oxygen-limited atmospheres and yeast growth may be substantially reduced.[7,11]

10.6.3 Heated Cured Meats

Heated cured meats such as frankfurter sausage or smoked pork loin differ from fresh meat or fish in the following respects:

1. The mammalian cells do not metabolize and neither consume any oxygen nor produce any carbon dioxide. Only the microflora consumes oxygen and releases carbon dioxide. These activities proceed slower in a package of processed meat than in packages of fresh meat or fish.[10]
2. The processing has changed the microbiological flora, ie, taxa such as *Pseudomonas*, *enterobacteriaceae*, *Shewanella*, and *Aeromonas* have been eliminated, or greatly reduced in numbers by the heat process, and post-process contaminants of these groups have severe difficulties in growing. *Brochothrix* has difficulties in competing.[10,12,13] This leads to a prolongation of shelf life even in air, where the growing microflora mostly will be dominated by yeasts (or, if the water activity is low enough, by molds).[11] Thus, if the shelf life must be further extended, the products can be vacuum packed or gas packed.

Vacuum Packaging

By vacuum packaging of, for example, emulsion sausages, the growth of yeasts is reduced, or prevented, and the dominant microorganisms are homofermentative *Lactobacillus* species.[12,14] Also substantial numbers of *Leuconostoc* and *Carnobacterium* can be found.[15]

The effect of storage temperature on the increase of aerobic count in vacuum packed emulsion sausage is shown in Figure 10-10. The spoilage of sausages is not directly linked to the bacterial numbers.[11] The flavor can be acceptable long after the total count has reached its maximum,[14] but before the sausages take on an offensive odor or taste, they become unacceptable due to slime formation; no slime is visual before the total count has exceeded 10^8 CFU g^{-1}.[14,16]

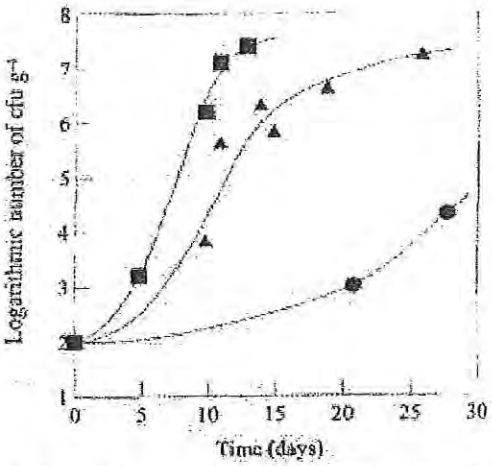

Figure 10-10 Increase in Aerobic Count on Vacuum Packed Emulsion Sausage Stored at Different Temperatures (Swedish Falukorv[16]). Filled squares indicate storage at 8°C, filled triangles indicate 4°C, and filled circles indicate 0°C. *Source:* Copyright © 1989, Göran Molin.

Gas Package with a Head Space

A major drawback of vacuum packing is that the product gets a wet surface. This reduces the acceptability of the product but has also bacteriological implications, eg, the product is more likely to become slimy. A gas package with a substantial head space can provide the product with a dryer surface, and less drip (free meat juice in the package). However, there must be nitrogen in the gas because with pure carbon dioxide the product will still exude water.[10,14]

Packaging emulsion sausages in pure nitrogen resulted in a longer shelf life than packaging in pure carbon dioxide, ie, the time until the flavor deteriorated and slime was detected was longer in nitrogen than in pure carbon dioxide.[14] No advantages or disadvantages in respect to shelf life were seen with carbon dioxide concentrations up to 50% (v/v) in nitrogen.[14] However, the addition of a certain amount of carbon dioxide (20% to 40%) in the nitrogen can be a hurdle for yeast or mold development in packages where some oxygen is present by, for example, accidental leakage.

Oxygen should be avoided in packages for heated, cured meats for at least the two following reasons: (1) oxygen enables the growth of molds and encourages growth of yeasts and (2) oxygen helps many lactobacilli to produce more adverse end-products, eg, H_2O_2, acetic acid, formic acid, and acetoin/diacetyl.[11,14] Hydrogen peroxide causes green discoloration.[16]

The recommended gas mixture for packaging heated, cured meats in modified atmosphere is 20% to 40% (v/v) carbon dioxide in 60% to 80% nitrogen.

Food Science Australia
A joint venture of CSIRO and Afisc

Report 994N001

Residual peroxide on crumpet and meat products.

12 February 1999

Prepared by

[redacted]

for

[redacted]

Technical Manager
BOC Gases
PO Box 288
CHATSWOOD NSW 2057

Food Science Australia
Commercial Report
Food & Packaging Technology Group

TITLE : Residual peroxide on crumpet and meat products.

CLIENT : [redacted]
Technical Manager
BOC Gases
PO Box 288
CHATSWOOD NSW 2057

FSA ref : 994N001

FSA contact : [redacted] Tel: [redacted]
Fax:

Date of Report : 12 February 1999

Food Science Australia
Commercial Report
Food & Packaging Technology Group

OBJECTIVE: Determine the residual hydrogen peroxide on the surface of Crumpet-Splits, sliced ham and frankfurts after being treated with various mixtures of acetic acid and hydrogen peroxide vapours.

SAMPLE: Samples of Crumpet-Splits, sliced ham and frankfurts were supplied by Laring Technologies for this examination.

TEST: The samples of Crumpet-Splits, sliced ham and frankfurts were exposed to acetic acid and hydrogen peroxide vapours in carbon dioxide. The peroxide vapours were generated by passing carbon dioxide through 50% hydrogen peroxide at approximately 24°C. The acetic acid vapours were generated by passing carbon dioxide through glacial acetic acid at approximately 24°C. Crumpet-Splits were stored at 25°C for 1 min, 5 min, 1 hour and 24 hours before being tested. Sliced ham and frankfurts were stored at 4°C for 1 min, 1 hour and 24 hours before being tested.

Residual hydrogen peroxide was detected using the Merck Reflectoquant analytical test kit. This comprised of the Reflectometer RQflex and Reflectoquant test strips (supplied by Merck Pty. Ltd. 207 Colchester Rd. Kilsyth Victoria 3137). This test kit has a measuring range of 0.5 to 25 mg/L H_2O_2.

Method 1. The peroxide on the surface of the samples was tested by placing the moistened test strips directly onto the sample surface for the required reaction time. In some samples there was insufficient surface liquid to give an even colour on the test strips.

Method 2. The sample was placed in a plastic bags and 20 ml of UHQ water added. Hydrogen peroxide concentration in the 20 ml of water was then measured. In some crumpet samples water was absorbed which made it difficult to obtain sufficient liquid to perform the peroxide test.

RESULTS:

H_2O_2 : AcOOH.

analytic result for residual H_2O_2.

Crumpets.

The Reflectometer readings (mg/L) for Method 1 of the Crumpet-Splits are given in Table 1. below. The results are for the test strip being moistened and placed on the underside of the crumpet. There are some results given for Method 2.

Table 1.

Gas Stream	H_2O_2 vapour	Acetic Acid vapour	Flow Rate L/min	Flushing period seconds	After 1 min.	After 5 min.	After 1 hour.	After 24 hours.
Control	0%	0%	40	4	Method 1 =Low[2]			
A.	100%	0%	40	4	Method 1 = 14.2	Method 1 = 11.2	Method 1 = 6.7	Method 1 = Low[2] Method 2 = 0.0[2]
B.	75%	25%	40	4	Method 1 = 16.5	Method 1 = 13.3	Method 1 = 4.6	Method 1 = Low[2] Method 2 = 0.0[2]
C.	50%	50%	40	4	Method 1 = 13.3	Method 1 = 5.7	Method 1 = +ve could not be read [3]	Method 1 = Low[2] Method 2 = 0.0[2]
D.	25%	75%	40	4	Method 1 = 10.0	Method 1 = 3.8	Method 1 = 0.8	Method 1 = 0.0[2] Method 2 = 0.0[2]
E.	0%	100%	40	4	Method 1 = 1.2 & error.[1] Method 2 = 0.0[2]	Not performed	Method 1 = 0.0[2]	Not performed

[1]This positive results appears to be due to the acetic acid interfering with the test strip.
[2]These readings are lower than the detection limit of 0.5 mg/L.
[3]The test strips developed a mottled blue colour which the Reflectometer could not read.

Sliced Ham.

The Reflectometer readings (mg/L) for the sliced ham are given in the Table 2 below.

Table 2.

Gas Stream	H_2O_2 vapour	Acetic Acid vapour	Flow Rate L/min	Flushing period seconds	After 1 min.	After 1 hour.	After 24 hours.
Control	0%	0%	40	3	Method 1 = Low[2]		
A.	100%	0%	40	3	Method 1 = +ve[1] Method 2 =4.8	Method 1 = Low[2] Method 2 = Low[2]	Method 1 = 0.0[2] Method 2 = 0.0[2]
B.	75%	25%	40	3	Method 1 = 0.3[2] Method 2 = 0.0[2]	Method 1 = Low[2] Method 2 = Low[2]	Method 1 = 0.0[2] Method 2 = 0.0[2]
C.	50%	50%	40	3	Method 1 = Low[2] Method 2 = Low[2]	Method 1 = Low[2] Method 2 = 0.0[2]	Method 1 = 0.0[2] Method 2 = 0.0[2]
D.	25%	75%	40	3	Method 1 = Low[2] Method 2 = Low[2]	Method 1 = Low[2] Method 2 = Low[2]	Method 1 = 0.0[2] Method 2 = 0.0[2]
E.	0%	100%	40	3	Method 1 = Low[2] Method 2 = Low[2]	Not performed	Not performed
F.	25%	75%	40	12	Method 1 = Low[2] Method 2 = Low[2]	Not performed	Not performed

[1]The test strips developed a mottled blue colour which the Reflectometer could not read.
[2]These readings are lower than the detection limit of 0.5 mg/L.

Frankfurts.

The Reflectometer readings (mg/L) for the frankfurts are given in the Table 3 below.

Table 3.

Gas Stream	H_2O_2 vapour	Acetic Acid vapour	Flow Rate L/min	Flushing period seconds	After 1 min.	After 1 hour.	After 24 hours.
Control	0%	0%	40	2	Method 1 = Low[2]		
A.	100%	0%	40	2	Method 1 = patchy 3.8 Method 2 =6.8	Method 1 = Low[2] Method 2 = 0.0[2]	Method 1 = Low[2] Method 2 = Low[2]
B.	75%	25%	40	2	Method 1 = too patchy Method 2 = 3.8	Method 1 = Low[2] Method 2 = Low[2]	Method 1 = Low[2] Method 2 = Low[2]
C.	50%	50%	40	2	Method 1 = 2.5 Method 2 = 2.2	Method 1 = Low [2] Method 2 = Low[2]	Method 1 = Low[2] Method 2 = Low[2]
D.	25%	75%	40	2	Method 1 = slight +ve[1] Method 2 = 0.1[2]	Method 1 = Low[2] Method 2 = 0.0[2]	Method 1 = Low[2] Method 2 = 0.0[2]
E.	100%	0%	40	2	Method 1 = Low[2] Method 2 = Low[2]	Method 1 = Low[2] Method 2 = Low[2]	Method 1 = Low[2] Method 2 = Low[2]
F.	25%	75%	40	8	Method 1 = 3.5 & patchy Method 2 = 1.5 & 4.6	Method 1 = Low[2] Method 2 = 0.0[2]	Method 1 = Low[2] Method 2 = Low[2]

[1]The test strips developed a mottled blue colour which the Reflectometer could not read.
[2]These readings are lower than the detection limit of 0.5 mg/L.

Comments.

Crumpet-Splits were the only product that had detectable levels of hydrogen peroxide one hour after treatment.

Sliced ham and frankfurts did not have detectable levels of hydrogen peroxide one hour after any of the treatments.

No hydrogen peroxide was detected on the Crumpet-Splits, sliced ham or frankfurts twenty four hours after treatment.

ATTACHMENT 3.2.1.
USFDA DIRECT FOOD SUBSTANCES GRAS and APPROVALS.

§ 182.8217 Calcium phosphate.

(a) *Product.* Calcium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8223 Calcium pyrophosphate.

(a) *Product.* Calcium pyrophosphate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8250 Choline bitartrate.

(a) *Product.* Choline bitartrate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8252 Choline chloride.

(a) *Product.* Choline chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8778 Sodium phosphate.

(a) *Product.* Sodium phosphate (mono-, di-, and tribasic).

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8890 Tocopherols.

(a) *Product.* Tocopherols.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8892 α-Tocopherol acetate.

(a) *Product.* α-Tocopherol acetate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8985 Zinc chloride.

(a) *Product.* Zinc chloride.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8988 Zinc gluconate.

(a) *Product.* Zinc gluconate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8991 Zinc oxide.

(a) *Product.* Zinc oxide.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8994 Zinc stearate.

(a) *Product.* Zinc stearate prepared from stearic acid free from chickedema factor.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

§ 182.8997 Zinc sulfate.

(a) *Product.* Zinc sulfate.

(b) *Conditions of use.* This substance is generally recognized as safe when used in accordance with good manufacturing practice.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart A—General Provisions

Subpart B—Listing of Specific Substances Affirmed as GRAS

184.1077 Potassium acid tartrate.
184.1081 Propionic acid.
184.1090 Stearic acid.
184.1091 Succinic acid.
184.1095 Sulfuric acid.
184.1097 Tannic acid.
184.1099 Tartaric acid.
184.1101 Diacetyl tartaric acid esters of mono- and diglycerides.
184.1115 Agar-agar.
184.1120 Brown algae.
184.1121 Red algae.
184.1133 Ammonium alginate.
184.1135 Ammonium bicarbonate.
184.1137 Ammonium carbonate.
184.1138 Ammonium chloride.
184.1139 Ammonium hydroxide.
184.1140 Ammonium citrate, dibasic.
184.1141a Ammonium phosphate, monobasic.
184.1141b Ammonium phosphate, dibasic.
184.1143 Ammonium sulfate.
184.1148 Bacterially-derived carbohydrase enzyme preparation.
184.1150 Bacterially-derived protease enzyme preparation.
184.1155 Bentonite.
184.1157 Benzoyl peroxide.
184.1165 n-Butane and iso-butane.
184.1185 Calcium acetate.
184.1187 Calcium alginate.
184.1191 Calcium carbonate.
184.1193 Calcium chloride.
184.1195 Calcium citrate.
184.1199 Calcium gluconate.
184.1201 Calcium glycerophosphate.
184.1205 Calcium hydroxide.
184.1206 Calcium iodate.
184.1207 Calcium lactate.
184.1210 Calcium oxide.
184.1212 Calcium pantothenate.
184.1221 Calcium propionate.
184.1229 Calcium stearate.
184.1230 Calcium sulfate.
184.1240 Carbon dioxide.
184.1245 Beta-carotene.
184.1250 Cellulase enzyme preparation derived from Trichoderma longibrachiatum.
184.1257 Clove and its derivatives.
184.1259 Cocoa butter substitute.
184.1260 Copper gluconate.
184.1261 Copper sulfate.
184.1262 Corn silk and corn silk extract.
184.1265 Cuprous iodide.
184.1271 L-Cysteine.
184.1272 L-Cysteine monohydrochloride.
184.1277 Dextrin.
184.1278 Diacetyl.
184.1282 Dill and its derivatives.
184.1287 Enzyme-modified fats.
184.1293 Ethyl alcohol.
184.1295 Ethyl formate.
184.1296 Ferric ammonium citrate.
184.1297 Ferric chloride.
184.1298 Ferric citrate.
184.1301 Ferric phosphate.
184.1304 Ferric pyrophosphate.
184.1307 Ferric sulfate.
184.1307a Ferrous ascorbate.
184.1307b Ferrous carbonate.
184.1307c Ferrous citrate.
184.1307d Ferrous fumarate.
184.1308 Ferrous gluconate.
184.1311 Ferrous lactate.
184.1315 Ferrous sulfate.
184.1316 Ficin.
184.1317 Garlic and its derivatives.
184.1318 Glucono delta-lactone.
184.1321 Corn gluten.
184.1322 Wheat gluten.
184.1323 Glyceryl monooleate.
184.1324 Glyceryl monostearate.
184.1328 Glyceryl behenate.
184.1329 Glyceryl palmitostearate.
184.1330 Acacia (gum arabic).
184.1333 Gum ghatti.
184.1339 Guar gum.
184.1343 Locust (carob) bean gum.
184.1349 Karaya gum (sterculia gum).
184.1351 Gum tragacanth.
184.1355 Helium.
184.1366 Hydrogen peroxide.
184.1370 Inositol.
184.1372 Insoluble glucose isomerase enzyme preparations.
184.1375 Iron, elemental.
184.1386 Isopropyl citrate.
184.1387 Lactase enzyme preparation from Candida pseudotropicalis.
184.1388 Lactase enzyme preparation from Kluyveromyces lactis.
184.1400 Lecithin.
184.1408 Licorice and licorice derivatives.
184.1409 Ground limestone.
184.1415 Animal lipase.
184.1420 Lipase enzyme preparation derived from Rhizopus niveus.
184.1425 Magnesium carbonate.
184.1426 Magnesium chloride.
184.1428 Magnesium hydroxide.
184.1431 Magnesium oxide.
184.1434 Magnesium phosphate.
184.1440 Magnesium stearate.
184.1443 Magnesium sulfate.
184.1443a Malt.
184.1444 Maltodextrin.
184.1445 Malt syrup (malt extract).
184.1446 Manganese chloride.
184.1449 Manganese citrate.
184.1452 Manganese gluconate.
184.1461 Manganese sulfate.
184.1472 Menhaden oil.
184.1490 Methylparaben.
184.1498 Microparticulated protein product.
184.1505 Mono- and diglycerides.
184.1521 Monosodium phosphate derivatives of mono- and diglycerides.
184.1530 Niacin.
184.1535 Niacinamide.
184.1537 Nickel.
184.1538 Nisin preparation.
184.1540 Nitrogen.
184.1545 Nitrous oxide.
184.1553 Peptones.

MAXIMUM USAGE LEVELS PERMITTED

Food (as served)	Percent	Function
Baked goods and baking mixes, § 170.3(n)(1) of this chapter.	0.2	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Condiments and relishes, § 170.3(n)(8) of this chapter.	.7	Do.
Fats and oils, § 170.3(n)(12) of this chapter	1.3	Do.
Gravies and sauces, § 170.3(n)(24) of this chapter	.8	Do.
Meat products, § 170.3(n)(29) of this chapter	.2	Formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
Processed fruits and fruit juices, § 170.3(n)(35) of this chapter.	.2	Emulsifier and emulsifier salt, § 170.3(o)(8) of this chapter; formulation aid, § 170.3(o)(14) of this chapter; stabilizer and thickener, § 170.3(o)(28) of this chapter.
All other food categories	.1	Do.

(d) [Reserved]

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[42 FR 14653, Mar. 15, 1977, as amended at 42 FR 55205, Oct. 14, 1977; 49 FR 5612, Feb. 14, 1984]

§ 184.1355 Helium.

(a) Helium (empirical formula He, CAS Reg. No. 7440-59-7) is a colorless, odorless, flavorless, nonflammable, inert gas. It is lighter than air and is produced by the liquefaction and purification of natural gas.

(b) The Food and Drug Administration is developing food-grade specifications for helium in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a processing aid as defined in § 170.3(o)(24) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 57270, Dec. 29, 1983]

§ 184.1366 Hydrogen peroxide.

(a) Hydrogen peroxide (H_2O_2, CAS Reg. No. 7722-84-1) is also referred to as hydrogen dioxide. It is made by the electrolytic oxidation of sulfuric acid or a sulfate to persulfuric acid or a persulfuric acid salt with subsequent hydrolysis and distillation of the hydrogen peroxide formed; by decomposition of barium peroxide with sulfuric or phosphoric acid; by hydrogen reduction of 2-ethylanthraquinone, followed by oxidation with air, to regenerate the quinone and produce hydrogen peroxide; or by electrical discharge through a mixture of hydrogen, oxygen, and water vapor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d ed. (1981), pp. 146-147,[1] which is incorporated by reference.

(c) In accordance with § 184.1(b)(2), the ingredient is used to treat food only within the following specific limitations:

[1] Copies may be obtained from the National Academy of Sciences, 2101 Constitution Ave. NW, Washington, DC 20037, or examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

Food	Maximum treatment level in food (percent)	Functional use
Milk, intended for use during the cheesemaking process as permitted in the appropriate standards of identity for cheese and related cheese products under part 133 of this chapter.	0.05	Antimicrobial agent as defined in § 170.3 (o)(2) of this chapter
Whey, during the preparation of modified whey by electrodialysis methods.	0.04	do.
Dried eggs, dried egg whites, and dried egg yolks as in §§ 160.105, 160.145, and 160.185 of this chapter.	Amount sufficient for the purpose.	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter
Tripe	do	Bleaching agent.
Beef feet	Amount sufficient for the purpose. (Hydrogen peroxide may be in the form of a compound salt, sodium carbonate peroxide).	Bleaching agent.
Herring	Amount sufficient for the purpose.	do.
Wine	do	Oxidizing and reducing agent as defined in § 170.3 (o)(22) of this chapter.
Starch	0.15	Antimicrobial agent as defined in §170.3 (o)(2) of this chapter, to produce thermophile-free starch; Remove sulfur dioxide from starch slurry following steeping and grinding operations of corn refining.
Instant tea	Amount sufficient for the purpose.	Bleaching agent.
Corn syrup	0.15	Reduce sulfur dioxide levels in the finished corn syrup.
Colored (annatto) cheese whey	0.05	Bleaching agent.
Wine vinegar	Amount sufficient for the purpose.	Remove sulfur dioxide from wine prior to fermentation to produce vinegar.
Emulsifiers containing fatty acid esters	1.25	Bleaching agent.

(d) Residual hydrogen peroxide is removed by appropriate physical and chemical means during the processing of food where it has been used according to paragraph (c) of this section.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[46 FR 44439, Sept. 4, 1981, as amended at 51 FR 27172, July 30, 1986]

§ 184.1370 Inositol.

(a) Inositol, or myo-inositol ($C_6H_{12}O_6$, CAS Reg. No. 87–89–8), is *cis*-1,2,3,5-*trans*-4,6-cyclohexanehexol. It occurs naturally and is prepared from an aqueous (0.2 percent sulfur dioxide) extract of corn kernels by precipitation and hydrolysis of crude phytate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 150, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in special dietary foods as defined in part 105 of this chapter at levels not to exceed current good manufacturing practice. It may also be used in infant formula in accordance with section 412(g) of the Act, or with regulations promulgated under section 412(a)(2) of the Act.

(d) Prior sanctions for this ingredient different from the uses established by

Iodometric Method

Solutions and Chemicals:

1. Sulfuric Acid, H_2SO_4, 2N.
2. Potassium Iodide, KI. In solid form or solution (166 g/l).
3. Ammonium Molybdate, $(NH_4)_5 MO_7 O_{24} \cdot 4H_2O$.
   Prepare a 15 percent solution of Ammonium Molybdate. The salt dissolves more readily when heated to 50°.
4. Sodium Thiosulfate Solution, $Na_2S_2O_3$. 0.1N.
5. Starch (Thyodene Solution).

Execution of Analysis:

A. Determination of concentration in grams/litre

1. Measure up the exact sample quantity with a pipette. Adjust the sample quantity to the expected Hydrogen Peroxide concentration:

Sample quantity, ml:	I	5	10	50	100
Expected conc. g/l:	1O	2	1	0.2	0.01-0.10

2. If the sample quantity is small, dilute with distilled water to about 50 ml.
3. Add 10 ml of 2 N Sulfuric Acid and 10 ml of Potassium Iodide Solution (or I spoon of Potassium Iodide).
4. Add I drop of Ammonium Molybdate Solution.
5. Titrate with 0.1 N Sodium Thiosulfate Solution to yellow colour.
6. Add a couple of drops of Thyodene solution as an indicator.
7. Continue titrating until colour changes (decolouration).

Calculation -H_2O_2

$$g/l = \frac{(a)(N)(17)}{(V)}$$

a = consumption of Sodium Thiosulfate Solution, ml.
N = normality of Sodium Thiosulfate Solution
V = sample quantity, ml.

B. Determination of concentration in weight percent

1. Weigh on an analytical balance 0.5g of Hydrogen Peroxide solution into a 450ml beaker.
2. Add 100 ml of distilled water and mix.
3. Pipette Vml into another beaker.

Sample quantity V ml:	20	50	100
Expected conc. %:	30-50	10-30	1-10

4. If the sample quantity is small, dilute to about 50 ml with distilled water.
5. Add 10 ml of 2 N Sulfuric Acid and 10 ml of Potassium Iodide Solution (or1 spoon of Potassium Iodide).
6. Add I drop of Ammonium Molybdate Solution
7. Titrate with 0.1 N Sodium Thiosulfate Solution to a yellow colour.
8. Add a couple of drops of Thyodene Solution as an indicator.
9. Continue titrating with 0.1 N Sodium Thiosulfate until colour changes (decolouration).
10. Calculation

$$\%H_2O_2 = \frac{(a)(N)(17)(100)(100)}{(1000)(g)(V)}$$

$$= \frac{(a)(N)(170)}{(g)(V)}$$

a = consumption of Sodium Thiosulfate Solution, ml.
N = normality of Sodium Thiosulfate Solution.
g = weighed-in sample quantity, grams.
V = sample volume, ml.

TEST STRIP Method.

Consumables and Equipment:

1. Reflectometer Rqflex

2. Reflectoquant peroxide test strips.
   ON: 1.16974.0001
   This test kit has a measuring range of 0.5 to 25 mg/L H_2O_2.

(Merck Reflectoquant analytical test kit supplied by Merck Pty. Ltd. 207 Colchester Rd. Kilsyth Victoria 3137).

Execution of Analysis:

Method 1 - SUFFICIENT SURFACE LIQUID:

The peroxide on the surface of the samples was tested by placing the moistened test strips directly onto the sample surface for the required reaction time. In some samples there was insufficient surface liquid to give an even colour on the test strips.

Method 2 - INSUFFICIENT SURFACE LIQUID:

The sample was placed in a plastic bag and 20 ml of UHQ water added. Hydrogen peroxide concentration in the 20 ml of water was then measured. In some crumpet samples water was absorbed which made it difficult to obtain sufficient liquid to perform the peroxide test.

Determination of Result:

After exposing the test strip to the sample by the appropriate method specified above the test strip is inserted into the Reflectometer Rqflex and the digital value read and reported directly as mg/L of hydrogen peroxide within the range of 0.5 to 25 mg/L H_2O_2.

ATTACHMENT #2 1 of 5.

OFFICIAL METHODS

AND

RECOMMENDED PRACTICES

OF THE

AMERICAN OIL CHEMISTS' SOCIETY

FOURTH EDITION

1994–1995 Associate Methods Editors

The following individuals have agreed to act as associate editors of analytical methods to facilitate the review process.

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Ci	
D	
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F and G	
H	
J	
M	
R	
S and T	
Spectrophotometric methods	

AOCS Official Method Cd 8b-90

Revised 1991, 1992, 1993, 1996
Official 1996

Peroxide Value
Acetic Acid–Isooctane Method

Definition: This method determines all substances, in terms of milliequivalents of peroxide per 1000 grams of sample, that oxidize potassium iodide under the conditions of the test. The substances are generally assumed to be peroxides or other similar products of fat oxidation.

Scope: Applicable to all normal fats and oils, including margarine. This method is highly empirical, and any variation in the test procedure may result in erratic results. Because this method gives erratic results at peroxide values ≥ 70, this method should not be used with the AOM test, AOCS Official Method Cd 12-57, with which peroxide values ≥ 70 may be encountered.

Apparatus

1. Pipet—0.5 mL, or other suitable volumetric apparatus capable of dispensing 0.5 mL of saturated potassium iodide (KI) solution.
2. Erlenmeyer flasks—with glass stoppers, 250 mL.

Reagents

1. Acetic acid–isooctane solution—3:2, v/v, prepared by mixing 3 volumes of reagent-grade glacial acetic acid (see Notes, Caution) with 2 volumes of reagent-grade isooctane (see Notes, Caution).
2. Potassium iodide (KI) solution—saturated, prepared fresh each day analysis is performed by dissolving an excess of KI in recently boiled distilled water. Make certain the solution remains saturated during use, as indicated by the presence of undissolved KI crystals. Store in the dark when not in use. Test the saturated KI solution by adding 2 drops of starch solution to 0.5 mL of the KI solution in 30 mL of the acetic acid–isooctane solution. If a blue color is formed that requires more than 1 drop of 0.1 N sodium thiosulfate solution to discharge, discard the KI solution and prepare a fresh solution.
3. Sodium thiosulfate ($Na_2S_2O_3 \cdot 5H_2O$) solution—0.1 N, accurately standardized vs. potassium dichromate primary standard as follows:
   (a) Sodium thiosulfate solution 0.1 N, prepared by dissolving 24.9 g of sodium thiosulfate in distilled water and diluting to 1 L.
   (b) The potassium dichromate primary standard should be finely ground, dried at 105 C for 2 hr and cooled in a desiccator. Weigh 0.16–0.22 g of potassium dichromate into a 500-mL flask or bottle by difference from a weighing bottle. Dissolve in 25 mL of water, add 5 mL of concentrated hydrochloric acid (35–37%), 20 mL of potassium iodide solution (15% solution, 15 g KI in 100 mL water) and rotate to mix. Allow to stand for 5 min and then add 100 mL of distilled water. Titrate with sodium thiosulfate solution, shaking continuously until yellow color has almost disappeared. Add 1–2 mL of starch indicator and continue the titration, adding the thiosulfate solution slowly until the blue color just disappears. The strength of the sodium thiosulfate solution is expressed in terms of its normality.

$$\text{Normality of } Na_2S_2O_3 \text{ solution} = \frac{20.394 \times \text{wt of } K_2Cr_2O_7, \text{ g}}{\text{mL of sodium thiosulfate}}$$

4. Sodium thiosulfate solution—0.01 N, accurately standardized. This solution may be prepared by accurately pipetting 100 mL of 0.1 N sodium thiosulfate into a 1000-mL volumetric flask and accurately diluting to volume with recently boiled distilled water.
5. Starch indicator solution—tested for sensitivity, prepared by making a paste with 1 g of starch (see Notes, 1) and a small amount of cold distilled water. Add, while stirring, to 200 mL of boiling water and boil for a few seconds. Immediately remove from heat and cool. Salicylic acid (1.25 g/L) may be added to preserve the indicator. If long storage is required, the solution must be kept in a refrigerator at 4–10 C. Fresh indicator must be prepared when the end point of the titration from blue to colorless fails to be sharp. If stored under refrigeration, the starch solution should be stable for about 2–3 weeks.

   Test for sensitivity—Place 5 mL of starch solution in 100 mL of water and add 0.05 mL of *freshly prepared* 0.1 N KI solution and one drop of a 50 ppm chlorine solution made by diluting 1 mL of a commercial 5% sodium hypochlorite (NaOCl) solution to 1000 mL. The deep blue color produced must be discharged by 0.05 mL of 0.1 N sodium thiosulfate.
6. Sodium lauryl sulfate (SDS)—≥ 98% [Aldrich Chemical (W. Milwaukee, WI, USA) or Mallinckrodt (Paris, KY, USA)]. Prepare 10% solution by dissolving 10 g SDS in 100 mL water.

Procedure for Fats and Oils

1. Weigh 5.00 ± 0.05 g of sample into a 250-mL Erlenmeyer flask with glass stopper and add 50 mL of the 3:2 acetic acid–isooctane solution. Swirl to dissolve the sample. Add 0.5 mL of saturated KI solution using a suitable volumetric pipet.
2. Allow the solution to stand for *exactly* 1 min, thoroughly shaking the solution at least three times during the 1 min, and then immediately add 30 mL of distilled water.
3. Titrate with 0.1 N sodium thiosulfate, adding it gradually and with constant and vigorous agitation (see Notes, 2). Continue the titration until the yellow iodine color has *almost* disappeared. Add 0.5 mL of 10% SDS

(Reagents, 6), and then add about 0.5 mL of starch indicator solution. Continue the titration with constant agitation, especially near the end point, to liberate all of the iodine from the solvent layer. Add the thiosulfate solution dropwise until the blue color just disappears (see Notes, 3 and 4).

4. Conduct a blank determination of the reagents daily. The blank titration must not exceed 0.1 mL of the 0.1 N sodium thiosulfate solution.

Procedure for Margarine

1. Melt the sample by heating with constant stirring on a hot plate set at low heat, or by heating in an air oven at 60–70 C. Avoid excess heating and particularly prolonged exposure of the oil to temperatures above 40 C.
2. When completely melted, remove the sample from the hot plate or oven and allow to settle in a warm place until the aqueous portion and most of the milk solids have settled to the bottom.
3. Decant the oil into a clean beaker and filter through a Whatman no. 4 paper (or equivalent) into another clean beaker. Do not reheat for filtration unless absolutely necessary. The sample must be clear and brilliant.
4. Proceed as directed in Procedure for Fats and Oils, paragraphs 1–4.

Calculations

1. Peroxide value (milliequivalents peroxide/1000 g sample) =

$$\frac{(S - B) \times N \times 1000}{\text{wt of sample, g}}$$

Where—

B = titration of blank, mL
S = titration of sample, mL
N = normality of sodium thiosulfate solution

Notes

Caution

Isooctane is flammable and a fire risk. Explosive limits in air are 1.1–6.0%. It is toxic by ingestion and inhalation. A properly operating fume hood should be used when working with this solvent.

Acetic acid in the pure state is moderately toxic by ingestion and inhalation. It is a strong irritant to skin and tissue. The TLV in air is 10 ppm.

Numbered Notes

1. "Potato Starch for Iodometry" is recommended, because this starch produces a deep blue color in the presence of the iodonium ion. "Soluble Starch" is not recommended because a consistent deep blue color may not be developed when some soluble starches interact with the iodonium ion. The following are suitable starches: Soluble Starch for Iodometry, Fisher S516-100; Soluble Potato Starch, Sigma S-2630; Soluble Potato Starch for Iodometry, J. T. Baker 4006-04.
2. There is a 15–30 sec delay in neutralizing the starch indicator for peroxide values 70 meq/kg and higher. This delay is due to the tendency of isooctane to float on the surface of an aqueous medium, and the time necessary to adequately mix the solvent in large volumes of aqueous titrant, thereby liberating the last traces of iodine. Based on collaborative study results (References, 1, 2), the recommendation is to use 0.1 N titrant for peroxide value ranges (10–150 meq/kg). Erratic results reported for this method, especially at higher peroxide values, appear to be related to the isooctane floating on the surface of the aqueous layer (References, 3). Rapid mechanical stirring (e.g., with magnetic stirrer) and/or use of a surfactant, such as sodium lauryl sulfate (Reagents, 6), is highly recommended.
3. If the titration is less than 0.5 mL using 0.1 N sodium thiosulfate, repeat the determination using 0.01 N sodium thiosulfate, using vigorous agitation and/or surfactant for the reason stated in Notes, 2.
4. The test should be carried out in diffuse daylight or in artificial light shielded from a direct light source (References, 4).

References

1. Brooks, D. D. and D. L. Berner, *Isooctane as an Alternative Solvent for Peroxide Value Determination. Study I,* poster presentation, AOCS National Meeting, Baltimore, MD, April 23, 1990.
2. Collaborative study results published in *INFORM 1:*884 (1990).
3. Brooks, D. D., S. K. Brophy, B. Hayden and G. R. Goss, *Alternative Solvents for Peroxide Value Determination,* poster presentation, AOCS National Meeting, Cincinnati, OH, May 10, 1989.
4. *J. Assoc. Off. Anal. Chem. 75:*507 (1992).
5. The International Standards Organization (ISO) successfully completed an international collaborative study of this method in 1996. The results were reported at the meeting of the ISO Commission on Oils and Fats in London in April 1996 in meeting document N576.

ATTACHMENT 4-2. 4 of 5

A.O.C.S. Official Method Cd 3d-63

Formerly Cd 3a-63
Revised 1987
Reapproved 1989

Acid Value

Definition: The acid value is the number of milligrams of potassium hydroxide necessary to neutralize the free acids in 1 gram of sample. With samples that contain virtually no free acids other than fatty acids, the acid value may be directly converted by means of a suitable factor to percent free fatty acids.

Scope: Applicable to crude and refined animal, vegetable, and marine fats and oils, and various products derived from them.

Apparatus:

1. Erlenmeyer flasks, 250 or 300 mL.

Reagents:

1. Potassium hydroxide (KOH), 0.1 N, accurately standardized and carbonate free. See AOCS Specification H 15-52 for guidance. Add 6 g reagent grade KOH to 1 liter of water in a 2 liter Erlenmeyer flask, boil 10 minutes with stirring, add 2 grams reagent grade barium hydroxide ($Ba(OH)_2$), boil an additional 5 to 10 minutes, cool, stopper flask and let stand several hours. Filter through sintered glass funnel and store in an alkali- resistant bottle protected from CO_2. Standardize by titration with primary standard grade potassium acid phthalate, using phenolphthalein indicator (see Notes, 1).
2. Solvent mixture consisting of equal parts by volume of isopropyl alcohol (AOCS Specification H 18-58) and toluene (AOCS Specification H 19-58). See Notes, Caution. The mixture must give a distinct and sharp end point with phenolphthalein in the titration as noted in Procedure, paragraph 5.
3. Phenolphthalein indicator solution, 1.0% in isopropyl alcohol.

Procedure:

1. Add indicator solution to the required amount of solvent in ratio of 2 mL to 125 mL and neutralize with alkali to a faint but permanent pink color.
2. Determine the sample size from Table 1 —

Acid value	Wt. of sample (± 10%), grams	Weighing accuracy, ± grams
0 to 1	20	0.05
1 to 4	10	0.02
4 to 15	2.5	0.01
15 to 75	0.5	0.001
75 and over	0.1	0.0002

3. Weigh the specified amount of well mixed liquid sample into an Erlenmeyer flask.
4. Add 125 mL of the neutralized solvent mixture. Be sure that the sample is completely dissolved before titrating. Warming may be necessary in some cases.
5. Shake the sample vigorously while titrating with standard alkali to the first permanent pink color of the same intensity as that of the neutralized solvent before the latter was added to the sample. The color must persist for 30 seconds.

Calculations:

The acid value, mg KOH/g of sample =

$$\frac{(A - B) \times N \times 56.1}{W}$$

Where —

A = mL of standard alkali used in the titration

B = mL of standard alkali used in titrating the blank

N = normality of standard alkali

W = grams of sample

To express in terms of free fatty acids as percent oleic, lauric, or palmitic, divide the acid value by 1.99, 2.81, or 2.19, respectively.

Precision:

Single determinations performed in two different laboratories should not differ by more than 0.22 for values less than 4 nor by more than 0.36 for values in the range 4 to 20.

Alternate procedure for highly colored samples:

Apparatus:

1. Glass electrode-calomel electrode pH meter for electrometric titration. A sleeve type calomel electrode should be used (see Notes, 2).
2. Variable speed mechanical stirrer with glass stirring paddle.
3. Buret, 10 mL, graduated in 0.05 mL divisions with a tip drawn to a fine opening and extending at least 10 cm below the stopcock.
4. Beakers, 250 mL.
5. Stand and mountings for electrodes, stirrer, and buret.

ATTACHMENT 4.2. 5 of 5

Acid Value

Cd 3d-63

Reagents:

Same as for the phenolphthalein titrimetric procedure except that the standard alkali should be standardized by electrometric titration of pure potassium acid phthalate, and no indicator solution is necessary.

Procedure:

1. Determine the sample size from Table 1 and weigh the sample into a 250 mL beaker.
2. Add 125 mL of solvent mixture.
3. Mount the beaker in the titration assembly so that the electrodes are half immersed. Start the stirrer and operate at speeds that will give vigorous agitation without spattering. Immerse the tip of the buret to 1 cm below the surface of the sample.
4. Titrate with suitable increments of alkali. After each addition of alkali, wait until the meter reading is essentially constant (usually within 2 minutes), then record buret and meter readings graphically. Limit increments of alkali so that changes in meter readings are 0.5 pH units (0.03 volts) or less; when inflections in titration curve occur, add alkali in 0.05 mL portions.
5. Remove titrated solution, rinse electrodes with isopropyl alcohol, and immerse in distilled water.
6. Perform a blank titration, using 125 mL of solvent mixture.

Calculation:

The acid value, mg KOH/g of sample =

$$\frac{(A - B) \times N \times 56.1}{W}$$

Where —

A = mL of standard alkali used in titrating to middle of inflection in titration curve of sample.

B = mL of standard alkali used in titrating to same pH meter reading for the blank.

N = normality of standard alkali.

W = grams of sample.

To express in terms of free fatty acids as percent oleic, lauric, or palmitic, divide the acid value by 1.99, 2.81 or 2.19, respectively.

Notes:

Caution

Isopropyl alcohol is flammable and a dangerouls fire risk. The explosive limits in air are 2% to 12%. It is toxic by ingestion and inhalation. The TLV in air is 400 ppm.

Toluene is flammable and a dangerous fire risk. Explosive limits in air are 1.27 to 7%. It is toxic by ingestion, inhalation and skin absorption. The TLV is 100 ppm in air. A fume hood should be used at all times when using toluene.

Numbered Notes

1. A standard methanolic potassium hydroxide (0.1 N) solution (see AOCS Specification H 15-52) may be used as an alternate titrant in place of the standard aqueous solution. The methanolic potassium hydroxide is reported to provide a complete solvent system, having a distinct, clear endpoint. See JAOAC 59: 658 (1976) regarding the ruggedness of the acid value method.
2. The pH meter should be standardized to pH 4.0 with standard buffer solution. Immediately before using, wipe the electrodes thoroughly with clean cloth or tissue and soak for several minutes in distilled water. At weekly intervals, or more often if necessary, clean the glass electrode in a suitable cleaning solution. Also, drain calomel electrode and refill with fresh potassium chloride (KCl) electrolyte at weekly intervals. Both electrodes should be stored in distilled water when not in use.

ATTACHMENT P3.2.1

7

Veratraldehyde.
Verbenol; 2-pinen-4-ol.
Zingerone; 4-(4-hydroxy-3-methoxyphenyl)-2-butanone.

(c) Δ-Decalactone and Δ-dodecalactone when used separately or in combination in oleomargarine are used at levels not to exceed 10 parts per million and 20 parts per million, respectively, in accordance with §166.110 of this chapter.

(d) BHA (butylated hydroxyanisole) may be used as an antioxidant in flavoring substances whereby the additive does not exceed 0.5 percent of the essential (volatile) oil content of the flavoring substance.

[42 FR 14491, Mar. 15, 1977, as amended at 42 FR 23148, May 6, 1977; 43 FR 19843, May 9, 1978; 45 FR 22915, Apr. 4, 1980; 47 FR 27810, June 25, 1982; 48 FR 10812, Mar. 15, 1983; 48 FR 51907, Nov. 15, 1983; 49 FR 5747, Feb. 15, 1984; 50 FR 42932, Oct. 23, 1985; 54 FR 7402, Feb. 21, 1989; 61 FR 14245, Apr. 1, 1996]

§ 172.520 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

The food additive "cocoa with dioctyl sodium sulfosuccinate for manufacturing," conforming to §163.117 of this chapter and §172.810, is used or intended for use as a flavoring substance in dry beverage mixes whereby the amount of dioctyl sodium sulfosuccinate does not exceed 75 parts per million of the finished beverage. The labeling of the dry beverage mix shall bear adequate directions to assure use in compliance with this section.

§ 172.530 Disodium guanylate.

Disodium guanylate may be safely used as a flavor enhancer in foods, at a level not in excess of that reasonably required to produce the intended effect.

§ 172.535 Disodium inosinate.

The food additive disodium inosinate may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the disodium salt of inosinic acid, manufactured and purified so as to contain no more than 150 parts per million of soluble barium in the compound disodium inosinate with seven and one-half molecules of water of crystallization.

(b) The food additive is used as a flavoring adjuvant in food.

§ 172.540 DL-Alanine.

DL-Alanine (a racemic mixture of D- and L-alanine; CAS Reg. No. 302-72-7) may be safely used as a flavor enhancer for sweeteners in pickling mixtures at a level not to exceed 1 percent of the pickling spice that is added to the pickling brine.

[56 FR 6968, Feb. 21, 1991]

§ 172.560 Modified hop extract.

The food additive modified hop extract may be safely used in beer in accordance with the following prescribed conditions:

(a) The food additive is used or intended for use as a flavoring agent in the brewing of beer.

(b) The food additive is manufactured by one of the following processes:

(1) The additive is manufactured from a hexane extract of hops by simultaneous isomerization and selective reduction in an alkaline aqueous medium with sodium borohydride, whereby the additive meets the following specifications:

(i) A solution of the food additive solids is made up in approximately 0.012 *n* alkaline methyl alcohol (6 milliliters of 1 *n* sodium hydroxide diluted to 500 milliliters with methyl alcohol) to show an absorbance at 253 millimicrons of 0.6 to 0.9 per centimeter. (This absorbance is obtained by approximately 0.03 milligram solids permilliliter.) The ultraviolet absorption spectrum of this solution exhibits the following characteristics: An absorption peak at 253 millimicrons; no absorption peak at 325 to 330 millimicrons; the absorbance at 268 millimicrons does not exceed the absorbance at 272 millimicrons.

(ii) The boron content of the food additive does not exceed 310 parts per million (0.0310 percent), calculated as boron.

(2) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, and methyl alcohol as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part

per million of benzene, 1.0 part per million of light petroleum spirits, and 250 parts per million of methyl alcohol. The light petroleum spirits and benzene solvents shall comply with the specifications in §172.250 except that the boiling point range for light petroleum spirits is 150 °F–300 °F.

(3) The additive is manufactured from hops by a sequence of extractions and fractionations, using methylene chloride, hexane, and methyl alcohol as solvents, followed by isomerization by sodium hydroxide treatment. Residues of the solvents in the modified hop extract shall not exceed 5 parts per million of methylene chloride, 25 parts per million of hexane, and 100 parts per million of methyl alcohol.

(4) The additive is manufactured from hops by a sequence of extractions and fractionations, using benzene, light petroleum spirits, methyl alcohol, *n*-butyl alcohol, and ethyl acetate as solvents, followed by isomerization by potassium carbonate treatment. Residues of solvents in the modified hop extract shall not exceed 1.0 part per million of benzene, 1.0 part per million of light petroleum spirits, 50 parts per million of methyl alcohol, 50 parts per million of *n*-butyl alcohol, and 1 part per million of ethyl acetate. The light petroleum spirits and benzene solvents shall comply with the specifications in §172.250 except that the boiling point range for light petroleum spirits is 150 °F to 300 °F.

(5) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the following solvents: Ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene, and water; followed by isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene and a further sequence of extractions and fractionations using one or more of the solvents set forth in this paragraph. Residues of the solvents in the modified hop extract shall not exceed 125 parts per million of hexane; 150 parts per million of ethylene dichloride, methylene chloride, or trichloroethylene; or 250 parts per million of isopropyl alcohol or methyl alcohol.

(6) The additive is manufactured from hops by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by: Hydrogenation using palladium as a catalyst in methyl alcohol, ethyl alcohol, or isopropyl alcohol acidified with hydrochloric or sulfuric acid; oxidation with peracetic acid; isomerization by calcium chloride or magnesium chloride treatment in ethylene dichloride, methylene chloride, or trichloroethylene (alternatively, the hydrogenation and isomerization steps may be performed in reverse order); and a further sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section.

(7) The additive is manufactured from hops as set forth in paragraph (b)(6) of this section followed by reduction with sodium borohydride in aqueous alkaline methyl alcohol, and a sequence of extractions and fractionations using one or more of the solvents listed in paragraph (b)(5) of this section. The additive shall meet the residue limitations as prescribed in paragraph (b)(5) of this section, and a boron content level not in excess of 300 parts per million (0.0300 percent), calculated as boron.

(8) The additive is manufactured from hops as a nonisomerizable nonvolatile hop resin by an initial extraction and fractionation using one or more of the solvents listed in paragraph (b)(5) of this section followed by a sequence of aqueous extractions and removal of nonaqueous solvents to less than 0.5 percent. The additive is added to the wort before or during cooking in the manufacture of beer.

§ 172.575 Quinine.

Quinine, as the hydrochloride salt or sulfate salt, may be safely used in food in accordance with the following conditions:

ATTACHMENT P3.2.2.

§ 177.2910 Ultra-filtration membranes.

Ultra-filtration membranes identified in paragraphs (a)(1), (a)(2), (a)(3), and (a)(4) of this section may be safely used in the processing of food, under the following prescribed conditions;

(a)(1) Ultra-filtration membranes that consist of paper impregnated with cured phenol-formaldehyde resin, which is used as a support and is coated with a vinyl chloride-acrylonitrile copolymer.

(2) Ultra-filtration membranes that consist of a sintered carbon support that is coated with zirconium oxide (CAS Reg. No. 1314-23-4) containing up to 12 percent yttrium oxide (CAS Reg. No. 1314-36-9).

(3) Ultra-filtration membranes that consist of an aluminum oxide support that is coated with zirconium oxide (CAS Reg. No. 1314-23-4) containing up to 5 percent yttrium oxide (CAS Reg. No. 1314-36-9).

(4) Ultrafiltration membranes that consist of a microporous poly(vinylidene fluoride) membrane with a hydrophilic surface modifier consisting of hydroxypropyl acrylate/tetraethylene glycol diacrylate copolymer.

(b) Any substance employed in the production of ultra-filtration membranes that is the subject of a regulation in parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with the specifications of such regulation.

(c) Ultra-filtration membranes are used in the physical separation of dissolved or colloidally suspended varying molecular size components of liquids during the commercial processing of bulk quantities of food.

(d) Ultra-filtration membranes shall be maintained in a sanitary manner in accordance with good manufacturing practice so as to prevent potential microbial adulteration of the food.

(e) Ultrafiltration membranes identified in paragraph (a)(4) may be used to filter aqueous or acidic foods containing up to 13 percent of alcohol at temperatures not to exceed 21 °C (70 °F).

(f) To assure safe use of the ultra-filtration membranes, the label or labeling shall include adequate directions for a pre-use treatment, consisting of conditioning and washing with a minimum of 8 gallons of potable water prior to their first use in contact with food.

(g) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter.

[42 FR 14572, Mar. 15, 1977, as amended at 53 FR 17925, May 19, 1988; 58 FR 48599, Sept. 17, 1993; 60 FR 54426, Oct. 24, 1995]

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Subpart A [Reserved]

Subpart B—Substances Utilized To Control the Growth of Microorganisms

Sec.

Subpart C—Antioxidants and Stabilizers

Subpart D—Certain Adjuvants and Production Aids

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FDA approves new antimicrobial agent for poultry

FDA's Office of Food Additive Safety Sept. 19 approved a new antimicrobial agent that can be used to disinfect poultry.

The antimicrobial, developed by Ecolab Inc., of St. Paul, Minn., is a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid and 1-hydroxyethylidene-1,1-disphosphonic acid. FDA published notice of Ecolab's food additive petition March 30.

The mixture may be used on poultry carcasses, poultry parts and organs. FDA conducted an expedited review of the petition because it was for an antimicrobial agent. The agency said use of the mixture would not have a significant impact on the environment.

FDA said it did not receive any comments opposing its approval of the mixture, which is now codified under "peroxyacids" at 21 CFR 173.370.

poly(oxyethylene) content averaging one mole, potassium salts of coconut oil fatty acids, and isopropyl alcohol or hexylene glycol.

(21) An aqueous solution containing sodium dodecylbenzenesulfonate. In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(22) An aqueous solution containing (1) di-*n*-alkyl(C_8-C_{10}) dimethylammonium chloride compounds having average molecular weights of 332–361, (2) *n*-alkyl (C_{12}-C_{18}) benzyldimethylammonium chloride compounds having average molecular weights of 351–380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with or without not over 1 percent each of groups with 8 and 10 carbon atoms, and (3) ethyl alcohol. The ratio of compound (1) to compound (2) is 60 to 40.

(23) An aqueous solution containing *n*-alkyl (C_{12}-C_{16}) benzyldimethylammonium chloride and didecyldimethylammonium chloride.

(24) An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), *alpha*-[*p*-(1,1,3,3-tetramethylbutyl)-phenyl]-*omega*-hydroxypoly-(oxyethylene) produced with one mole of the phenol and 4 to 14 moles ethylene oxide, and *alpha*-alkyl(C_{12}-C_{15})-*omega*-hydroxy[poly(oxyethylene) poly(oxypropylene)] (having an average molecular weight of 965).

(25) An aqueous solution containing elemental iodine (CAS Reg. No. 7553-56-2), potassium iodide (CAS Reg. No. 7681-11-0), and isopropanol (CAS Reg. No. 67-63-0). In addition to use on food processing equipment and utensils, this solution may be used on beverage containers, including milk containers and equipment and on food-contact surfaces in public eating places.

(26) [Reserved]

(27) An aqueous solution containing decanoic acid (CAS Reg. No. 334-48-5), octanoic acid (CAS Reg. No. 124-07-2), and sodium 1-octanesulfonate (CAS Reg. No. 5324-84-5). Additionally, the aqueous solution may contain isopropyl alcohol (CAS Reg. No. 67-63-0) as an optional ingredient.

(28) An aqueous solution containing sulfonated 9-octadecenoic acid (CAS Reg. No. 68988-76-1) and sodium xylenesulfonate (CAS Reg. No. 1300-72-7).

(29) An aqueous solution containing dodecyldiphenyloxidedisulfonic acid (CAS Reg. No. 30260-73-2), sulfonated tall oil fatty acid (CAS Reg. No. 68309-27-3), and neo-decanoic acid (CAS Reg. No. 26896-20-8). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

(30) An aqueous solution containing hydrogen peroxide (CAS Reg. No. 7722-84-1), peracetic acid (CAS Reg. No. 79-21-0), acetic acid (CAS Reg. No. 64-19-7), and 1-hydroxyethylidene-1,1-diphosphonic acid (CAS Reg. No. 2809-21-4).

(31) An aqueous solution containing elemental iodine, *alpha*-alkyl(C_{10}-C_{14})-*omega*-hydroxypoly(oxyethylene)poly-(oxypropylene) of average molecular weight between 768 and 837, and *alpha*-alkyl(C_{12}-C_{18})-*omega*-hydroxypoly(oxyethylene) poly(oxypropylene) of average molecular weight between 950 and 1,120. In addition to use on food-processing equipment and utensils, this solution may be used on food-contact surfaces in public eating places.

(32) An aqueous solution containing (i) di-*n*-alkyl(C_8–C_{10})dimethyl- ammonium chloride compounds having average molecular weights of 332 to 361, (ii) *n*-alkyl(C_{12}–C_{18})benzyldimethyl- ammonium chloride compounds having average molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with no more than 1 percent of groups with 8 and 10, (iii) ethyl alcohol, and (iv) *alpha*-(*p*-nonylphenyl)-*omega*-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of *p*-nonylphenol with 9 to 12 moles of ethylene oxide. The ratio of compound (i) to compound (ii) is 3 to 2.

(33) An aqueous solution containing (i) di-*n*-alkyl-(C_8-C_{10})-dimethylammonium chloride compounds having average molecular weights of 332 to 361; (ii) *n*-alkyl(C_{12}-C_{18}) -benzyldimethylammonium chloride compounds having molecular weights of 351 to 380 and consisting principally of alkyl groups with 12 to 16

TEST STRIP Method.

Consumables and Equipment:

1. Reflectometer Rqflex

2. Reflectoquant peracetic test strips.
   ON: 1.16975.0001
   This test kit has a measuring range of 1.0 to 22.5 mg/L.

(Merck Reflectoquant analytical test kit supplied by Merck Pty. Ltd. 207 Colchester Rd. Kilsyth Victoria 3137).

Execution of Analysis:

Method 1 - SUFFICIENT SURFACE LIQUID:

The peroxide on the surface of the samples was tested by placing the moistened test strips directly onto the sample surface for the required reaction time. In some samples there was insufficient surface liquid to give an even colour on the test strips.

Method 2 - INSUFFICIENT SURFACE LIQUID:

The sample was placed in a plastic bag and 20 ml of UHQ water added. Hydrogen peroxide concentration in the 20 ml of water was then measured. In some crumpet samples water was absorbed which made it difficult to obtain sufficient liquid to perform the peroxide test.

Determination of Result:

After exposing the test strip to the sample by the appropriate method specified above the test strip is inserted into the Reflectometer Rqflex and the digital value read and reported directly as mg/L of peracetic acid within the range of 1.0 to 22.5 mg/L H_2O_2.

AUTO TITRATION METHODOLOGY

SOLIDS.

EQUIPMENT:	1] RADIOMETER COPENHAGEN RTS822 RECORDING AUTOMATIC TITRATION SYSTEM. 2] pH probe – pHC2401-7 3] Three decimal point balance. 4] pH 4.0 and 7.0 buffers. 5] 100ml titration vessels. 6] De-ionised water. 7] 1 normal Sodium Hydroxide 'NORMADOSE' ampoule. 7] Approximate 1 normal standardised NaOH solution. 8] Universal indicator.
METHOD:	Weigh approximately 10gram of sample into a tared SORVALL emulsifier cup.
	Weigh approximately 100gram of approximately 45^{o}C distilled water into the tared SORVALL emulsifier cup containing the approximate 10gram of sample.
	Emaciate on high speed for a minimum of 1 minute or until sample is completely dispersed.
	Stand SORVALL cup and emaciated sample, with lid removed into a water bath at approximately 45^{o}C for 15 minutes to volatilise any carbonic acid. Ensure no condensate from water bath enters the SORVALL cup.
	Weigh approx. 25 gram of emaciated sample into a tared 100ml-titration vessel.
	Occasionally add four drops of universal indicator.
	Ensure up button is in the fully depressed position.
	Wash down pH probe and titration assembly with distilled water.

	Place the pre-weighed approximately 25gram of sample in the 100ml-titration flask onto titration assembly stand and immerse titration assembly into the sample. Press start button.
	Titrate sample to an endpoint of pH 7.0. Ensure enough original sample is weighed to achieve a titration volume of at least 0.1ml.
CALIBRATOIN AND ACCURACY:	Each diluted ampoule is titrated against a known acetic acid solution, and then referred back to a known standardised sodium hydroxide solution to standardise the new diluted ampoule.
	Flush burette prior to commencement of a new day's analysis.
	pH meter is calibrated at least once per day against pH 4.0 and 7.0 buffers.
	Each titration is performed in duplicate.
CALCULATION:	MLS TITRATION * NORMALITY NaOH*60.25/1000 = X. **% Acetic acid** = X * [grams sample / grams diluent] * grams titrated / 100.

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NEW SOLUTIONS
FOR CONVENIENCE CHALLENGES

.... Modern social pressures effect our eating habits and food preferences....

Demands of work, studies and other commitments stress the resources of our time poor society. These lifestyles promote preferences for lighter, pre-prepared or "fast" food without compromising flavour and physical qualities.

Food processors have responded by stocking supermarket shelves with gourmet foods, RTE salads, fresh pasta, entrees and many other pre-packaged, "heat-n-serve" dishes that scream

- "Fresh"
- "No added preservative"
- "Low salt"
- "Low fat"
- "Microwave ready" etc

While these products are extremely attractive, they present the food processor with new formulation and process challenges, at a time when food safety issues are paramount.

Many food groups by their nature cannot be heat processed. Other foods are subject to post processing re-contamination. Traditionally, these have been protected by preservation hurdles. These physical or chemical restraints on microbial growth are pH, salts, water activity, preservatives and MAP. They have been relied upon alone or in combination to inhibit microbial growth and extend shelf life.

In response to customer pressures there has also been a systematic reduction of reliance on many of these barriers. In some products this has raised safety issues amongst regulators and responsible processors. Vigilance in the form of HACCP and the need for new, efficient alternative processes has been the outcome.

In the perishable food groups there are products where no totally satisfactory solution to the microbial safety and spoilage demands of the products exist.

For quite a number of these foods a **VAPOREX** process has been successfully trialed and applications developed.

Licences have been granted for the commercialisation of processes based on this technology for crumpets and fresh breadcrumbs in Australia and New Zealand.

Food groups where **VAPOREX** has global applications are:

- Meat and Chicken
- Smallgoods
- Cheese
- Frozen meals
- Baked goods
- "Fresh" pasta
- Wholegrain cereals
- Herbs and Spices
- Fresh and Dried fruit

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This process applies optimised traditional food approved biocides, vapourised in a carrier gas, usually Food Grade CO_2.

The biocides, which may be employed alone or in combination, are:-

- Acetic acid
- Carbonic acid
- Hydrogen peroxide

Minimal final levels of biocides are required in the food because the surface concentrations which can be achieved by partitioning the active biocide to the surface water of the food are so high. Transient surface pHs below 2 are possible.

When delivered in the gas phase, biocides are considered to be 100 to 1000 times more effective.

When treating products with an open cellular structure, such as baked goods, vacuum may be used to enhance penetration of the gas mixture.

SLICED BREAD

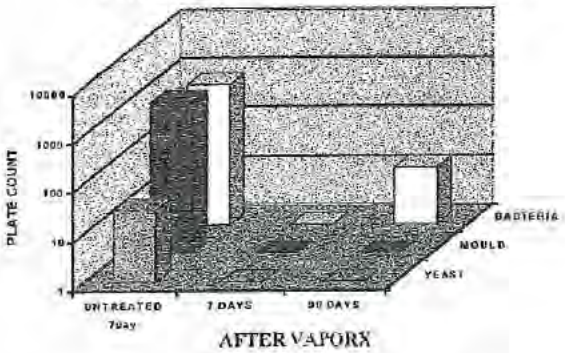
- **Process:** VAPOREX AC
- **Biocide:** Acetic Acid, FG 90%
- **Treatment:** Vacuum, one cycle
- A_w 0.95

TVAC LETHALITY Greater than 99.99% at 90 days

YEAST & MOULD LETHALITY Greater than 99.999% at 90 days

STALING Appreciably delayed

VAPOREX TREATED RETURNED BREAD



AFTER VAPORX

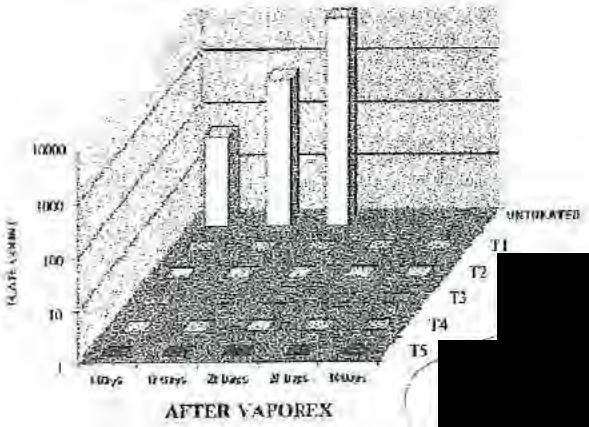
FRANKFURTS

- **Process:** VAPOREX AC
- **Biocide:** Acetic Acid, FG 90%
- **Treatment:** No vacuum, one cycle
- A_w 0.97

TVAC LETHALITY Greater than 99.99% at 74 days

YEAST & MOULD LETHALITY Greater than 99.99% at 74 days

VAPOREX TREATED FRANKFURTS



AFTER VAPOREX

Australian & International Patents Pending

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FRANKFURT FACT SHEET

Frankfurts, with skins, were initially sourced from retail outlets and a minimum effective treatment was established utilising a cool acetic and carbonic acid gas mix.

A series of trials were then conducted to highlight any detrimental effects the process may have on flavour, colour and the casing integrity during storage at 4°C and the cooking process.

The following observations were made and subsequently validated during on-site customer trials:

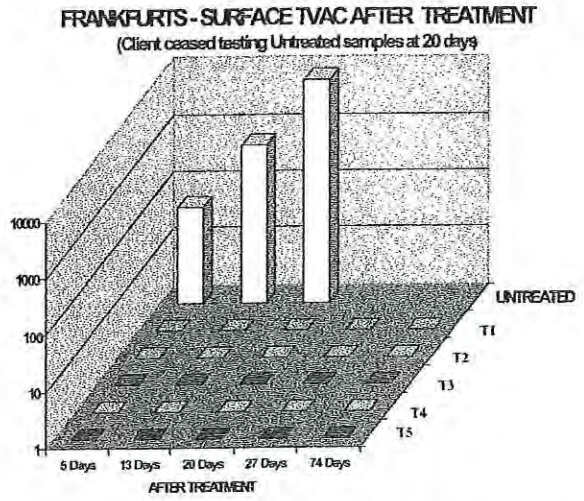
- No change to the colour or physical integrity of the casing.
- Absence of slime formation on the casing surface at all sampling times.

An acceptable flavour profile was achieved with T1. Treatments, T2-T4, developed incremental degrees of metallic off flavours from the synthetic acetic acid. Acidity was detected only at the T5 treatment.

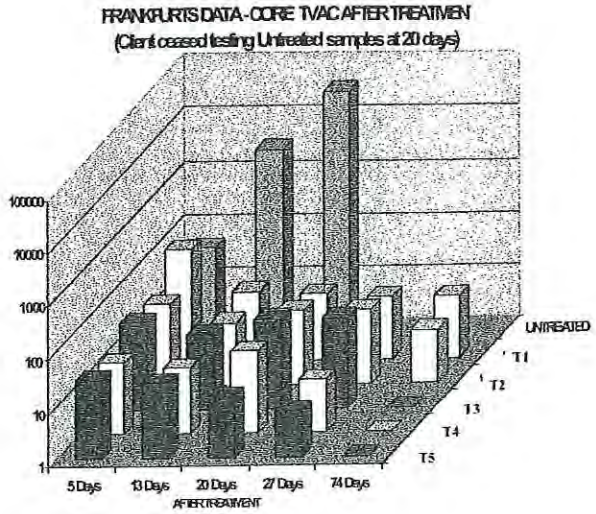
- Use of natural acetic acids and/or the blending of hydrogen peroxide into the gas mix can further minimise detrimental flavour effects.
- pH profile for T1 was:

DESCRIPTION	pH
UNTREATED	6.6
SURFACE @ 30 seconds	3.8
SURFACE @ 48 hours	5.8
CORE @ 48 hours	6.0
CORE @ 72 days	6.1

- Excellent microbial surface control was achieved by all treatments. This is shown by the following results from independent analysis:-



Microbiological bioburdens of frankfurt core samples also indicated excellent control which was proportional to treatment and exhibited gradual die off through to 74 days. A shelf life of 74 days or greater was not required by the customer. Counts on untreated controls were not performed beyond 20 days.



Excellent microbiological control can be achieved with frankfurts and other such meat products processed into edible casings when treated by the VAPOREX process.

- As shown by the core counts, the VAPOREX process can provide additional quality to in process products, beyond it's primary aim. This advantage is achieved because in many formulations the existing preservative systems are not at their optimal pH. The acidulation resulting from the VAPOREX process enhances this preservative effect.

  Of greater importance is the fact that these internal preservatives, at the permitted concentrations, can only tolerate very low microbial loadings. When the surface microbial loading is controlled the internal preservative/s can more effectively control the lower internal microbial loading.

- The process consumable cost is approximately 1 cent per Kg under laboratory conditions.

RECOMMENDED EXPERIMENTAL PROTOCOL

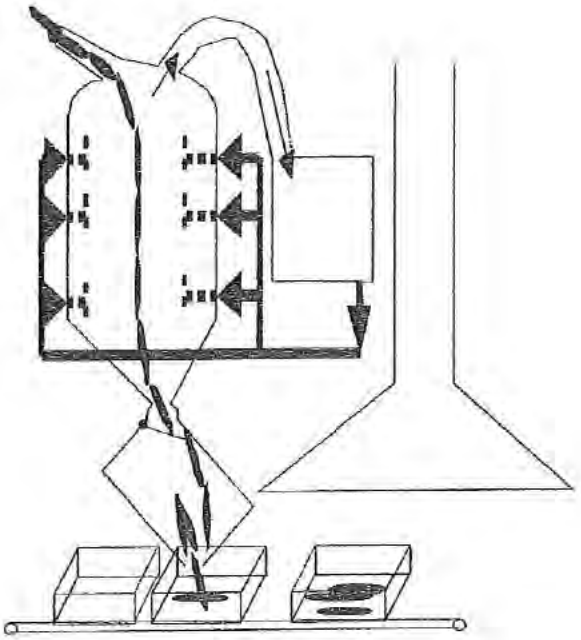
- Introduce hydrogen peroxide gas mix to the acetic and carbonic acid gases at appropriate temperatures in order to optimise this treatment, if required.

- Treatment could be applied in a simple vertical counter-current type applicator. Due to the fact that some manufacturers hand pack this product, a sterile airflow over the packing table is recommended. See **DIAG. 1.**

CRITICAL POINT:

- Minimise time between treatment and packing.

DIAG. 1



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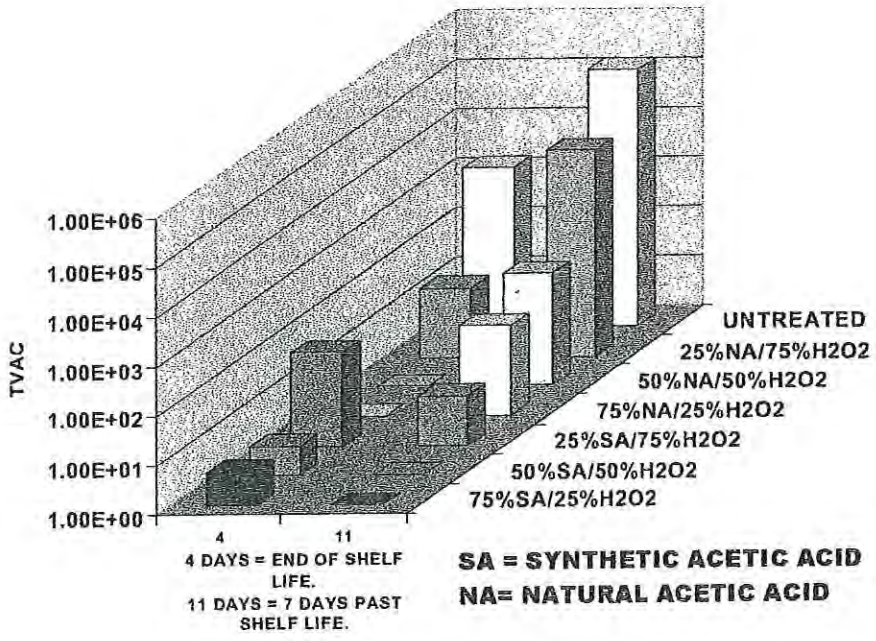
SLICED MEATS FACT SHEET

Sliced meats were successfully treated at laboratory scale, on an individual slice basis. In order to resolve acetic flavour problems, hydrogen peroxide gas mix was added to the acetic acid gas mix and delivered to the product.

The following process improvements were achieved:

- Lethality achieving reproducible TVAC's of <10 c.f.u/g. in two different sliced meat formulations.
  The following graph demonstrates the degree of microbial control achieved by varying
  - the type of acetic acid
  - ratio of hydrogen peroxide vapour to acetic acid vapour.
- Flavour profiles and colour were unchanged at 7 days past the specified shelf life. Assessment was stopped at this point.
- Decreased treatment temperature/time: 11°C to 15°C / 3 seconds.
- Textural improvements to a high cereal solids formulation.



VAPOREX

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RECOMMENDED PROTOCOL

Excellent results have been produced at laboratory scale, however, commercialisation of sliced meats remains a challenge to **VAPOREX** because:

- sliced and shaved meats have a low core mass to absorb transferred acetic acid.
- mechanical slicing of meats is routinely performed at speeds of 800 to 1200 slices per minute [13 to 20 per second].

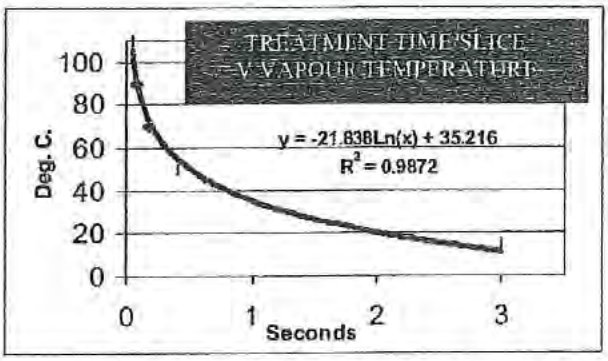
Therefore, a commercially acceptable treatment must be achieved by maximising lethality with the minimum amount of transferred biocide.

The following process parameters will form the basis of any process development:-

- **BIOCIDES**
  - 99% acetic acid, Food Grade
  - hydrogen peroxide; Food Grade 35% maximum concentration approved for use as a processing aid. Approval for extension of use required in Australia.
  - consider hurdle effect of carbonic acid as a possible third biocide but may contribute additional moisture.
- **GAS BLEND**
  - hydrogen peroxide
  - acetic acid
- **GAS GENERATION PRESSURE**
  - Optimum **GGP** required to achieve the minimum flow rate of conditioned vapour needed for the process.
- **GAS GENERATION TEMPERATURE**
  - Maximum **GGT** without physically degrading the sliced meat with excessive biocides and/or heat.
- **POST GAS GENERATION HEATING**
  - If the heat transfer from the **GGT** is not limiting, heat the generated gas mixes until degradation thresholds and then reduce the heat accordingly.

APPLICATION OF GAS MIXES

To achieve the desired process aims it is mandatory that all surfaces of the sliced meat are contacted for sufficient time to achieve results consistent with the laboratory trials.



From this data, 91 to 101°C GGT is indicated to treat 13-20 slices per second , ie 0.077 to 0.05 sec/slice.

Even at these high gas temperatures, slice temperature should not rise significantly. This will depend on the transfer rate from gas phase to the slice during the very short exposure time.

Treatment of the individual slice needs to occur at the knife. Additionally the knife itself should be targeted to minimise cross contamination.

There may also be advantages in directing the gas mix from the slice and knife area over the incoming logs. The gas scrubber could generate the driving force for this.

The process starts with the knife face and conveyor and progresses to the logs in the feeding magazine, gas delivery is by appropriate **VAPOREX** sparging manifolds between the magazine and knife face.

Post treatment protection of the slices prior to packaging should be reviewed to ensure it is consistent with the improvements achieved with this process.

Conversion of any **M.A.P.** packing equipment to **VAPOREX** could assist in the post treatment protection.

Australian & International Patents Pending

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❖ **Technological justification for the use of the substances as additives or processing aids.**

VAPOREX process is based primarily on acetic acid conforming to FCCIV. Acetic acid has been trialed on a wide range of foodstuffs and found to be quite lethal against the naturally occurring bioburdens and also against *Listeria monocytogenes* in formal challenge trials. These results have been achieved using concentrations of acetic acid in the order of 10 percent of what is required for inhibition of self-preserved foods such as mayonnaise.

However, some products exhibit an acetic acid flavour detriment e.g. sliced meats, and products where the surface area to mass ratio is very low.

Hydrogen peroxide:
With specific reference to sliced meats and collaborative work with a major smallgoods manufacture; data has been generated that indicates various combinations of acetic acid gas and hydrogen peroxide gas have greater lethality and no acetic acid flavour impact than treatments utilising acetic acid alone.
In other words a commercially acceptable process achieving a substantial improvement in the microbiological quality of sliced meat could not be obtained with acetic acid alone due to the resultant acidic flavour.
A commercially acceptable product could only be achieved by incorporating hydrogen peroxide gas into the acetic acid gas.
These gases were generated separately then mixed at varying ratios.
Extremely acid sensitive products, such as Lychees may be treatable only with hydrogen peroxide.
Please refer to: **ATTACHMENT 2.2.1 PROCESS SHEET. 980812-SH-SANDWICH-HAM-DATA-F-980925.xls** and **ATTACHMENT 2.2.1 RAW DATA. 980812-SANDWHICH-HAM-DATA-MICRO-FINAL.doc** previously supplied and accompanying this document.

Peracetic acid:
Vaporex was concerned that the mixture of these two gases and the subsequent partitioning of these separate biocides to the surface moisture of foods may result in the formation, perceived or actual, of peracetic acid. Additionally, it has been extrapolated that peracetic acid should be equally if not more effective than the mixtures of acetic acid and hydrogen peroxide.

Supporting data:
It was the intention of Vaporex that by this stage of the application process formal challenge data would have been made available for hydrogen peroxide and peracetic acid to support these reasonable assumptions. Unfortunately this data may not be available until early 2003.

This situation is not ideal, however as an early growth company resources must be focused on obtaining a commercial success with acetic acid in products where it already has approval.

- **Evidence for classification.**

Hydrogen peroxide only:
Please refer to: **ATTACHMENT 2.5.2. 990210-FSA-PEROXIDE-RESIDUALS-REPORT-FINAL.doc** previously supplied and accompanying this document.

Peracetic acid:
Until supporting data is available it is assumed that the only residual from this substance will be acetic acid. As the peracetic acid will only be used in foods where acetic acid has existing approval Vaporex does not envisage any regulatory issues.

- **Target organisms.**

Target organisms of primary concern are pathogens, however the data so far indicates that once the process passes the break point where log reductions of two or more are achieved within 24 hours most vegetative organisms are equally affected.
Supporting data:
Challenge trial studies 1 and 3 in FSA report: **011130-FSA-REPORT-103489-MICROBIAL-CHALLENGE-STUDIES-ON-VAPOREX-TREATED-FRANKFURTS.pdf** [previously supplied and accompanying this document] are similar to treatments used for general shelf life studies with a major smallgoods manufacture and typical of less aggressive VAPOREX treatments.
Please refer to: **VAPOREX-FF-FACTS-F-1030.PDF** previously supplied and accompanying this document.

- **Proposed treated foods.**

The VAPOREX process is only effective on solid food groups such as: meats, bakery, cheese, fruit and vegetables.
Therefore, in this first instance clarification of the proposed treated foods can be achieved by making the general claim for solid foods only and excluding liquid and semi liquid foods such as: fruit juices, cordials, milk, cream, yoghurt, saurces, dressings and mayonnaise etc.
If this degree of clarification is sufficient a more appropriate list of proposed treated foods can be created if required.

- **Teleconference.**

As discussed any time on 27th march 2002 would be fine.

micro tech
SYDNEY • MELBOURNE

ATTENTION: [redacted]
BOC GASES
799 Pacific Highway
CHATSWOOD NSW 2057

cc [redacted]

FAX

SAMPLE: **Shelf Life Verification Study of Ham Slices - as received**
Samples received @ 4.00 pm on 13 August 1998 and stored @ 4°C.
Samples were tested at Day 12 on 4 September 1998

Order No: 00020

Sample Details	Lab Ref No	Total Viable Aerobic Count M2.1 cfu/g
980812B-SL+7-1 Control	17829BG	2.6×10^4
980812-B-SL+7-2 Control	17830BG	3.4×10^6
980812-B-SL+7-3 Control	17831BG	2.7×10^6
980812-B-SL+7-4 Control	17832BG	7.0×10^3
980812-B-SL+7-5 Control	17833BG	2.8×10^5
980812-A1-1	17834BG	20 (est)
980812-A1-2	17835BG	Less than 10
980812-A1-3	17836BG	20 (est)
980812-B1-1	17837BG	10 (est)
980812-B1-2	17838BG	Less than 10
980812-B1-3	17839BG	10 (est)
980812-A2-1	17840BG	10 (est)
980812-A2-2	17841BG	Less than 10
980812-A2-3	17842BG	Less than 10
980812-B2-1	17843BG	Less than 10
980812-B2-2	17844BG	10 (est)
980812-B2-3	17845BG	10 (est)
980812-A3-1	17846BG	10 (est)
980812-A3-2	17847BG	Less than 10
980812-A3-3	17848BG	Less than 10
980812-B3-1	17849BG	Less than 10
980812-B3-2	17850BG	Less than 10

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SYDNEY • MELBOURNE

[redacted]

BOC Gases

Sample Details	Lab Ref No	Total Viable Aerobic Count M2.1 cfu/g
980812-B3-3	17851BG	Less than 10
980812-A4-1	17852BG	10 (est)
980812-A4-2	17853BG	Less than 10
980812-A4-3	17854BG	Less than 10
980812-B4-1	17855BG	Less than 10
980812-B4-2	17856BG	10 (est)
980812-B4-3	17857BG	40 (est)
980812-A5-1	17858BG	Less than 10
980812-A5-2	17859BG	30 (est)
980812-A5-3	17860BG	20 (est)
980812-B5-1	17861BG	Less than 10
980812-B5-2	17862BG	Less than 10
980812-B5-3	17863BG	10 (est)

[redacted]

Date: 07.09.98

MASM, AAIFST
Consultant Microbiologist

The data pertains solely to the analytical and sampling procedure(s) used and the condition and homogeneity of the sample(s) as received. The data therefore may not be representative of the lot or batch or other samples. Consequently the data may not necessarily justify the acceptance or rejection of a lot or batch, a product recall or support legal proceeding. This report does not imply that Microtech has been engaged to consult upon the consequences of the analysis and for any action that should be taken as a result of the analysis.

Certificate No: 48869

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BOC GASES
799 Pacific Highway
CHATSWOOD NSW 2057
[redacted]

cc: [redacted]

SAMPLE: **Shelf Life Verification Study of Ham Slices - as received**
Samples received @ 4.00 pm on 13 August 1998 and stored @ 4°C.
Samples were tested at Day 16 on 28 August 1998

Sample Details	Lab Ref No	Total Viable Aerobic Count M2.1 cfu/g
980812-B-SL-1; Control	17794BG	400 (est)
980812-B-SL-2; Control	17795BG	1.2×10^6
980812-B-SL-3; Control	17796BG	100 (est)
980812-B-SL-4; Control	17797BG	7.0×10^5
980812-B-SL-5; Control	17798BG	5.9×10^3
980812-A1-1	17799BG	Less than 10
980812-A1-2	17800BG	Less than 10
980812-A1-3	17801BG	Less than 10
980812-B-1-1	17802BG	Less than 10
980812-B1-2	17803BG	Less than 10
980812-B1-3	17804BG	10 (est)
980812-A2-1	17805BG	30 (est)
980812-A2-2	17806BG	Less than 10
980812-A2-3	17807BG	Less than 10
980812-B2-1	17808BG	Less than 10
980812-B2-2	17809BG	60 (est)
980812-B2-3	17810BG	10 (est)
980812-A3-1	17811BG	Less than 10
980812-A3-2	17812BG	Less than 10

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[redacted]
BOC Gases

Shelf Life Verification Study of Ham Slices

Sample Details	Lab Ref No	Total Viable Aerobic Count M2.1 cfu/g
980812-A3-3	17813BG	Less than 10
980812-B3-1	17814BG	Less than 10
980812-B3-2	17815BG	Less than 10
980812-B3-3	17816BG	Less than 10
980812-A4-1	17817BG	Less than 10
980812-A4-2	17818BG	Less than 10
980812-A4-3	17819BG	Less than 10
980812-B4-1	17820BG	40 (est)
980812-B4-2	17821BG	Less than 10
980812-B4-3	17822BG	Less than 10
980812-A5-1	17823BG	40 (est)
980812-A5-2	17824BG	Less than 10
980812-A5-3	17825BG	Less than 10
980812-B5-1	17826BG	Less than 10
980812-B5-2	17827BG	Less than 10
980812-B5-3	17828BG	10 (est)

[redacted]
Date: 31.08.98
MASM, AAIFST
Consultant Microbiologist

Certificate No: 48765

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