypobromous Acid to Mysid Shrimp (Mysidopsis bahia) Under Flow-through Conditions*: SLS Report. No. 88-5-2722; Study No. 1199.0188.6109.515; Surprenant, D. (1988) *Acute Toxicity of Hypobromous Acid to Eastern Oysters (Crassostrea virginica) Under Flow-through Conditions*: SLS Report. No. 88-5-2726; Study No. 1199.0188.6109.504; Surprenant, D. (1988) *Acute Toxicity of Hypobromous Acid to Sheepshead minnow (Cyprinodon variegatus) Under Flow-through Conditions*: SLS Report. No.

conducted by combining sodium bromide with sodium hypochlorite in a mole ratio of 1.2 to 1.0 to yield hypobromous acid. Thus, the data obtained in these studies are not directly relevant to the current environmental assessment as hypobromous acid is not expected to be released as a result of the proposed use of DBDMH.

Additional data included in the printout are from a 1999 paper by Fisher, et al. (reference number 6320 in the ECOTOX database) (copy attached as Appendix 3) in which sodium bromide again was tested in the presence of an activator (sodium hypochlorite) designed to generate hypobromous acid. Thus, this testing also was intended to examine the toxicity of bromine oxidants, not bromide ion, *per se*.[9] Therefore, the various toxicity datapoints ascribed to the Fisher paper also are of no direct relevance to the present evaluation of the aquatic toxicity of bromide ion.

Once these data are excluded from consideration, it is evident from Appendix 2 that bromide ion is not acutely toxic to freshwater or marine organisms, and that the NOECs from extended exposure also are comparatively high. A sampling of the relevant data is provided in the following table. Note that, where more than one value is given for the same endpoint in the same species, we have included only the lowest relevant value.

Representative Aquatic Toxicity Data on Sodium Bromide

Test Organism	Endpoint	Duration	Concentration
Daphnia magna	NOEC (behavior)	21 days	91 mg/L
Rotifer	NOEC (reproduction)	48 hours	1000 mg/L
Green algae	NOEC (population growth)	3-4 months	>500 mg/L
Daphnia magna	LC_{50}	24 hours	500 mg/L

88-5-2736; Study No. 1199.0188.6109.505. Unpublished studies prepared by Springborn Life Sciences, Inc.

9 Indeed, as noted on page 766 of the paper, although excess sodium bromide was used in this testing, the toxicity observed was considered by the authors to be due to the oxidants and not to the sodium bromide.

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Daphnia magna	NOEC (reproduction viability)	21 days	7.5 mg/L
Daphnia magna	NOEC (general reproduction)	19 days	3.0 mg/L
Bluegill	LC_{50}	96 hours	> 1000 ppm
Rainbow trout	LC_{50}	96 hours	>1000 ppm
Medaka, high eyes	LC_{50}	34 days	1500 mg/L
Medaka, high eyes	LC_{50}	72 hours	24,000 mg/L
Medaka, high eyes	NOEC (multiple)	34 days	250 mg/L
Fathead minnow	LC_{50}	96 hours	16479 mg/L
Guppy	LC_{50}	124 days	7800 mg/L
Guppy	LC_{50}	96 hours	16,000 mg/L
Guppy	NOEC (reproduction)	124 hours	7.8 mg/L

The lowest LC_{50} given in the table above is 500 mg/L, in Daphnia magna. Other LC_{50} values cited in the database for sodium bromide in Daphnia range from 6100 mg/L to over 15,000 mg/L. Thus, relying on the lowest LC_{50} value of 500 mg/L clearly represents a conservative estimate of the toxicity of bromide ion to this species.

A wide range of NOEC values for bromide ion in Daphnia also have been published. The value shown in the above table, 3.0 mg/L, is the lowest NOEC established in a study by Soares, et al. (1992; ref. 5857 on ECOTOX database; see Appendix 4) in which nine different clones were tested to evaluate interclonal and environmental variation in the results obtained in the assay. For four of the clones, the NOEC was reported as <3 mg/L, for two clones the NOEC was 3 mg/L, and for the remaining clones the NOEC varied from 7.5 to 19 mg/L. These results suggest a fairly wide range of sensitivity in the different organisms tested. Moreover, 21-day or 23-day NOECs for reproduction in Daphnia of 7.5, 7.8, 16, and 91 mg/L are referenced elsewhere in the ECOTOX printout. Based on the entirety of the data available, we respectfully submit that the use of a NOEC of 3.0 mg/L is sufficiently conservative for purposes of establishing a safe level of bromide ion in bodies of water receiving effluent.

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In the past, FDA has calculated the toxic concentration criterion (TCC) for a test compound as either the lowest NOEC or 1/100th of the lowest LC_{50}. In this case, the lowest LC_{50} divided by 100 is 5.0 mg/L; thus, the lower TCC is that derived from the minimum NOEC, or 3.0 mg/L. By contrast, the maximum concentration at which bromide ion may be present in rivers or other bodies of water that receive POTW effluent was estimated above as 0.400 ppm (0.400 mg/L). This is approximately an order of magnitude below the estimated TCC for bromide ion. The maximum concentration at which bromide ion may be present in rivers or other bodies of water as a result of direct discharge of poultry wastewater was estimated above as 2.5 ppm or 2.5 mg/L). This maximum bromide ion level is based on worst-case assumptions which are not expected to ever occur. It is unrealistic to assume that a poultry processor would add the maximum level of DBDMH to all process water in its establishment. Thus, we respectfully submit that the possible presence of bromide ion in waste water from poultry processing facilities as a result of the proposed use of DBDMH does not present any concern with regard to potential aquatic toxicity.

To further put into perspective the possible release levels of bromide ion as a result of the proposed use of DBDMH, we note that a survey of bromide levels in drinking water supplies indicates that bromide is commonly present at far higher levels than those calculated here. Specifically, a survey report set forth as Appendix 5 demonstrates average $Br^{(-)}$ ion concentrations in randomly selected utility samples of 61 to 64 mg/L (ppm). The worst-case release concentration calculated here represents a minute fraction of this background level.

9. Use of Resources and Energy

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The use of DBDMH will not require additional energy resources for treatment and disposal of waste water, as the DMH byproduct readily degrades. The raw materials used in the

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production of the compound are commercially manufactured materials that are produced for use in a variety of chemical reactions and production processes. Energy used specifically for the production of the proposed use of DBDMH is not significant. Moreover, as DBDMH will be used in place of other antimicrobial treatments that currently are permitted for use in the poultry industry, the use of DBDMH as described will not lead to a net increase in the consumption of resources and energy.

10. Mitigation Measures

Based on the foregoing, no significant adverse environmental impacts are expected to result from the intended use of DBDMH. Thus, the use of the subject food-contact substance is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this Food Contact Notification. The alternative of not approving the action proposed herein would simply result in the continued use of other products by the poultry processing industry; such action would have no environmental impact. In view of the excellent properties of DBDMH as an antimicrobial treatment for poultry, the improvements in food safety that will result from its use, and the absence of any identified significant environmental impact that would result from its use, the clearance of the use of DBDMH as described herein appears to be environmentally safe and desirable in every respect.

12. List of Preparers

George M. Ricks, M.S., C.I.H., Senior Industrial Chemist, Albemarle Corporation, 451 Florida Street, Baton Rouge, LA 70801-1765.

13. Certification

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: 7/8/04

George M. Ricks, M.S., CIH

Albemarle Corporation

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