



Jelly confectionery – Interpretation & reporting



Agenda



1. Chain of custody of the sample
2. Appearance
3. Removal from container and handling
4. Size and SPC ...
5. Solubility test and appearance after test
6. End seal removal
7. Bite and compression tests
8. Recent developments
9. Court cases
10. Overall conclusions



Chain of custody of the sample



1. Appearance of sample – integrity, sealed?, seal reference
2. Sample reference, Customer reference
3. Sample description
4. Date received
5. Number of items received
6. Batch Number / Best before
7. List of ingredients
8. Warnings / instructions (and any other information, e.g. spoons)
9. Balance used and calibration
10. Calipers / rules used and calibration
11. Analyst / date of tests recorded



Appearance



- Colour / flavour / opacity (all items)
- Container – is it a 'semi rigid mini-cup'? (all items)
- Are any containers damaged / have any samples leaked? (all items)
- Is there any sign of mould growth? (all items)
- Is the end seal of the mini-cup intact? (all items)
- Record weights (in their mini-cups) (test ≥ 6 items)
- Record dimensions (in their mini-cup) (test ≥ 6 items)
 - Height, base diameter, tip diameter



Removal from container and appearance – (test ≥ 6 items)

- How easy is the film seal to remove by hand?
- Is there any liquid present?
- How easy is it to eject the contents from the container by hand?
- Contents remain intact, including during gentle handling?
- Attitude, e.g. self-supporting / viscous / fluid
- Handling
 - Slippery / non-slippery / intact / breaks up ...
- Record dimensions of the jelly itself (i.e. out of its mini-cup)
 - Height, base diameter, tip diameter
- Do the contents fit into SPC – base first / tip first?

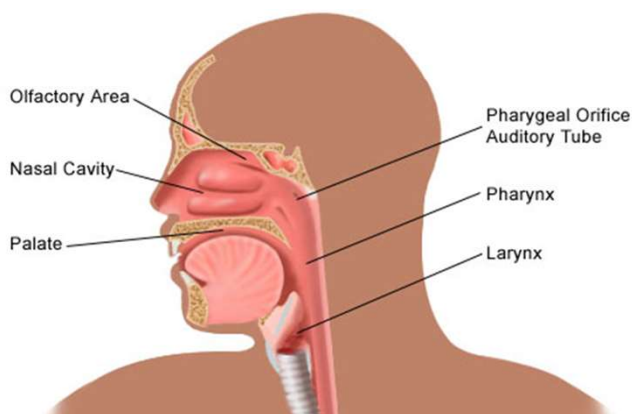


Take photographs

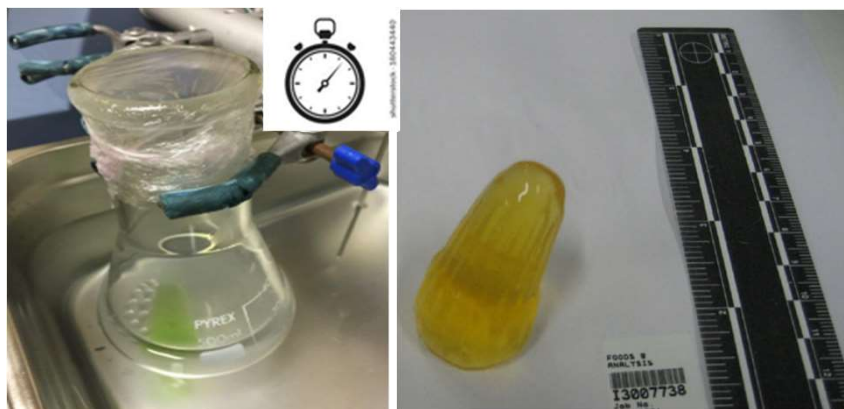


Interpretation

- Size and shape are fundamental characteristics of choking hazards
- Food in general is a major source of choking fatalities
- But only jelly mini-cups have legislative cognizance
- A product that fits or almost fits the SPC may pass the oropharynx to lodge in the larynx
- Restricts access of air to the lungs
- Brain anoxia supervenes within minutes



Solubility test and appearance after solubility test – (test ≥ 6 items)



Has the item retained its shape?

Is the item self-supporting?

Weight:
Weight lost:

Height:
Base diameter:
Tip diameter:



Interpretation



- Possible to form an opinion now ...
- In a semi-rigid mini-cup ✓
- End seal peels off (relatively) easily ✓
- Slippery surface ✓
- Does not dissolve shaken in artificial saliva at 37°C in 2 min ✓
- Self-supporting before and after the solubility test ✓
- Fits into a small parts cylinder in any attitude ✓
- All ✓ then product can be regarded as a choking risk as it conforms to the regulation definition

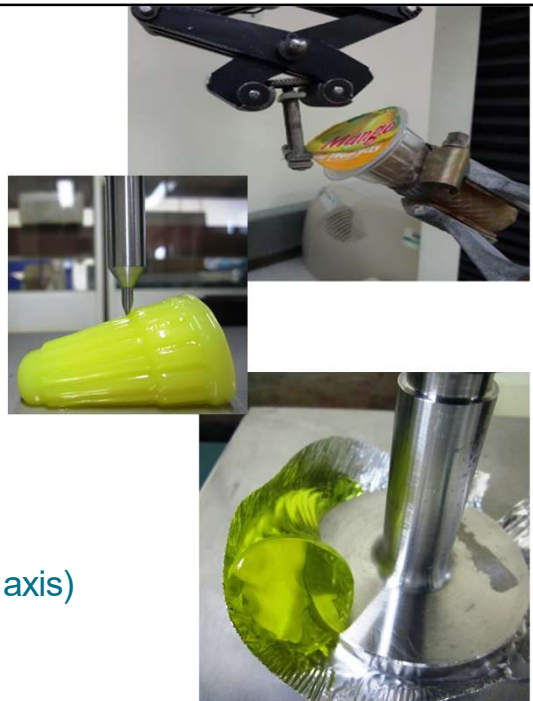
... firm consistence, contained in semi rigid mini-cups or mini-capsules, intended to be ingested in a single bite by exerting pressure on the mini-cups or mini-capsule to project the confectionery into the mouth





Bite / compression tests

- Remember – how easy was the end seal to remove?
- Can be measured ...
- What would a child do?
- Force required to puncture base seal...
- Force required to puncture item (bite test):
- Force required to rupture base seal (compression):
- Force required to compress item (horizontal axis) (when out of container):





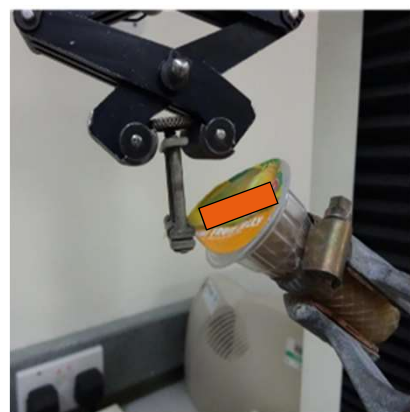
Data in the following slides are for illustrative purposes only



End seal removal, Newtons, N



Case	1720-1	1720- 15
Mean (<i>n</i>)	37.5 N (10)	25.1 N (7)
Lowest	17.8 N	13.9 N
Highest	90 N	36.2 N



Force to puncture end seal, N



Case	1	2	3	1720-15
Mean, (<i>n</i>)	9.3 N (1)	11.6 N (3)	14.1 N (2)	11.2 N (4)
Lowest		9.7 N	12.6 N	7.4 N
Highest		13.5 N	15.7 N	13.5 N



Indentor, 'bite' test, Newtons, N



Case	1	2	3	1720-15
Mean (<i>n</i>)	0.37 N (2)	0.19 N (3)	0.21 N (2)	0.03 N (3)
Lowest	0.35 N	0.19	0.13 N	0.02 N
Highest	0.30 N	0.19	0.29 N	0.05 N



Compression tests, Newtons, N

Force to break seal by 'squeezing' the mini-cup

Case	1	2	3	1720-15
Mean (n)	86 N (1)	117.2 N (5)	124.7 N (4)	120.0 N (5)
Lowest		71.9 N	85.9 N	80.3 N
Highest		239 N	142.2 N	145.6 N

Force to compress when out of its mini-cup (*)

Mean (n)	33 N (1)	33.3 N (3)	18.2 N (3)	2.6 N (6)
Lowest		23.3 N	3.5 N	0.3 N
Highest		42.3 N	42.8 N	10.6

* i.e. force being applied when jelly ejected from under disc



Item no	Flavour	Intact or almost so (1)	Self supporting (2)	Classification		
				Fits definition (3)	Questionable	Does not fit definition
22	Mango	0	0	0	1	0
17	Mango	0	1	0	1	0
16	Mango	0	1	0	1	0
20	Mango	0	1	0	1	0
9	Mango	0	1	0	1	0
29	Mango	0	1	0	1	0
15	Mango	1	1	1	0	0
49	S'berry	1	1	1	0	0
28	Mango	1	1	1	0	0
31	G'apple	1	1	1	0	0
43	G'apple	1	0	1	0	0
40	G'apple	1	1	1	0	0
18	Mango	1	0	1	0	0
8	Mango	1	1	1	0	0
48	S'berry	1	1	1	0	0
51	S'berry	1	1	1	0	0
35	G'apple	1	1	1	0	0
37	G'apple	1	1	1	0	0
58	P'apple	0	0	0	0	1
55	P'apple	0	0	0	0	1
Totals		12	15	12	6	2



60 % (12/20) conform to the Regulation 1333/2008 definition of jelly mini-cup



Summary opinion

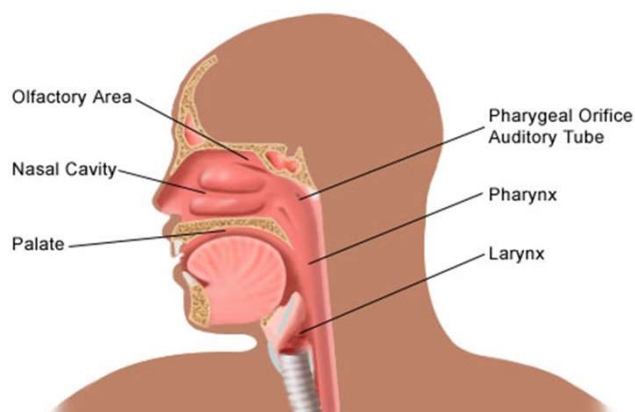


- The jelly confectionery in the referee sample exhibits considerable variation from item to item
- Some items clearly do not fall within the regulatory definition of a 'jelly mini-cup' because they have very little structural strength
- For others it is at least questionable if they satisfy the definition owing to the ease with which they can be broken up
- However, the majority of items (60 % of those examined) conform to the Regulation (EC) No 1333/2008 definition of jelly mini-cup and by their labelling contain additives, agar (E406) and locust bean gum E410, the use of which is prohibited in jelly mini-cups
- Hence the products do not comply with Regulation (EC) No 1333/2008 implemented in England by the Food Additives, Flavourings, Enzymes and Extraction Solvents (England) Regulations 2013



How firm is firm?

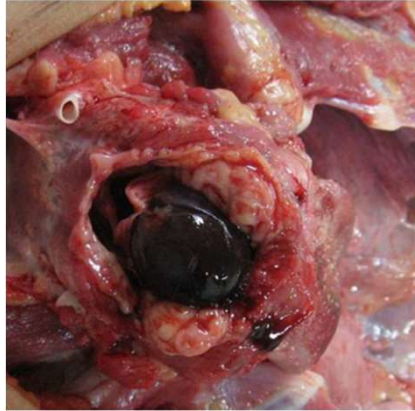
Viewer discretion re next slide...



Examples of choking fatalities



4 yr old boy, grape caught between the tonsils, tongue and soft palate *in situ*



70 year old
...banana...found dead in bed ... **Café Coronary**



Nikolić, S. and Živković, V., 2013, *Forensic science, medicine, and pathology*, 9(3), pp.452-453

Edirisinghe, P.A.S., 2011. A Café Coronary Death due to a 'Banana'. *Sri Lanka Journal of Forensic Medicine, Science & Law*, 1(1)



Typical food choking case



The Telegraph

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Child died choking on a sausage at nursery

A coroner has issued a warning about food given to toddlers after a two-year-old boy died when he choked on a piece of sausage which had formed "a perfect plug" in his throat.

Toddler Adam Milner died in 2009 after choking on a piece of sausage, ... parents made the agonising decision to turn off his life support four days later. Inquest revealed he had suffered oxygen starvation and a heart attack. An intensive care consultant gave expert evidence that airway clearance and resuscitation within minutes of him choking would have been required for Adam to have made a full recovery.

Daily Telegraph, 05 March 2011, Child died choking on a sausage at nursery,
<http://www.telegraph.co.uk/news/uknews/8362418/Child-died-choking-on-a-sausage-at-nursery.html>



Jelly mini-cup cases



- Bolton 2003
 - 8 month old boy died
- Japan 1994 - 2008
 - 22 deaths linked to jelly mini-cups containing konjac between 2002- 2008 and 32 cases of choking accidents between 1994-2008
- USA 1995 – 2008
 - Six children died from choking on mini-cup jelly
- Korea 2001 – 2007
 - Five Korean children choked on mini-cup jelly, 3 died



Bolton 2003



- Mohammed Muneeb Akhtar died after eating a Troofy mini gel, containing a binding agent called konjac
- The inquest was told by the pathologist that “two teaspoons of the jelly [were found] blocking the baby's throat.”
- Recording a verdict of accidental death, the Bolton coroner said: “He had a chest infection but it is my belief that the largest cause of his death was the sweet. I hope the family can draw some comfort from the fact that as a result of this loss other children will be protected”



<https://www.manchestereveningnews.co.uk/news/greater-manchester-news/sweets-ban-after-toddler-dies-1136270>



Japan



- 22 deaths linked to jelly mini-cups containing konjac in Japan between 2002-2008 and 32 cases of choking accidents between 1994-2008, at least one victim was left in a vegetative state
- One Civil case reported
 - Found for defendant company, confirmed on appeal
 - Product was frozen by the child's grandmother and was still partially frozen when given to the child
 - There is a warning on products 'Children and elderly persons should not eat this product due to the danger of choking'

Kawawa, Noriko. "Jelly Mini-Cups Containing Konjac: Is a Warning Enough to Protect Vulnerable Consumers?." *Australian Journal of Asian Law* 13.2 (2013)



Japanese High Court



- Behaviour of the parent or guardian is of prime importance
- Small children can't peel off the lid, guardians should cut the jelly into pieces before feeding it to them
- Dangerous characteristics not caused by [intrinsically] harmful ingredients
- [Japanese] public opinion ... Konjac is good for beauty and health
- Many jelly products (+konjac) sold in the [Japanese] market without choking accidents
- Rate of choking accidents caused by konjac jelly lower than caused by mochi
 - Mochi, a traditional Japanese festive food made by steaming waxy rice, then applying external force and mixing to increase its viscosity. It is highly cohesive and adhesive, and easy to choke on
- No fatal accidents in healthy persons from 15 to 64 years old
- Some choking accidents does not imply a general product safety problem



Kawawa's view



- Noted Japanese konjac trade association requests for retailers not to place jelly mini-cups containing konjac near snacks for children
- Alternative safer product designs (size and shape, pre-crushed, ...) and foreseeability
- Discussed technical legal issues on product liability tort
- Referred to Australian 2010 ban on jelly cups containing konjac having a height or width of less than or equal to 45 mm
- Kawawa argued that the warning was not adequate to protect vulnerable consumers such as young children and the elderly, and that the Japanese product safety regime should be strengthened to protect vulnerable persons against injury from food and other harmful products



U.S. and Republic of Korea



J Agric Environ Ethics (2014) 27:735–748
DOI 10.1007/s10806-013-9487-2

ARTICLES

The Mini-Cup Jelly Court Cases: A Comparative Analysis from a Food Ethics Perspective

Suk Shin Kim

- Kim describes Court rulings in 3 countries (Japan, Korea, USA) on “mini-cup jelly”
- Defined in the paper as a firm jelly containing konjac and packaged in bite-sized plastic cups

Kim, Suk Shin. "The Mini-Cup Jelly Court Cases: A Comparative Analysis from a Food Ethics Perspective." Journal of Agricultural and Environmental Ethics 27.5 (2014): 735-748



USA cases



- 1995-2008 six children died from choking on mini-cup jellies
- 2002 FDA issued Import Alert:
 - ‘Districts may detain without physical inspection all mini-cup gel candies containing konjac.... The candies have ‘smooth slippery surfaces when placed in the mouth ... slides along the tongue toward the back of the mouth, ... poor control over its direction, positioning, and timing/coordination with swallowing, and thus effectively bypassing the teeth.’
- 3 families won civil actions sequentially in 2003 in separate courts.
- Yvonne and Gil Enrile v. Sheng Hsiang Foods, 2004
 - Michelle Enrile choked on a piece of the candy, lingered in a coma for 27 months, and died....
- Jury found by special verdict that: “defendants’ [product] was defective and also that Sheng Hsiang was negligent.”



Republic of Korea



- 2001-2007, five Korean children choked on mini-cup jelly, 3 died
- Two of the families brought civil actions
- First case Seoul Central District Court decided in favour of the Plaintiff
 - Even though [it] contained not konjac but carrageenan, it was very hard, cohesive, bite-sized so as to be eaten by sucking in, and it was too slippery, non dissolving, and elastic to bite a piece off in the mouth. Therefore, the jelly had the high risk of inducing choking and was defective. The warning ‘Be careful while eating!’ printed on the packaging was not sufficient to prevent the choking accident
- 2nd case the Seoul District Court again decided in favour of the Plaintiff parents, Overturned on appeal ... not clear whether the importer had actually imported the particular mini-cup jelly



Kim



- Cites Korean tightening of jelly mini-cup regulations in 2007 that
 - Increased the minimum size from 45 to 55 mm and
 - Reduced the compression strength from 7 N to 5 N to increase softness.
- Kim concluded that
 - Unlike Koreans and Americans, the Japanese have long used konjac as a food additive
 - However jelly mini-cup is unacceptable because it is unsafe, unwholesome, and unfit for children’s consumption



Template E



- Aperture diameter of the small parts cylinder is 31.7 mm Ø
- Template E is 44.5 mm Ø used additionally in EN71-1 to address balls capable of entering and blocking the airways at the back of the mouth and upper throat
- Template E to evaluate potential choking has been applied to jelly mini-cups and its inclusion widens the scope of products considered within the definition of ‘intended to be ingested in a single bite’
- However, this is not unreasonable, for example Kim, citing the Food Safety Commission of Japan:
 - “The main risk factors pertaining to mini-cup jelly may include its shape (spherical or oval); size (<4.5 cm); manner of consumption (sucking in one gulp or pushing on the cup); and physical properties (hard, cohesive, elastic, water insoluble, and sticky).”



Conclusions



- Many foods and other items represent a choking risk ...
- But only jelly mini-cups have food law cognizance
- No guidance from Commission or FSA on what 'firm' means
- Our paper remains the only peer reviewed guidance ...
- Products appear to be changing ...
 - Gel strength weaker – products less firm ...
 - Anecdotally, larger or more fluid products available
 -



GC guidance



- If product is contained in a semi-rigid mini-cup (etc.)
 - Has slippery surface & not soluble in artificial saliva in 2 minutes at 37°C
 - Significant proportion of items in the sample are self-supporting and do not break up into small pieces in handling and/or before and after the solubility test
 - Fits into a small parts cylinder in any attitude
- Can be regarded as a choking risk
- If labelling indicates Reg. 1333/2008 Part E / Annex II gel-forming additives present (report should note)
 - Product is non-compliant
- If equipment is available, then compression and bite tests can be carried out to augment the above findings



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Questions and discussion



