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Risk assessment of asthmatic reactions from sulphur dioxide and sulphites in mincemeat

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Contents

1 Statement of Purpose

To characterise the risk of asthmatic reactions in the Victorian population from the consumption of mincemeat containing sulphur dioxide and sulphites and cooked in the intended manner.

2 Summary

Foods and beverages containing sulphur dioxide and sulphites can trigger asthmatic reactions in some people. The addition of sulphur dioxide and sulphites to a range of specified foods is permitted in Australia, but labelling is mandatory. The addition of sulphites to raw meat, including mincemeat is illegal. In Victoria 2.74% of samples of mincemeat from retail butchers shops contained SO_2 and sulphites, and levels in illegally contaminated mincemeat in NSW were in the range 28 – 1539 ppm (mean 350 ppm). People with asthma and sensitivity to SO_2 and sulphites are sometimes exposed to these additives in mincemeat without their knowledge. It was estimated that 50,313,000 servings of mincemeat are purchased in retail butchers shops per annum in Victoria. An exposure assessment estimated that children with asthma and sensitivity to SO_2 and sulphites consume 1630 servings of mincemeat containing 50 mg or more of SO_2/sulphites per annum in Victoria, and adults with asthma and sensitivity to SO_2 and sulphites consume 800 servings containing 50 mg or more of SO_2/sulphites per annum in Victoria. Thus it would be expected that an asthmatic child or adult with sensitivity to SO_2/sulphites would consume a serving of mincemeat with 50 mg or more SO_2/sulphites approximately once every 23 years. It has been proposed that SO_2 is the chemical form which triggers asthmatic reactions. Decreasing pH increases the release of SO_2 from sulphites as free ions and reversibly bound forms. While 50 mg of sodium metabisulphite in citric acid solution produced asthmatic reactions in 65% of children with chronic asthma and 66 mg of sodium metabisulphite in apple juice produced asthmatic reactions in 22% of children with chronic asthma, the proportions of asthmatic reactions when the same amount of sulphites are present in cooked mincemeat may be much lower because of the higher pH of meat, and the chemical characteristics of meat. Despite exposure through illegal additions to mincemeat no reports were found of severe asthmatic reactions having occurred as a result of the consumption of mince meat to which SO_2 and sulphites had been added. This may be due to a lack of reporting, use of medication preventing/relieving reactions or because the pH and chemical characteristics of mincemeat minimises the release of SO_2, the chemical form that may trigger asthmatic reactions. A clearer characterisation of the likelihood of reactions given the estimated level of exposure requires data from a double blind challenge study of consumption of cooked mincemeat with added sulphites, by asthmatic people with SO_2/sulphite sensitivity.

3 Hazard Identification

Sulphur dioxide (220) and sodium and potassium sulphites (221, 222, 223, 224, 228) are permitted additives to a range of foods in the Australian Food Standards Code. Foods to which it is permitted to add these anti-browning preservative agents include alcoholic beverages, cheeses, various fruit and vegetable products, crustacea, flour products, biscuits cakes and pastries. The permitted maximum levels in these foods varies between 20 mg/kg (processed ginger) and 3000 mg/kg (dried fruits and vegetables). In the category of meat and meat products it is not permitted to add sulphur dioxide and sodium and potassium sulphites to raw meat, poultry and game (which includes raw mincemeat), nor to whole cuts or pieces of these meats. Addition of sulphur dioxide and sodium and potassium sulphites is permitted in processed comminuted meat, poultry and game products at a maximum level of 100 mg/kg and in edible casings and sausage and sausage meat containing raw, unprocessed meat at a maximum level of 500 mg/kg. Where the addition of sulphur dioxide and sodium and potassium sulphites is permitted it must be declared on the food label.

Asthmatic and other adverse reactions can occur in a small proportion of the population in response to sulphur dioxide and sulphites. The declaration of the presence of these additives on the labels of foods permitted to contain them provides a means by which people who react to sulphur dioxide or sulphites can avoid exposure.

Illegal additions of sulphites to mince meat have been detected. In 2004 a survey of samples of meat and meat products from 50 butchers in NSW found sulphur dioxide illegally present or present in excessive levels in 59 of 101 samples (Food S@fety Bytes, 2004). A survey of samples from butcher shops in Queensland conducted in the period November 2002 – April 2003, found 25 of 177 samples of mincemeat (14.1%) were positive for sulphur dioxide in the range 5 – 1070 ppm (Mark Hansen, Qld Health). The illegal addition of sulphites to mincemeat by some butchers was characterised in the report of the Queensland survey as these butchers playing “Russian Roulette” with consumers, who are exposed to sulphur dioxide and sulphites in foods where it would not be expected. Surveys in previous years may not reflect current incidence levels. In Victoria the improper use of preservatives was reported as being at a very low incidence in 04/05, and in 05/06 and 06/07 sampling detected improper use of SO_2 in less than 3% of samples (PrimeSafe Annual Report 04/05, PrimeSafe Annual Report 05/06, PrimeSafe Annual Report 06/07), The incidence of SO_2 in mince meat samples from retail butchers shops is 2.74% (B. Casey *pers. comm*.). The proportion of positive samples of mince meat in 06/07 in NSW is not available but levels in positive samples were in the range 20 – 1538 ppm (mean 350 ppm). Of the contaminated mincemeat samples 15% had contamination levels above 500 ppm, the maximum permitted level in sausages.

There is clear evidence that sulphites consumed in some foods and beverages cause asthma and other adverse reactions in sensitive individuals; however there are a lack of reports or challenge studies that provide evidence of sulphites in mince meat causing asthmatic reactions.

4 Hazard Characterisation

Gastric lesions are associated with general toxicity to sulphur dioxide and sulphites in animal studies. To avoid general toxicity the acceptable daily intake (ADI) for sulphur dioxide and sulphites is 0.7 mg/kg bw/day. This level was recommended by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) based on a no observed adverse affect level (NOAEL) of 70/mg/kg bw/day in rats combined with a 100x safety factor (10x inter-species difference, 10x inter-individual difference) (WHO, 1999). For an individual weighing 60 kg the ADI is an intake of 42 mg, and if the exposure was from a single food type the ADI would be reached by eating 100 g of the food containing 420 ppm sulphur dioxide and sulphites.

In a small proportion of the human population other symptoms have occurred in response to exposure to sulphur dioxide and sulphites, which have been characterised as hypersensitivity to these additives. These symptoms have included asthma, rhinitis (inflammation of the nasal passages often associated with discharge), rhinoconjunctivitis, urticaria (hives), angio-oedema (swelling of the tongue and throat), headache, gastrointestinal distress and anaphylaxis. In challenge studies, reactions in some individuals have been associated with elevated levels of immunoglobulin E (IgE) indicating a classic atopic allergic reaction, while in others reactions have occurred without an associated rise in IgE or positive skin prick test indicating that more than one mechanism is involved in causing symptoms amongst sensitive individuals (WHO, 1999). Irritation of the airways by SO_2 gas is one possible mechanism (www.allergy.org.au/content/view/128/146, website of The Australasian Society of Clinical Immunology and Allergy accessed on 13/2/08). The dose of sulphur dioxide and sulphites that cause reactions varies according to the medical condition of the individual, their medication, and the food to which sulphites have been added. In one individual, who had suffered severe asthmatic symptoms on exposure to sulphites in dried apricots and sulphited salad, a few sips of wine containing sulphites at a concentration of 92 ppm caused a fatal anaphylactic reaction (WHO, 1999). The reporting of adverse reactions to fresh fruit and vegetables treated with sulphites led to a ban on the use of sulphites on these foods, except potatoes and grapes, in the US in 1986 (WHO, 1999). The combination of new regulations and consumer awareness led to a major decline in the number of reports to the FDA's Adverse Reaction Monitoring System and in 1995 only six cases were reported (www.cfsan.fda.gov/~dms/fdsulfit.html accessed 2/2/08).

Food Standards Australia New Zealand (FSANZ) provides information on the sulphites in foods. They indicate that people with asthma should be aware of foods containing high levels of sulphites and that fruit juice or drink, wine, dried fruit and delicatessen meats have been implicated in reports of asthma (http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2001/forasthmasufferersth1152.cfm).

Individuals and small groups suspected of sulphite hypersensitivity have been tested in several single-blind and double-blind challenge studies. Doses in the range of 1-200 mg have produced symptoms. The size of the dose that produces symptoms varies substantially among individuals. One man developed an itchy rash and swelling in the face after consuming 100 ml of beer containing 3-4 ppm of sulphite (a dose of 0.3 - 0.4 mg) while other individuals can ingest 200 mg without any reaction. Prevalence studies for sensitivity to sulphites among groups of people with asthma have been undertaken for adults and children. Asthmatic reactions in these studies are often measured by a reduction of >20% in forced expiratory volume in one second (FEV_1). The prevalence of sulphites/SO_2 sensitivity among adults with asthma has been estimated as 4%, and among children 20-30% (WHO, 1999).

The response to sulphites in foods among sensitive individuals varies with the type of food containing the sulphites, or the mode of administration. Sulphites added to food can exist in several forms as sulphur dioxide (SO_2), bisulphite and sulphite ions and in various reversibly

bound and irreversibly bound forms. The proportion of sulphites in each of these forms in a food type depends on the food chemistry. For example bound forms do not occur on lettuce. Challenge studies have examined reactions by delivery of sulphites in capsules, in fruit juices, in lemonade, vegetables, dried fruits and vegetables and shrimps (WHO, 1999). Lowering the pH in the acidic range increases the amount of SO_2 released, and delivery of sulphites in an acidic solution has been observed to increase the number of reactions in group challenge studies (WHO, 1999). SO_2 production from metabisulphites and sulphites is not expected in raw sausage meat with a pH of 6.2-6.8 (Banks and Board, 1982). The pH of mince meat will usually be in the range 5.5 – 6.0. In a single-blind challenge study of 29 children with chronic asthma no reactions were observed when 100 mg of sodium metabisulphite was ingested in a capsule, but when 50 mg was ingested in a citric acid solution there were reactions in 19 children (WHO, 1999). No challenge studies of reactions in people with asthma to cooked mince meat containing sulphites have been reported, so it is not possible to estimate the concentrations of sulphites in cooked mince meat which might produce asthmatic reactions in individuals with SO_2 and sulphite hypersensitivity.

No reports of adverse reactions to sulphites in mincemeat in Australia or elsewhere were found in the scientific literature. Adverse reactions from sulphites are not notifiable illnesses in Australia. Officers in the food safety units or sections of State and Territory Health Departments were contacted in Victoria, Tasmania, New South Wales, Western Australia, Queensland, South Australia, the Australian Capital Territory and the Northern Territory (Darwin urban region only). No response was received from Queensland. There was no recollection among the officers contacted of any reports of adverse reactions from the consumption of mincemeat except in South Australia where over an 11 year period, there had been 1 or 2 reports of minor incidents, with the presence of sulphites in mincemeat being confirmed by testing in one of these cases. Education officers with the Asthma Foundation of Australia and the Asthma Foundation of Victoria were not aware of any reports of incidences of asthmatic reactions from the consumption of mincemeat containing sulphites, nor of any enquiries about sulphites in mincemeat.

In summary the causation of adverse reactions in sensitive individuals from sulphites added to foods is dependent on the size of the dose, the individual and the food. Reactions to sulphites in cooked mince meat have not been tested in challenge studies. It is possible that the prevalence of reactions may be lower/the concentration of sulphites causing asthmatic reactions higher when sulphites are present in cooked mince, in comparison with foods which are more acidic or contain lesser concentrations of bound forms.

5 Exposure Assessment

5.1 Incidence of Contaminated Mince Meat

Sulphur dioxide was detected in 2.74% of samples of mince meat samples from retail butcher shops in Victoria in the most recent sampling undertaken by the regulatory authority PrimeSafe (B. Casey *pers. comm.*). The number of samples taken is not available, so the exposure model does not include an estimate of the uncertainty associated with the incidence of contamination in meat. Approximately 1/3 of mince is sold through butchers shops, and 2/3 through major supermarkets chains in Australia (Ian Jenson, *pers. comm*.). Since the latter are supplied with minced meat from centralised production and packaging facilities it is considered extremely unlikely that this product will contain sulphite. Accordingly, it is assumed asthmatics will be exposed to sulphite only from minced meat purchased from butcher shops.

5.2 Concentration of SO_2 in Contaminated Mince Meat

The presence of sulphites in mincemeat can be determined simply on-site by inspectors using the malachite green test. In this test the malachite green dye is mixed with mince meat and decolourises if sulphites are present. The Monier-Williams method is a standard method for quantitative laboratory determinations. Data on the concentration of SO_2 in contaminated mince meat detected in the PrimeSafe sampling program were not available. However data on the concentration of SO_2 contaminated samples detected in NSW in the period August 2006 – March 2007 were available. From this data a cumulative distribution was defined to characterise the probability of SO_2 concentrations in contaminated mince meat (Table 1). The maximum level detected was 1538 ppm. The level of detection, or minimum level reported as adulteration was not available, so for the probability distribution this was assumed to be 10 ppm.

Table 1 Cumulative Distribution Parameters for SO_2 concentrations (ppm) in contaminated mincemeat

SO_2 Concentration (ppm)	Probability that Contaminated Mince Meat Contains $\leq$* the SO_2 Concentration
78	0.1
90	0.2
115	0.29
143	0.39
188	0.51
238	0.61
328	0.71
373	0.8
1041	0.9
1538	1

* $\leq$ less than or equal to

Sulphites are present in foods in a variety of forms which include free sulphur dioxide, sulphite ions, reversibly bound forms and irreversibly bound forms, S-sulphonates. S-sulphonates are formed by the reaction of sulphites with the disulfide bonds of cystine, peptides and proteins (Pena-Egido et al, 2005).

$$RS - RS + SO_3^{2-} \rightarrow RS - SO_3^{-} + RS^{-}$$

The Monier-Williams method is the standard method for the measurement of SO_2. This method measures the total sulphites which includes SO_2, free sulphite and the reversibly bound forms. In the measurement of total sulphites, free SO_2 is the SO_2 released when treated with acid, and an alkali treatment releases SO_2 from reversibly bound forms. S-sulphonates are not included in the measurement of total sulphites. S-sulphonates as a proportion of total sulphites+S-sulphonates are in the range 17-39% in raw beef burgers (Pena-Egido et al, 2005). While the S-sulphontes do not play a role in sulphite/SO_2 sensitivity, the proportions of s-sulphonates in a raw mince product suggests that the amount of sulphites added to beef mince is higher than that indicated by the total sulphites measurement.

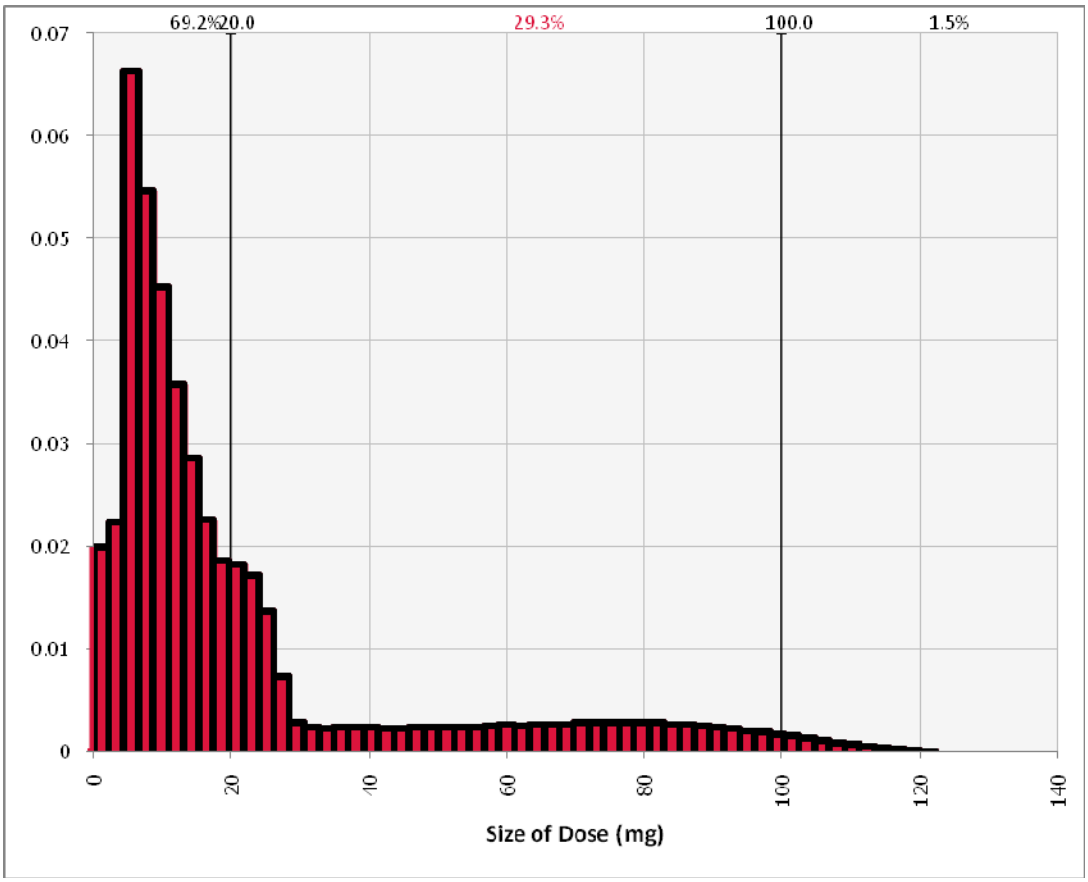
5.3 Loss during Cooking

A reduction of the concentration of total sulphites has been measured when raw beef burgers have been cooked by frying and grilling. When beef burgers were fried in pre-heated sunflower oil for 5 minutes the loss of total sulphites was in the range 32 – 66 % (Mean 40.9, SD 12.6%) (Armentia-Alvarez et al, 1993). When beef burgers were grilled for 12 minutes at 150 °C the loss of total sulphites was in the range 22 – 35 % (Mean 28, SD 5.1) (Pena-Egido, et al, 2005). Thus cooking method affects the proportion of sulphites lost during cooking. It was suggested variation in fat content may contribute to variation observed by a single method of cooking. Mince is also cooked by other methods for which data is not available including braising which is a combination of browning in fat or oil and then cooking slowly in a small amount of liquid. The time and temperature of the various cooking methods will vary according to the recipe and the cook. Rarely would mince be cooked without the addition of other ingredients that may also affect the loss of sulphites. Without more precise data about the proportion of mince cooked by various methods, and the % losses associated with each method, the loss of sulphites during cooking is estimated in this risk assessment by a pert distribution with a most likely value of 30%, a minimum of 20% and a maximum of 65%.

5.4 Estimated Doses of SO_2 and Sulphites in 100g servings of Cooked Contaminated Mincemeat

The estimated doses of SO_2 and sulphites in 100 g servings of cooked mince meat contaminated with SO_2 and sulphites was estimated by simulation with @Risk v 5.0 (Palisade Corporation) (500,000 iterations) and represented by a probability distribution (Fig 1). To illustrate how to interpret this graph lines are drawn at 20 mg and 100 mg doses. The probability of a contaminated serving containing less than 20 mg SO_2 and sulphites is 69.2%, the probability that a contaminate serving contains between 20 mg and 100 mg SO_2 and sulphites is 29.3%, and the probability that a contaminated serving contains more than 100 mg SO_2 and sulphites is 1.5%

Fig. 1 Probability distribution of the total amount of SO_2 and sulphites (mg) in a 100g serving of contaminated mincemeat



5.5 Number of Servings of Mince Meat in Victoria

MLA provided data on the total serves of fresh meat purchased in a seven day period in each month. For the 12 month period July 2006 to June 2007 the total number of serves purchased in 12 weeks (1 week of each month) was 34,832,000. From this it is estimated that the number of serves purchased in Victoria in these 12 months (52 weeks) was 150,939,000. As 1/3 of mince meat is sold through retail butchers shops, it is estimated that 50,313,000 servings are sold through retail butchers shops per annum in Victoria. This estimate of the number of serves of mincemeat purchased at retail butchers shops and consumed in Victoria in 06/07 is under the assumption that the purchased meat was used for humans, and none for pet food. An average serving size of 100 g of uncooked mincemeat was selected for the assessment.

5.6 Proportion of People with Asthma and Sensitivity to SO_2 and Sulphites

It is estimated that in Australia 14-16% of children and 10-12% adults have asthma (The Asthma Foundation of Victoria, 2005). It is estimated among people with asthma 20-30% children and 4% adults are sensitive to sulphites by oral ingestion (WHO, 1999). The upper age limit in the groups of children in prevalence surveys on which this estimate was based varied in the range 13 – 16 years. For the exposure assessment the population of children with asthma and sensitive to

sulphites was estimated to be 3.75% (15% x 25 %) and among adults 0.44% (11% x 4%). At June 2007 the population of Victoria was 5,205,200 and the proportion of the Australian population aged 0-14 years was 19.4% (Australian Bureau of Statistics, 2007a, 2007b). Therefore it is estimated that the proportion of the population who are children with asthma and sensitivity to SO_2/sulphites is 0.73% (37,900 children), and the proportion of the population who are adults with asthma and sensitivity to SO_2/sulphites is 0.35% (18,500 adults).

5.7 Number of Servings of Mincemeat in Victoria Eaten by Asthmatic People with Sensitivity to Sulphites

Education officers at the Asthma Foundation of Australia and the Asthma Foundation of Victoria were not aware that raw mincemeat sometimes contains illegal additions of sulphites, and had not had any queries from people with asthma about sulphites in mincemeat. Therefore for the exposure assessment there is no assumption that people with asthma are likely to avoid mincemeat, or choose their place of purchase of mincemeat to avoid the possibility of sulphite exposure. There are a few websites where illegal contamination of mincemeat is mentioned, however the impact of these websites on consumer behaviour is not known. The website of the Australasian Society of Clinical Immunology and Allergy (www.allergy.org.au) included in a list of foods that contain sulphites “Meat – sulfites are sometimes added illegally to mincemeat or sausage meat”, and the same wording occurred on another website www.allergycapital.com.au authored by Dr Raymond Mullins. The website www.fedupwithfoodadditives.info authored by Sue Dengate of the Food Intolerance Network also has information on sulphites in mincemeat and recommends quizzing butchers and using test strips to detect SO_2.

Assuming the same frequency of consumption of servings of mincemeat by children and adults, and that 2.74% of servings purchased from retail butchers shops are contaminated with sulphites, then it is estimated that asthmatic children with sensitivity to sulphites eat 10,000 servings of mincemeat containing sulphites per annum in Victoria, and asthmatic adults with sensitivity to sulphites eat 4,900 servings of mincemeat containing sulphites per annum in Victoria (rounded to the nearest hundred) (Table 2). From the estimated there are 37,900 children and 18,500 adults with asthma and sensitivity to SO_2/sulphites, it is estimated that a child or adult with asthma and sensitivity to SO_2/sulphites would be exposed to mincemeat containing sulphites once every 4 years.

It is estimated that of the servings of cooked mincemeat contaminated with sulphites, 1,630 servings of cooked mince meat consumed by SO_2-sensitive asthmatic children and 800 servings of cooked mince meat consumed by SO_2-sensitive asthmatic adults would contain a dose of 50 mg or higher of SO_2 and sulphites, per annum in Victoria. It is estimated that a child or adult with asthma and sensitivity to SO_2/sulphites would consume a serving a mincemeat containing 50 mg or more of sulphites once every 23 years.

Table 2: Estimated number of contaminated servings (100g) in dose ranges eaten by asthmatic children and adults with SO_2/sulphite sensitivity in Victoria per annum (rounded to the nearest 10).

SO_2 and Sulphites in Servings (mg)	Proportion of Contaminated Servings	Servings Eaten by AS* Children in Vic pa.	Servings Eaten by AS* Adults in Vic pa.
0 - 10	0.417	4180	2040
10 - 20	0.275	2760	1340
20 - 30	0.122	1220	600
30 - 40	0.023	230	110
40 - 50	0.023	230	110
50 - 60	0.024	240	120
60 - 70	0.026	260	130
70 - 80	0.028	280	140
80 - 90	0.026	260	130
90 - 100	0.021	210	100
100 – 122	0.015	150	70
Totals	1	10020	4890

*AS = asthmatic persons with SO_2/sulphite sensitivity

6 Risk Characterisation

The exposure assessment indicated that people with asthma and sensitivity to SO_2 and sulphites are sometimes exposed to doses of SO_2 and sulphites in cooked mince meat that exceed even the ADI for the general population (42 mg for a 60 kg adult, 14 mg for a 20 kg child). It is not possible to estimate how many asthmatic reactions in the Victorian population might occur from the estimated size and frequencies of exposure in cooked mincemeat. While some people have had serious reactions to doses of a few milligrams, others have not reacted until doses have reached 200 mg (WHO, 1999). There are no challenge studies of sulphites in cooked mince meat to indicate doses that may elicit asthmatic reactions. In one study of children with chronic asthma who were allergic to airborne allergens, 19 of 29 children reacted to 50 mg doses of metabisulphites in a citric acid solution, while none of these children reacted to a dose of 100 mg in a capsule. In another study 8 of 37 children with chronic asthma had asthmatic responses to 66 mg of metabisulphite consumed in apple juice. The exposure assessment estimates 1,630 servings of cooked mince meat consumed by SO_2-sensitive asthmatic children and 800 servings of cooked mince meat consumed by SO_2-sensitive asthmatic adults would contain a dose of 50 mg or higher of SO_2 and sulphites, per annum in Victoria. This represents an exposure to a dose of 50 mg or more of SO_2/sulphites by an asthmatic child or adult once every 23 years. While doses of 50 mg of sulphites in acidic solutions have caused asthmatic reactions to sensitive individuals, it is not known whether asthmatic reactions would occur when this amount of sulphites are present in mincemeat. No record was found of asthmatic reactions in association with the consumption of mincemeat in Victoria, and officers in the Food Safety Section of the Victorian State Government Department of Health and the Asthma Foundation of Victoria were not aware of reactions having had occurred. An epidemiological study of children in New Zealand found an association between the consumption of hamburgers and asthma symptoms, but no cause to explain the association was identified in this analysis (Wickens et al, 2005).

The lack of reports of asthmatic reactions from the consumption of mincemeat combined with the estimate of exposures in this assessment would suggest either that asthmatic reactions are occurring but are not being reported, or reactions are not occurring despite the exposure. Reporting may not occur because the reactions are mild, do not occur due to the use of preventative medication, are readily ameliorated through the use of reliever medication, or because in meals containing a variety of ingredients mincemeat may not be considered a possible suspect if a reaction occurs. The other possible cause for the lack of evidence of reactions occurring is that the concentration of SO_2, the chemical form which may be responsible for triggering reactions is very low in mincemeat with added sulphites. It is more likely for reactions to be reported if they are severe. The lack of reports of severe asthmatic reactions associated with the consumption of cooked mincemeat in Victoria and elsewhere perhaps indicates they are not occurring, despite exposure. A clearer characterisation of the likelihood of reactions given the estimated level of exposure requires data from a double blind challenge study of the consumption of cooked mincemeat with added sulphites by asthmatic people with SO_2/sulphite sensitivity.

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