

Dietary Exposure Calculations

Dr. Joe Boison

**Canadian Food Inspection Agency,
Saskatoon, Canada**

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Global Estimated Chronic Dietary Exposure (GECDE) Calculations

New approaches for estimating drug residues: GEADE and GECDE

- The general equation for both acute and chronic dietary exposure estimates is:

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

Global Estimated Chronic Dietary Exposure (GECDE)

The GECDE uses median residues combined with two different types of consumption data to estimate chronic dietary exposure.

- Firstly, the highest exposure at the 97.5th percentile of consumption is selected from all the foods relevant to exposure.
- Secondly, the mean dietary exposures from all the other relevant foods are then added to estimate total exposure.
- The mean dietary exposure is derived from the total population; in other words, non-consumers of the food are included in the mean calculation.

Global Estimated Chronic Dietary Exposure (GECDE)

Infants: Toddlers from 12 to 35 months; 36 months to 9 yrs

**GECDE = Highest exposure from one animal product +
Total mean exposure from all other products**

Children: from 2 up and including 6 yrs

Adolescents from 10 up to and including 17 yrs

Adults: from 18 yrs up to and including 64 yrs

Elderly: 65 up to and including 74 yrs

Food Consumption Data Bank for Chronic exposure General Popn

	General Population						
Food type	JECFA Model Diet	Mean Tpop (Highest GEMS /Food Cluster)	Highest Mean Tpop	Country (Age class)	Highest Mean value GEMS/ Food cluster	High Level chronic consumers	Country (Age class)
Beef and other bovines		47	63	Brazil	63	291	Brazil
All mammalian muscle	300	114	100	Australia	114	415	
Mammalian liver	100	-	2	France	2	237	Brazil
Mammalian	50	-	0.5	France	0.5	166	Czech Rep

INPUT DATA FOR EXPOSURE CALCULATIONS

The EDI is 20.9 µg/person per day, which represents 35% of the upper bound of the ADI.

NOAEL					
Safety factor					
ADI		1 µg.kg bw			
ADI (person)		60 µg.kg/60 kg bw			
ARfD		µg.kg bw			0.01
Body weight (adults)		60 kg			
Body weight (Children)		15 kg			
Body weight (infants)		5 kg			
Food	Median	95	M:T	median (corrected)	95 (corrected)
Muscle	5	62	0.69	7.6	89.6
Liver	29	241	0.36	80.6	670.6
Kidney	6	43	0.5	12.2	85.4
Fat	74	163	0.38	195.0	429.7

Tissue	Median concentration* (µg/kg)	Standard Food Basket (kg)	MR:TR ratio ¹	Daily intake (µg)
Muscle (Beef and other Bovines)	5.3	0.3	0.69	2.4
Liver (mammalian)	29.0	0.1	0.36	8.1
Kidney (mammalian)	6.1	0.05	0.50	0.6
Fat (mammalian)	74.1	0.05	0.38	9.8
TOTAL			EDI	20.9

* Median concentration at 120 days.

Chronic Dietary Calculation GECDE For General Population

Category	Type	Corrected Median residues	Food consumption on high chronic g/d	Food consumption mean chronic g/d	High chronic exposure µg/person/day	High chronic exposure µg/kg/day	mean Chronic exposure µg/person/day	mean Chronic exposure µg/kg/day	GECDE µg/person/day	GECDE µg/kg/day	%ADI	High exposure from all foods included in GECDE	Median	unit
Mammalian muscle	Beef and other Bovines	7.61	291	63	2.21	0.04	0.48	0.01	0.48	0.01	0.80	High exposure from all foods included in GECDE	24.38	µg/person/day
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter	195.01	125	14	24.38	0.41	2.73	0.05	24.38	0.41	40.6	Mean exposure from all foods included in GECDE	0.6	µg/person/day
Mammalian offal	Mammalian liver	80.61	237	2	19.11	0.32	0.16	0.00	0.16	0.00	0.27	GECDE	25.0	µg/person/day
Mammalian offal	Mammalian kidney	12.19	166	0.5	2.02	0.03	0.01	0.00	0.01	0.00	0.01	High Exposure /Mean BW kg bw	0.41	µg/kg bw/day
											0.4	Mean exposure /Mean BW kg bw	0.01	µg/kg bw/day
												GECDE/Mean BW kg bw	0.42	µg/kg bw/day
												%ADI	42%	

GECDE Calculation for Children

Category	Type	Corrected Median residues	Food consumption high chronic g/d	Food consumption mean chronic g/d	High chronic exposure $\mu\text{g}/\text{person}/\text{day}$	High chronic exposure $\mu\text{g}/\text{kg}/\text{day}$	mean Chronic exposure $\mu\text{g}/\text{person}/\text{day}$	mean Chronic exposure $\mu\text{g}/\text{kg}/\text{day}$	GECDE $\mu\text{g}/\text{person}/\text{day}$	GECDE $\mu\text{g}/\text{kg}/\text{day}$	%ADI	High exposure from all foods	Median	unit
Mammalian muscle	Beef and other Bovines	8	159	37	1.21	0.08	0.28	0.02	0.3	0.02	1.88	High exposure from all foods	8.30	$\mu\text{g}/\text{person}/\text{day}$
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter	195	29	1.7	5.66	0.38	0.33	0.02	0.3	0.02	2.21	Mean exposure from all foods	0.5	$\mu\text{g}/\text{person}/\text{day}$
Mammalian offal	Mammalian liver	81	103	3	8.30	0.55	0.24	0.02	8.3	0.55	55.35	GECDE	8.9	$\mu\text{g}/\text{person}/\text{day}$
Mammalian offal	Mammalian kidney	12	150	0.5	1.83	0.12	0.01	0.00	0.0	0.00	0.04	High Exposure /Mean BW kg bw	0.55	$\mu\text{g}/\text{kg bw}/\text{day}$
												Mean exposure /Mean BW kg bw	0.04	$\mu\text{g}/\text{kg bw}/\text{day}$
												GECDE/Mean BW kg bw	0.59	$\mu\text{g}/\text{kg bw}/\text{day}$
												%ADI	59%	

GECDE for Infants

Type	Corrected Median residues	Food consumption high chronic g/d	Food Consumption mean chronic g/d	High chronic exposure µg/person /day	High chronic exposure µg/kg/day	mean Chronic exposure µg/person/day	mean Chronic exposure µg/kg/day	GECDE µg/pers on/day	GECDE µg/kg/day	%ADI	High exposure from all foods	Median	unit
Beef and other Bovines	8	68	2.5	0.52	0.10	0.02	0.00	0.0	0.00	0.38	High exposure from all foods	2.50	µg/person/d ay
Mammalian trimmed fat, skin and added fat excluding butter	195	0	0	0.00	0.00	0.00	0.00	0.0	0.00	0.00	Mean exposure from all foods	0.02	µg/person/d ay
All mammalian offal	81	31	0.1	2.50	0.50	0.01	0.00	2.5	0.50	49.98	GECDE	2.5	µg/person/d ay
					0.00						High Exposure /Mean BW kg bw	0.50	µg/kg bw/day
											Mean exposure /Mean BW kg bw	0.00	µg/kg bw/day
											GECDE/Mean BW kg bw	0.50	µg/kg bw/day
											%ADI	50%	

GECDE Report

Category	Type	Median concentration*	Mean consumption**	97.5 th consumption***	MR:TR	Exposure (µg/kg bw/day)		GECDE****	
		(µg/kg)	(whole population, g/d)	(consumers only, g/d)	ratio ¹	Mean	97.5 th	µg/kg bw/day	%ADI
General Population									
Mammalian muscle	Beef and other Bovines	5	63.0	291	0.69	0.01	0.04	0.01	0.8
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter	74	14.0	125	0.38	0.05	0.41	0.41	40.6
Mammalian offal	Mammalian liver	29	2.0	237	0.36	0.00	0.32	0.00	0.3
Mammalian offal	Mammalian kidney	6	0.5	166	0.50	0.00	0.03	0.00	0.0
TOTAL						0.0	0.4	0.4	42
Children									
Mammalian muscle	Beef and other Bovines	5	37.0	159	0.69	0.02	0.08	0.02	1.9
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter	74	1.7	29	0.38	0.02	0.38	0.02	2.2
Mammalian offal	Mammalian liver	29	3.0	103	0.36	0.02	0.55	0.55	55.4
Mammalian offal	Mammalian kidney	6	0.5	150	0.50	0.00	0.12	0.00	0.0
TOTAL						0.0	0.6	0.6	59

Global Estimated Acute Dietary Exposure (GEADE) Calculations

ARfD

It is an “estimate of the amount of a substance in food or drinking water, expressed on a bodyweight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all the known facts at the time of the evaluation” (FAO, 1967)

Acute dietary exposure assessments

- Therefore, in a deterministic acute exposure assessment, a high consumption amount (typically the 97.5th percentile) is multiplied by a high chemical concentration amount, where a distribution of chemical concentrations is known.
- In some circumstances, a factor is also included to account for variability in the chemical concentration data set arising from lack of homogeneity in foods or due to small data sets being use.
- Although acute dietary exposure assessments generally focus on exposure from a single food, exposure from a range of dietary sources can be taken into account if this is relevant.

$$\text{GEADE} = \frac{97.5^{\text{th}} \text{ percentile food consumption (1 person day)} \times \text{High residue tissue}}{\text{Body weight (kg)}}$$

Dietary Consumption Factors

- The basic dietary intake factors (food basket items) which are used in the dietary intake calculations based on a standard food basket (EDI or TMDI) are:
 - 300 g of muscle
 - 100 g of liver
 - 50 g of kidney
 - 50 g of tissue fat
 - 100 g of eggs
 - 1500 g of milk
 - 50 g of honey
- The intake factors for tissues, milk and eggs were first used by the 34th JECFA, based on dietary survey and food balanced sheet information, and the approach was confirmed

Food Consumption data for estimating acute exposure to veterinary drugs

Food Type as raw material	97.5 th percentile, GP, 1 day (g/per/day)	97.5 th percentile, GP, 1 day (g/kg bw/day)	97.5 th percentile, CHN, 1 day (g/pers/day)	97.5 th percentile CHN 1 day (g/kg bw/day)
	Mammalian muscle			
Beef and other bovines	514 (Australia)	10.7 (Bulgaria)	337 (Germany)	12 (Bulgaria)
Pork and other porcines	704 (Brazil)	13.3 (Poland)	312 (Poland)	22.0 (Belgium)
Sheep and other ovines	1000 (Slovakia)	11.1 (Slovakia)	311 (Denmark)	9.7 (Spain)

Food Consumption data for estimating acute exposure to veterinary drugs

Food Type as raw material	97.5 th percentile, GP, 1 day (g/per/day)	97.5 th percentile, GP, 1 day (g/kg bw/day)	97.5 th percentile, CHN, 1 day (g/pers/day)	97.5 th percentile CHN 1 day (g/kg bw/day)
	Mammalian muscle			
Goat and other caprines	479 (Brazil)	10.6 (Greece)	200 (Greece)	10.6 (Greece)
Horses and other equines	400 (France)	11.4 (France)	210 (Belgium)	15.0 (Belgium)
Rabbit	780 (Poland)	25.4 (Italy)	444 (Belgium)	25.4 (Italy)
All mammalian muscle	1000 (Slovakia)	25.4 (Italy)	337 (Germany)	25.4 (Italy)
Mammalian trimmed fat, skin & added fat	258 (China)	4.8 China)	73 (Poland)	2.6 (Poland)

Food Consumption data for estimating acute exposure to veterinary drugs

Food Type as raw material	97.5 th percentile, GP, 1 day (g/per/day)	97.5 th percentile, GP, 1 day (g/kg bw/day)	97.5 th percentile, CHN, 1 day (g/pers/day)	97.5 th percentile CHN 1 day (g/kg bw/day)
	Mammalian trimmed fat, skin and added fat			
Mammalian liver	439 (Ireland)	8.3 (Bulgaria)	165 (Italy)	9.1 (Thailand)
Mammalian Kidney	360 (France)	12.9 (France)	300 (Czech Republic)	12.4 (Greece)
Mammalian lung	330 (China)	5.7 (China)	150 (China)	9.4 (China)
All mammalian offal	1000 (Poland)	16.3 (Italy)	300 (Czech Rep)	12.5 (Belgium)

Consumption Data for Chronic Assessment

Category	Type	Mean total population	Highest Mean total population	Highest mean value between Clusters	High-level chronic (adults)	Mean children	High-level chronic (children)	Mean Infants	High-level chronic (infants)
Mammalian muscle	Beef and other Bovines	47	63	63	291	37	159	2.5	68
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter	14	4.4	14	125	1.7	29		
Mammalian offal	Mammalian liver		2	2	237	3	103	0.1	31
Mammalian offal	Mammalian kidney		0.5	0.5	166	0.5	150		
Mammalian offal	All mammalian offal	8	4	8	269	3	193	0.1	31

Consumption Data for GEADE Assessment

Category	Type	Code	Current model diet	Children			
				General, p 97.5, g/person/day	General, n, p 97.5, g/kg bw/day	Children, p 97.5, g/person/day	Children, p 97.5, g/kg bw/day
Mammalian muscle	Beef and other Bovines	MM0812		514	10.7	337	12
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter		50	258	4.8	73	2.6
Mammalian offal	Mammalian liver	MO 1281/1285	100	439	8.3	165	9.1
Mammalian offal	Mammalian kidney	MO 1280/1284	50	360	12.9	300	12.4

GEADE for the Total Population

Category	Type	Corrected 95 day	Consumption, p 97.5, g/person/ day	Consumption, p 97.5, g/kg bw/day	Acute exposure µg/person/day	Acute exposure µg/kg bw/day	#DIV/0!	GEADE (per person)	95 residue µg/kg	µg/pers on/day
Mammalian muscle	Beef and other Bovines	90	514	10.7	46	1	#DIV/0!	GEADE (per person)	294.4	µg/pers on/day
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter	430	258	4.8	110.9	2.1	#DIV/0!	GEADE (per Kg bw based on mean BW)	4.9	µg/pers on/day
Mammalian offal	Mammalian liver	671	439	8.3	294.4	5.6	#DIV/0!	GEADE (per kg bw)	5.6	µg/pers on/day
Mammalian offal	Mammalian kidney	85	360	12.9	30.7	1.1	#DIV/0!	%ArFD	#DIV/0!	%

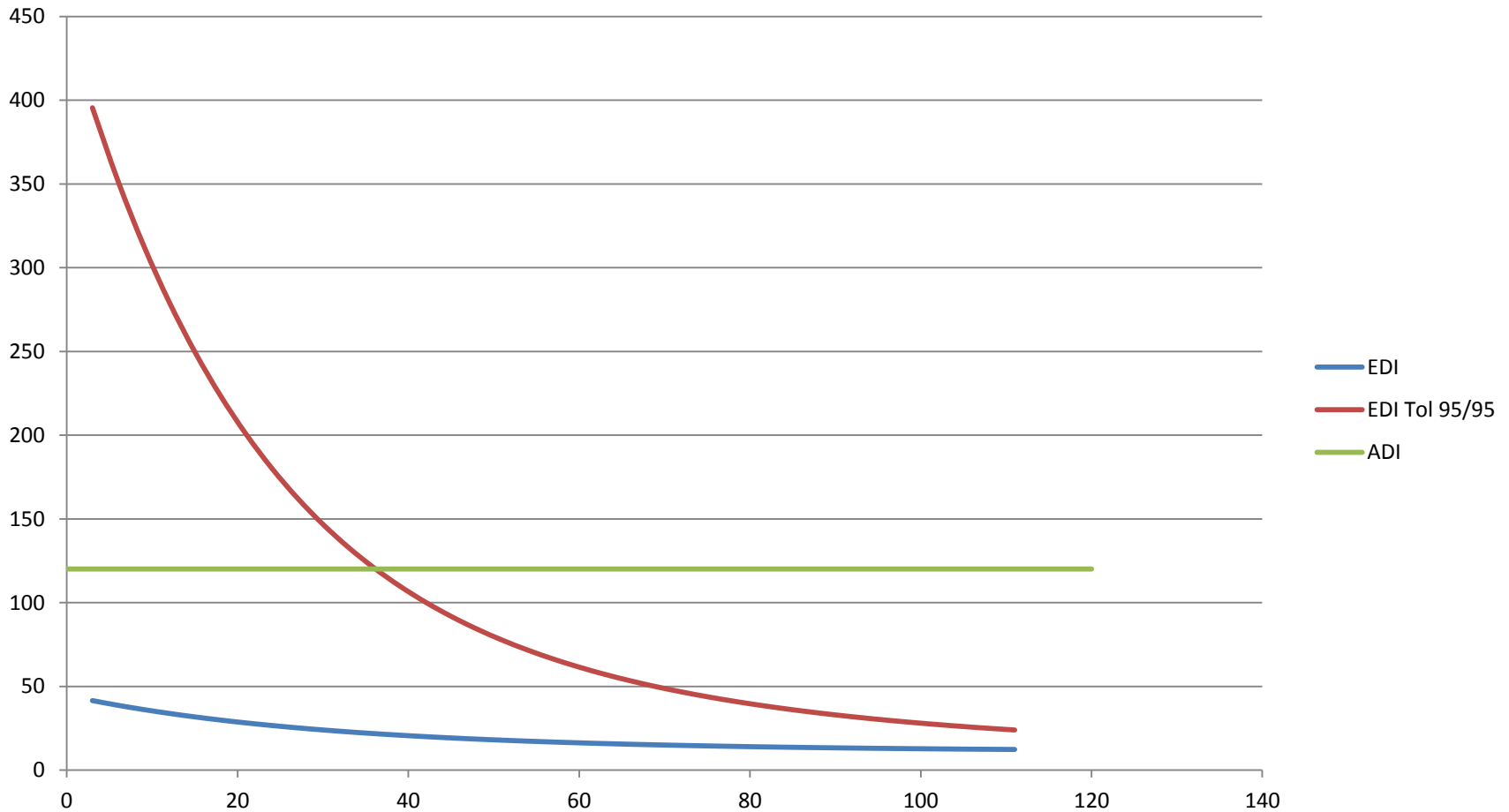
GEADE for Children

Type	Corrected 95	Consumption, p 97.5, g/person/day	Consumption, p 97.5, g/kg bw/day	Acute exposure µg/person/day	Acute exposure µg/kg bw/day	#DIV/0!	GEADE (per person)	95 residue µg/kg	µg/person/day
Beef and other Bovines	90	337	12	30.2	1.1	#DIV/0!	GEADE (per person)	110.6	µg/person/day
Mammalian trimmed fat, skin and added fat excluding butter	430	73	2.6	31.4	1.1	#DIV/0!	GEADE (per Kg bw based on mean BW)	7.4	µg/person/day
Mammalian liver	671	165	9.1	110.6	6.1	#DIV/0!	GEADE (per kg bw)	6.1	µg/person/day
Mammalian kidney	85	300	12.4	25.6	1.1	#DIV/0!	%ArFD	#DIV/0!	%

GEADE Report

Category	Type	95 th concentration*	97.5 th Consumption**	MR:TR	GEADE***	
		(µg/kg)	(1 Person-µg/kg bw/day)	ratio ¹	µg/kg bw/day	%ARfD
General Population						
Mammalian muscle	Beef and other Bovines	62	10.7	0.69	1	
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter	163	4.8	0.38	2.1	
Mammalian offal	Mammalian liver	241	8.3	0.36	5.6	
Mammalian offal	Mammalian kidney	43	12.9	0.50	1.1	
Children						
Mammalian muscle	Beef and other Bovines	62	12	0.69	1.1	
Mammalian trimmed fat, skin and added fat	Mammalian trimmed fat, skin and added fat excluding butter	163	2.6	0.38	1.1	
Mammalian offal	Mammalian liver	241	9.1	0.36	6.1	
Mammalian offal	Mammalian kidney	43	12.4	0.50	1.1	23

Graphical Comparison of the Exposure Data



Graphical Display for the Exposure Assessments

