

29 June 2016
[16–16]

Call for submissions – Application A1113

Extension of the use of Propionates in Processed Meat

FSANZ has assessed an Application made by Axiome Pty Ltd on behalf of Kemin Industries (Asia) PTE Ltd to extend the use of propionates as anti-microbial preservatives in processed meat products and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 August 2016

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The following document which informed the assessment of this Application are available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/A1113Propionates-in-Processed-Meat.aspx>:

SD1 Risk and technical assessment report

Executive summary

Axiome Pty Ltd, on behalf of Kemin Industries (Asia) Pte Ltd, submitted an Application seeking permission to extend the use of propionic acid and its calcium, sodium and potassium salts (hereon collectively referred to as “propionates”¹), to processed and processed comminuted meat, poultry and game products (hereon collectively referred to as “processed meat, poultry and game”).

The justification for the Application is to have alternative anti-microbial preservatives to limit microbial growth, in particular *Listeria monocytogenes* in processed meat, poultry and game products.

The Applicant seeks approval for the use of propionates as a preservative, under the conditions of good manufacturing practice (GMP), in the following food categories of the Australia New Zealand Food Standards Code (the Code):

- (i) Processed meat, poultry and game products in whole cuts or pieces, and
- (ii) Processed comminuted meat, poultry and game products.

GMP means the amount of additive used must be limited to the lowest possible level necessary to achieve the desired effect.

In the Australia New Zealand Food Standards Code (the Code), all four propionates are currently permitted to be added to breads and bakery products and flour products, including noodles and pasta (at GMP levels to 4000 mg/kg, depending on the product). Sodium propionate and calcium propionate are also permitted, under conditions of GMP, in a variety of other foods categories, including oil emulsions, fruit and vegetable products, formulated beverages, and sauces. Propionic acid, sodium propionate and calcium propionate are permitted to be added to solid formulated supplementary sports foods at a Maximum Permitted Level of 400 mg/kg.

In the Codex General Standard for Food Additives (GSFA) propionates are currently listed for use under the conditions of GMP in the two processed meat food categories which are the focus of the Application.

The United States Food and Drug Administration permits the use of propionic acid and its sodium salt, as preservatives, in “ready to eat” meat and poultry up to 0.5% (0.5 mg/kg).

Propionic acid is a normal intermediary metabolite in humans and is naturally present in a wide variety of foods e.g. cheese, butter. Propionic acid and its sodium, calcium and potassium salts have a long history of use as food additives. Assessments by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the European Food Safety Authority (EFSA) have concluded that there is no evidence of systemic toxicity resulting from oral exposure to propionates. Establishment of an acceptable dietary intake (ADI) expressed in numerical form was therefore not deemed necessary by JECFA and EFSA; FSANZ concurs with this decision. Due to the absence of systemic toxicity resulting from oral exposure to propionates, a dietary exposure assessment was not conducted for this Application.

Evidence submitted in support of this Application provides adequate assurance that propionates fulfil the stated technological function as anti-microbial preservatives in processed meat, poultry and game products. Any additional dietary exposure to propionates resulting from their proposed use as food additives in processed meat, poultry and game products presents no identified public health and safety concerns.

¹ Use of the term propionates in this document refers collectively to propionic acid (INS 280), sodium propionate (INS 281), potassium propionate (INS 282) and calcium propionate (INS 283).

The use of propionates under the proposed conditions of GMP is not expected to affect the taste of the processed meat, poultry and game products.

1 Introduction

1.1 The Applicant

The Applicant is Kermin Industries (ASIA) Pte Ltd. Kermin Industries (ASIA) Pte Ltd are part of Kermin Industries Inc. who manufacture speciality ingredients for global food and feed industries, including food technologies. Kermin Industries Inc. was founded in 1961 and its headquarters are in Iowa, USA. In Australia and New Zealand, Kermin Industries Inc. are represented by Hawkins Watts Ltd.

1.2 The Application

This Application seeks to extend the approval for use of the anti-microbial food preservatives, propionates, under conditions of good manufacturing practice (GMP), to certain processed meat, poultry and game products. Allowing this extension will provide an additional risk management tool for the control of microbial activity, namely *Listeria monocytogenes*, in the afore-mentioned products.

If this Application is approved it will give all meat processing industries in Australia and New Zealand the option to use these propionates as preservatives in processed meat, poultry and game products.

1.3 The current standard

Propionic acid (INS 280), calcium propionate (INS 282), potassium propionate (INS 283) and sodium propionate (INS 281) are food additives with the technological purpose of anti-microbial preservatives. They have been permitted food additives in the Code for many years, in a range of food categories at a range of levels. A summary of the current permissions, as in Schedule 15, is given below:

Current permissions for propionates in the Code

Propionate	Food category	Condition
Propionates	Bread and bakery products	Up to an MPL ² of 4000 mg/kg
Propionates	Flour products, including noodles and pasta	Up to an MPL of 2000 mg/kg
Sodium and calcium propionate	oil emulsions	GMP
Sodium and calcium propionate	fruit and vegetable spreads including jams, chutneys and related products	GMP
Sodium and calcium propionate	fruit and vegetable juices and fruit and vegetable juice products	GMP
Sodium and calcium propionate	formulated beverages	GMP
Sodium and calcium propionate	sauces and toppings, including mayonnaises and salad dressings	GMP
Propionic acid and its sodium and calcium salts	Solid formulated supplementary sports foods	Up to an MPL of 400 mg/kg

² MPL – Maximum Permitted Level

1.3.1 Codex standard

The Codex General Standard for Food Additives (GSFA)³ permits the use of propionates, as food additives (preservatives), under the conditions of GMP in the following two food categories:

- 08.2 Processed meat, poultry and game products in whole cuts or pieces, and
- 08.3 Processed comminuted meat, poultry and game products.

1.3.2 The United States Food and Drug Administration

The United States Food and Drug Administration (USFDA), permit the use of propionic acid and sodium propionate, as anti-microbials (preservatives) in “ready to eat” meat and poultry up to 0.5%⁴.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ’s risk assessment is provided in SD1. In summary, evidence submitted in support of this Application provides adequate assurance that propionates fulfil the stated technological function as anti-microbial preservatives in processed meat, poultry and game products. Any additional dietary exposure to propionates resulting from their use as food additives in processed meat, poultry and game products presents no identifiable public health and safety concerns.

Propionic acid is a normal intermediary metabolite in humans and is naturally present in a wide variety of foods e.g. cheese, butter. Propionic acid and its sodium, calcium and potassium salts have a long history of use as food additives. Assessments by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the European Food Safety Authority (EFSA) have concluded that there is no evidence of systemic toxicity resulting from oral exposure to propionates. Establishment of an acceptable dietary intake (ADI) expressed in numerical form was therefore not deemed necessary by JECFA and EFSA; FSANZ agrees with this statement.

³ Codex Alimentarius (2014) General Standard for Food Additives, CODEX STAN 192-1995 (Revision 2015), Table 3, food category numbers 08.2 Processed meat, poultry, game products or in whole pieces or cuts, 08.3 processed comminuted meat, poultry and game products.
<http://www.fao.org/gsfaonline/additives/index.html?lang=en#P> Accessed on 27 May 2016.

⁴ US FDA 21 CFR 184 <http://www.ecfr.gov/cgi-bin/text-id.x?SID=5da6fa0bb90c2f8f8548889522619fdc&mc=true&node=pt21.3.184&rgn=div5> Accessed 27 May 2016

In addition, propionates have been safely permitted as food additives in the Code for many years, in a range of food categories as detailed in Schedule 15.

A dietary exposure assessment was not conducted because of the lack of systemic toxicity resulting from oral exposure to propionates.

2.2 Risk management

2.2.1 Levels of addition

This application is an extension to the existing use of propionates in food in Australia and New Zealand. In the absence of any public health or safety issues associated with this extended use identified by the risk assessment conducted by FSANZ, FSANZ proposes to permit the use of propionates (propionic acid (INS 280), sodium propionate (INS 281), potassium propionate (INS 282) and calcium propionate (INS 283) in processed meat, poultry and game products under conditions of GMP, as requested.

The use of propionates in processed meats, poultry and game at proposed levels to satisfy GMP is not expected to affect the taste of the products. Therefore their use in processed meat, poultry and game products is not expected to result in any change in consumption pattern.

2.2.2 Specification

As this Application is an extension of use, the additive is already permitted in other foods and a specification already exists, no amendment to the specification is necessary.

2.2.3 Analytical methods

Analytical methods for identifying and quantifying propionates in foods and beverages, including processed meat, poultry and game products, already exist (see SD1, section 2.3).

2.2.4 Labelling

Propionates when used as food additives must be declared in the list of ingredients on the label of most packaged foods in accordance with Standard 1.2.4 Information requirements – statement of ingredients.

Subsection 1.2.4—7(1) of Standard 1.2.4 provides that a substance used as a food additive must be listed in a statement of ingredients. This can occur in two ways:

- if the substance can be classified into a class of additives listed in Schedule 7 -
 - the class name to be declared (e.g. ‘preservative’) as indicated in Schedule 7; and
 - followed in brackets by the name (propionic acid, calcium propionate, sodium propionate or potassium propionate) or code number (280, 281, 282 or 283) of the substance as indicated in Schedule 8; or
- otherwise—the name of the substance (propionic acid, calcium propionate, sodium propionate or potassium propionate) as indicated in Schedule 8.

These labelling provisions will apply to the use of propionates in processed meat, poultry and game products, allowing consumers to identify whether propionates have been added.

There are some exemptions to these requirements that apply to food for sale that is not required to bear a label. These exemptions are set out in section 1.2.1—6 in Standard 1.2.1 – Requirements to have labels or otherwise provide information and include a food that is made and packaged on the premises from which it is sold, or is packaged in the presence of the purchaser. Food sold in these situations does not have to bear a label and therefore any processed meat, poultry and game sold in this manner would not have to declare the presence of added propionates under Standard 1.2.4.

2.3 Risk management conclusion

Based on the risk assessment conclusions, other than amending the Code to permit their extended use there are no additional risk management measures needed for the extension of use of propionates in processed meat, poultry and game under conditions of GMP.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders.

The benefits and costs associated with the proposed amendments to the Code have been considered based on regulatory impact principles. The level of analysis is commensurate to the nature of the Application and significance of the impacts.

The Office of Best Practice Regulation (OBPR), in a letter dated 24 November 2010 (reference 12065), advised that a Council of Australian Government Regulatory Impact Statement is not required for this matter.

Based on the information provided, the OBPR advised that the proposal is likely to have a minor regulatory impact on business, community organisations or individuals. Given the market characteristics, the proposed change is not likely to have significant competition impacts; and if the Application is approved, any change by businesses in response to changes to the Code will be voluntary.

However, FSANZ has undertaken a limited qualitative impact analysis as part of its assessment of the Application under section 29 of the FSANZ Act, in which the following regulatory options were considered:

- (1) prepare a draft variation to the revised Code to permit the requested extension of use of propionates at GMP levels in processed meat, poultry and game;
- (2) reject the Application.

The likely impacts of these options were assessed but this is not intended to be an exhaustive, quantitative economic analysis. Rather, the qualitative effects of each option are described below, and are deliberately limited to broad areas such as trade and consumer choice.

Option 1 – prepare a draft variation to the revised Code

Sector	Costs or benefits
Consumers	Consumers are likely to benefit from an extension of the use of propionates due to the availability of an additional risk management tool for the control of microbial action in processed meats. This could result in a reduction in exposure to microbiologically contaminated processed meat, poultry and game products and greater public health and safety. There may be an increase in the cost of processed meat, poultry and game products from using the food additive(s) as anti-microbial agents, but this if any, is expected to be small.
Industry	If this Application is approved it could benefit processed meat, poultry and game manufacturers and importers in Australia and New Zealand. They could manufacture for sale in Australia and New Zealand or import, processed meats, game and poultry which have used propionates (under GMP conditions) similar/the same as those available overseas. In addition, if approved this Application will provide meat, poultry and game processors with an additional tool to manage the risk of microbial activity in these products. The use of the additives may result in an increase in cost per stock unit but this is expected to be outweighed by the reduction in the costs associated with product recalls. Industry would need to bear the cost of the use of these additives in their products. However this is a voluntary cost, as the option to use these preservatives is voluntary.
Governments	There should be no cost to government enforcement agencies since propionates are already permitted to be added to various food categories. There are existing methods of analysis for the presence of propionates in food. Governments may in fact benefit as the reduction in the risk of illness from food borne contamination could result in a reduction in food recalls and therefore reduced administrative, reporting and other associated costs.

Option 2 – reject the Application

Sector	Costs or benefits
Consumers	There are no benefits to consumers with this option. The potential cost would be the loss of an additional tool to combat microbial activity in processed meats, poultry and game.
Industry	Industry would lose an additional tool to manage the risk of microbial action in processed meat, poultry and game. This may result in high cost to industry if a product recall was triggered as a result of microbial contamination in processed meat, poultry and game products. As propionates are allowed in processed meat, poultry and game products in other global areas industry could be at a disadvantage compared to international competitors.
Governments	There would be no direct benefits to governments.

Based on the assessment above, FSANZ's current preferred option is Option 1, to permit an extension of the use of propionates to processed meat, poultry and game products, and has prepared a draft variation to the Code. The direct and indirect benefits that would arise from a food regulatory measure varied as a result of the application outweigh the costs to the community, Government or industry that would arise from the variation of the food regulatory measure.

Notwithstanding this assessment and the preparation of a draft variation, stakeholders are encouraged to provide any additional relevant information as part of the consultation process. Submissions will help inform FSANZ's decision on whether to approve, vary or reject the draft variation.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

Propionates have been permitted as food additives in the Code for many years, in a range of food categories as detailed in Schedule 15. FSANZ has undertaken a risk assessment on the safety and efficacy associated with the requested extension of use (see SD1 and Section 2.1 above) and concluded that there are no public health and safety concerns from extending the use of propionates, as anti-microbial preservatives, in processed meat, poultry and game products under GMP conditions.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

This variation to the Code does not vary the generic labelling requirements applicable to the use of propionates in processed meat, poultry and game products. The existing labelling requirements that apply to the use of propionates will also apply to this variation, and so will maintain the current level of information provided to consumers.

2.4.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any relevant issues relating to the prevention of misleading or deceptive conduct for this Application.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

This Application was assessed using the best available scientific evidence. The Applicant submitted information on scientific studies and technical aspects in support of the Application. Other resource material including general technical information was also used to assess this Application.

- **the promotion of consistency between domestic and international food standards**

The proposed amendment (food additive permission) makes the Australian and New Zealand regulations for the use of propionates in processed meat, poultry and game consistent with an international Codex standard (see Section 1.3.1)

- **the desirability of an efficient and internationally competitive food industry**

The draft variation is voluntary and as such is not expected to affect the efficiency or competitiveness of Australia and New Zealand's food industry.

- **the promotion of fair trading in food**

FSANZ has not identified any relevant issues relating to the promotion of fair trading in food for this Application.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Policy Guideline 'Addition to Food of Substances other than Vitamins and Minerals'⁵ includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that extending the use of propionates to processed meat, poultry and game products under GMP conditions, as anti-microbial preservatives, is consistent with these specific order policy principles.

2.5 Risk communication

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

The draft variation will be considered for approval by the Board taking into account public comments received from this call for submissions.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum).

⁵ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

If the decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.5.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There is one relevant international standard (Codex) and amending the Code to extend the use of propionates, as anti-microbial preservatives, in processed meat, poultry and game products is unlikely to have a significant effect on international trade as the Code amendment will be consistent with the existing international standard and voluntary. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

3 Draft variation

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1113 – Extension of use of Propionates in Processed Meat) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1113 – Extension of use of Propionates in Processed Meat) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variations commence on the date of gazettal.

Schedule

[1] Schedule 15 is varied by adding the following to both category 8.2 and category 8.3 in the Table to section S15—5, in numerical order –

“

280 281 282 283	Propionic acid and sodium and potassium and calcium propionates	GMP
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“

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1113 which seeks to extend the use of propionates as anti-microbial preservatives in certain processed meat, poultry and game products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has approved a draft variation to Schedule S15–5 which would allow the use of propionic acid and its calcium, potassium and sodium salts as anti-microbial preservatives in certain processed meat, game and poultry products under conditions of GMP. Permitting this extension of use of propionates to these products would provide manufacturers with an additional tool in the risk management of microbial activity, namely in the control of *Listeria monocytogenes*.

The draft variation would provide consistency with a Codex international standard.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1113 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report.

A Regulation Impact Statement was not required because the proposed variations to Schedule S15–5 are likely to have a minor impact on business and individuals (OBPR reference 12065).

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

The item of this variation amends Schedule 15.

Subitem [1] amends category 8.2 and category 8.3 in the Table to section S15—5. The amendment inserts into each category: a reference to propionic acid (INS 280), sodium propionate (INS 281), potassium propionate (INS 282) and calcium propionate (INS 283);

and a condition that the maximum permitted level set for each substance is at GMP (Good Manufacturing Practice).

The effect of this amendment is to permit the use of propionic acid and its calcium, sodium and potassium salts as food additive for any processed meat, poultry and game product which falls within category 8.2 or 8.3 subject to the condition that the maximum permitted level for the latter is at GMP . This means the amount of additive used must be limited to the lowest possible level necessary to accomplish its desired effect.
