

The logo for FSSAI (Food Safety and Standards Authority of India) features the word "fssai" in a stylized, lowercase font with a green leaf-like element above the 'i'.

भारत सरकार
FOOD SAFETY AND STANDARDS
AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food
Ministry of Health and Family Welfare, Government of India



FSSAI –CHIFSS Orientation Workshop

“Risk Assessment Framework Structure – Novel Foods and Additives”

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Risk Assessment Structure Frame Work-Case Study- Additives

- Erythrosine INS no 127 - Additive
(Colour)
- Caffeine - Additive & Naturally present
(Stimulant) in certain foods

Erythrosine

Hazard Identification

Technical Data

Xanthene Dye Mw 879.84g/mol
CAS Registry Number 16423-68-0
Disodium 2-(2,4,5,7-tetraiodo-6-oxido-3-oxoxanthen-9-yl) benzoate
Red odorless powder or granules
Log P (octanol-water) of 4.95 at 25°C
Soluble in water (<9% w/w) and ethanol.

Toxicological Evaluation

- Absorption, Distribution, Metabolism & Excretion
- Developmental Toxicology
- Reproductive Toxicology
- Genotoxicity
- Effect on Thyroid, Increased T4 levels in Serum (hyper thyroidism) Anxiety, Irritability, Nervousness, Hyperactivity
- 200mg/day for 14 days Human clinical study
- Increased level of Protein Bound Iodine & Iodine in Blood
- 60mg /day No effect

Hazard Characterization

- Lowest Observed Adverse Effect Level
- 200mg/day Human Clinical Trail
- No Observed Adverse Effect Level
- 60mg/day Human Clinical Trail or 1mg/day (60mg/60 kgbw)
- ADI $1\text{mg}/10(\text{safety factor}) = 0.1\text{mg}/\text{kgbw}$



Exposure Assessment

Extent of intake/exposure of the Erythrosine to the humans

$$\text{Dietary exposure} = \frac{\sum (\text{Concentration of chemical in food} \times \text{food consumption})}{\text{Body weight (kg)}}$$

- Post Regulation
- National Food Consumption Data
- General Population
- Body weight

Approaches for Food Consumption Data

- Poundage
- Household
- Individual
- Model Diets
- Total Diet

Food Consumption - Combination of Poundage and Household survey

Dietary exposure is calculated using

- Theoretical Maximum Daily Intake (TMDI)

Approach based on the following assumptions:

- A person consumes all the 19 commodities
- Additive Quantity - upper limit as per FSSR
- The colored foods are ingested and nothing is discarded.
- The amount of the food additive in the food does not change as a result of storage, cooking or processing techniques.

FSSR prescribes limits for Erythrosine in 8 food categories 19 sub categories

1. Dairy Products and Analogues Excluding Products category 2.0
2. Edible ices, including Sorbet
3. Fruits & Vegetables
4. Confectionery
5. Cereal & Cereal Products
6. Bakery Products
7. Meat & Meat Products including Poultry
8. Beverages excluding Dairy Products

Permitted levels : 25mg/kg to 100mg/kg

Food	Regulatory limit mg/kg or Litre	NO of days consumed &Quantity	Frequency	Average Intake /day	Quantity of Erythrosine
Flavoured milk	50	120 days 200ml	Twice a week	18ml	0.88 mg
Ice cream	50	4000ml/year	-	11ml	0.55mg
Jam, Jellies , Marmalade	100	500g/month for 4 people	Daily	4.0 g	0.42 mg
Similar Exercise was done for rest of the 16 categories					7.0 mg
Total quantity per day					8.85mg

Scenario I

- All the foods which have Erythrosine are consumed
- The total average intake of Erythrosine per day by an individual is 8.85mg

Scenario II

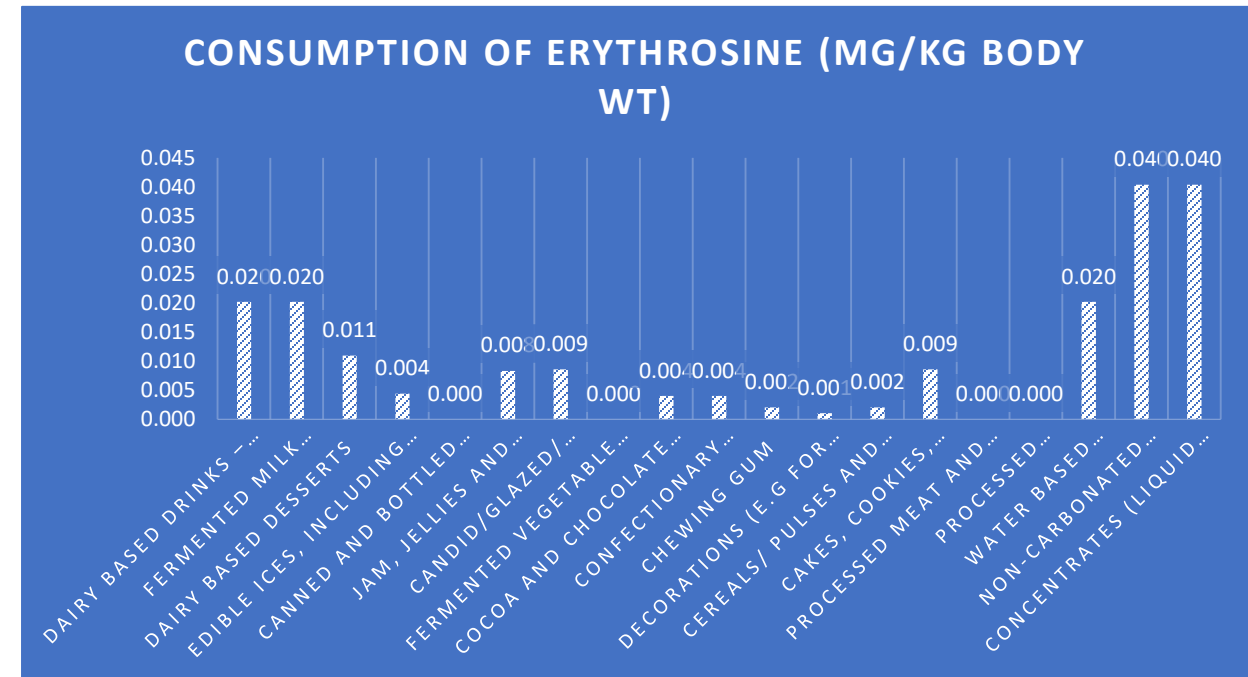
- Only of one food commodity each category was considered
- Total average intake of Erythrosine per day by an individual is 3.38mg

Risk characterization

Acceptable Daily Intake for Erythrosine = 0.1mg/Kg
Reference Body weight for Indians = 50kg
ADI for Erythrosine for Indians = $50 \times 0.1 = 5.0\text{mg}$

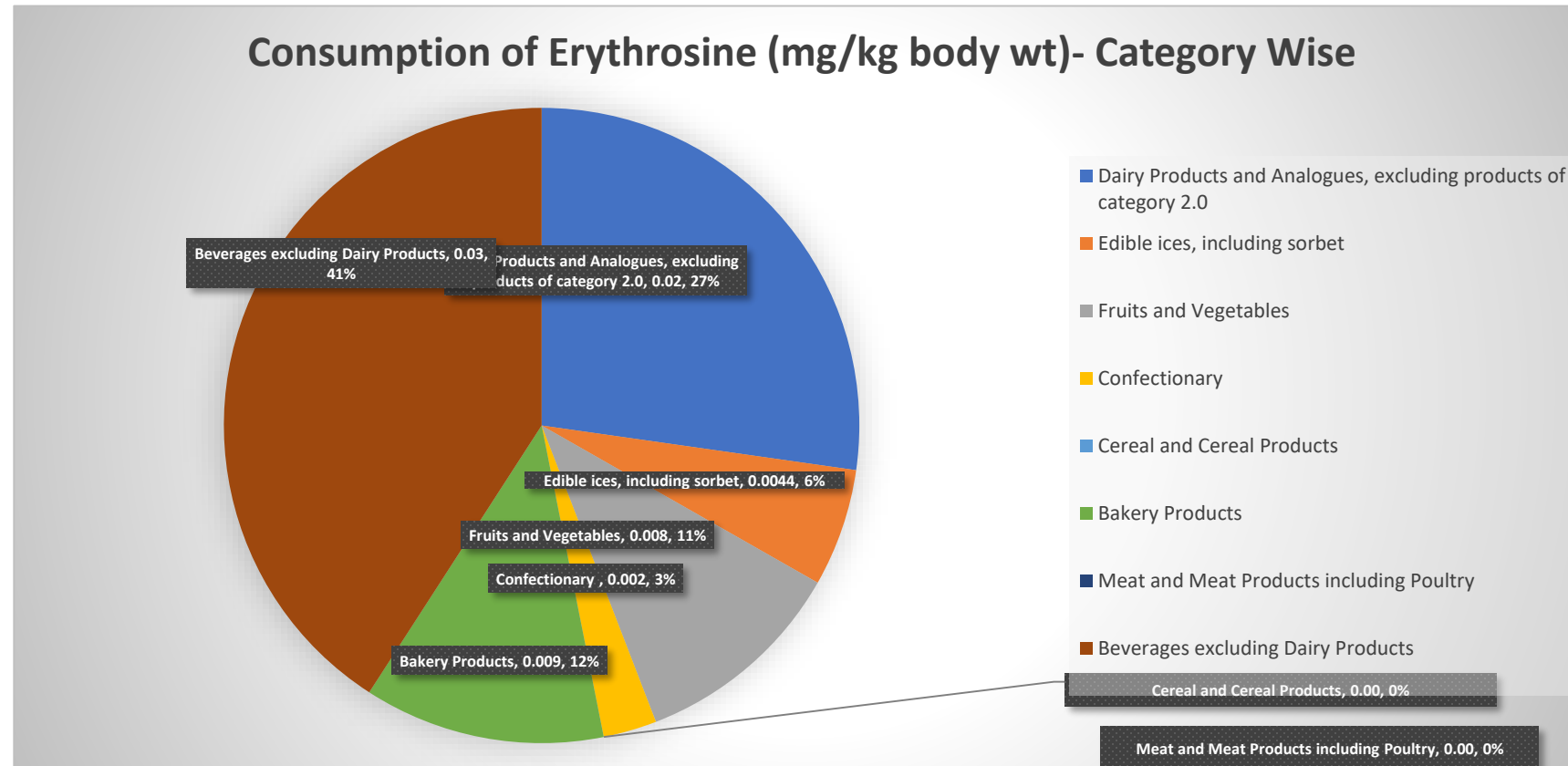
Scenario I

Theoretical Maximum Daily Intake of Erythrosine =
8.85mg
(8.85mg is 180% of ADI)



Scenario II

Theoretical Maximum Daily Intake of Erythrosine = 3.38mg
(3.38mg is 68% of ADI)



Caffeine

Hazard Identification

Technical Data

Chemical name 1,3,7 Tri methylxanthine

Common sources:

- Kola nut
- Cacao beans
- Guarana
- Coffee bean
- Tea leaves

Human Trials/Epidemiological Studies	Dose	Remarks
Adults	400mg/day	Review on Caffeine health effects. No health concerns in relation to acute toxicity, calcium balance, cardio vascular health, cancer or male fertility(Landolt etal 1995)
Healthy Adult Volunteers	3mg/kgbw (Single dose)	Increase in anxiety in some cases(Nickell & Uhde 1994)
Adults	Not more than 2.5mg/kgbw	No safety concern(FSANZ, 2000 Health Canada,2006 Nordic Working Group and Food Toxicology & Risk evaluation,2008 Belgium Superior Health Council 2012)
Healthy adults	≤ 400mg/day or 5.7mg/kgbw	No safety concern if consumed throughout day except Pregnant women (EFSA Panel on Dietetic Products, Nutrition and Allergies ,2015)
Healthy Adults	≤ 400mg/day	No safety concern(Nawrot ,2003. ILSI's systematic review etal ,2017)

Hazard Characterization

Caffeine has been the subject of more scientific safety studies than any other food ingredient. The safety of caffeine can best be described in a narrative form, and is not usefully expressed in terms numerical value like an "acceptable daily intake" (ADI). So, based on various studies it is generally accepted that up to 400mg consumption of per day has no safety concern.

Commodity	Permitted levels	Serving size	Frequency	Average intake	Caffeine quantity mg
Caffeinated beverages	300ppm	250ml	3times/week	106.8ml	32
Carbonated water	145ppm	300ml	2times/week	86.0ml	12.5
Non carbonated beverages	145ppm	300ml	2times/week	86.0ml	12.5
Plain Chocolate	25mg/50g	50g	Alternate day	25.0g	13.0
Milk Chocolate	10mg/50g	50g	Alternate day	25.0g	5.0
Total added Caffeine intake					75.0mg

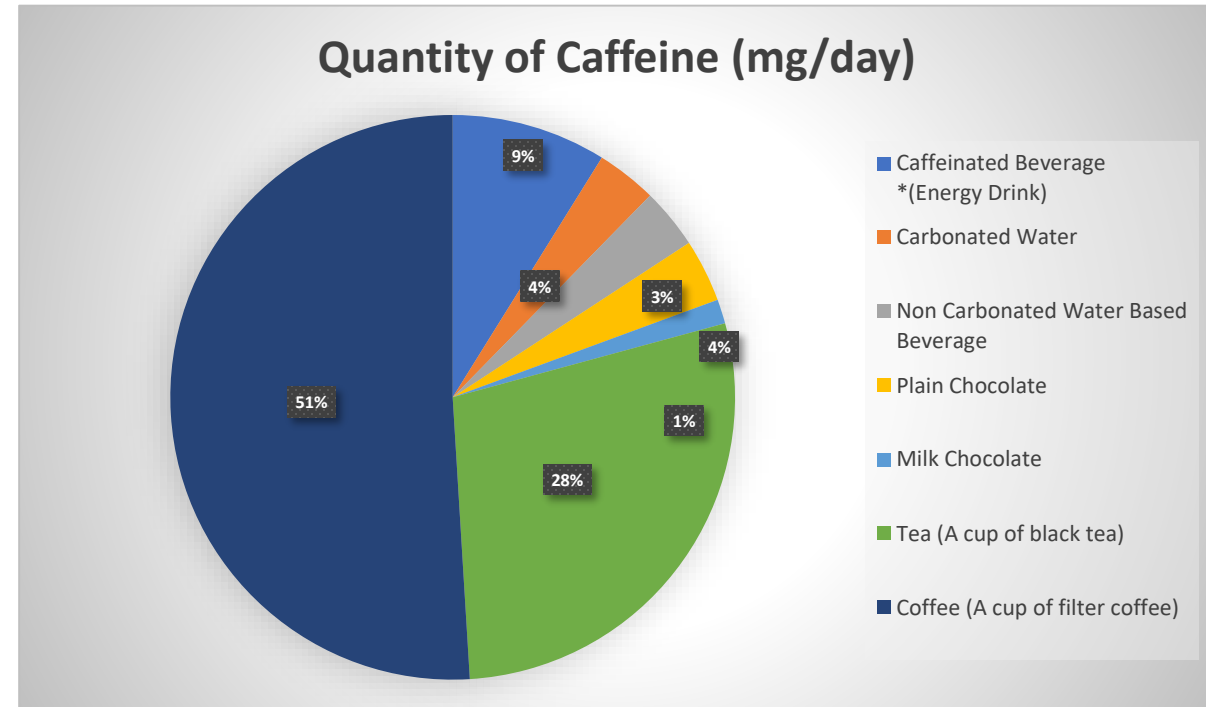
Commodity	Caffeine quantity generally present	Serving size	Frequency	Average intake	Caffeine quantity mg
Tea(A cup of black tea)	50mg/220ml	150ml	3 times/daily	450ml	102
Coffee(A cup of filter coffee)	90mg/200ml	150ml	3 times/daily	450ml	184
Total caffeine content from natural source					286

Total dietary intake of Caffeine = 75+286= 361mg/day

Risk Characterization

Scenario I

- Where we assume a person takes a possibly all beverages/foods where Caffeine is present
- Total daily caffeine intake = 361mg



Scenario II

A person only consumes products in which caffeine is naturally present either tea or coffee and with following combinations

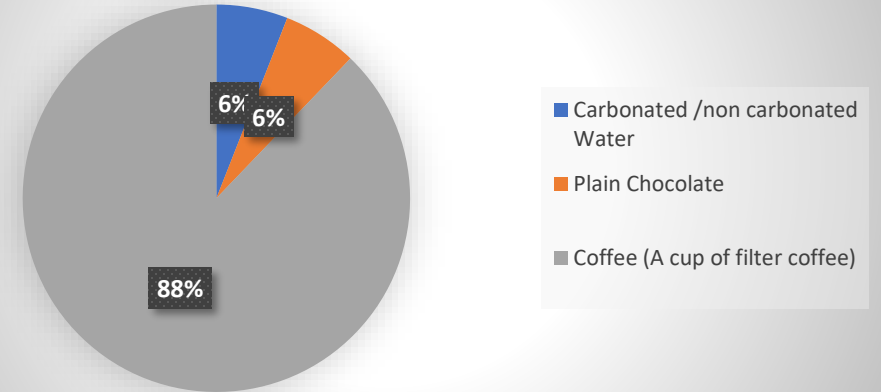
i. Coffee+ Carbonated/Non Carbonated + Plain chocolate = 209.5mg

ii. Tea+ carbonated/Non Carbonated+ Milk chocolate = 119.5mg

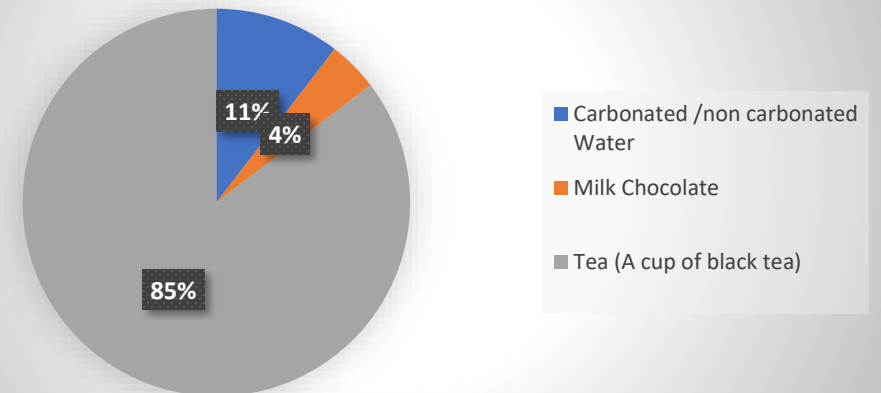
lii Add Caffeinated beverage to Coffee group (209.5+32) = 241.5mg

lv Add Caffeinated beverage to Tea group (119.5+32) = 151mg

Assumption 1 -Quantity of Caffeine (mg/day)



Assumption 2 - Quantity of Caffeine (mg/day)





Estimates of intakes of BHT (Example)



First level screening by Budget method ----- Exceeded the ADI

Estimates provided by 10 countries - using GSFA levels of use - consistently exceeded ADI

Mean intake	230 %	ADI China
	240%	ADI US
High intake	600-2000 %	ADI

Intake estimates using national levels of use

% of ADI	Method of estimate
30	Poundage method
20-30	Household surveys and sales data
10-30	Model diet
0.1-30	Individual data
0.003	Total diet study (Japan)

Conclusion : Unlikely to exceed ADI

Recommendation: May review MLs potentially contributing to high intake ie Fats and oils free from water, chewing gum & processed fish and fish products

Thanks