Food Safety
AUTHORITY OF IRELAND

Expanded FSAI Risk Ranking Model for Chemicals in Food

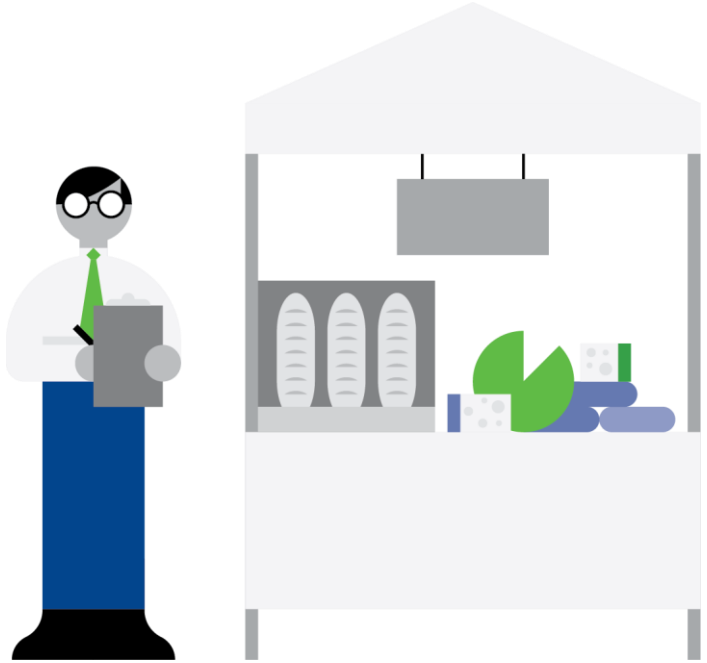
Presented by Dr. Jamie Wilson

28 November 2024

Presentation Outline

- Why develop a risk ranking model?
- FSAI Risk Ranking Model – Example
  - Exposure score
  - Toxicity score
  - Policy flag

- Risk Ranking Model Development
  1. Data Harmonisation
  2. Exposure Estimation
  3. Aggregation
- Next Steps



Why Develop a Risk Ranking Model?

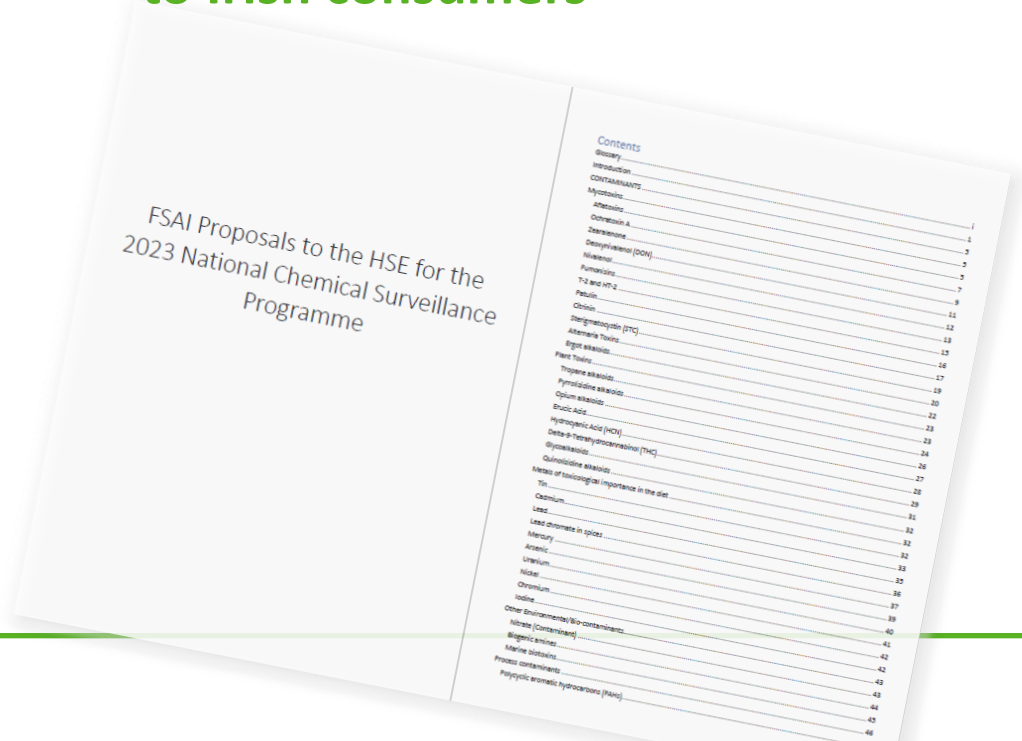
Annual National Chemical Monitoring Programme - “wish list”

Proposal is currently based on:

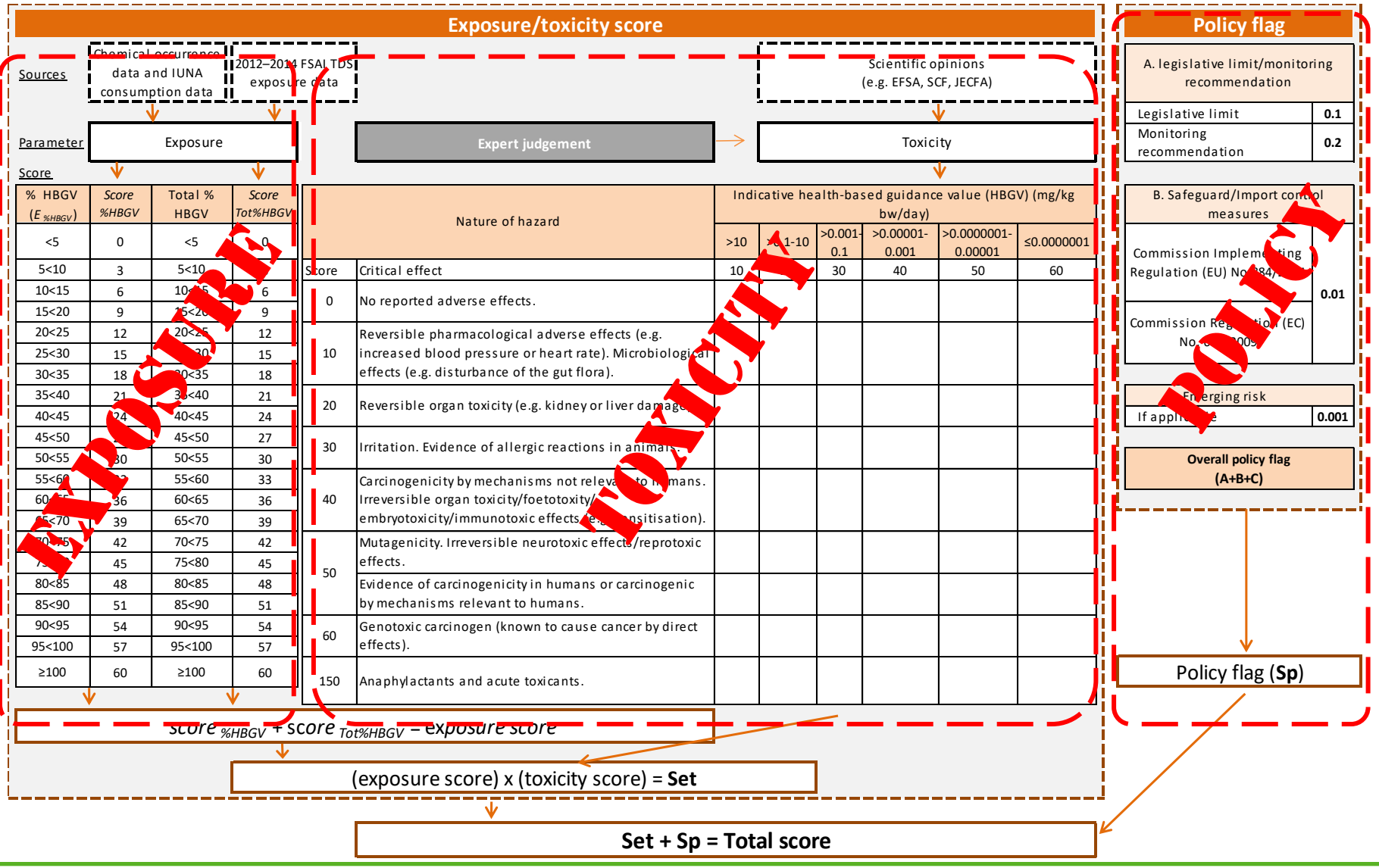
- Legislative requirements
- Risk to consumers
- Non-compliance rate
- Current EU priorities
- RASFF alerts
- Emerging issues
- Findings from Directorate F-Health and Food Audits

Need to establish formalised ‘Risk Ranking’ approach to:

- provide a risk basis for controls
- make best use of resources
- shift focus to areas of most concern to Irish consumers



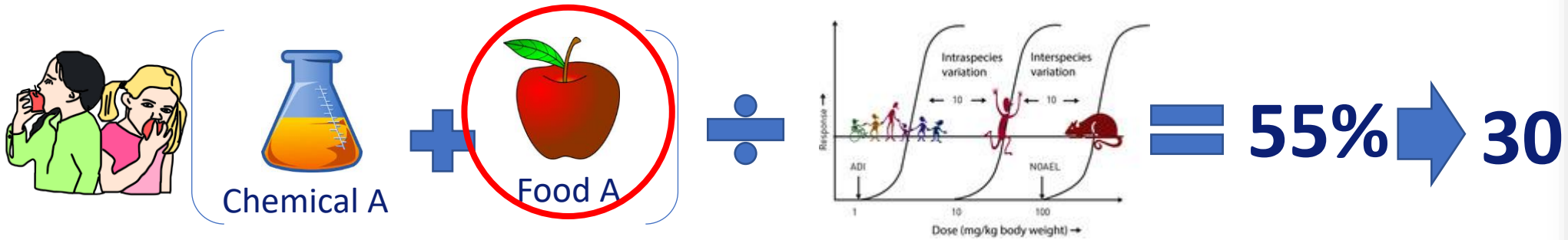
Overview of Risk Ranking Model



Exposure Score

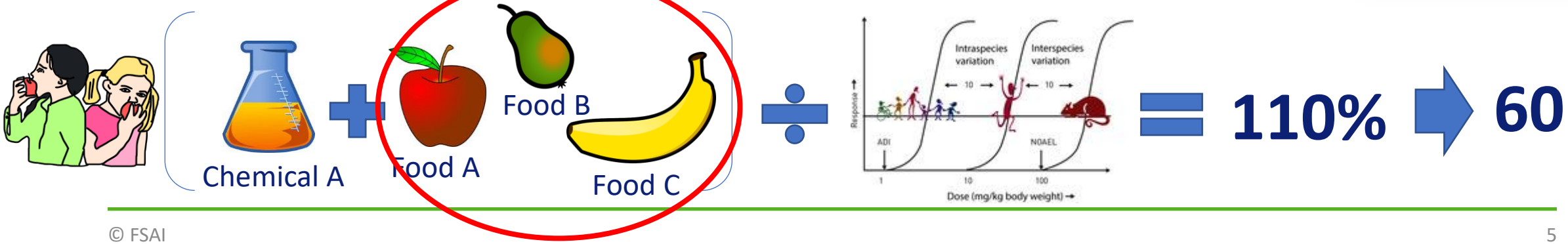
$$Score_{\%HBGV} + Score_{Tot\%HBGV} = \text{Exposure score}$$

$$\frac{Mean\ exposure\ to\ contaminant\ A\ in\ \boldsymbol{food\ A}}{(indicative)\ health\ based\ guidance\ value} \times 100 = E_{\%HBGV}$$



% contribution to (indicative) HBGV ($E_{\%HBGV}$)	$score_{\%HBGV}$
<5	0
5<10	3
10<15	6
15<20	9
20<25	12
25<30	15
30<35	18
35<40	21
40<45	24
45<50	27
50<55	30
55<60	33
60<65	36
65<70	39
70<75	42
75<80	45
80<85	48
85<90	51
90<95	54
95<100	57
≥100	60

$$\frac{Mean\ exposure\ to\ contaminant\ A\ in\ \boldsymbol{all\ food}}{(indicative)\ health\ based\ guidance\ value} \times 100 = E_{Tot\%HBGV}.$$



Exposure Score Example – Acrylamide in Crisps

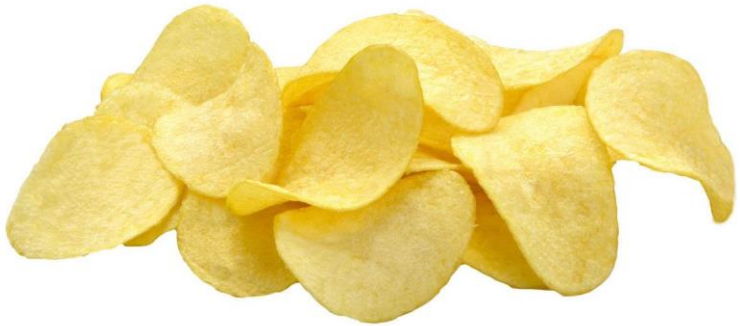
$$\frac{Exposure\ to\ acrylamide\ in\ crisps\ (0.038\ \mu g/kg\ bw/day)}{(indicative)\ HBGV\ (0.017 \mu g/kg\ bw/day)} \times 100 = \boldsymbol{E_{\%HBGV}\ (224.6\%)}$$

Highest score = 60

$BMDL10\ of\ 0.17$ mg/kg bw/day $for\ neoplatic\ effects\ in\ mice \div 10000$
$= 0.017$ µg/kg bw/day

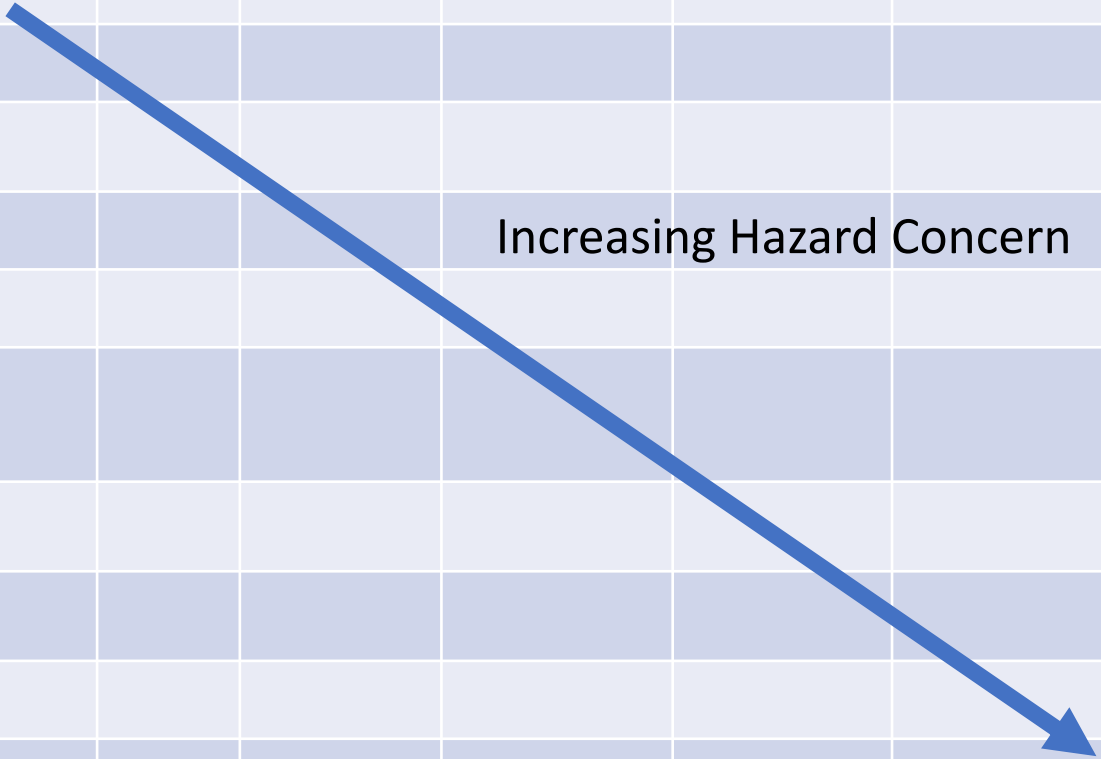
$$\frac{Exposure\ to\ acrylamide\ in\ all\ food\ (0.165\ \mu g/kg\ bw/day)}{(indicative)\ HBGV\ (0.017 \mu g/kg\ bw/day)} \times 100 = \boldsymbol{E_{Tot\%HBGV}\ (971.4\%)}$$

Highest score = 60



Calculation of Toxicity Score

Nature of hazard (EXPERT JUDGEMENT)		(indicative) Health-based guidance value (HBGV) (mg/kg bw/day)					
		>10	>0.1–10	>0.001–0.1	>0.00001-0.001	>0.0000001–0.00001	≤0.0000001
Score	**Critical effect**	**10**	**20**	**30**	**40**	**50**	**60**
0	No reported adverse effects						
10	Reversible pharmacological adverse effects (e.g. increased blood pressure or heart rate). Microbiological effects (e.g. disturbance of the gut flora).						
20	Reversible organ toxicity (e.g. kidney or liver damage)						
30	Irritation. Evidence of allergic reactions in animals.						
40	Carcinogenicity by mechanisms not relevant to humans. Irreversible organ toxicity/foetotoxity/embryotoxicity/ immunotoxicological effects (e.g. sensitisation).						
50	Mutagenicity. Irreversible neurotoxic effects. Irreversible reprotoxic effects.						
	Evidence of carcinogenicity in humans or carcinogenic by mechanisms relevant to humans						
60	Genotoxic carcinogen (known to cause cancer by direct effects).						
150	Anaphylactants and acute toxicants.						



 (Source: Clare and Price, 2012; Hanlon et al. 2015)

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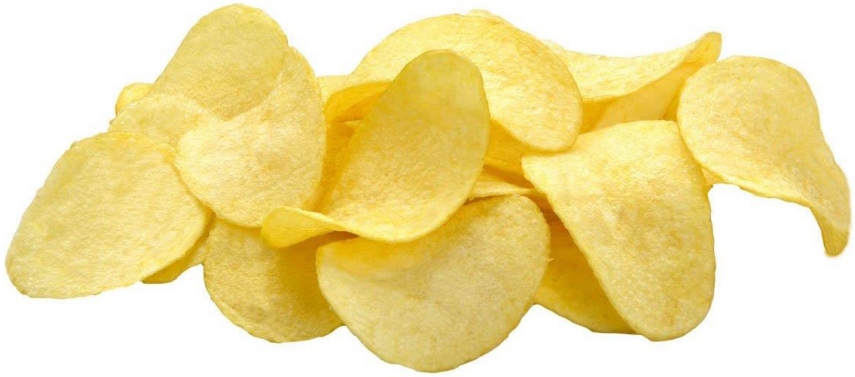
0	No reported adverse effects						
10	Reversible pharmacological adverse effects (e.g. increased blood pressure or heart rate). Microbiological effects (e.g. disturbance of the gut flora).						
20	Reversible organ toxicity (e.g. kidney or liver damage)						
30	Irritation. Evidence of allergic reactions in animals.						
40	Carcinogenicity by mechanisms not relevant to humans. Irreversible organ toxicity/foetotoxity/embryotoxicity/ immunotoxicological effects (e.g. sensitisation).				Acrylamide score (40+40)=80		
50	Mutagenicity. Irreversible neurotoxic effects. Irreversible reprotoxic effects.						
	Evidence of carcinogenicity in humans or carcinogenic by mechanisms relevant to humans						
60	Genotoxic carcinogen (known to cause cancer by direct effects).						
150	Anaphylactants and acute toxicants.						

 (Source: Clare and Price, 2012; Hanlon et al. 2015)

Policy Flag – What Legislation Applies?

A. Legislative limit/monitoring recommendation	
Legislative limit	0.1
Monitoring recommendation	0.2
B. Safeguard measures/Increased import control frequency provisions	
Commission Implementing Regulation (EU) No 884/2014	0.01
Commission Regulation (EC) No 669/2009	
C. Emerging risk	
If applicable	0.001
Overall policy flag (A+B+C)	

Total Score – Acrylamide



Substance	Food	Exposure Score	Toxicity Score	Policy Flag	Total Score
Acrylamide	Crisps	120	80	0.2	9600.2

Pilot Study Results

Substance	Category name (TDS)	Group name (TDS)	Exposure Score Total	Toxicity Score Total	Policy Flag Total	Total Score
Aflatoxin B1	Fine bakery ware	Other cakes buns and pastries	120	120	0	14,400
	Pizza	Pizza tomato and cheese	120	120	0	14,400
	Fine bakery ware	Plain biscuits	120	120	0	14,400
	Fine bakery ware	Chocolate biscuits	120	120	0	14,400
Acrylamide	Snacks	Crisps	120	80	0.2	9,600.2
	Fine bakery ware	Plain biscuits	120	80	0.2	9,600.2
	Potatoes	Chips, homemade from frozen pre-prepared	120	80	0.2	9,600.2
	Breakfast cereals	Wheat-type cereals	102	80	0.2	8,160.2
Cadmium	Milk and cream	Low-fat, skimmed and fortified milks	27	90	0	2,430
	Fresh vegetables	Lettuce	24	90	0.3	2,160.3
	Potatoes	Potatoes without skin (boiled)	24	90	0.3	2,160.3
	Fresh vegetables	Carrots (boiled)	24	90	0.3	2,160.3
Fumonisin B1	Breakfast cereals	Cornflakes	1	50	0.1	50.1
	Wheat flour	White flour	1	50	0	50
	Fine bakery ware	Other cakes buns and pastries	1	50	0	50
	Herbs and spices	Herbs	1	50	0	50

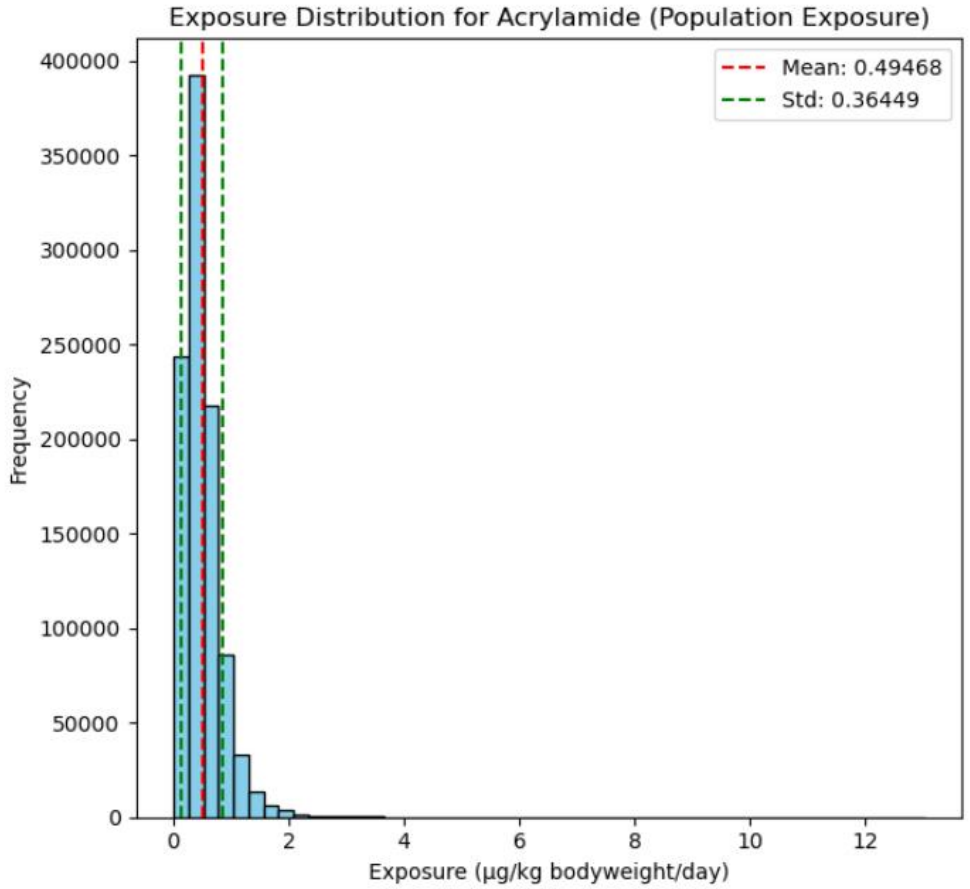
Updates to Risk Ranking Model

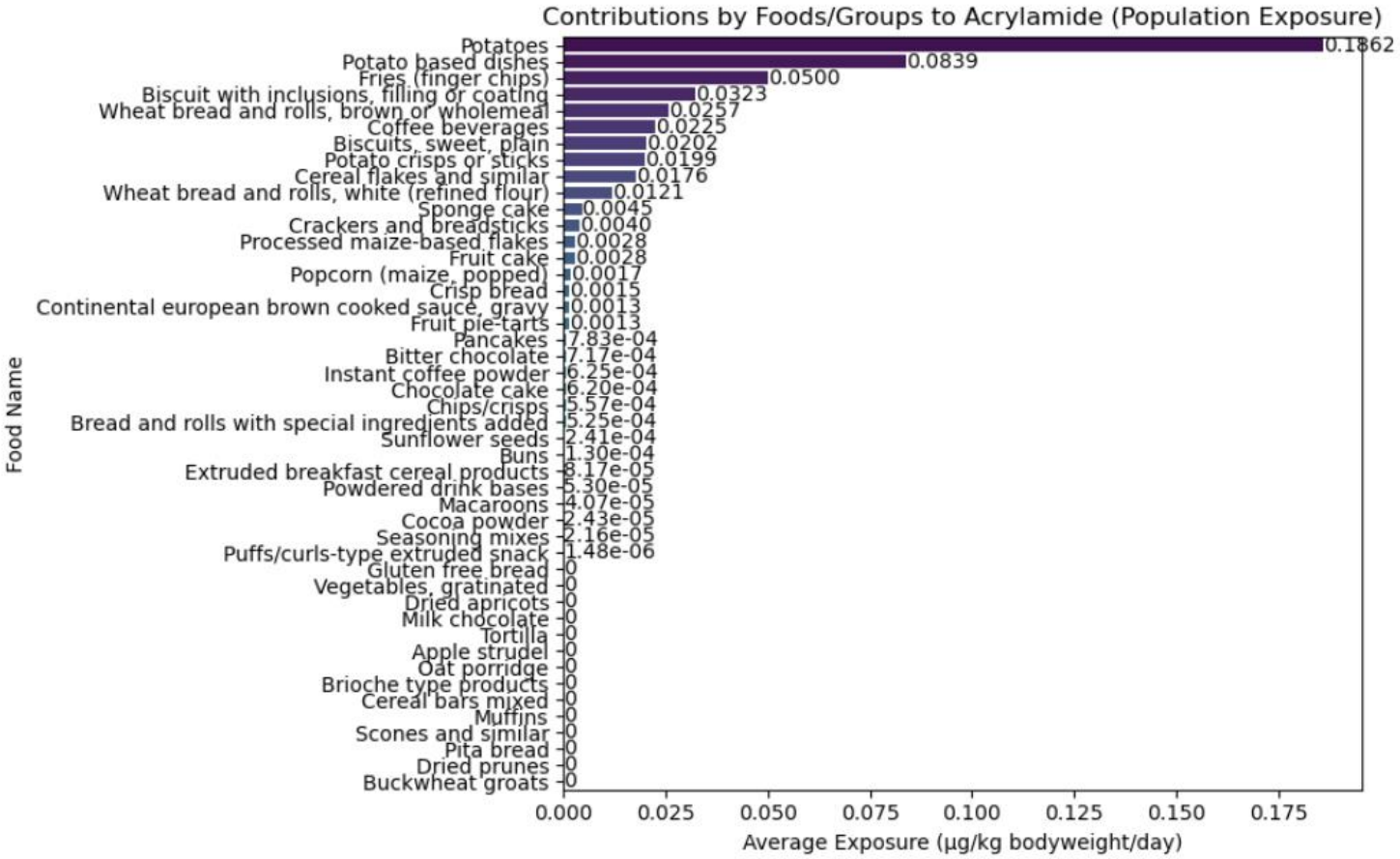
- Data Harmonisation
  - Multiple Foodex2 matching strategies
- Exposure Estimation with Monte Carlo Simulations
- Aggregation by Foodex2 Level/Food Groups
- Inclusion of Food Processing using RPC model
- Incorporation of Open Food Tox for HBGVs

Exposure Dashboard Example

Select Level: Population Exposure

Select Group: All





Risk Ranking for National Chemical Sampling Plan

L3 Code	L3 Name	L4 Code	L4 Name	L5 Code	L5 Name	Mean Exposure (µg/kg bw/day)	E%HBGV (%)	Food Score	Total Score	Exposure Score	Toxicity Score	Policy Flag	Risk Ranking Score
A009V	Biscuits					0.052	306.7	60	60	120	80	0.3	9600.3
		A009X	Biscuits, sweet, plain			0.02	118.6	60	60	120	80	0	9600
		A00AE	Biscuit with inclusions, filling or cc			0.032	188	60	60	120	80	0	9600
A043V	Savoury sauces					0.0013	7.8	3	60	63	80	0	5040
		A043Z	Continental european brown coo			0.0013	7.8	3	60	63	80	0	5040
A03VC	Dishes excluding pasta or rice dishes, sandwiches and					0.13	791.8	60	60	120	80	0	9600
		A03VD	Potato based dishes			0.13	791.8	60	60	120	80	0	9600
				A011N	Fries (finger	0.05	296.2	60	60	120	80	0.1	9600.1
A0EQY	Chips, crisps, fries and dough-based analogues					0.02	120.3	60	60	120	80	0	9600
		A0EQX	Chips/crisps			0.02	120.2	60	60	120	80	0	9600
				A011L	Potato crisp:	0.02	117	60	60	120	80	0.1	9600.1
		A0EQV	Puffs/curls-type extruded snack			0.0000015	0	0	60	60	80	0	4800
A0BY0	Leavened bread and similar					0.038	225	60	60	120	80	0	9600
		A004X	Wheat bread and rolls			0.038	221.9	60	60	120	80	0.1	9600.1
				A004Y	Wheat brea	0.012	70.8	42	60	102	80	0	8160
				A005E	Wheat brea	0.026	151	60	60	120	80	0	9600
		A005K	Bread and rolls with special ingre			0.00053	3.1	0	60	60	80	0	4800

Next Steps

- Full Incorporation of Open Food Tox and Expansion of Food Processing Factors
- Inclusion of Policy Flags
- Exposure Modelling:
  - Validation
  - Markov chain Monte Carlo?
- Non-Linear Scoring Methods
- Dashboard Development
- Merging with National Chemical Sampling Plan

Thank you for your attention

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