



Laboratory of the Government Chemist

LGC
Queens Road
Teddington
Middlesex
TW11 0LY
9th September 2011

Aluminium In Imported Noodles

Summary

The background to the occurrence of aluminium in imported instant noodles is discussed as is the rationale for the current European Commission maximum limit of 10 mg kg⁻¹ of aluminium in noodles.

Recommendations for the analysis and reporting of aluminium in imported noodles are given and a more refined risk assessment is suggested.

Introduction

In early 2011 the Government Chemist concluded a Supplementary Expert Opinion¹ Case on the aluminium content of imported noodles and it was considered desirable to offer some reflections on the issues raised in the hope that this may assist both the food trade and regulators.

¹ Pursuant to the provisions of Article 11(5) of Regulation 882/2004 *on official controls*, *Official Journal of the European Union L 165 of 30 April 2004*

Background

It is understood that the issue of elevated concentrations of aluminium in imported noodles was first discovered in Germany in November 2008 and confirmed by controls carried out by several other Member States. The concentrations of aluminium found ranged between 50 and 150 mg kg⁻¹,² and more elevated concentrations were reported elsewhere.³ These are higher than would generally be expected for naturally occurring concentrations of aluminium in foods.⁴ As a consequence, EU law⁵ on increased level of official controls on imports was amended by regulation (EU) No 878/2010 of 6 October 2010 to require 10% of Chinese noodle imports to be analysed.

Many types of noodles are produced based on wheat flour, some containing egg, mung bean starch, rice, potato, buckwheat and other starches.^{6,7} The three main styles of Asian wheat noodles are reported to be white salted, yellow alkaline and instant noodles. Wheat flour is the primary ingredient with the amount of water added in initial manufacture appears in practice to be less than 35% of the weight of flour. The other main ingredient is salt(s) - either in the form of sodium chloride or alkaline salts or a combination of these. The alkaline salts are often referred to as lye water or kan swi and are typically mixtures of sodium and potassium carbonates.⁸

² The Health and Consumers Directorate-General of the European Commission, 2011, The Rapid Alert System for Food and Feed (RASFF) Annual Report 2009, available at http://ec.europa.eu/food/food/rapidalert/docs/report2009_en.pdf accessed 19 04 2011

³ On 28/10/2009 Germany reported a RASFF, REF.2009.1412 recording aluminium concentrations of 265 mg kg⁻¹ and 340 mg kg⁻¹ in noodles from Vietnam.

⁴ MAFF UK - 1997 Total Diet Study - Aluminium, Arsenic, Cadmium, Chromium, Copper, Lead, Mercury, Nickel, Selenium, Tin And Zinc, LGC analyses.

⁵ COMMISSION REGULATION (EC) No 669/2009 of 24 July 2009 on increased levels of official controls on imports of certain feed and food of non-animal origin, Official Journal of the European Union, 25.7.2009, L 194/11, as amended.

⁶ OH, NH., *et al*, 1983, Noodles.I. Measuring the textural characteristics of cooked noodles, Cereal Chem. 60(6), 433-438

⁷ Kim, Y.S., *et al*, 1996, Suitability of edible bean and potato starches for starch noodles, Cereal Chem, 73(3), 302-308

⁸ Lan T.T. Bui, Darryl M. Small, 2007, The influence of formulation and processing on stability of thiamine in three styles of Asian noodles, Food Chemistry, 102(4), 1394-1399 and references therein.

It has been speculated that the use of potassium aluminum sulfate, ammonium aluminum sulfate or other aluminium containing additives in noodles gave rise to the elevated findings noted above. Chinese legal provisions are reported to be that maximum aluminum residues should not exceed 100 mg kg⁻¹ and that although aluminum-free leavening agents have been researched the lower price of aluminum based additives and the lack of relevant training are factors in the excessively high aluminium findings.⁹ The problem has been the subject of much research in China.¹⁰

In December 2010 and in January and February 2011 there were a total of 12 global recalls due to aluminium in noodles. Most, but not all of the products were from China and a variety of noodles were involved: instant, wheat, bowl, block, egg and potato. The reported aluminium concentrations varied from 10 to 28 mg kg⁻¹.¹¹ The lower end of these cited concentrations tends to lend support to trade reports¹² that current aluminium findings in noodles imported into the UK may owe more to the natural concentrations of aluminium in Asian wheat flour than the use of additives. It is also reported by the trade that Chinese authorities are taking stringent measures aimed to prevent the export of noodles with aluminium concentrations greater than 10 mg kg⁻¹.

Toxicology of aluminium

The human toxicology of aluminium from food, water and food contact materials was the subject of a comprehensive report in 2008 from EFSA.¹³ The reader is referred to the full report for a considered view of the toxicology of aluminium but in brief, and echoing the Panel's view that in many important respects, toxicological evidence is limited, the EFSA Panel concluded that:

- aluminium is unlikely to be a human carcinogen at dietary relevant doses;

⁹ China Trade Information website: Feb 24 2011, http://en.zgzu.com/2011_02_Some-members-of-the-European-Union-banned-Chinese-noodles.html accessed 19 04 2011

¹⁰ There are many web reports in abstract form, e.g. CHEN Yun-sheng, LU Pei-pe, HE Ai-tao., 2009, Analysis On Aluminum Content Among Six Types Of Wheat Flour Food In Hengyangchen, Modern Preventive Medicine, 2009-16, SEEN IN ABSTRACT ONLY, http://en.cnki.com.cn/Article_en/CJFDTOTAL-XDYF200916054.htm accessed 19 04 2011.

¹¹ Government Chemist Programme, monthly surveillance of global food recalls.

¹² Trade sources, personal communications, April 2011, *sub judice*

¹³ Scientific Opinion of the [EFSA] Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC), Opinion on safety of aluminium from dietary intake, *The EFSA Journal* (2008) 754, 2-34

- exposure to aluminium via food does not constitute a risk for developing Alzheimer's disease.

The Panel noted that in animal studies several compounds containing aluminium have the potential to produce neurotoxicity, embryotoxicity, to affect the male reproductive system and have affected the developing nervous system in offspring. The Panel also noted that there are very few specific toxicological data for food additives containing aluminium. Thus the Panel considered it prudent to take the adverse findings from animal studies into account when setting a tolerable intake for all dietary sources.

For these and other detailed technical reasons the EFSA Panel considered it appropriate (in 2008) to establish a tolerable weekly intake (TWI) for aluminium of 1 mg aluminium per kilogram body weight per week (1 mg aluminium/kg bw/week).

The TWI was reviewed again in 2011 by JECFA which established¹⁴ a provisional tolerable weekly intake (PTWI) of 2 mg/kg body weight based on a no-observed-adverse-effect level (NOAEL) of 30 mg/kg body weight per day and application of a safety factor of 100. This PTWI applies to all aluminium compounds in food, including food additives. The previous JECFA PTWI of 1 mg/kg body weight was withdrawn however the EFSA TWI of 1 mg aluminium/kg bw/week remains the toxicological basis for risk assessment in the EU.

Both EFSA and JECFA consider that aluminium intake approached and may exceed TWIs. The EFSA Panel was aware that the TWI of 1 mg/kg bw/week is likely to be exceeded in a significant part of the European population. By way of illustration the group of persons aged 4 to 18 years in the UK consume on average some 1.7 milligrams per kilogram body weight per week. Cereals and cereal products, vegetables, beverages and certain infant formulae appear to be the main contributors to the European dietary aluminium exposure.

For adults JECFA estimated that mean dietary exposure to aluminium-containing food additives from consumption of cereals and cereal-based products was approaching the PTWI of 2 mg/kg body weight. Estimates of dietary exposure of children to aluminium-containing food additives, including high dietary exposures (e.g. 90th or 95th percentile), can exceed the JECFA PTWI by up to 2-fold. For potassium aluminium silicate-based pearlescent

¹⁴ JECFA, JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES, Seventy-fourth meeting, Rome, 14–23 June 2011, SUMMARY AND CONCLUSIONS, Issued 4 July 2011

pigments at the maximum proposed use levels and using conservative estimates, anticipated dietary exposure at the highest range of estimates is 200 times higher than the PTWI. JECFA emphasized that whereas substances that have long half-lives and accumulate in the body are not generally considered suitable for use as food additives, consumption of aluminium-containing food additives would not be a health concern, provided that total dietary exposure to aluminium is below the PTWI. JECFA recommended that provisions for food additives containing aluminium included in the *Codex* General Standard for Food Additives should be compatible with the revised PTWI for aluminium compounds of 2 mg/kg body weight as aluminium from all sources.

Further risk management options are awaited from the Commission.

Current limits on aluminium in food in the EU

The Government Chemist noted that the aluminium TWI of 1 mg/kg bw/week was arrived at by EFSA for precautionary toxicological reasons, including having regard to animal studies that *suggested the potential* for neurotoxicity, embryotoxicity, male reproductive system and developing nervous system effects. It was also noted that the TWI is likely to be exceeded in a significant part of the UK population and that most food contains less than 5 mg kg⁻¹ of aluminium. This led the Government Chemist to the view that a limit for aluminium of 10 mg kg⁻¹ was appropriate in order to prevent additional aluminium input into the UK diet. This opinion was supported by the known history of recent RASFF rejections of noodles based on the limit of 10 mg kg⁻¹ and that the limit stemmed from a view taken by the European Commission supported by the Standing Committee on the Food Chain and Animal Health.¹⁵ The relevant minute of the Standing Committee meeting reads as follows:

“Following requests for clarification as regards the proposed listing of noodles from China under Annex I to Regulation (EC) No 669/2009, the Commission clarified that, based upon available data, the level of 10 mg/kg could be used to distinguish noodles with acceptable unavoidable background presence of aluminium from noodles presenting unacceptable levels. Vote: qualified majority by 338 votes in favour, 7 votes abstained.”

¹⁵ Directorate-General Sanco D – D(2010) 658863 Summary Record of the Standing Committee on the Food Chain and Animal Health, Held in Brussels on 14 July 2010, (Section Controls and Import Conditions)

The Government Chemist further notes that the EFSA Panel report collated data on aluminium-containing food additives (other than colours and sweeteners) authorised for use in the European Union. For example, E 520, E 521, E 522 and E 523, respectively aluminium sulphate, aluminium sodium sulphate, aluminium potassium sulphate, and aluminium ammonium sulphate are permitted in egg white up to 30 mg kg⁻¹ and in candied, crystallized and glacé fruit and vegetables up to 200 mg kg⁻¹, individually or in combination, expressed as aluminium. E 541, sodium aluminium phosphate, acidic is approved for use in fine bakery wares (scones and sponge wares only) up to a maximum of 1000 mg kg⁻¹ expressed as aluminium. There are also many other uses permitted in limited categories of foods, including supplements at *quantum satis* concentrations. In view of the toxicological findings both the Commission and *Codex* seem likely to review aluminium limits in food.

Analytical considerations

Aluminium is readily determined in food by a range of methods including microwave pressure acid digestion followed by ICP-OES or ICP-MS.¹⁶ The expanded measurement uncertainty (MU) associated with such a determination in routine circumstances at around 10 mg kg⁻¹ is about 15% - 20%. Much lower MU can be achieved but at the increased cost associated with more, and multiday, replicate analyses. Standard Reference Materials are readily available containing certified concentrations of aluminium and one of these along with appropriate blanks and spiked samples to provide matrix matched recovery checks and at appropriate replicates are recommended for analytical batch runs. It may be the case that efforts should be made by the analytical profession to improve the routine precision and any potential technical bias in aluminium determinations. It is also important in regulatory work to report and have regard to the MU, basing regulatory decisions that depend on the criminal burden of proof on the mean result minus the MU when appraising a result against a limit. Lastly, it is considered important to carry out and report a moisture determination when reporting aluminium results.

¹⁶ Inductively Coupled Plasma coupled with Optical Emission Spectrometry or Mass Spectrometry.

Conclusions

The Government Chemist, for the reasons stated above, supports a maximum limit for aluminium of 10 mg kg⁻¹ applied to ambient instant noodles. It is considered that it would have assisted trade and regulatory interests if the European Commission and the Standing Committee had articulated the reasons for the limit more fully.

It is also considered that it would be interesting to investigate the natural occurrence of aluminium in Asian wheat flour. If indeed it is the case that naturally occurring aluminum in such raw material is somewhat higher than European or North American concentrations in wheat this would suggest some merit in a revised risk assessment of the additional burden of aluminium intake at maxima somewhat higher than 10 mg kg⁻¹ commensurate with higher natural concentrations, if any, found for Asian wheat flours. Reinforcing this view are simple calculations (data not shown) that varying the limit by small increments around 10 mg kg⁻¹ would have only marginal impact on dietary impact.¹⁷ A revised risk assessment would, of course, best be done in the context of overall revised risk management and risk communication strategies to reduce European population exposure to aluminium.

For further information please contact Michael Walker at michael.walker@lgc.co.uk

Any view, information or advice given by LGC, the Laboratory of the Government Chemist, is formulated with care, but is based necessarily upon the information and data provided to it as part of the enquiry. No responsibility can be taken for the use made of any view, information or advice given, whether by the enquirer or a third party. In particular, any view, information or advice given should not be taken as an authoritative statement or interpretation of the law, as this is a matter for the courts.

¹⁷ Note: it was not possible within the resources of the Government Chemist to ascertain typical dietary intakes of noodles; the calculations were based on a portion size of 33g as reported by the trade but only limited assumptions of weekly intakes of such portions were considered.