

# Maximum levels for DON in cereals and cereal products: Update on Codex and Health Canada activities

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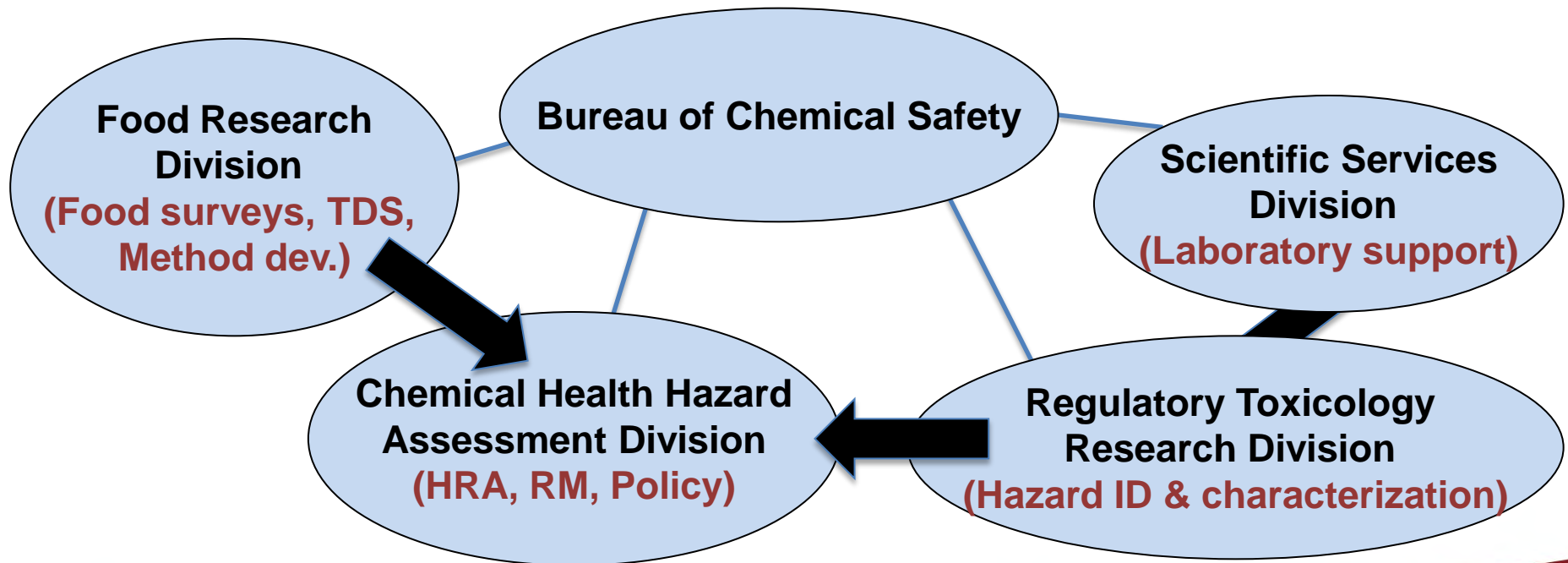


# Presentation Outline

- Canadian federal organizations involved in mycotoxin monitoring, research and regulation
- International Involvement relating to food safety standards
- Considerations in setting maximum levels (MLs) for contaminants in food
- Codex DON MLs (2015)
- Canadian regulations governing chemical contaminants in food
- Health Canada DON ML review

# Bureau of Chemical Safety, Food Directorate, Health Canada

- Sets policies and standards, conducts risk assessments, research, and evaluation activities related to chemicals in foods offered for sale in Canada
- 4 main Divisions:





## Other Federal Organisations

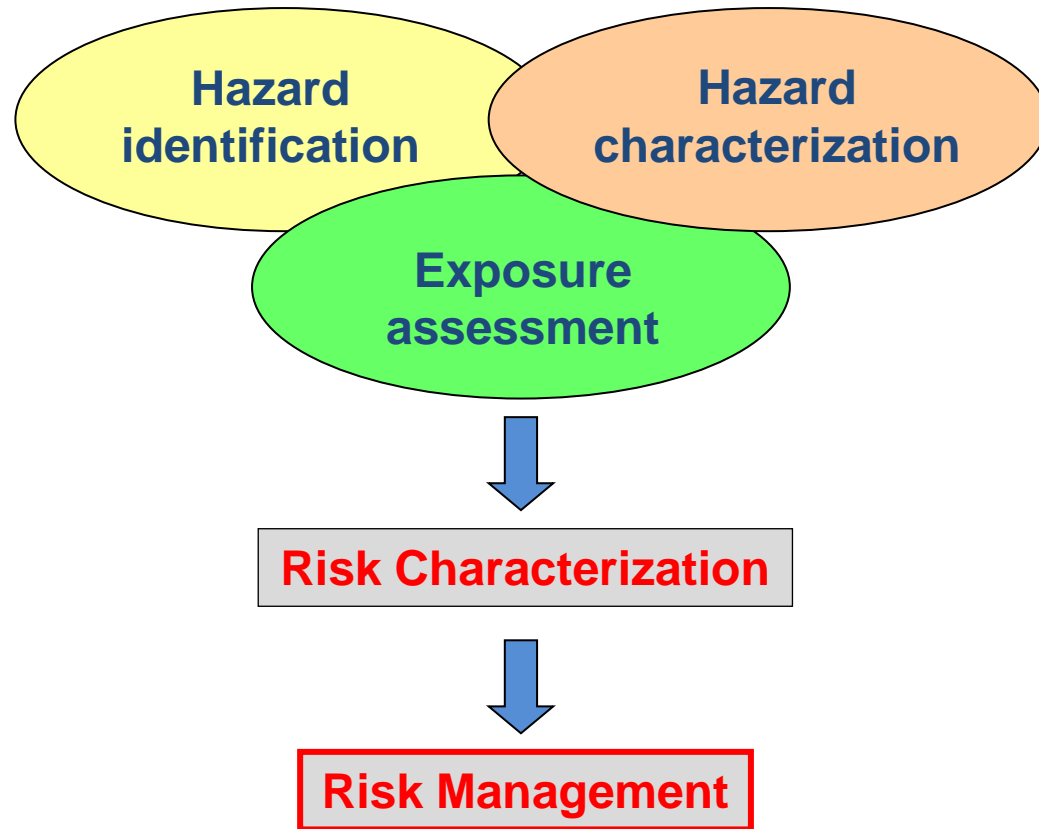
- **Canadian Food Inspection Agency**
  - Enforces MLs established by Health Canada
  - Federal agency that conducts compliance monitoring of chemical contaminants in foods sold in Canada
  - Also has a surveillance program
- **Canadian Grain Commission**
  - Establishes and maintains standards of quality for Canadian grain; administers and enforces *Canada Grain Act* and *Canada Grain Regulations*
  - Conducts research relating to the occurrence of fungi and associated mycotoxins in raw and processed grain
  - Assesses Canadian grain for compliance with domestic and international mycotoxin standards
- **Agriculture and Agri-Food Canada**
  - Conducts research relating to mycotoxins; e.g. crop genetic enhancement and genomics; mycotoxin analysis laboratory

## International Involvement

- Health Canada is an active participant in various international committees relating to food safety
- **Joint FAO/WHO Expert Committee on Food Additives (JECFA)**
  - hazard characterization and risk assessment of contaminants in food
- **Codex Committee on Contaminants in Food (CCCF)**
  - develops and proposes international food safety standards and codes of practice (CoPs) for adoption by the Codex Alimentarius Commission (CAC)
- **International Food Chemical Safety Liaison Group (IFCSLG)**
  - forum for government organizations involved in the risk assessment, risk management, and/or communication of food chemical safety to discuss and collaborate on issues of mutual interest

# Considerations in Setting MLs for Contaminants in Food

- Health Canada employs the risk analysis framework consistent with that employed by other international regulatory organizations



## Contaminant MLs - Codex Considerations

- Foods that are important in international trade
- Contribution of the food to total dietary exposure
- Science-based; health risk assessment conducted
- Protective of human health
- As Low As Reasonably Achievable (ALARA principle)
- Impact on trade
- Impact on food quality and/or food security

## Codex DON MLs

- Codex Committee on Contaminants in Food (CCCCF) forwarded DON MLs to the CAC for adoption in 2015

Commodity/Product Name	Maximum Level (mg/kg) (ppm)	Notes
Cereal-based foods for infants and young children (dry matter basis)	0.2	All cereal-based foods intended for infants (up to 12 months) and young children (12 to 36 months)
Flour, meal, semolina and flakes derived from wheat, maize or barley	1.0	
Cereal grains (wheat, maize and barley) destined for further processing	2.0	“Destined for further processing” means to undergo an additional processing/treatment that has proven to reduce levels of DON before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Codex members may define the processes that have been shown to reduce levels



## Codex Supporting Documents - DON MLs

- DON sampling plan and performance criteria for methods of analysis
  - endorsed by the Codex Committee on Methods of Analysis and Sampling (CCMAS)
  - HC scientists actively involved in CCMAS
- *Code of Practice (CoP) for the Prevention and Reduction of Mycotoxin Contamination in Cereals*
  - Annex 4: trichothecenes producing *Fusarium spp.*
  - Focus on good agricultural and good manufacturing practices (GAP, GMP)
- JECFA (2010) toxicological reference values for DON and its acetylated derivatives
  - group PMTDI (chronic): 1 µg/kg bw per day
  - group ARfD (acute): 8 µg/kg bw per day

## Contaminant MLs – Health Canada Considerations

- Generally considers assessments conducted by JECFA and MLs and CoPs adopted by the CAC for their applicability in Canada
  - Consideration of characteristics unique to Canada that result in occurrence, exposure, etc. that differ from those internationally
- Considers MLs of Canada's primary trading partners and how Canadian MLs may impact trade with Canada's primary trading partners
- MLs are one of several measures that can be applied to mitigate the potential risk of adverse human health effects from exposure to a particular chemical contaminant
- Other RM approaches: product recalls, consumption advice, further monitoring and corrective actions at the farm or processing and manufacturing levels

# Modernization of the Canadian Regulatory Framework

- Modernized federal regulatory framework for chemical contaminants in food
  - *Incorporation by Reference* (IbR)
- IbR allows a document/list not in regulations to be made part of regulations
  - IbR documents can be more easily and effectively maintained
  - Some IbR'd documents are managed by Health Canada
- Regulatory MLs in Division 15 and all contents of B.01.046, and B.01.047 are consolidated in an incorporated list (effective May 4, 2016):
  - *List of Contaminants and Other Adulterating Substances in Foods*
  - IbR into section B.15.001, Division 15, *Food and Drug Regulations (FDR)*
- Modernized regulatory framework will enable regulatory MLs to be more readily updated and new MLs established, as required, enabling Health Canada to respond in a timely fashion to changing scientific developments

## Consolidation of Lists of MLs

- Other MLs historically maintained on Health Canada's website:
  - *List of Maximum Levels for Various Chemical Contaminants in Food*
    - Presently houses MLs for DON in soft wheat (*under review*)
- Objective is to consolidate all MLs into the single regulatory list that is incorporated by reference into the *FDR*
- Consolidation will involve a systematic review of existing MLs that are outside of the incorporated list
- Consolidation will take place over time and will involve public and stakeholder consultation

# Canadian Regulatory Framework for Chemical Contaminants

- MLs are established or updated based on the most up-to-date scientific information available and undergo public consultation prior to adoption
- The adulteration provisions and MLs in the incorporated list are regulations that are enforceable by the CFIA
- The MLs in the historically web-posted list are enforceable by the CFIA under the provisions in Part I, Section 4(1) of the *Food and Drugs Act*:

No person shall an article of food that:

- (a) has in or on it any poisonous or harmful substance;**
- (b) is unfit for human consumption;
- (c) consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance;
- (d) is adulterated;
- (e) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions

## Existing Canadian MLs for DON in Soft Wheat

- Uncleaned soft wheat (developed in 1980s; presently under review)
  - 2 mg/kg for use in staple foods
  - 1 mg/kg for use in infant foods
- At the time, DON was mainly found in soft wheat; concentrations in hard wheat were much lower and an ML was not considered necessary
- The DON MLs for soft wheat are not considered reflective of the contemporary Canadian situation
- Elevated or unusual DON concentrations are assessed by Health Canada on a case-by-case basis

## Health Canada DON ML Review

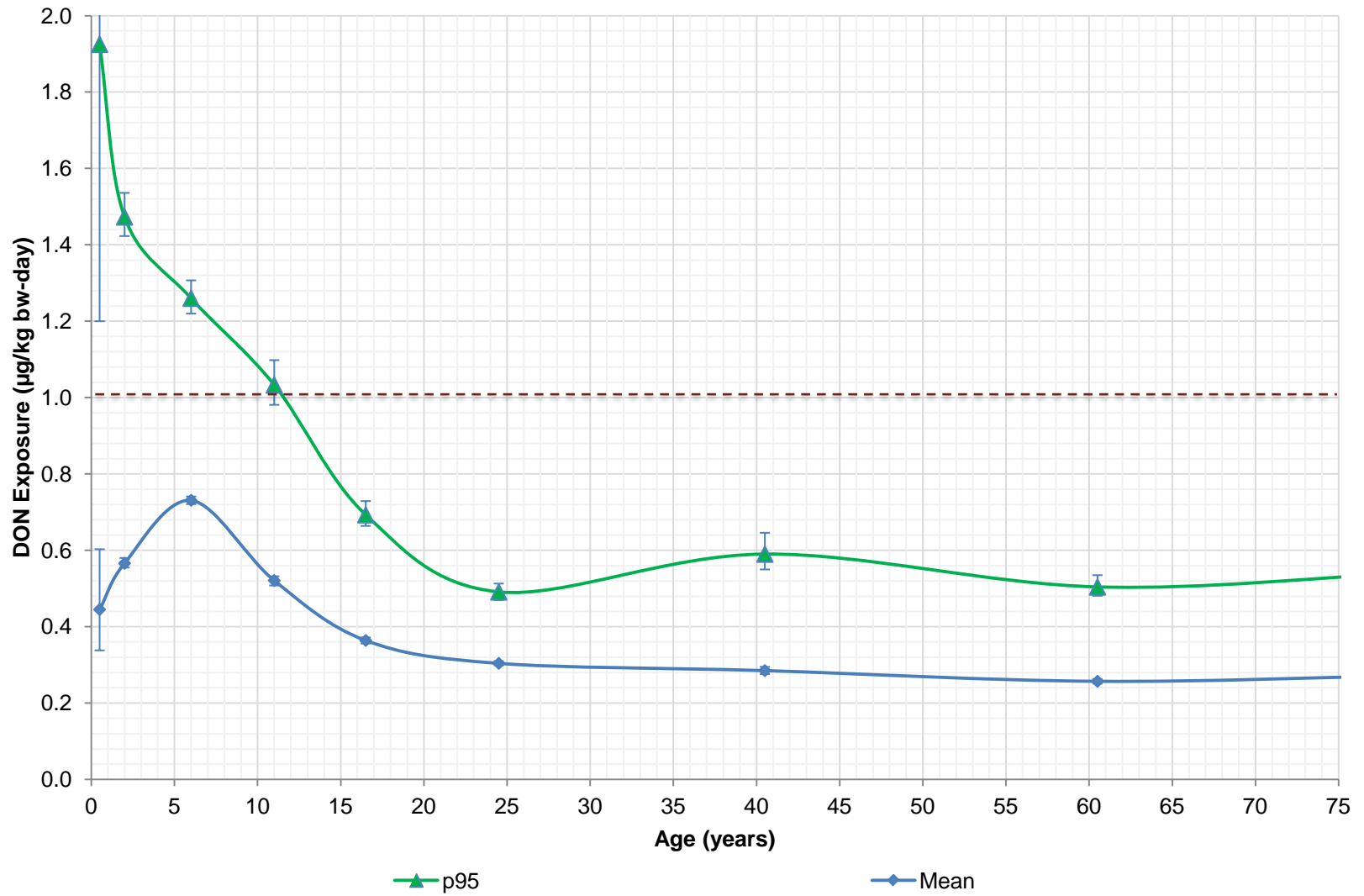
- Reviewed JECFA's hazard characterization for DON
  - Supports the PMTDI (chronic) of 1 µg/kg bw per day
- Compiled 5 years (2009-2014) of CFIA monitoring data for DON in cereal-based foods and food ingredients sold in Canada
- Acetylated DON compounds (3-AcDON or 15-AcDON) not included – very low prevalence
  - Canadian Grain Commission (Tittlemier et al. 2013): export monitoring > 8000 samples; < 1% positive detections of either 3-AcDON or 15-AcDON
  - CFIA multi-mycotoxin surveys (2012-15): semi-processed and finished foods ~ 2400 samples; 0.2% positive detections
  - detectable levels were found only in raw or semi-processed wheat, corn, rye, barley, grain peas, and canola; no positive detections in finished foods

# Health Canada DON ML Review

- Completed a probabilistic dietary exposure assessment
- 5 years of DON occurrence data (CFIA, 2009-2014)
- Consumption data from the Canadian Community Health Survey (CCHS), Cycle 2.2 – Nutrition (Statistics Canada, 2004)
  - 24-hour recall survey ~ 30,000 individuals throughout Canada
  - Second survey, non-consecutive day, 1/3 of respondents
    - used to adjust for within-person variability in food consumption and obtain best estimates of long term or chronic exposure



# Dietary Exposure to DON in Canada



# Contribution of foods to overall dietary exposure

Age Group	Food Group	% Contrib.	Total % Contrib.
Infants (< 1 yr)	Multigrain Infant Cereal	32.63	34.8
	Rice-based Infant Cereal	2.16	
	Whole Wheat Bread	15.96	28.2
	White Bread	12.26	
	Crackers	5.39	9.8
	Cookies	4.43	
	Oat-based Breakfast Cereal	2.56	
	Hot Oatmeal	1.53	5.4
	Multigrain Breakfast Cereal	1.27	
	All-Purpose Flour	4.53	4.5

Age Group	Food Category	Total % Contrib.
Toddlers (1-3 yrs)	Bread	36
	Pasta	24
	Breakfast cereal	14
	Flour	13
	Crackers, cookies, waffles, pancakes, mixes	13
	Infant Cereal	0.4

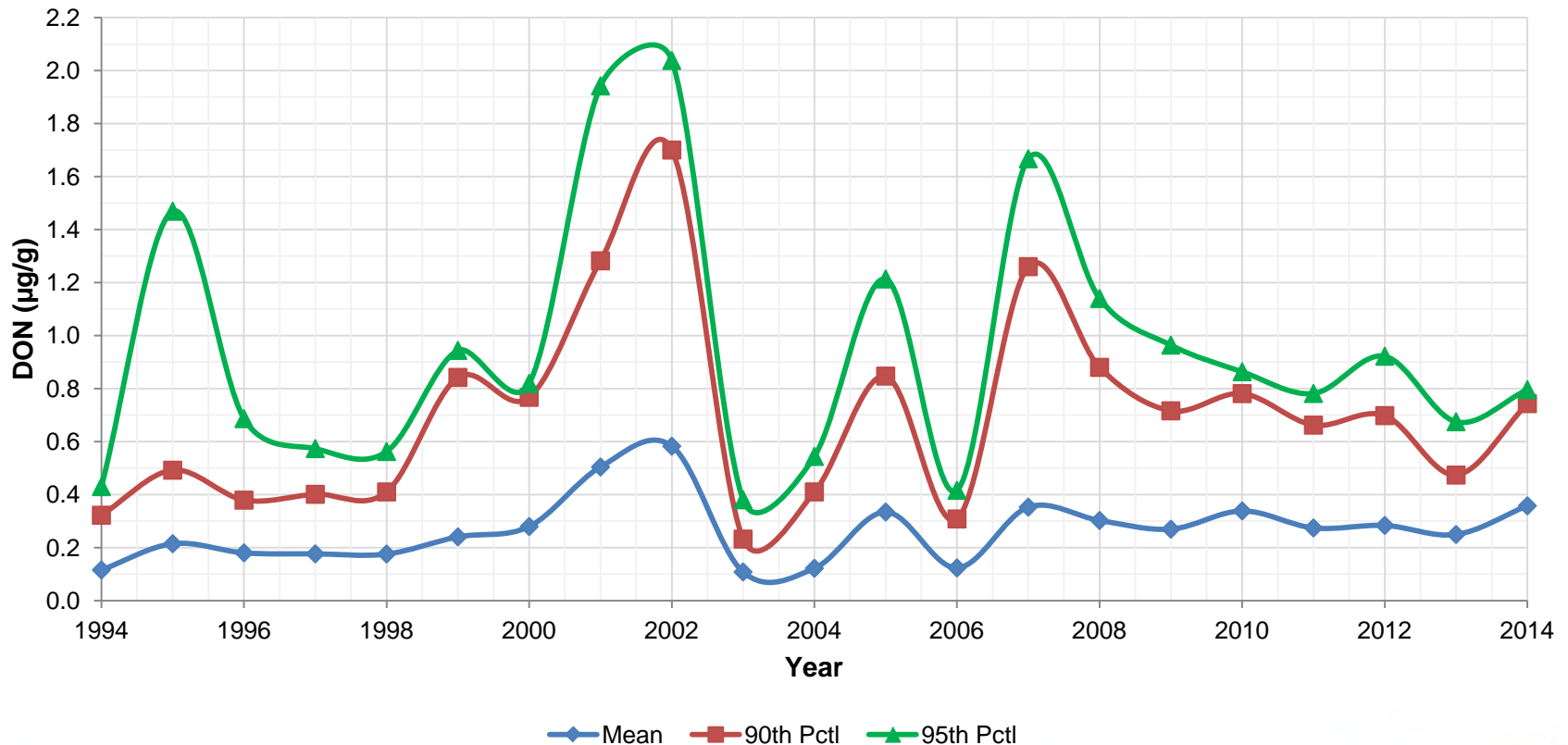
- Wheat products contribute the large majority of exposure in all age groups
- Oats is the next largest contributor (< 5%)
- Maize, barley, rye, other cereal grains negligible contribution

# Health Canada DON ML Review - Next Steps

- Consider 'bad DON years'

## DON in Hard Wheat Grown in Canada: 1994-2014

*(Export data from the Canadian Grain Commission)*



## Health Canada DON ML Review - Next Steps

- Impact assessment of hypothetical DON MLs, including levels that correspond to the Codex MLs for cereal-based foods that are directly consumed or used directly as ingredients in finished foods
- Flour, meal, semolina and flakes derived from wheat, maize or barley (Codex ML: 1 ppm)
  - Wheat-based foods contribute the largest majority to DON exposure in Canada (80-90%), followed by oats (< 5%)
- Cereal-based foods for infants and young children (Codex ML: 0.2 ppm)
  - Health Canada expressed support at CCCF for ML of 0.5 ppm based on its achievability and health protection

# Health Canada Process for Regulatory Changes

- **Notice of Proposal (NoP)** – formal notification on proposed changes to the IbR'd list; 75-day comment period to allow feedback from stakeholders and the public
  - Posted on Health Canada's website
  - parallel World Trade Organization (WTO) notification
  - Prior to NoP being published, HC would typically have pre-consulted with other federal and provincial government departments and stakeholders
- **Notice of Modification (NoM)**
  - Web posted provided no new data are submitted that would alter the proposal and after comments adequately addressed
  - Notifies that a change has been made to the *List of Contaminants and Other Adulterating Substances in Foods*, which is IbR into the *FDR*
  - Coming into force dates typically immediate but can be considered on a case-by-case basis

# Stay Informed of Canadian Regulatory Changes

- **Chemical Contaminants e-Notice:** issued advice, regulatory and scientific developments relating to food contaminants in Canada

[http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/chem\\_e-notice-avis-eng.php](http://www.hc-sc.gc.ca/fn-an/securit/chem-chim/chem_e-notice-avis-eng.php)

## Conclusions

- HC develops health-based MLs for mycotoxins in foods for human consumption taking into consideration information from other government groups and stakeholders
- In 2015 Codex adopted MLs for DON in cereal grains and various cereal-derived foods
- HC scientists and evaluators participate in JECFA risk assessments and toxicological reviews
- HC participates in the CCCF's work to establish MLs and CoPs and CCMAS's work to develop sampling and analysis plans
  - Considers the outcomes of these committees for relevance in Canada

# Conclusions

- Health Canada's existing MLs for DON in soft wheat are under review
  - MLs for other food ingredients and finished foods being considered
  - Codex MLs are considered for relevance to Canada
  
- Revised MLs for DON in foods that are to be sold in Canada would be included in the *List of Contaminants and Other Adulterating Substances in Foods*, which is IbR into the *FDR*



# Questions?



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