
Exposure to Perchlorate and Anti-thyroid Agents in the Diet: A Comparative Analysis

RB Belzer,¹ RC Pleus,² GM Bruce,² and MK
Peterson²

¹ Regulatory Checkbook, Washington, DC

² Intertox, Seattle, WA

Background

- Perchlorate (ClO_4^-) has been discovered in drinking water supplies at numerous locations.
 - USEPA has proposed an oral reference dose (RfD) of 0.00003 mg/kg-day (1 ppb DWEL)
 - Derived from animal data
 - Based on potential adverse effects to the thyroid gland via iodide uptake inhibition (IUI) at the sodium iodide symporter
 - Includes a composite uncertainty factor of 300
 - Comparative exposure analysis provides a cross-check of the validity of USEPA's proposed RfD
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Logic Behind the Analysis

- Nitrates are well-known to inhibit iodide uptake
 - Perchlorate and nitrate can be compared by adjusting for their relative potencies
 - Scientific literature says perchlorate is 10 to 1,000 times as potent per unit of mass
 - Our best professional judgment: 300
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PER

Derivation

- Derived from Wyngaarten et al. 1953 study directly relevant to this issue
- Biphasic dose-response curve creates uncertainty
 - Best professional judgment of 300 more likely to be high than low
 - High values are conservative

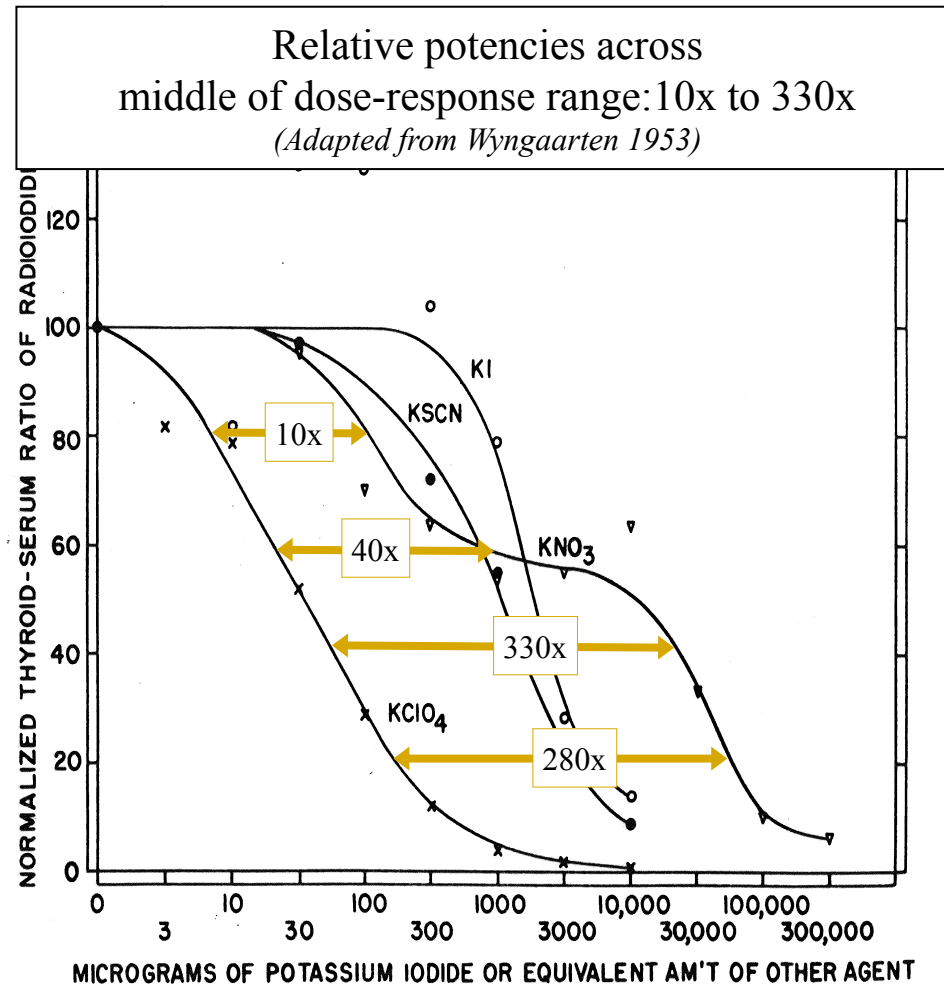


FIG. 1. The effects of iodide, thiocyanate, perchlorate, and nitrate ions upon the concentration gradient of I^{131} , when these agents were given in increasing doses, accompanying a constant dose of I^{131} . The ordinate is thyroid-serum I^{131} ratio, normalized to express the control gradient for each group as 100, and averaged for each agent. The abscissa is the dose of potassium iodide or equivalent dose of thiocyanate, perchlorate, or nitrate, plotted logarithmically.

Methods

- Convert RfD into a daily dose (0.002 mg/day)
 - Based on a 64.2 kg reference woman
 - Pregnant females are the presumed sensitive subpopulation
 - Calculate nitrate exposure from foods based on standard references for
 - Nitrate content
 - Serving sizes
 - Focus on single servings, not complete diet
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Perchlorate Equivalency Ratio (PER)

- Calculate ratio of nitrate to perchlorate exposure using Perchlorate Equivalency Ratios (PERs)
 - $PER = 10 \rightarrow$ perchlorate is 10 times as potent
 - $PER = 300 \rightarrow$ perchlorate is 300 times as potent
 - $PER = 1,000 \rightarrow$ perchlorate is 1,000 times as potent
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An Additional Comparison

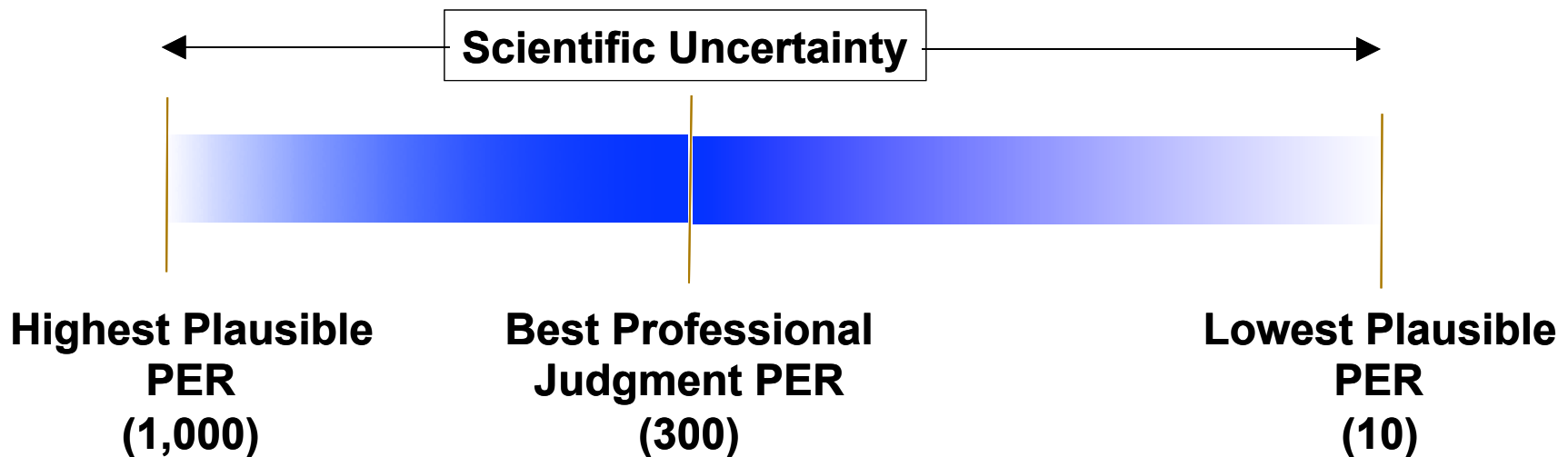
- USEPA's Maximum Contaminant Level (MCL) for nitrate is 10 ppm (10,000 ppb)
 - Based on methemoglobinemia (“blue baby” syndrome)
 - Lowest PER implied by nitrate MCL is 10,000
 - USEPA says methemoglobinemia is the most sensitive health endpoint
 - Therefore, IUI must not occur at levels below 10,000 ppb
 - Why is this relevant?
 - Perchlorate risk assessment may imply that nitrate causes significant thyroid risk below 10 ppm
 - If true, then nitrate MCL is not protective
 - If false, then perchlorate risk assessment overstates risk from low-level perchlorate exposure
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Scenarios Illustrated

- Highest Plausible PER Scenario (1,000)
 - Best Professional Judgment PER Scenario (300)
 - Lowest Plausible PER Scenario (10)
 - Lowest PER implied by nitrate MCL (10,000)
 - Illustrated later with hash marks
 - Outside zone of scientific plausibility
 - Implied by USEPA risk assessment and pharmacology of perchlorate and nitrate
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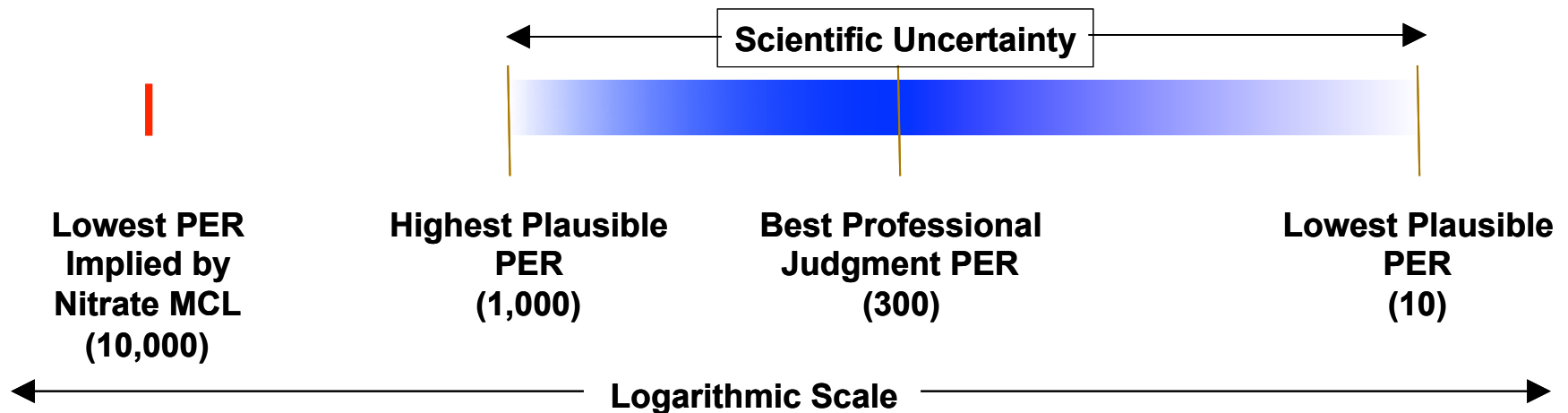
How to Interpret the Stripe Graphs

- Within foods, perchlorate potency increases to the left
- Across foods, nitrate levels increase to the right
- Each stripe captures full PER range
 - Illustrates scientific uncertainty
 - Darkest at Best Professional Judgment PER Scenario (300)



How to Interpret Stripe Graphs with Red “Hash Marks”

- Shows lowest possible PER derived from nitrate MCL (10,000)
- Provides robustness check across drinking water standards



Perchlorate RfD Equivalents in Dairy and Processed Meats

- Milk contains nitrates from pasture
 - Processed meats contain nitrates as food additives
 - Some people are concerned about added nitrates because of the formation of nitrosamines, a suspected carcinogen
 - Few are probably aware of nitrates' anti-thyroid properties
 - All calculations that follow are per serving of food and do not take into account a complete diet
 - Dietary analysis would show much greater nitrate intake
 - Perchlorate exposure is based on 2 liters of drinking water per day
 - Exposures are additive
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Sequence for the Comparative Exposure Analysis

■ Scenarios

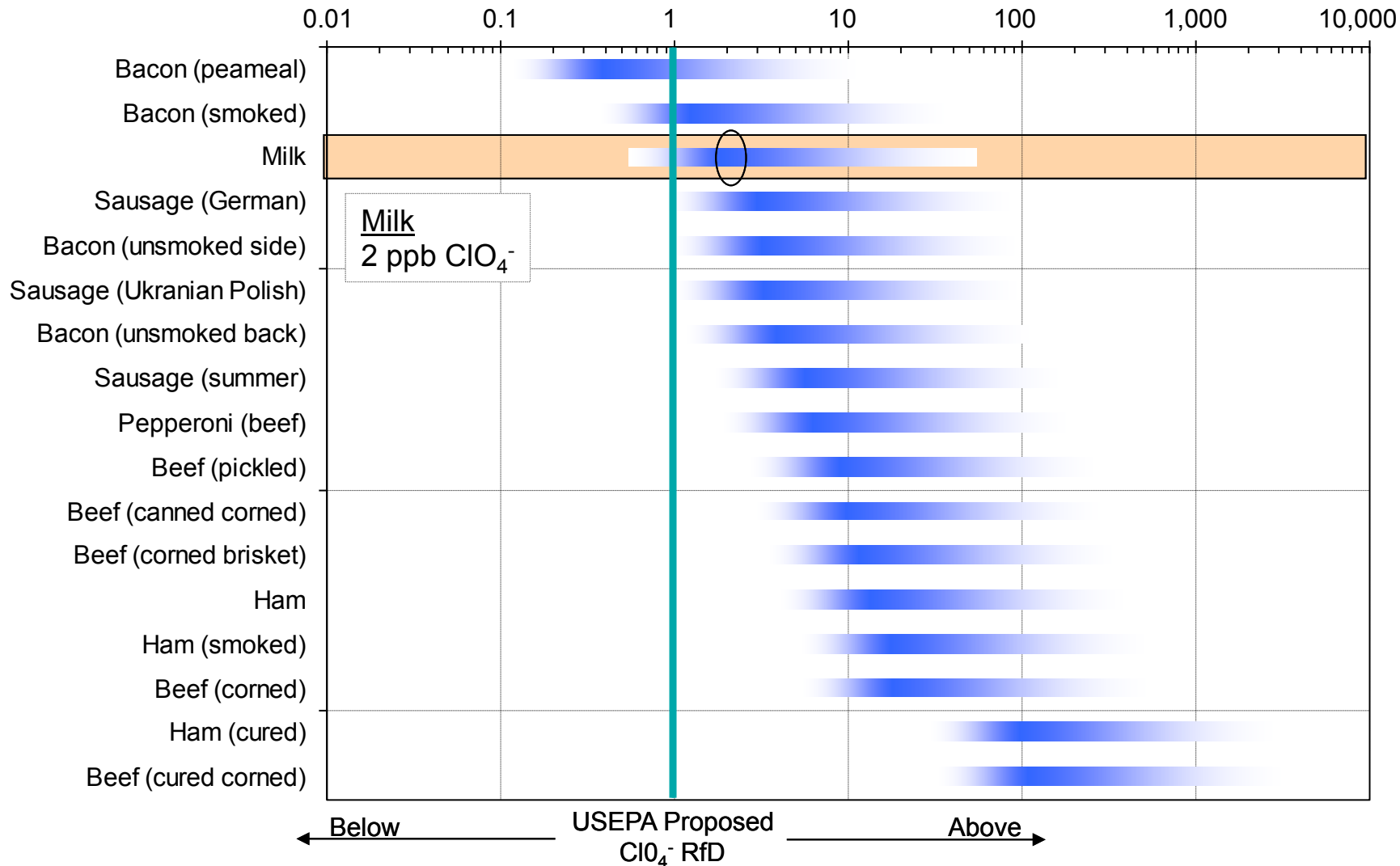
- Best Professional Judgment (300)
- Highest Scientifically Plausible PER (1,000)
- Lowest PER Implied by Nitrate MCL (10,000)

■ Alternative Presentations

- IUI per serving expressed in ppb perchlorate equivalent in drinking water
 - Maximum “safe” servings to stay below same exposure as USEPA proposed perchlorate RfD
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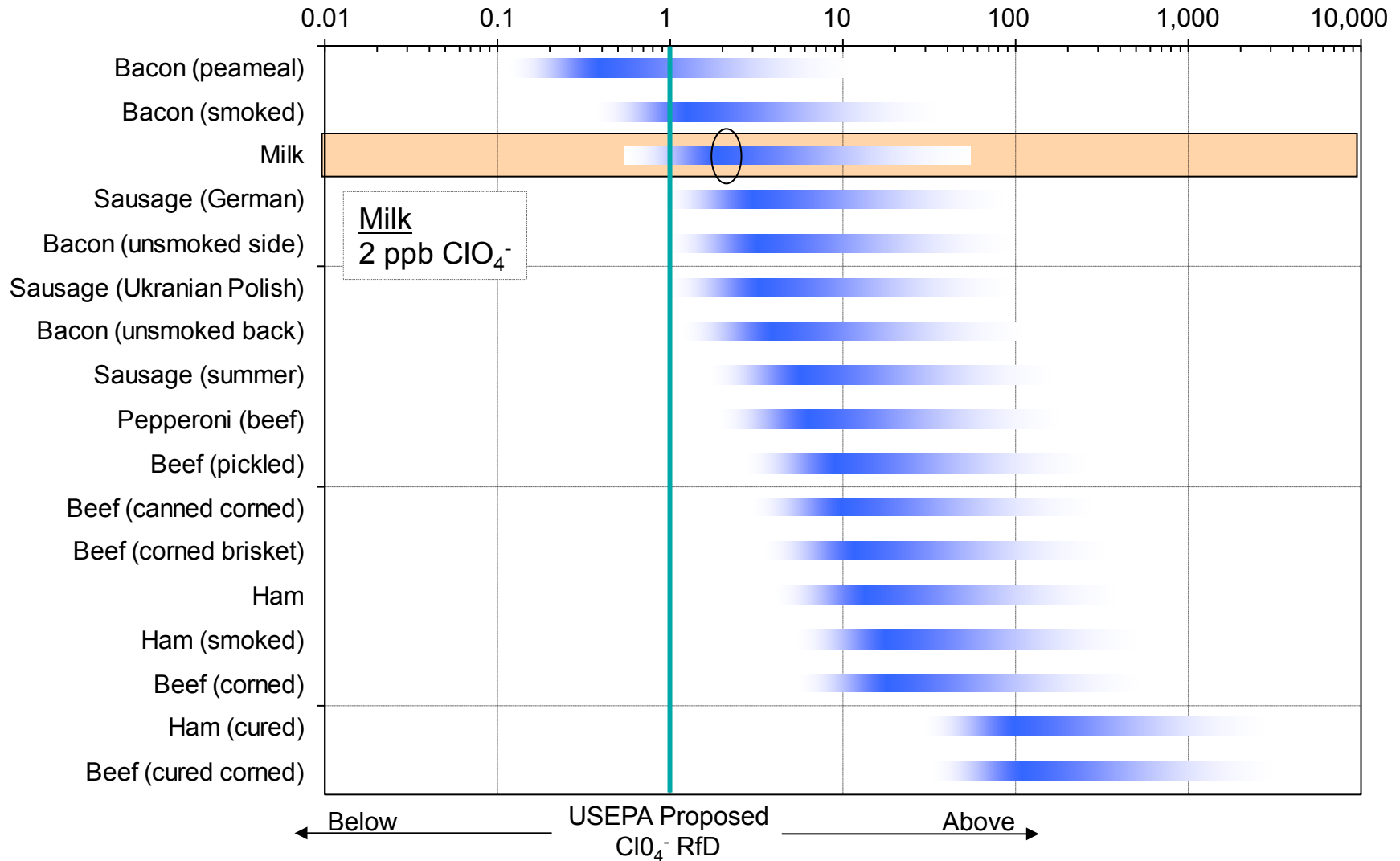
Iodide Uptake Inhibition from Single Servings of Dairy or Processed Meats Expressed in Parts per Billion Perchlorate in Drinking Water

Best Professional Judgment PER Scenario



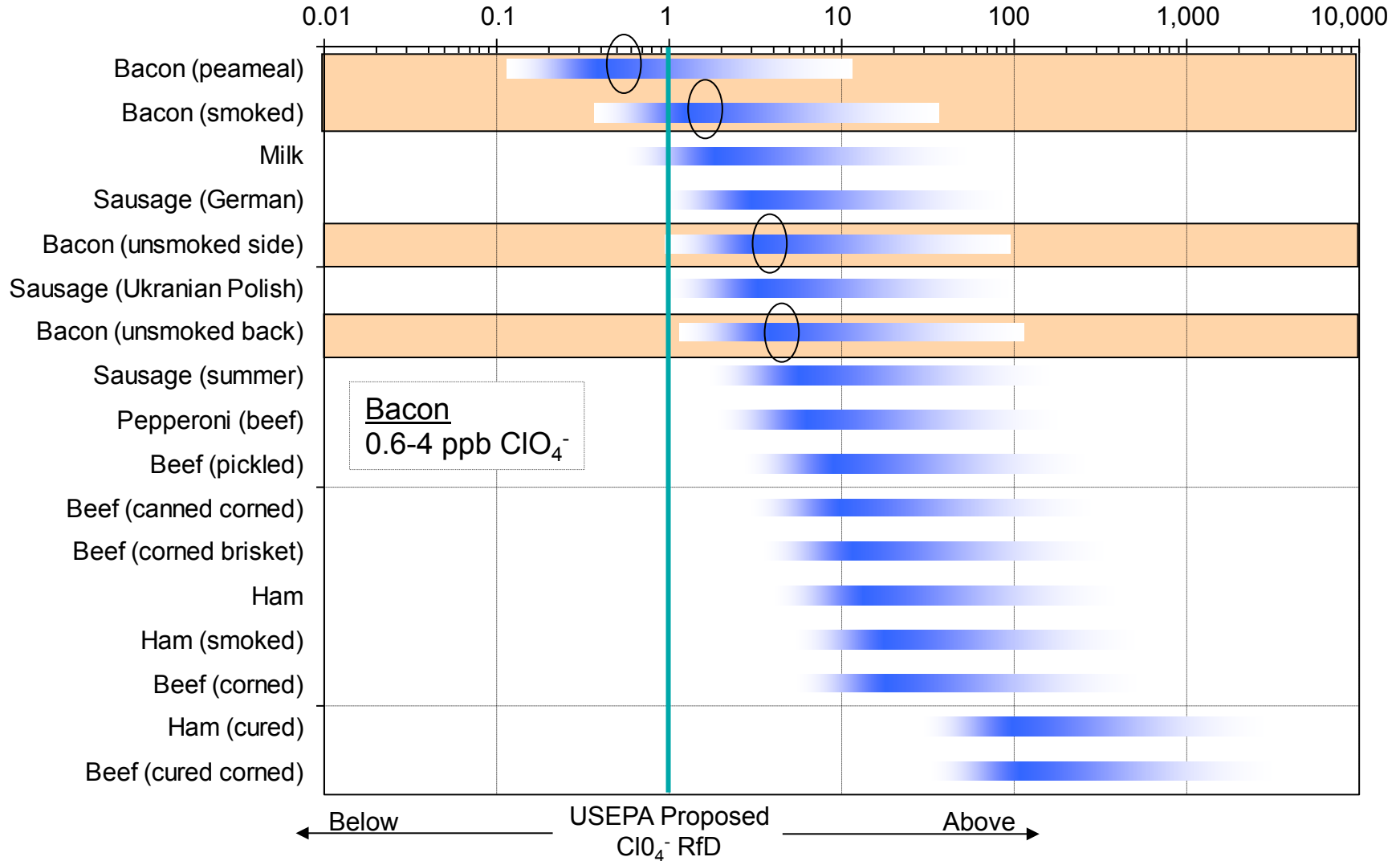
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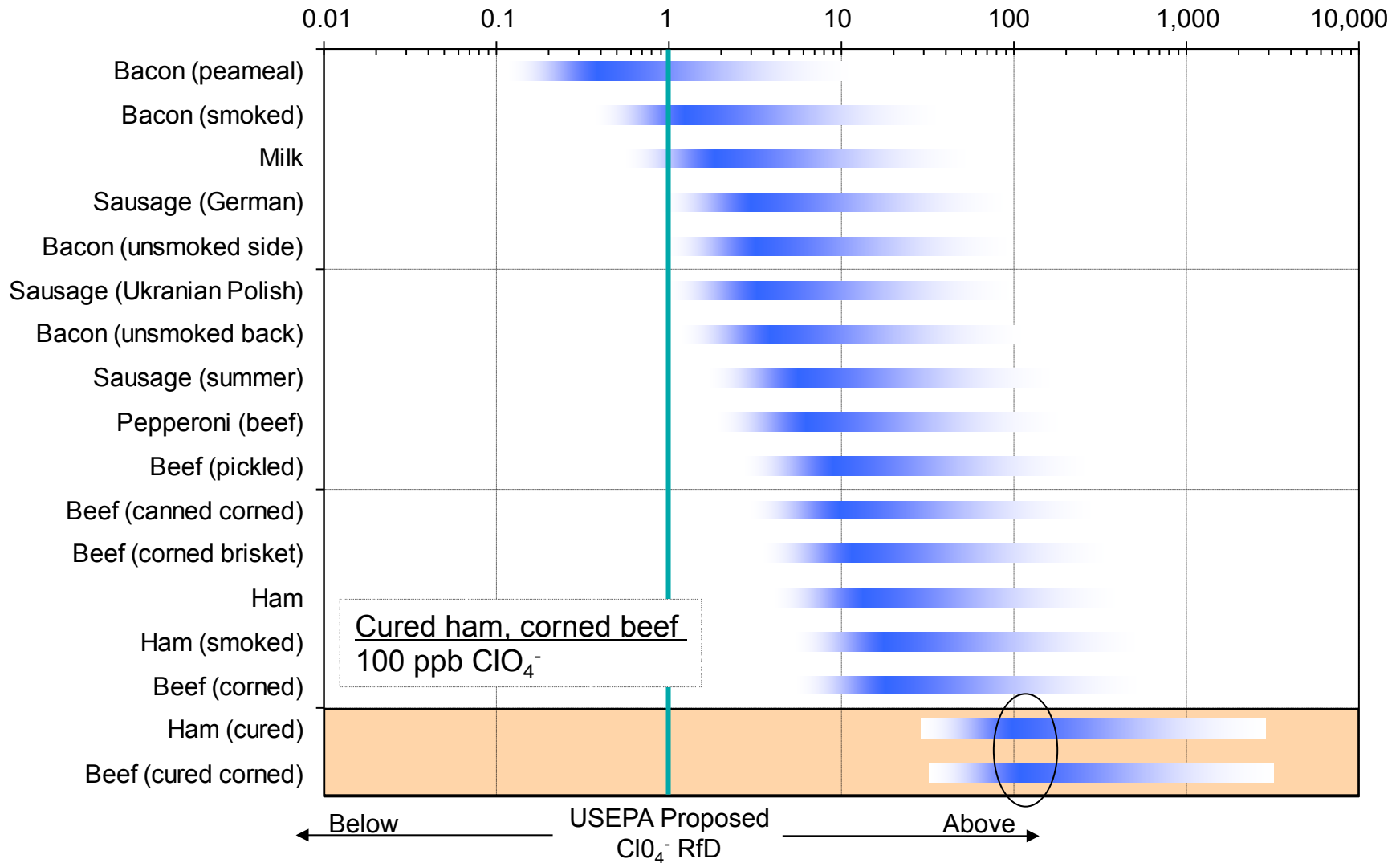
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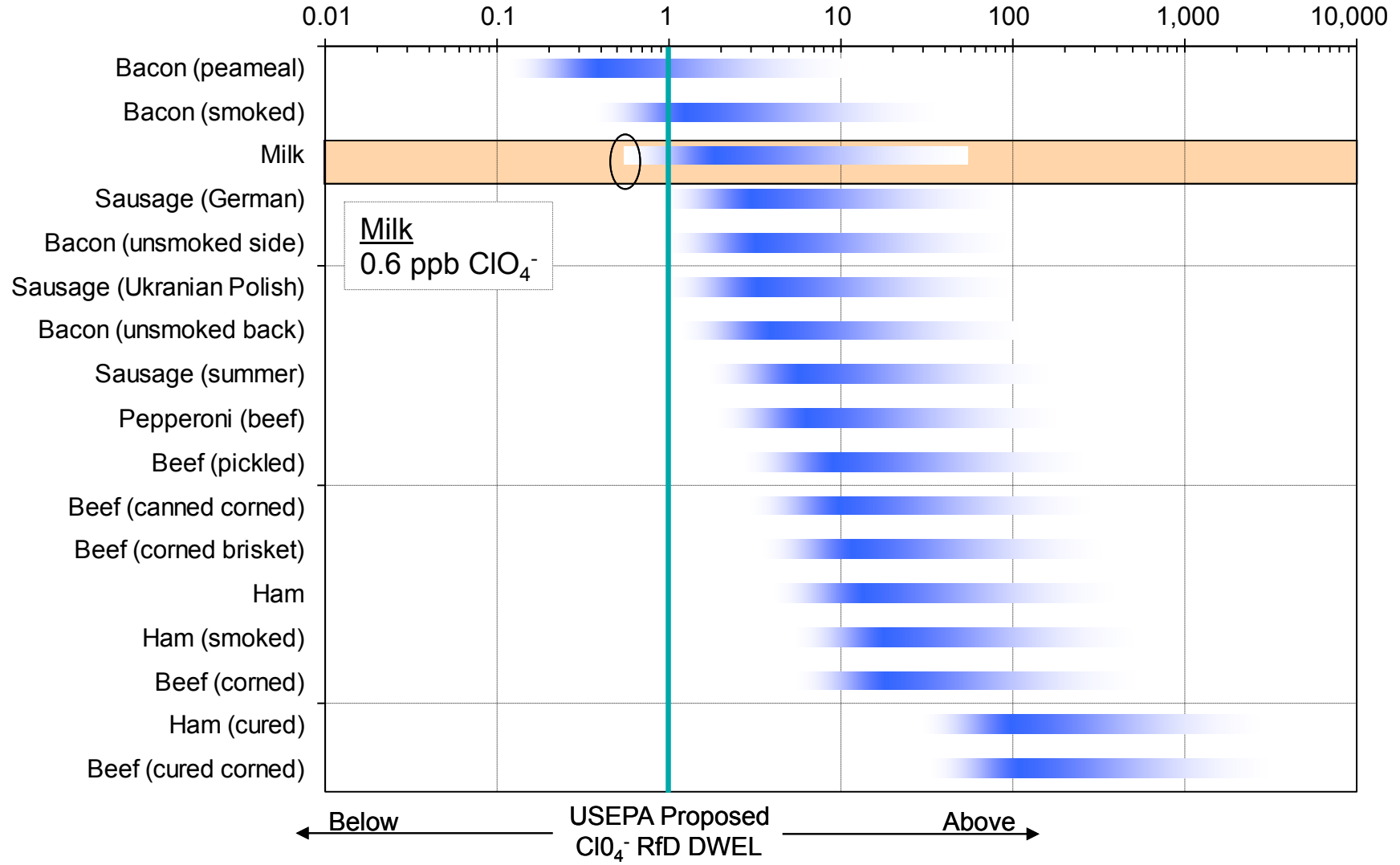
Milk and Processed Meats— Highest Plausible PER Scenario

- **Stripe graph illustrates results**
 - Upper-bound value of each stripe applies
 - Perchlorate equivalents increase exponentially to the right
 - **For 10 of 15 processed meats, single servings**
 - Exceed USEPA proposed perchlorate RfD
 - Exceed RfD by as much as 30 times
 - **Notable examples**

■ Milk	0.6	ppb
■ Bacon	0.1-1	ppb
■ Cured ham, corned beef	30	ppb
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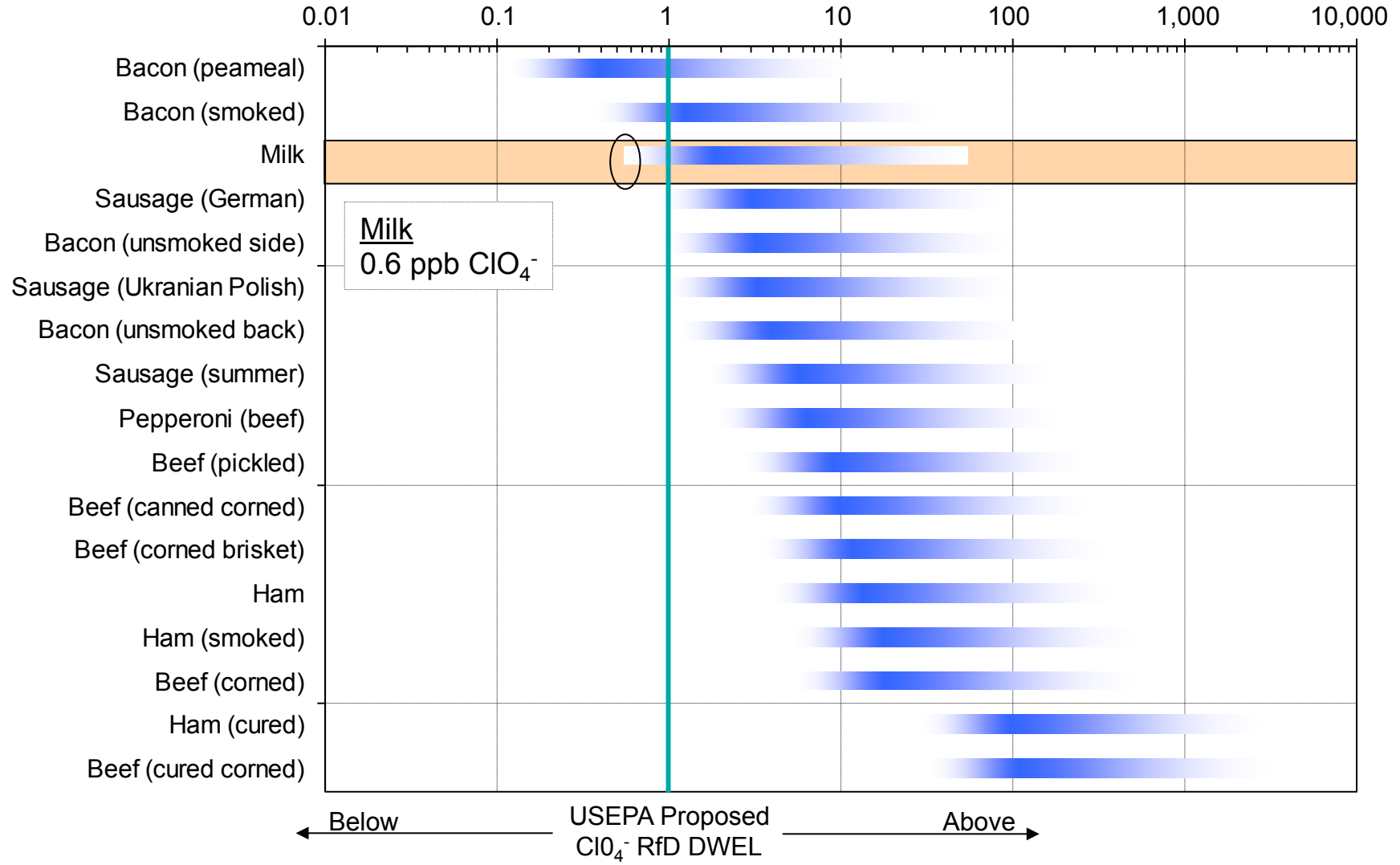
Iodide Uptake Inhibition from Single Servings of Milk or Processed Meats Expressed in Parts per Billion Perchlorate in Drinking Water

Highest Plausible PER Scenario



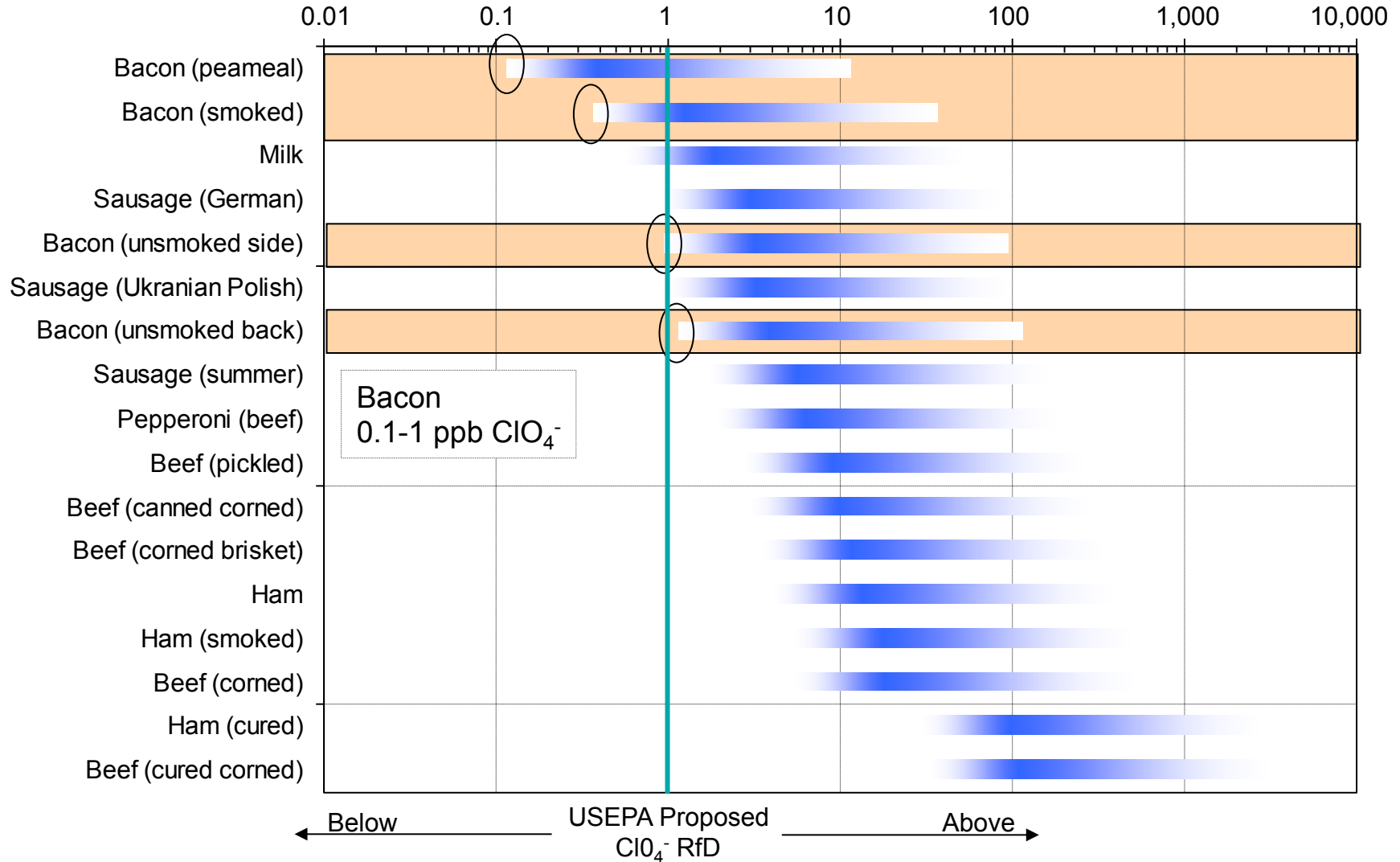
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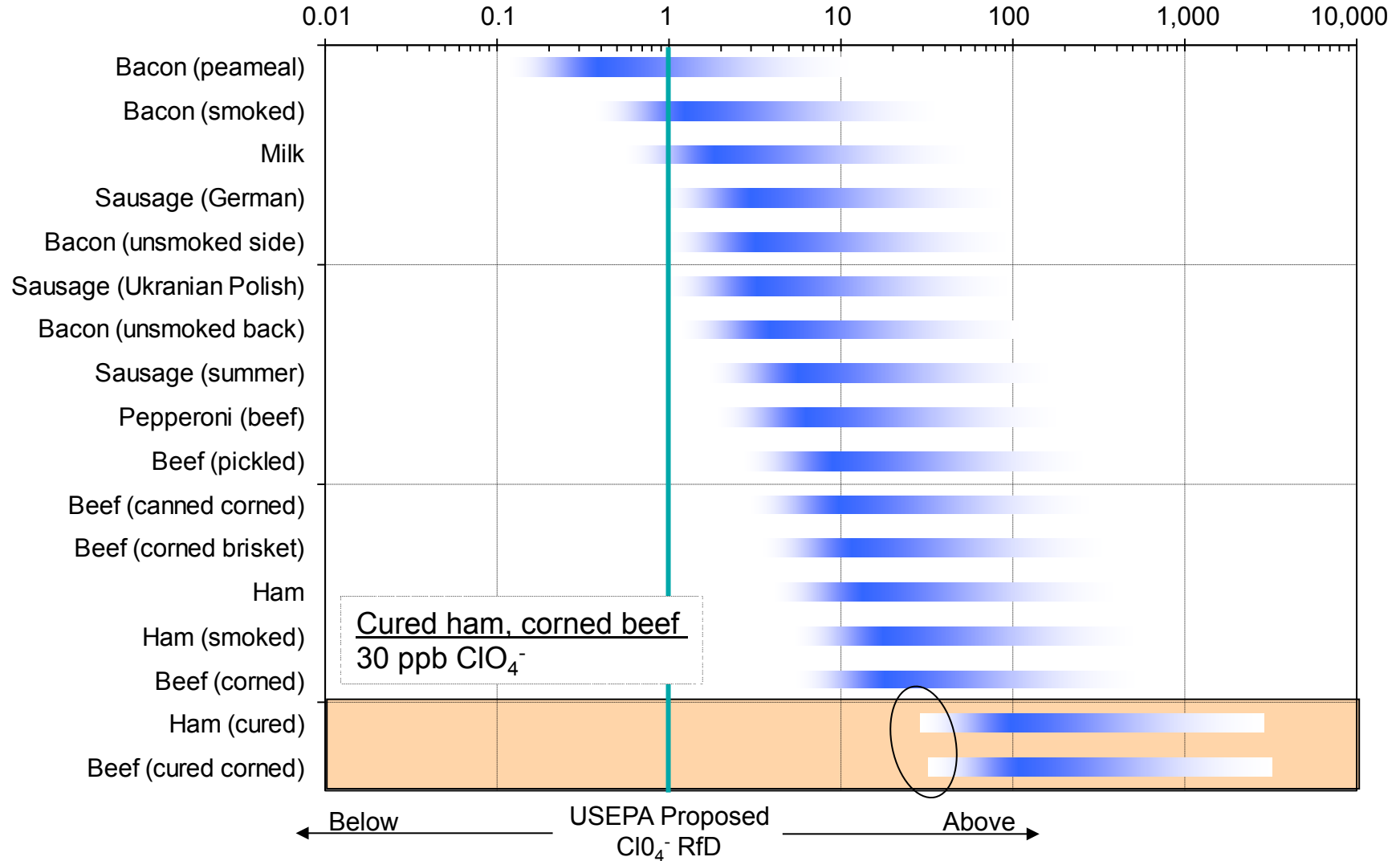
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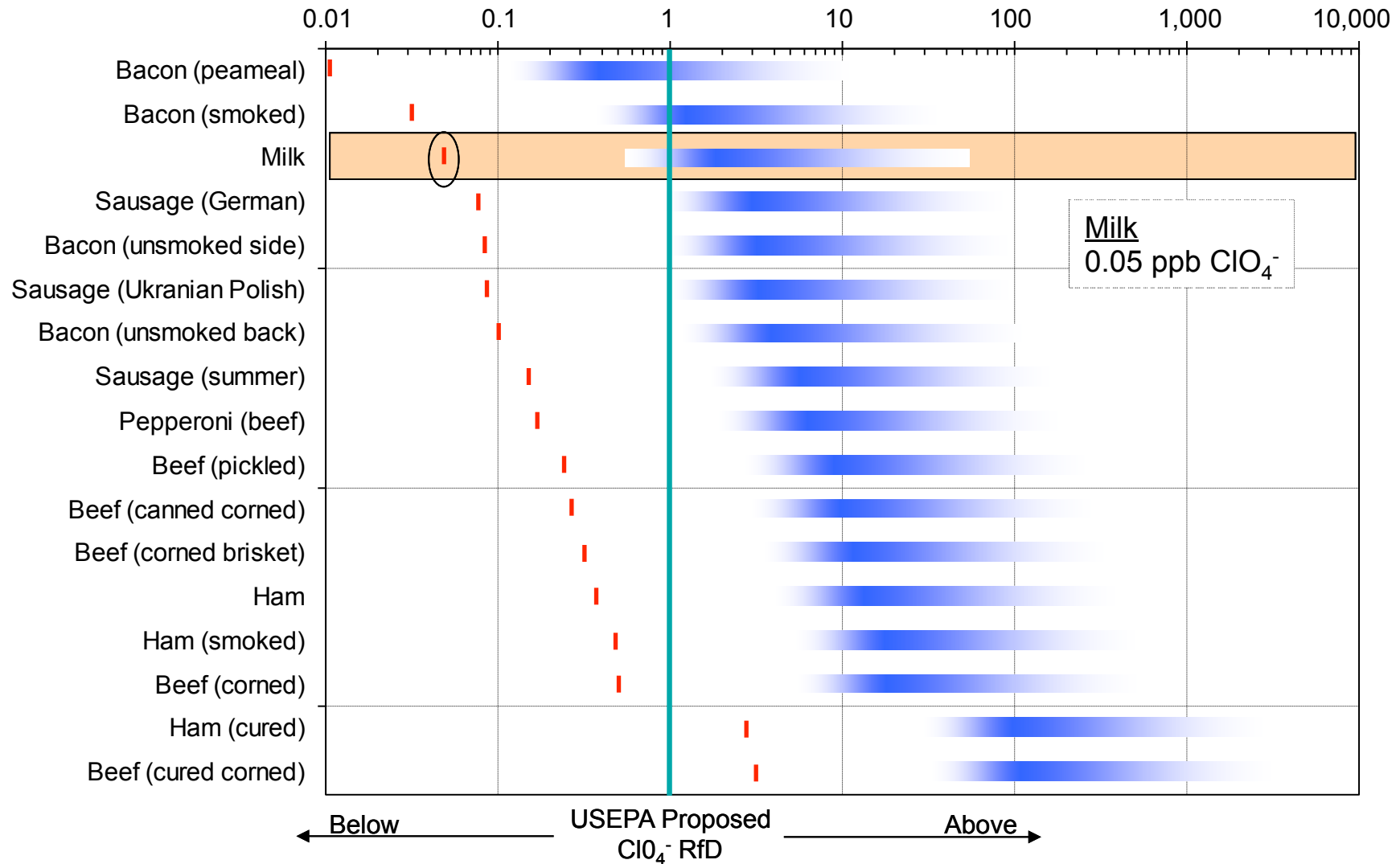
Dairy and Processed Meats— Nitrate MCL Scenario (10,000)

- **Stripe graphs illustrate results**
 - Red hash marks apply
 - Values increase exponentially to the right
 - No scientific evidence supporting these values, but implied by ratio of nitrate MCL to proposed perchlorate DWEL
 - **For 2 of 15 processed meats, single serving**
 - Exceeds USEPA's proposed perchlorate RfD
 - Exceeds RfD by as much as 3 times
 - **Notable examples**

■ Milk	0.05	ppb
■ Bacon	0.01-0.1	ppb
■ Cured ham, corned beef	2-3	ppb
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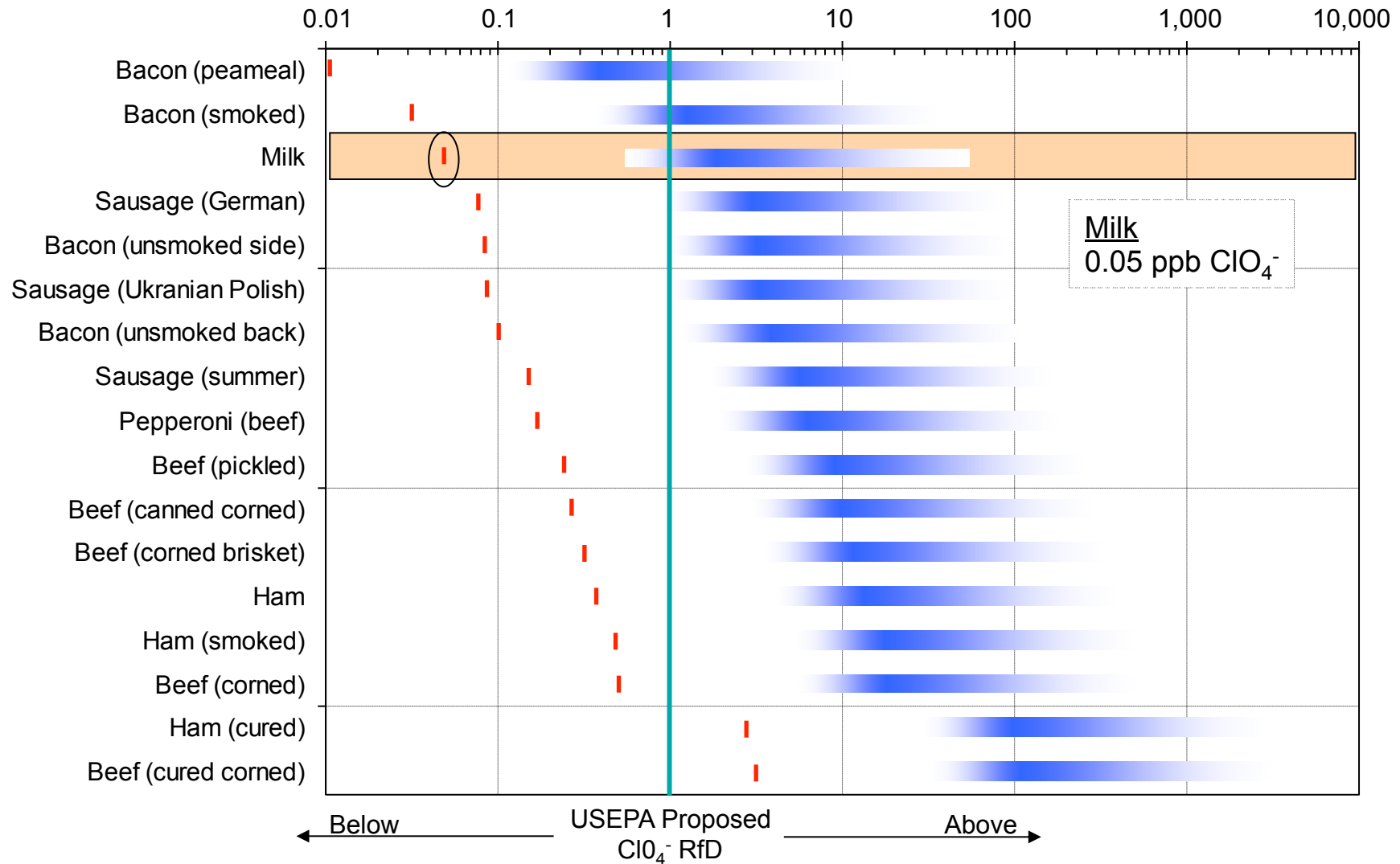
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Nitrate MCL Scenario



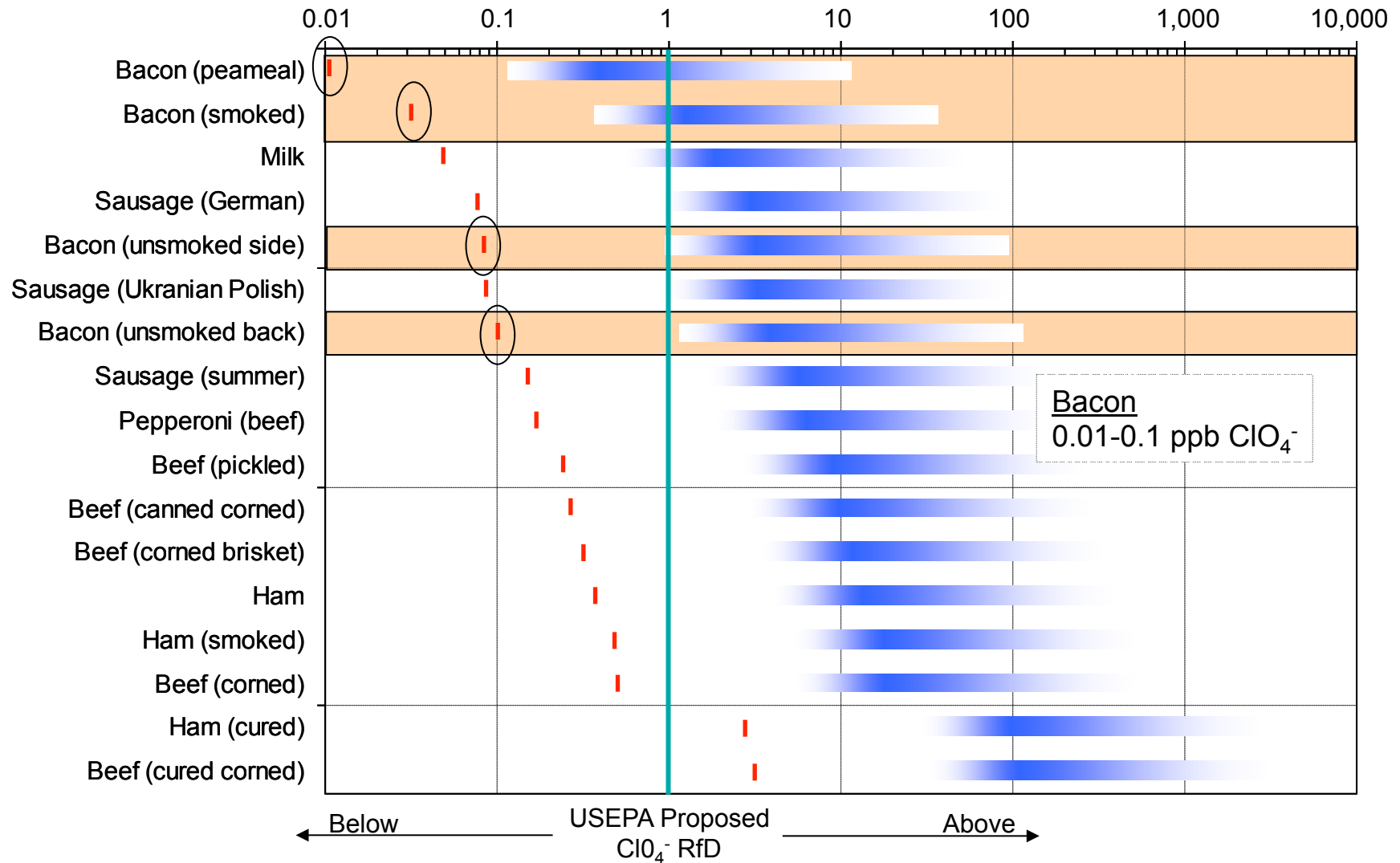
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Nitrate MCL Scenario



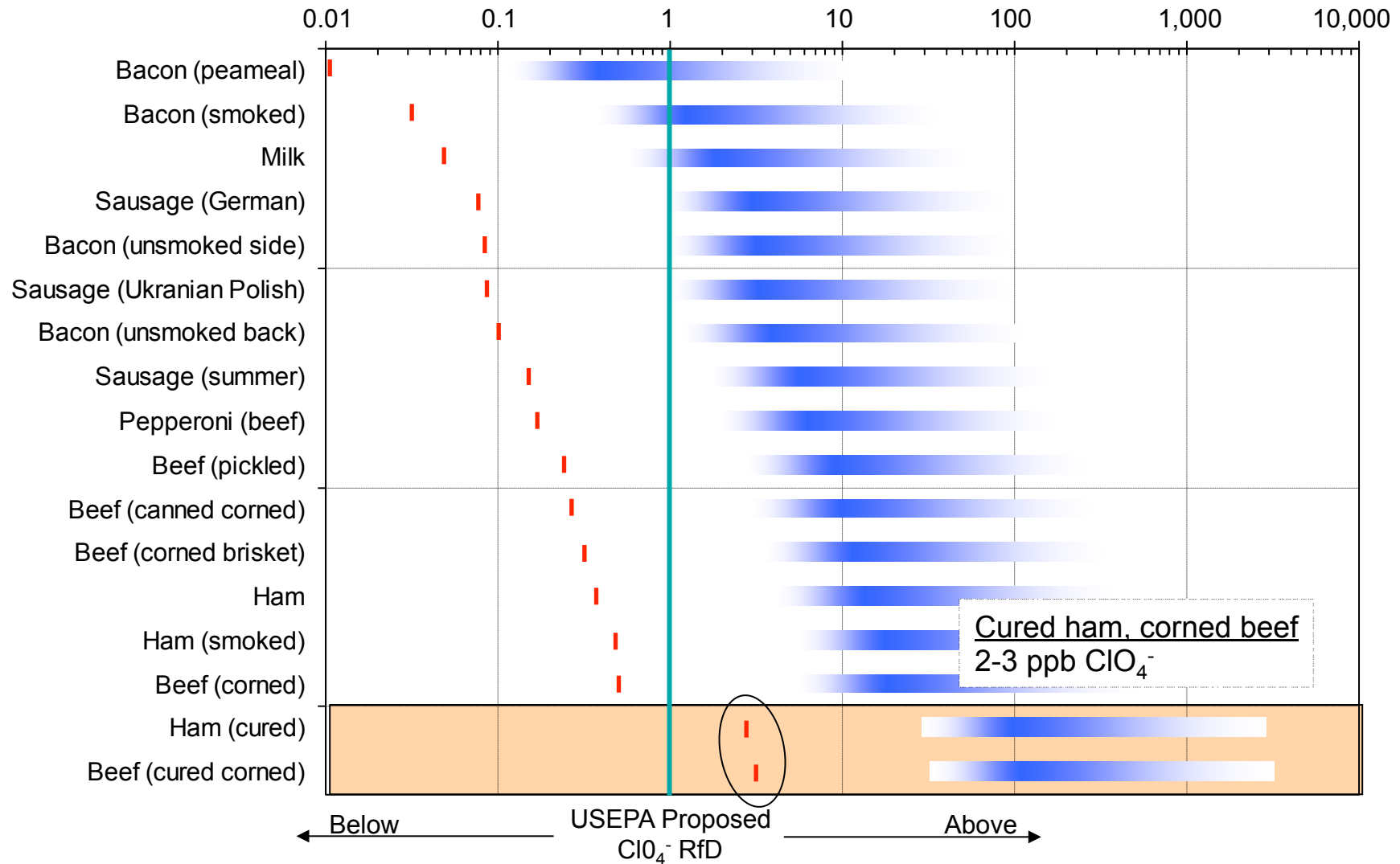
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Nitrate MCL Scenario



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Nitrate MCL Scenario

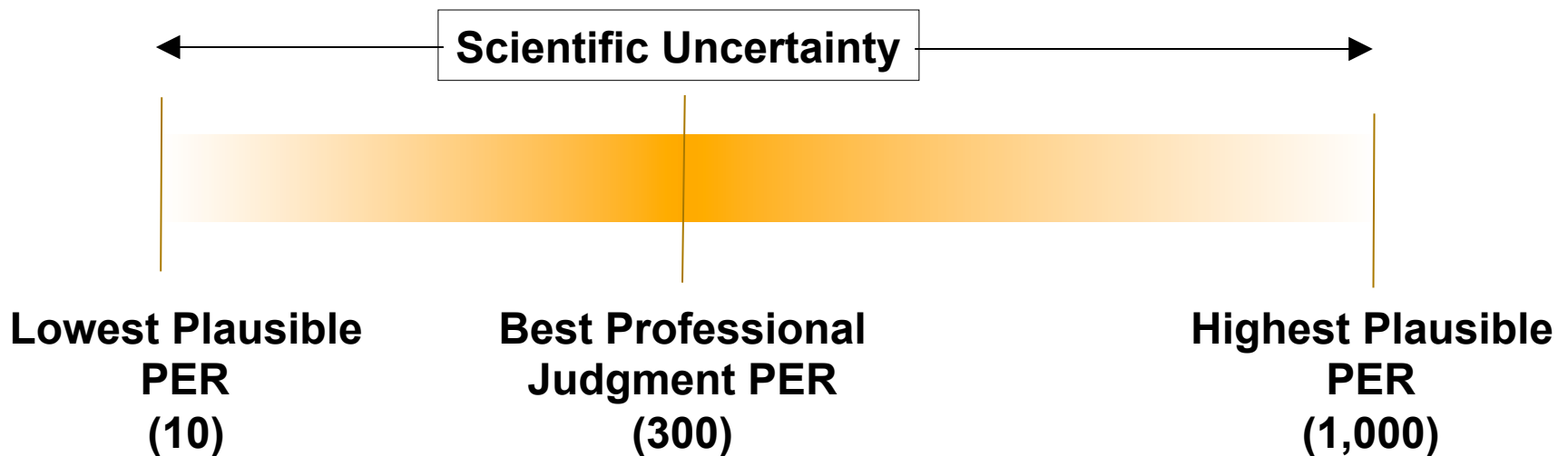


Maximum “Safe” Consumption of Dairy and Processed Meats

- Same information presented in opposite way
 - Consumption must stay below 1 serving to avoid exceeding USEPA’s proposed RfD
 - Per-serving calculations do not take into account complete diet
 - This significantly overstates actual “safe” consumption levels if proposed perchlorate RfD is correct
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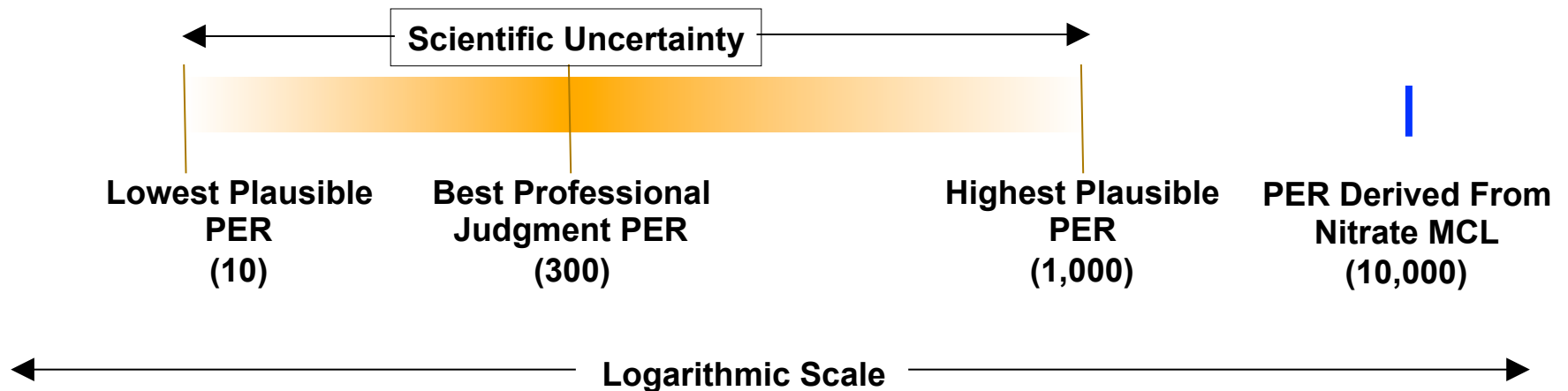
How to Interpret the Graphs

- Within foods, perchlorate potency increases to the left
- Across foods, nitrate levels increase to the left
- Each stripe captures full PER range
 - Illustrates scientific uncertainty
 - Darkest at Best Professional Judgment Scenario



How to Interpret Stripe Graphs with “Hash Marks”

- Shows lowest PER implied by nitrate MCL (10,000)
- Provides robustness check across drinking water standards

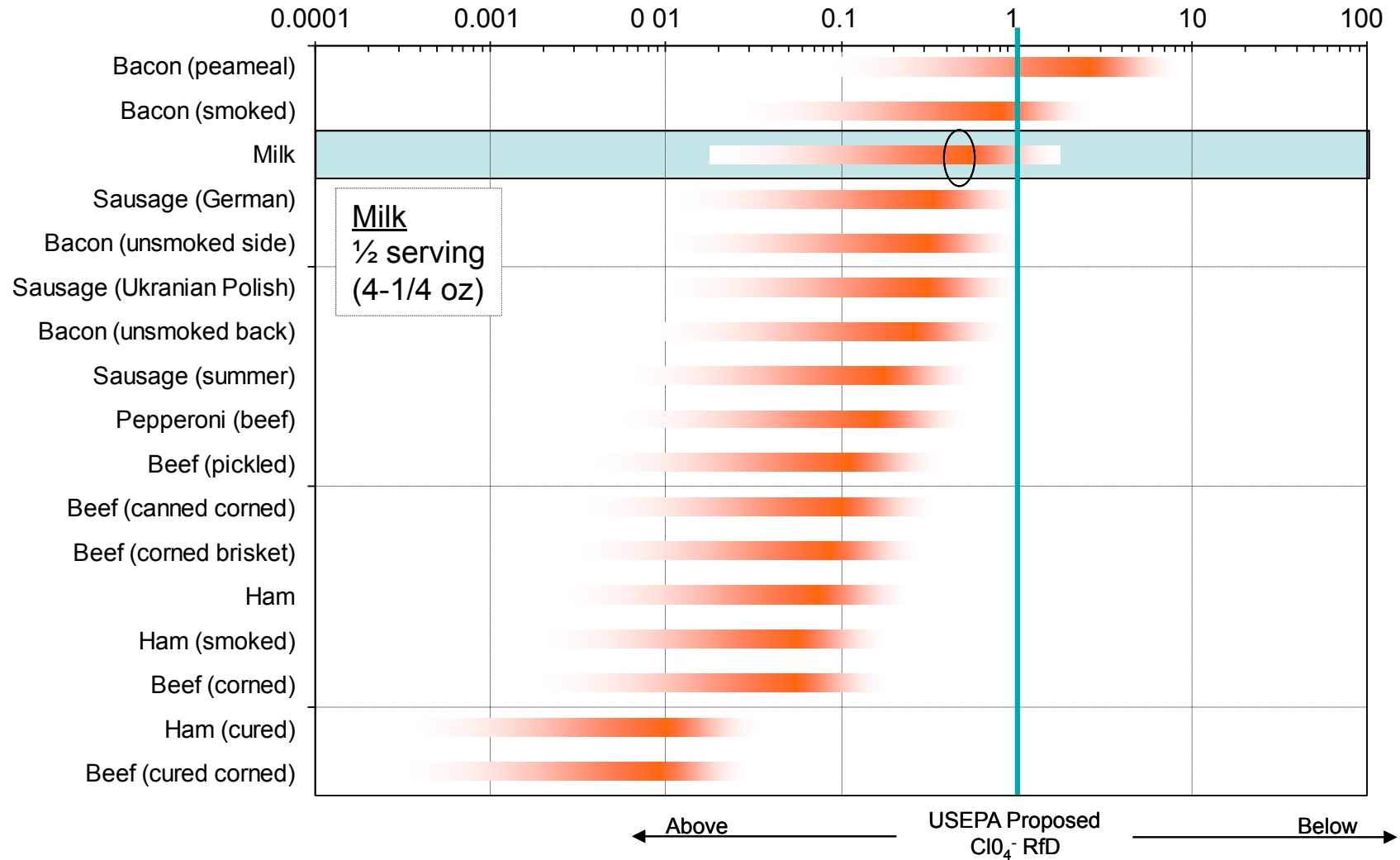


Maximum “Safe” Consumption— Best Professional Judgment PER Scenario

- Stripe graphs illustrate results
 - Middle values within each stripe apply
 - Servings allowed decrease exponentially to the left
 - Milk consumption must stay below $\frac{1}{2}$ serving
 - For 14 of 15 meats, consumption must stay below $\frac{1}{2}$ serving
 - Examples
 - 2 of 4 bacon types below 4 g
 - Cured ham, corned beef below 1 g
-

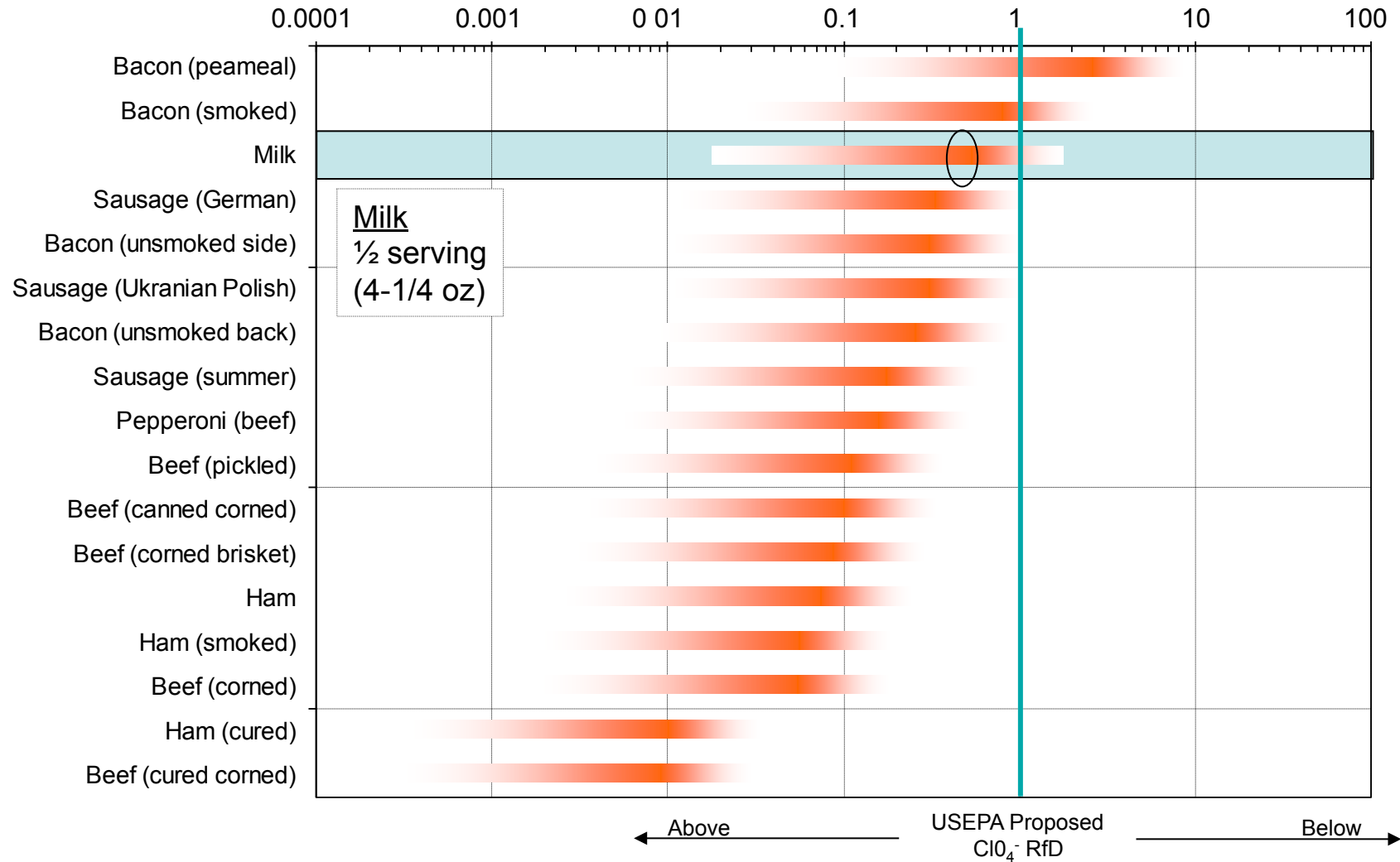
Maximum Servings of Milk or Processed Meats Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Best Professional Judgment PER Scenario



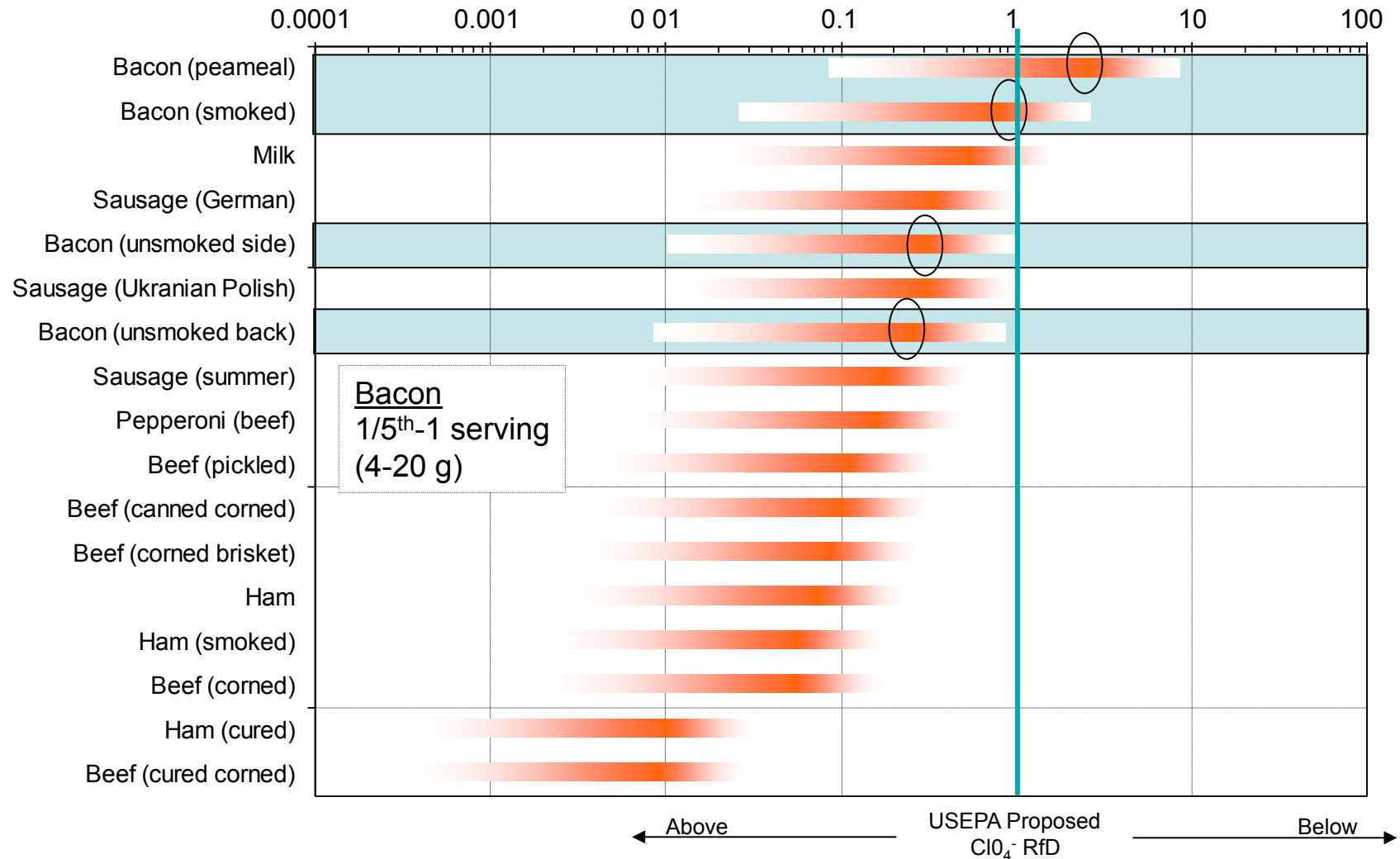
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Best Professional Judgment PER Scenario



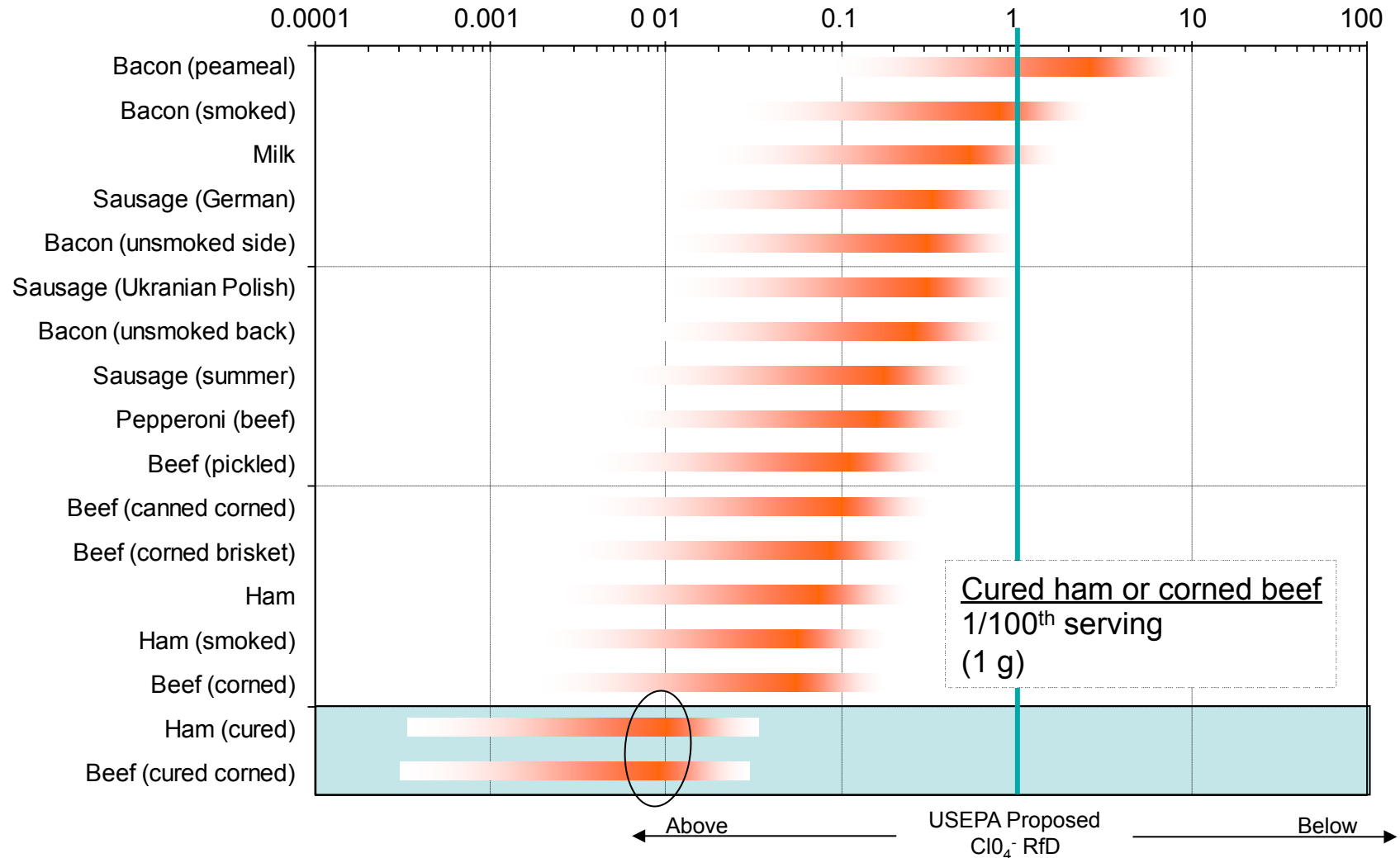
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Best Professional Judgment PER Scenario



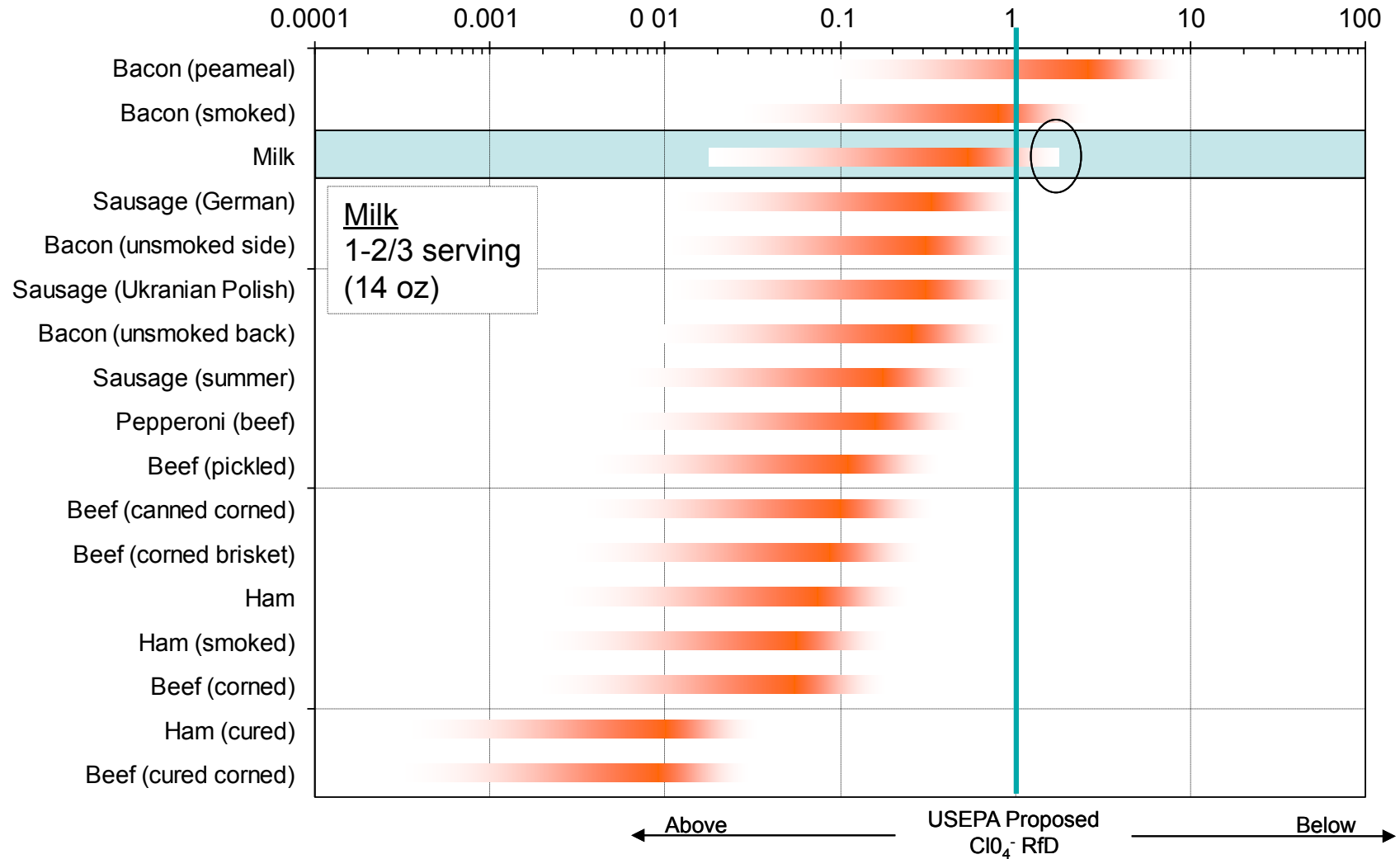
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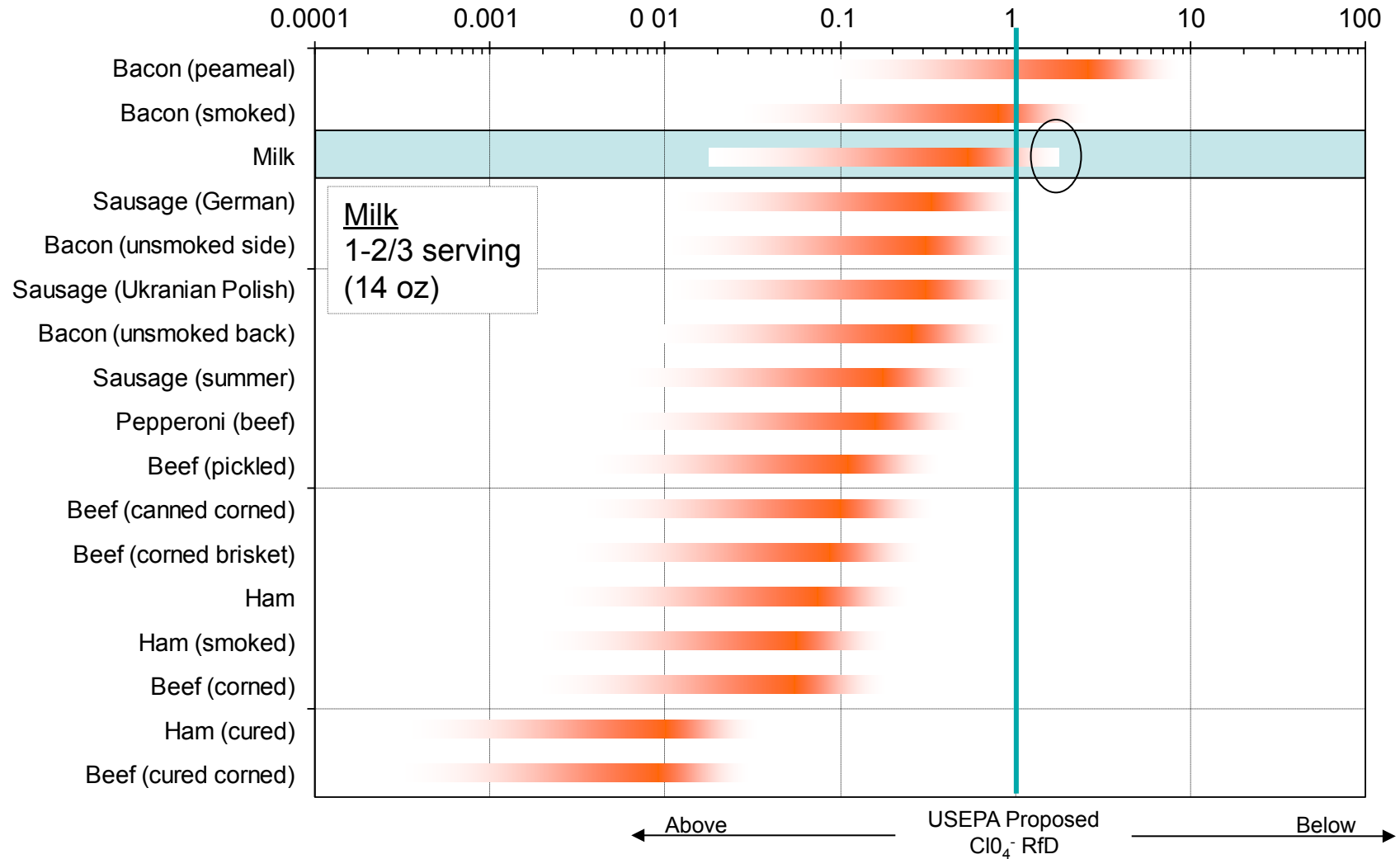
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Maximum Plausible PER Scenario



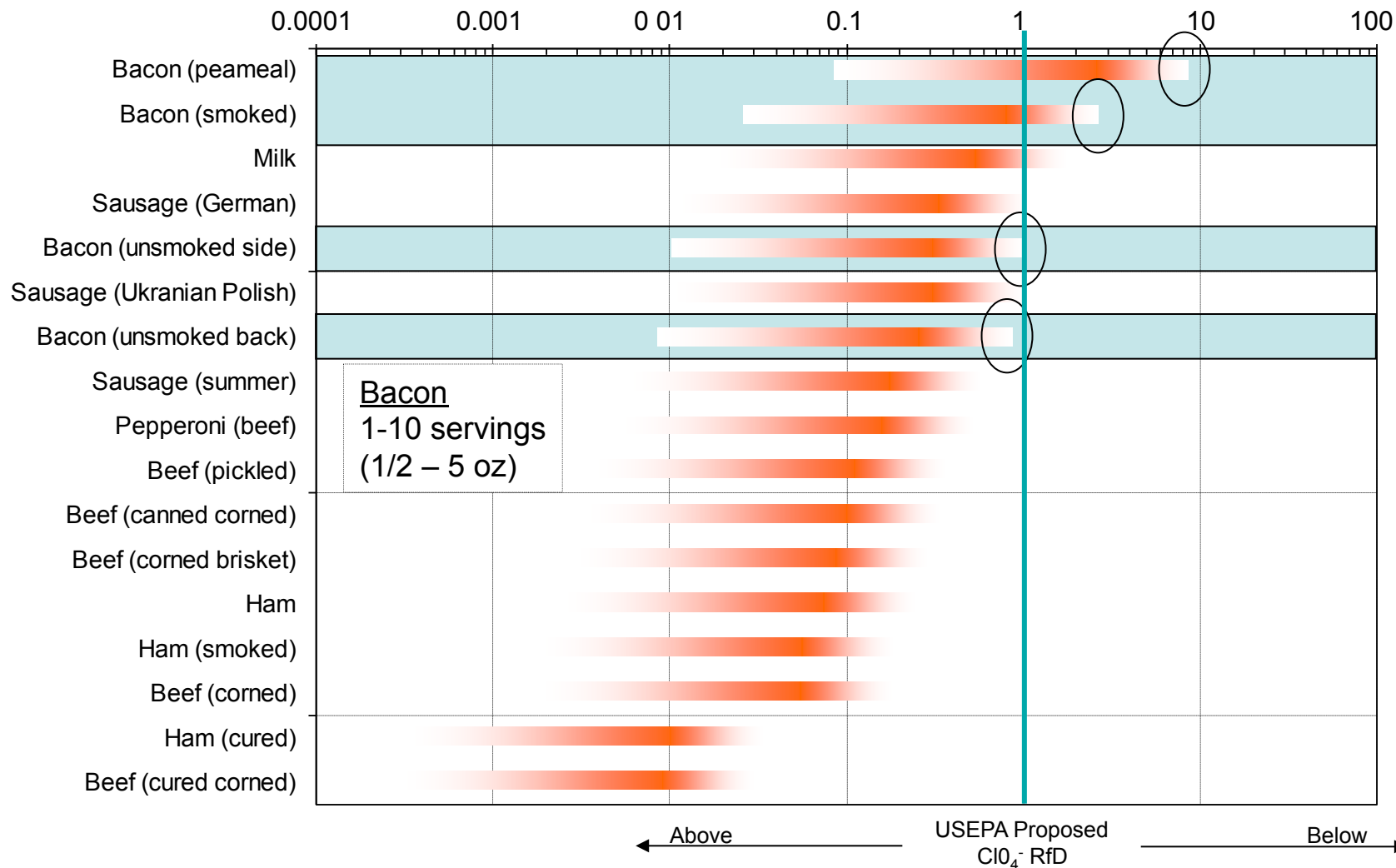
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Maximum Plausible PER Scenario



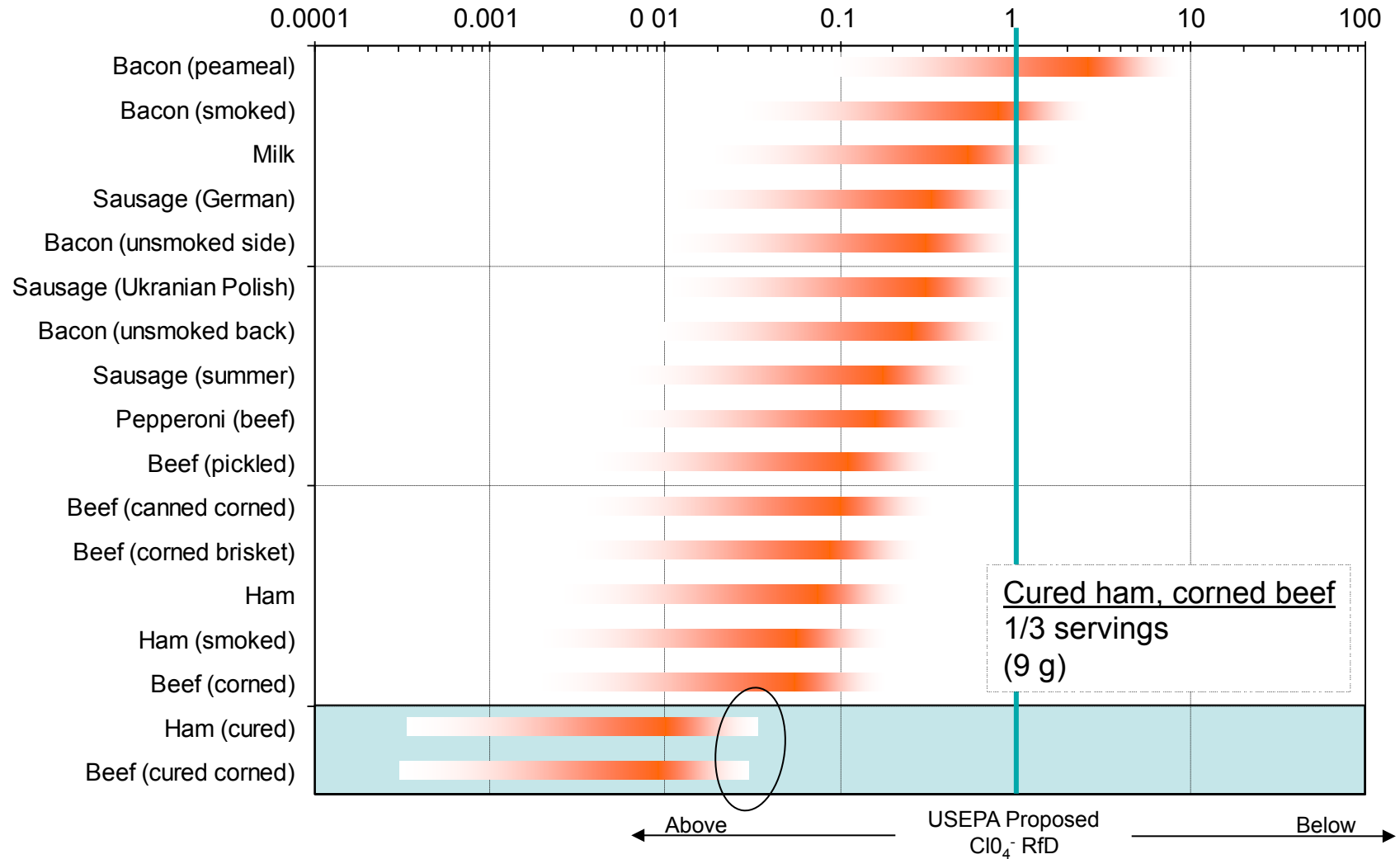
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Maximum Plausible PER Scenario



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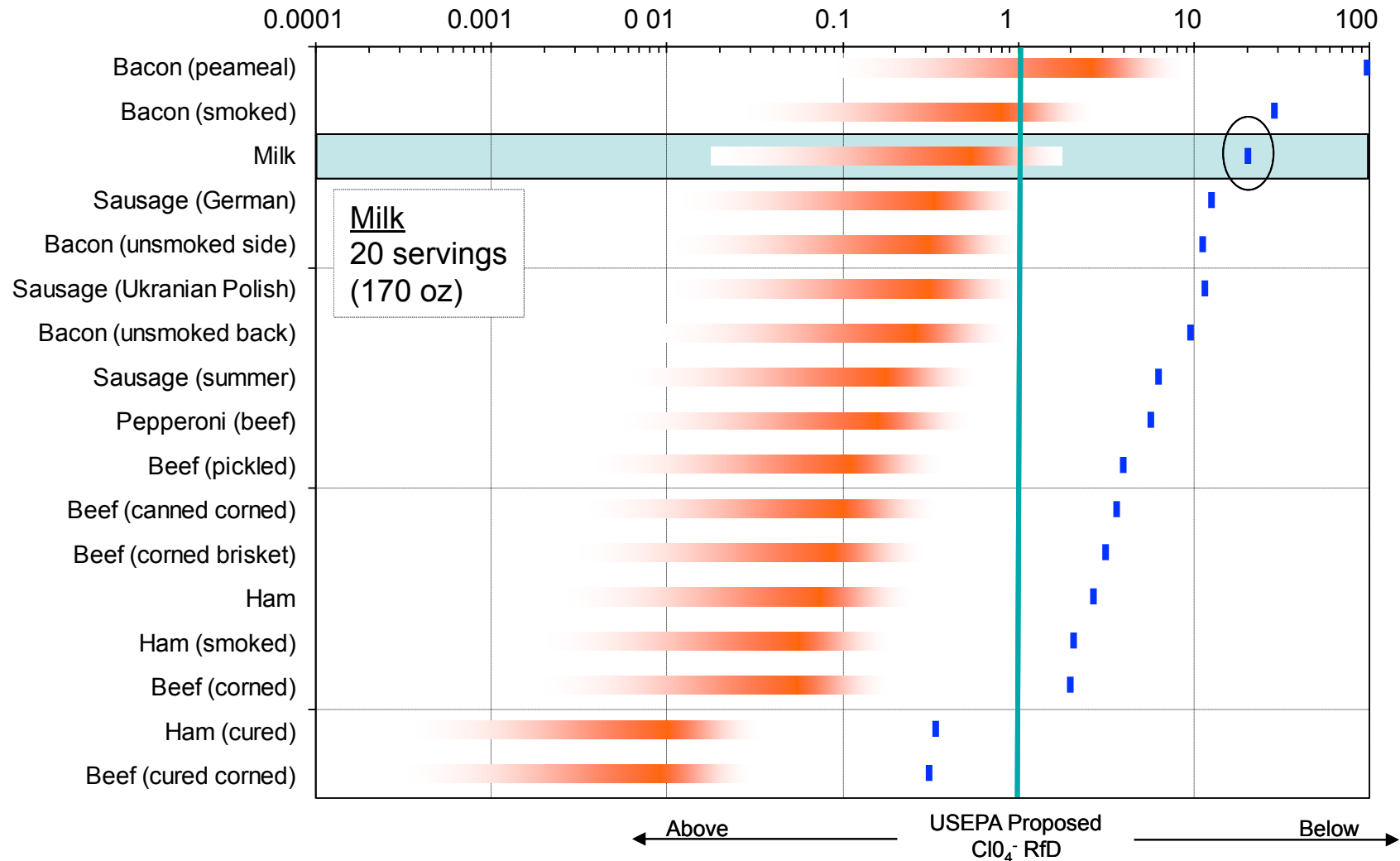


Maximum “Safe” Number of Servings— Nitrate MCL PER Scenario

- Stripe graphs illustrate results
 - Blue hash marks apply
 - Values decrease exponentially to the left
 - No scientific evidence supporting PER this high, but PER this high or higher is implied by nitrate MCL and perchlorate DWEL
 - For 2 of 15 meats, consumption must stay below ½ serving
 - For some foods, consumption is largely unconstrained
 - Milk below 170 oz
 - For a few foods, consumption must be severely reduced
 - Bacon below 5 to 50 oz
 - Cured ham, corned beef below 2/3 oz
-

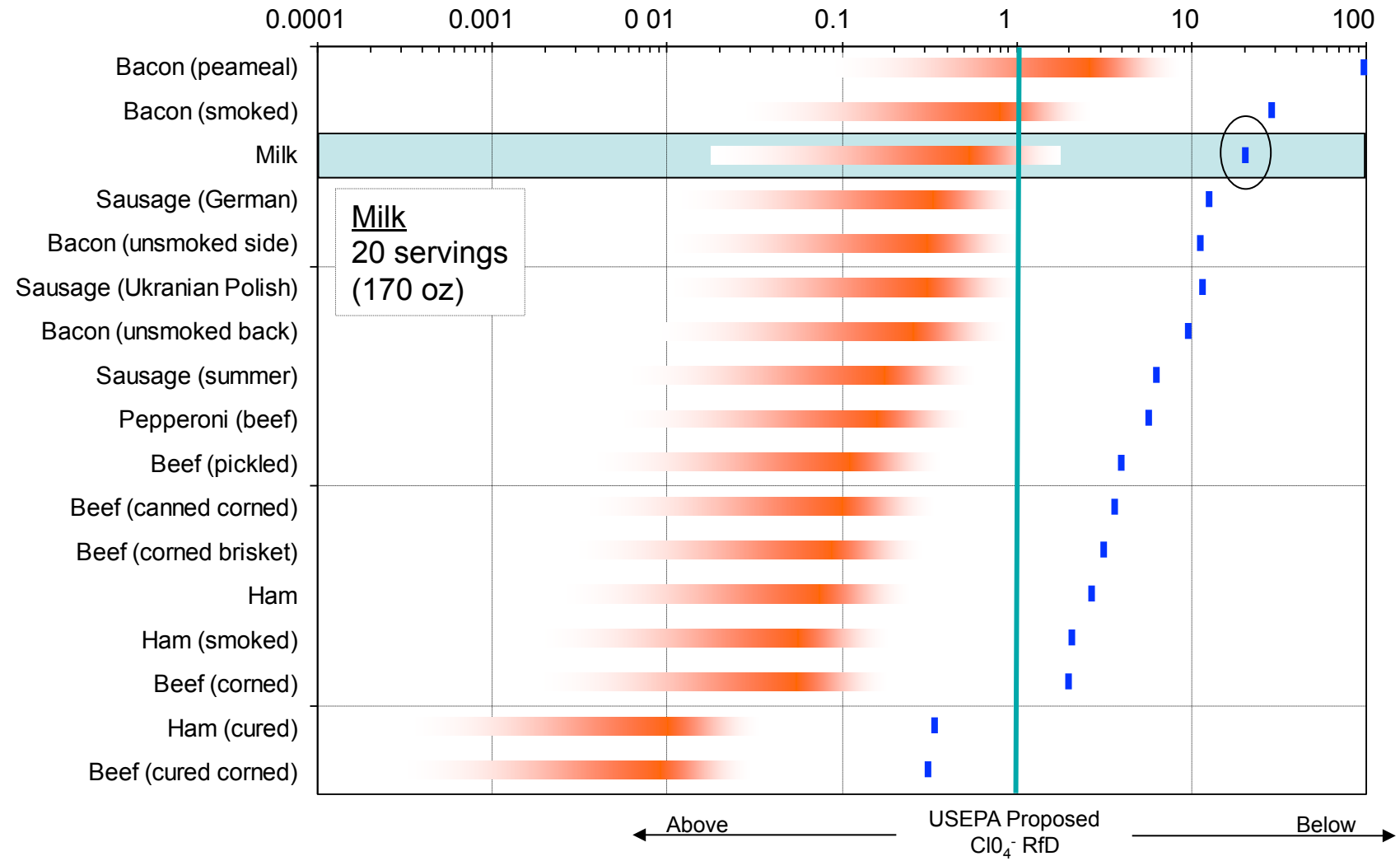
Maximum Servings of Milk or Processed Meats Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Nitrate MCL PER Scenario



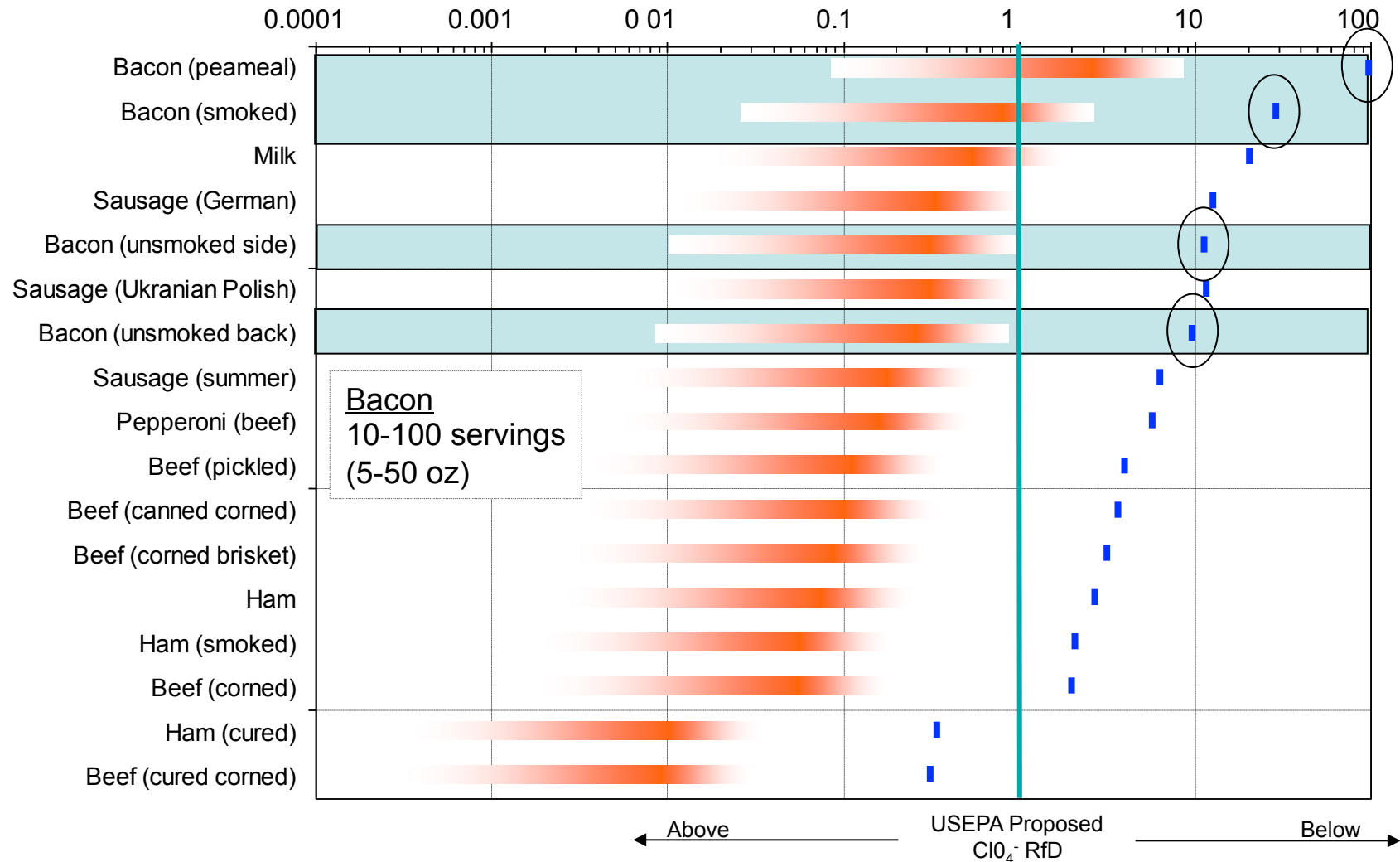
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Nitrate MCL PER Scenario



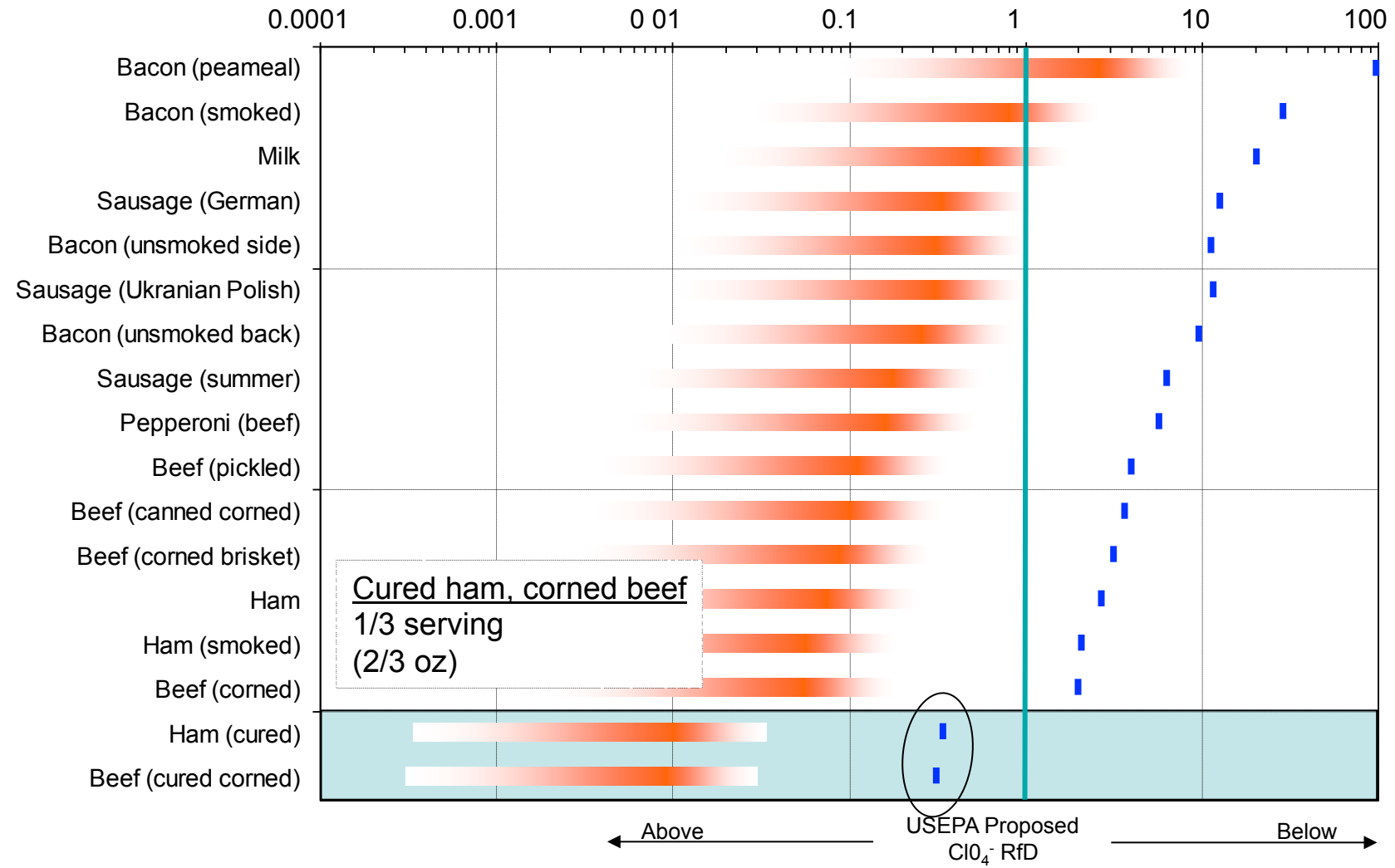
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Nitrate MCL PER Scenario



Maximum Servings of Milk or Processed Meats Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Nitrate MCL PER Scenario



Equivalent Exposures in Vegetables

- Nitrates are normal constituents in vegetables
 - Sources
 - Soil
 - Synthetic fertilizer
 - Organic fertilizer
 - Irrigation water
 - All calculations are per serving of food and do not take into account a complete diet
 - A full dietary analysis would show total nitrate intake to be much greater
 - Exposures should be additive
-

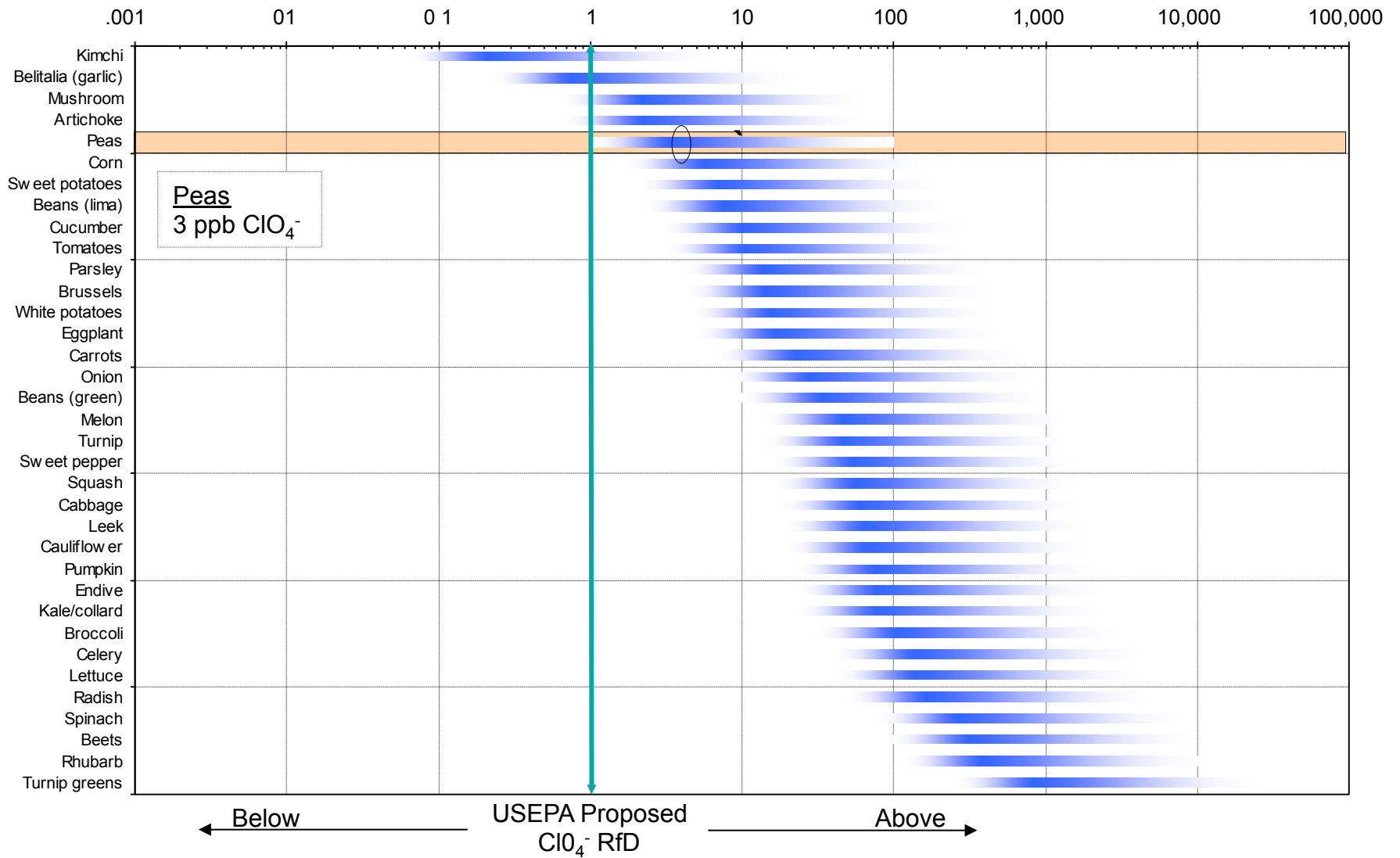
Vegetables—

Best Professional Judgment PER Scenario

- Stripe graphs illustrate results
 - Middle value of each stripe applies
 - Values increase exponentially to the right
 - For 33 of 35 vegetables, single servings...
 - Exceed IUI permitted by USEPA proposed perchlorate RfD
 - Exceed it by much more than dairy or processed meats
 - Examples of perchlorate drinking water equivalents
 - Peas 3 ppb
 - Cucumber & tomatoes 10 ppb
 - Broccoli, celery & lettuce 100 ppb
 - Turnip greens 800 ppb
-

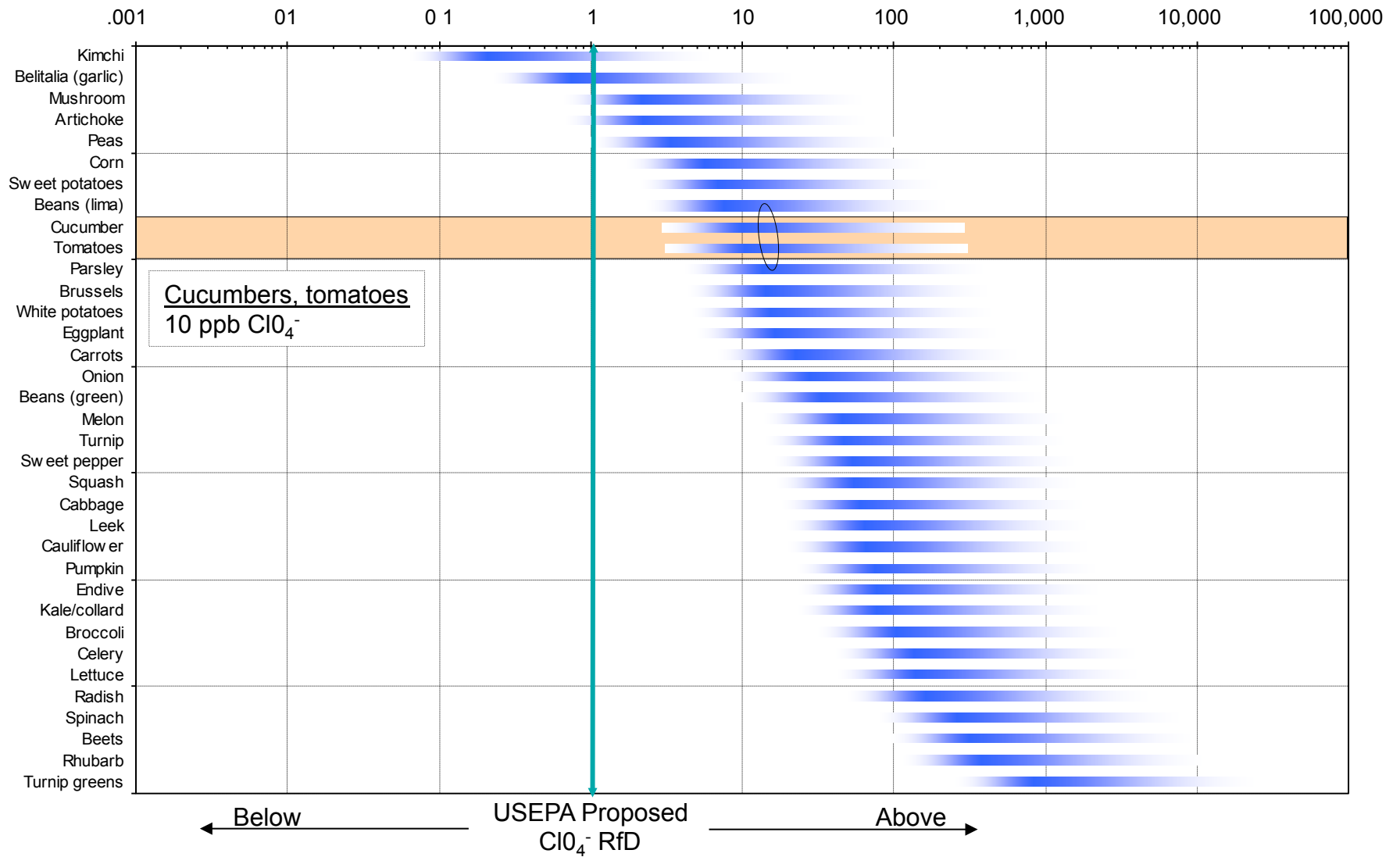
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Best Professional Judgment PER Scenario



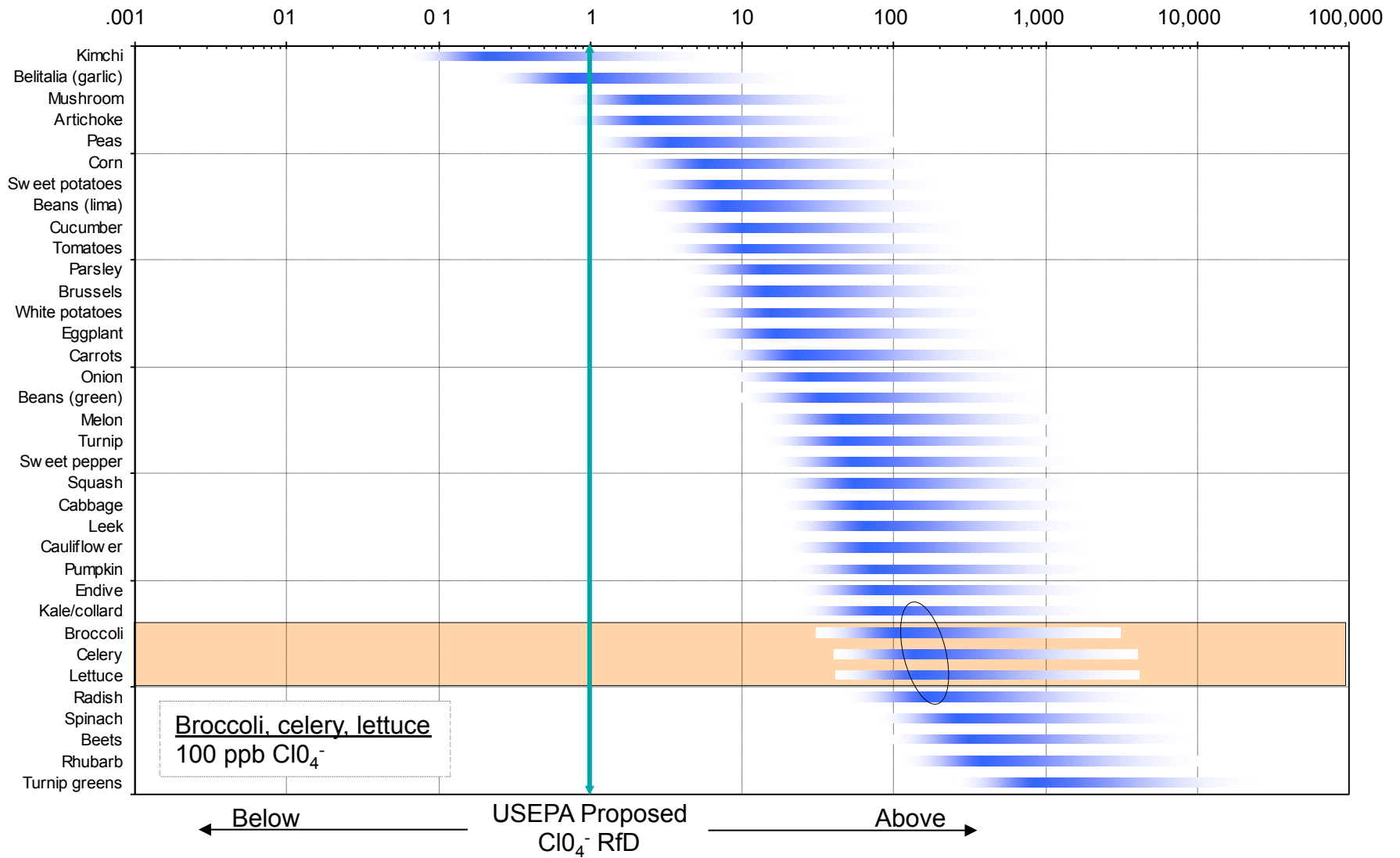
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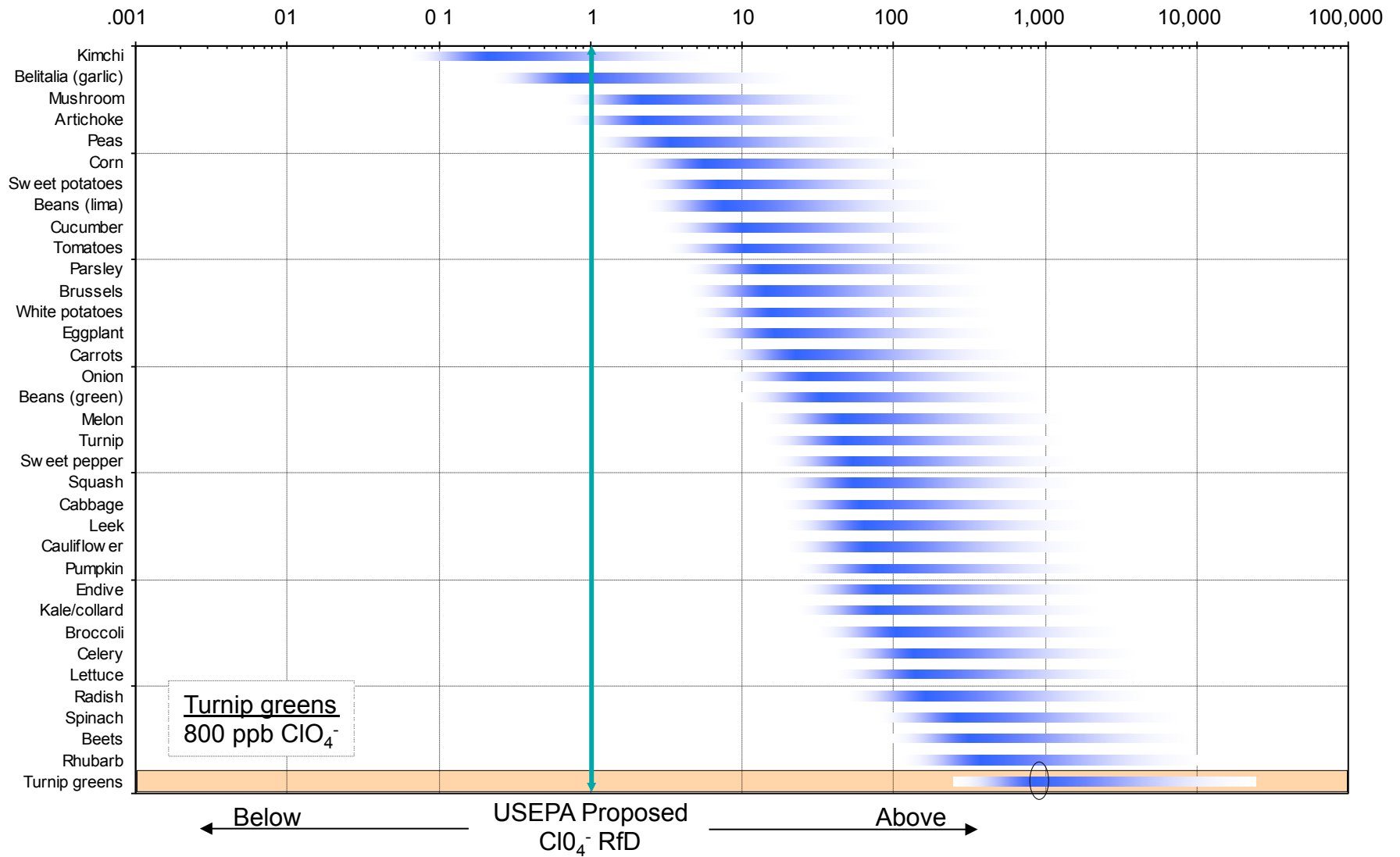
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Best Professional Judgment PER Scenario



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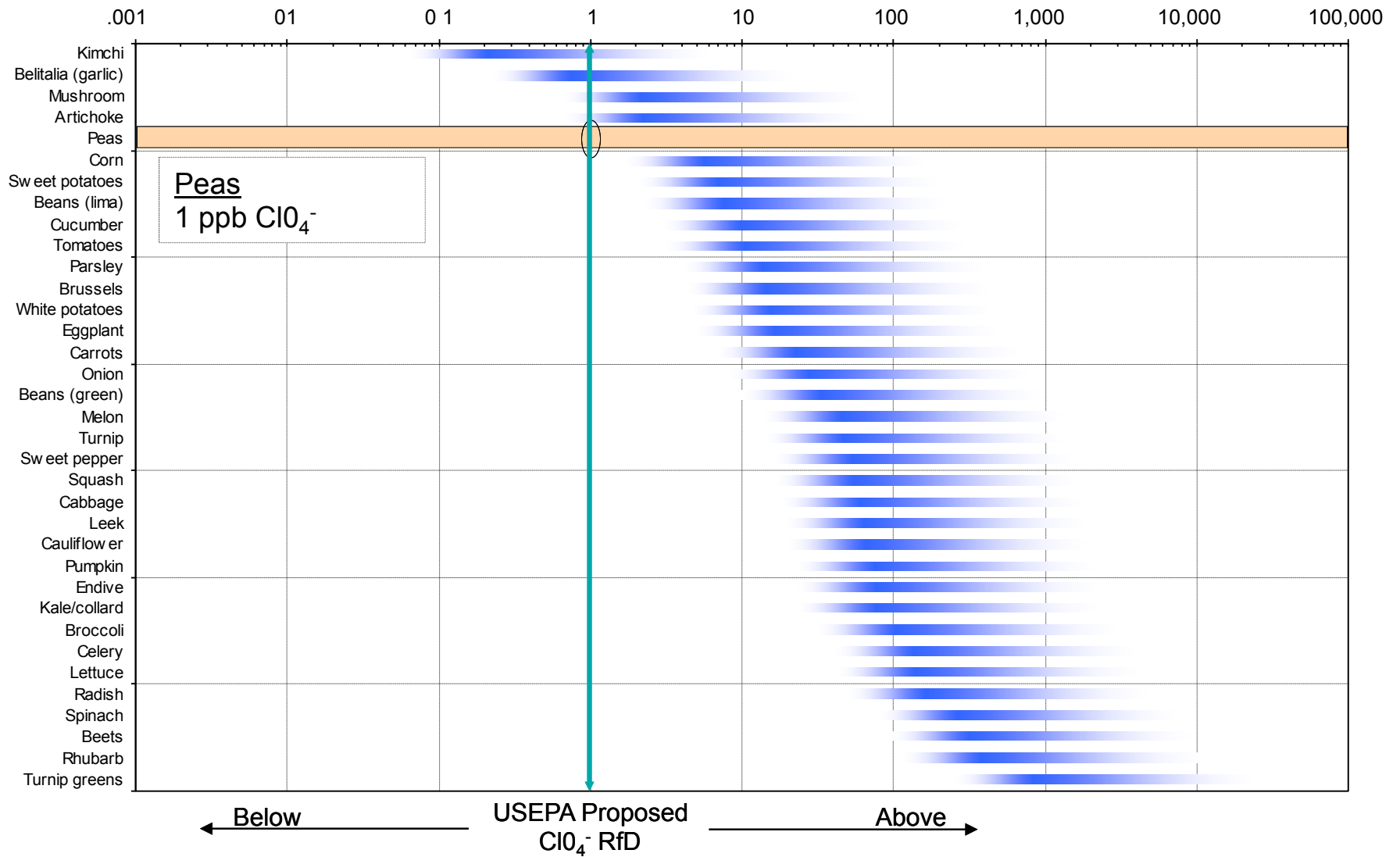


Vegetables— Highest Plausible PER Scenario

- Stripe graphs illustrate results
 - Lower-bound value of each stripe applies
 - Values increase exponentially to the right
 - For 30 of 35 vegetables, single servings...
 - Exceed IUI permitted by USEPA proposed perchlorate RfD
 - Exceed RfD by much more than dairy or processed meats
 - Examples of perchlorate drinking water equivalent levels
 - Peas 1 ppb
 - Cucumber & tomatoes 3 ppb
 - Broccoli, celery & lettuce 30 ppb
 - Turnip greens 300 ppb
-

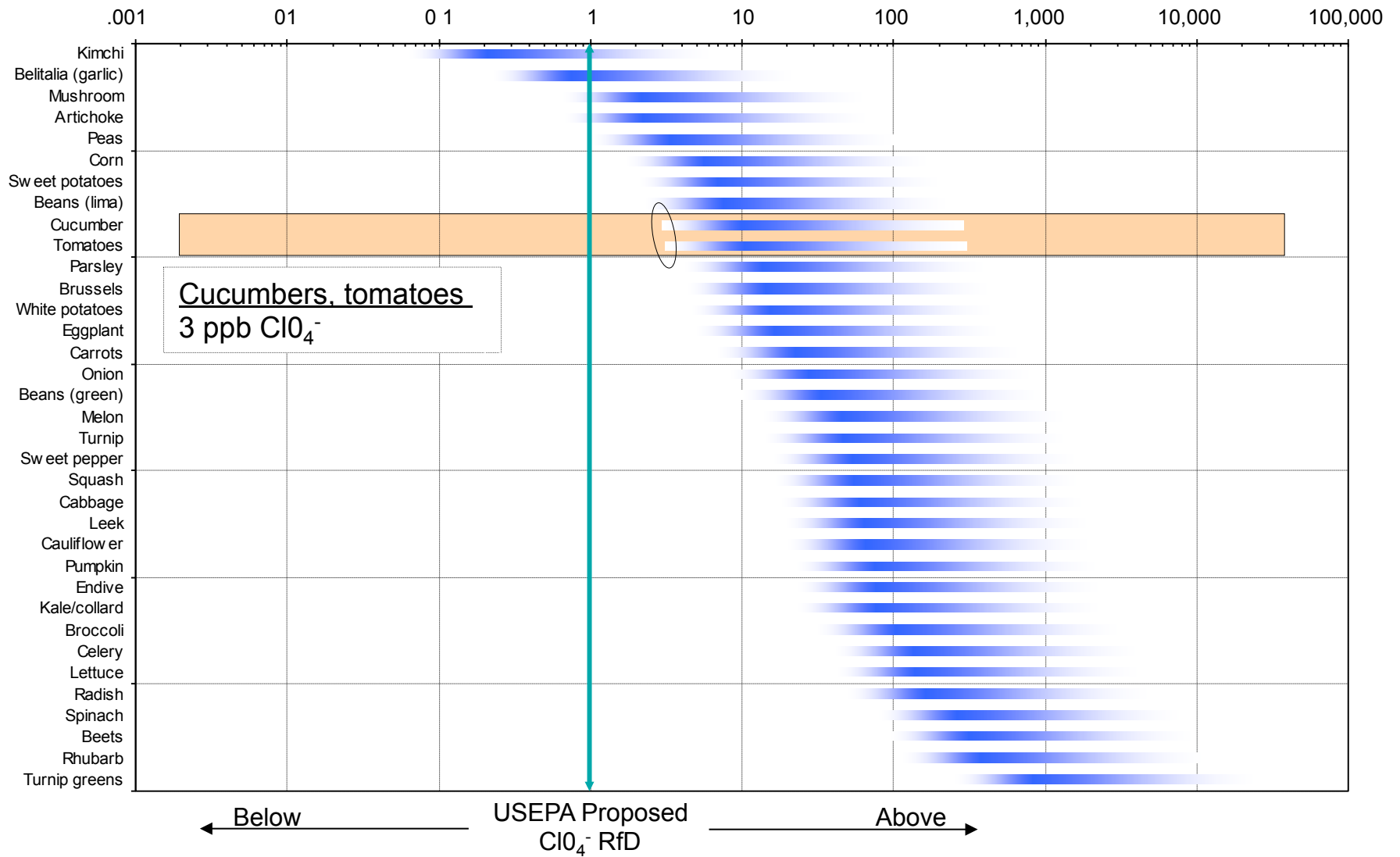
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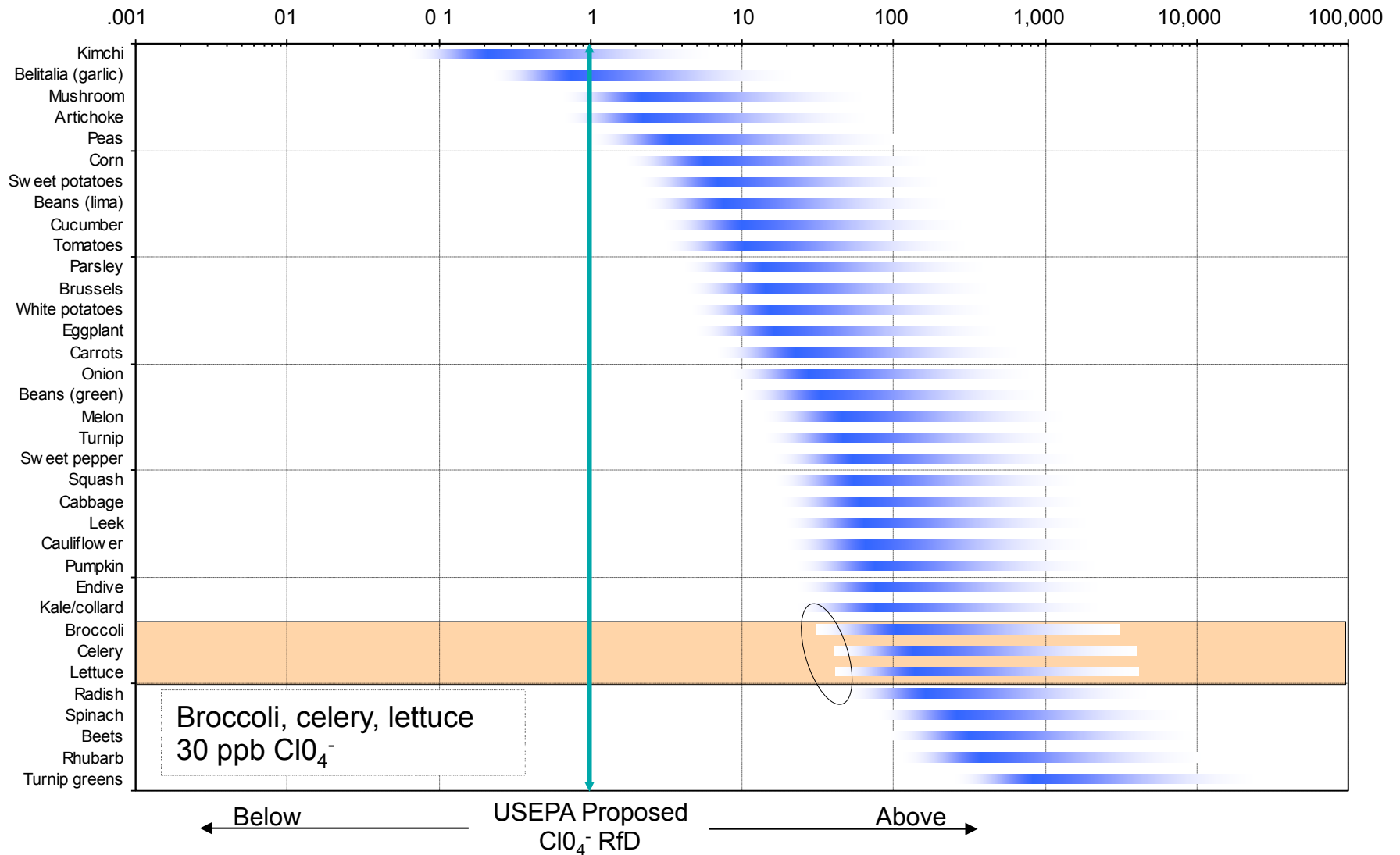
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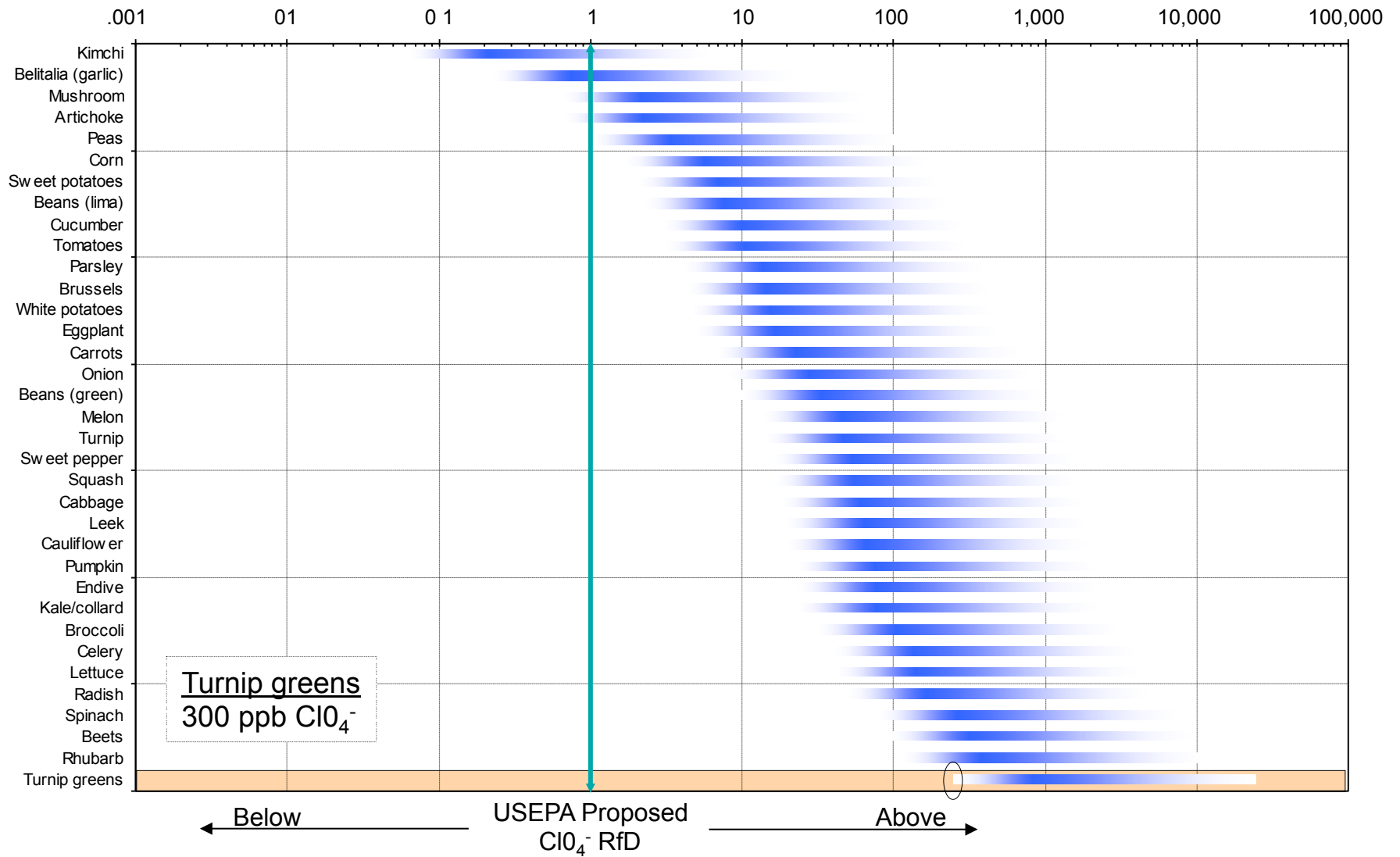
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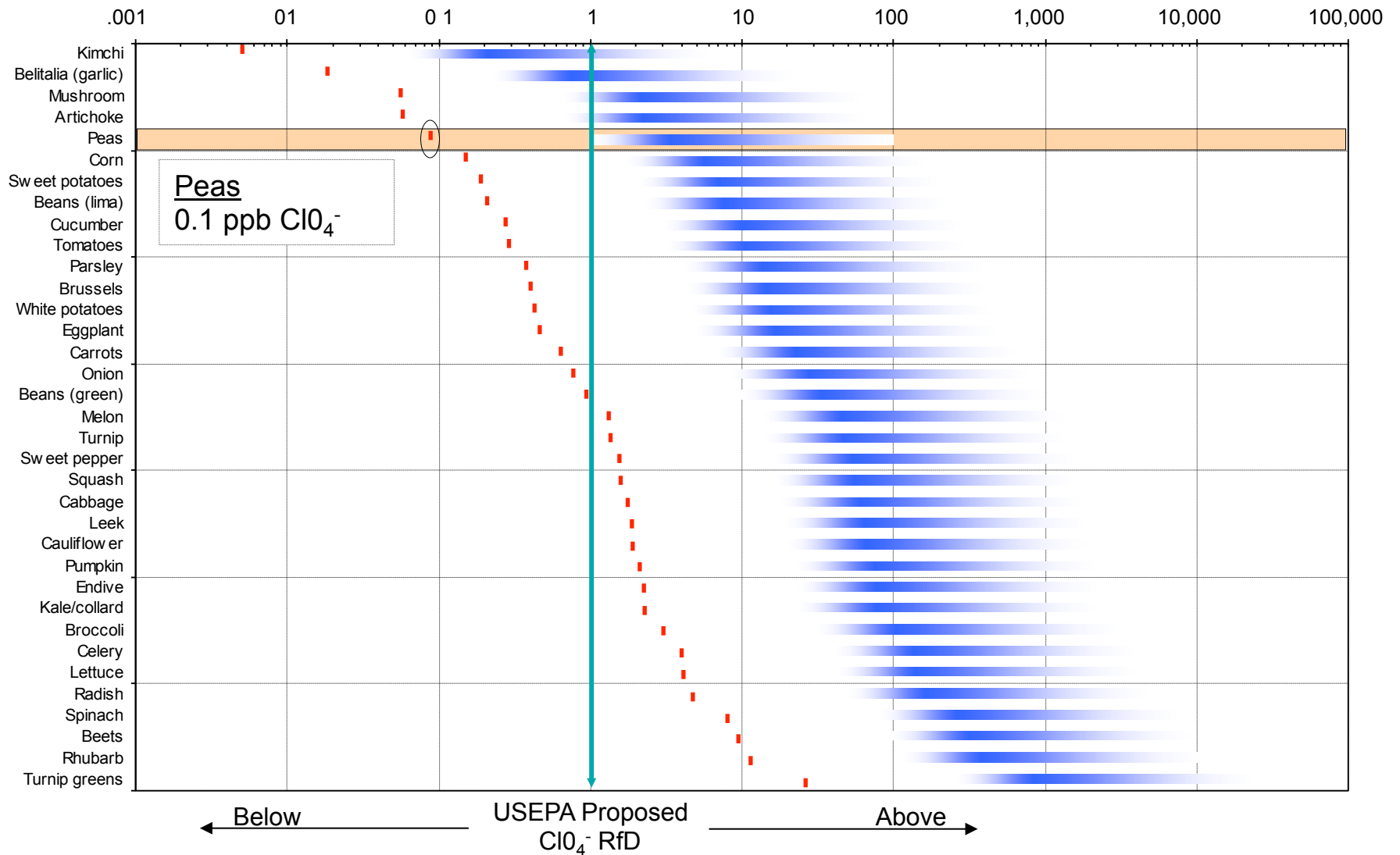
Vegetables—

Nitrate MCL PER Scenario

- Stripe graphs illustrate results
 - Red hash marks apply
 - Values increase exponentially to the right
 - No scientific evidence supporting PER this high, but PER this high or higher is implied by nitrate MCL and perchlorate DWEL
 - for 18 of 35 vegetables, single servings...
 - Exceed IUI permitted by USEPA proposed perchlorate RfD
 - Exceed RfD by much more than dairy or processed meats
 - Examples
 - Peas 0.1 ppb
 - Cucumber & tomatoes 0.3 ppb
 - Broccoli, celery & lettuce 3 ppb
 - Turnip greens 25 ppb
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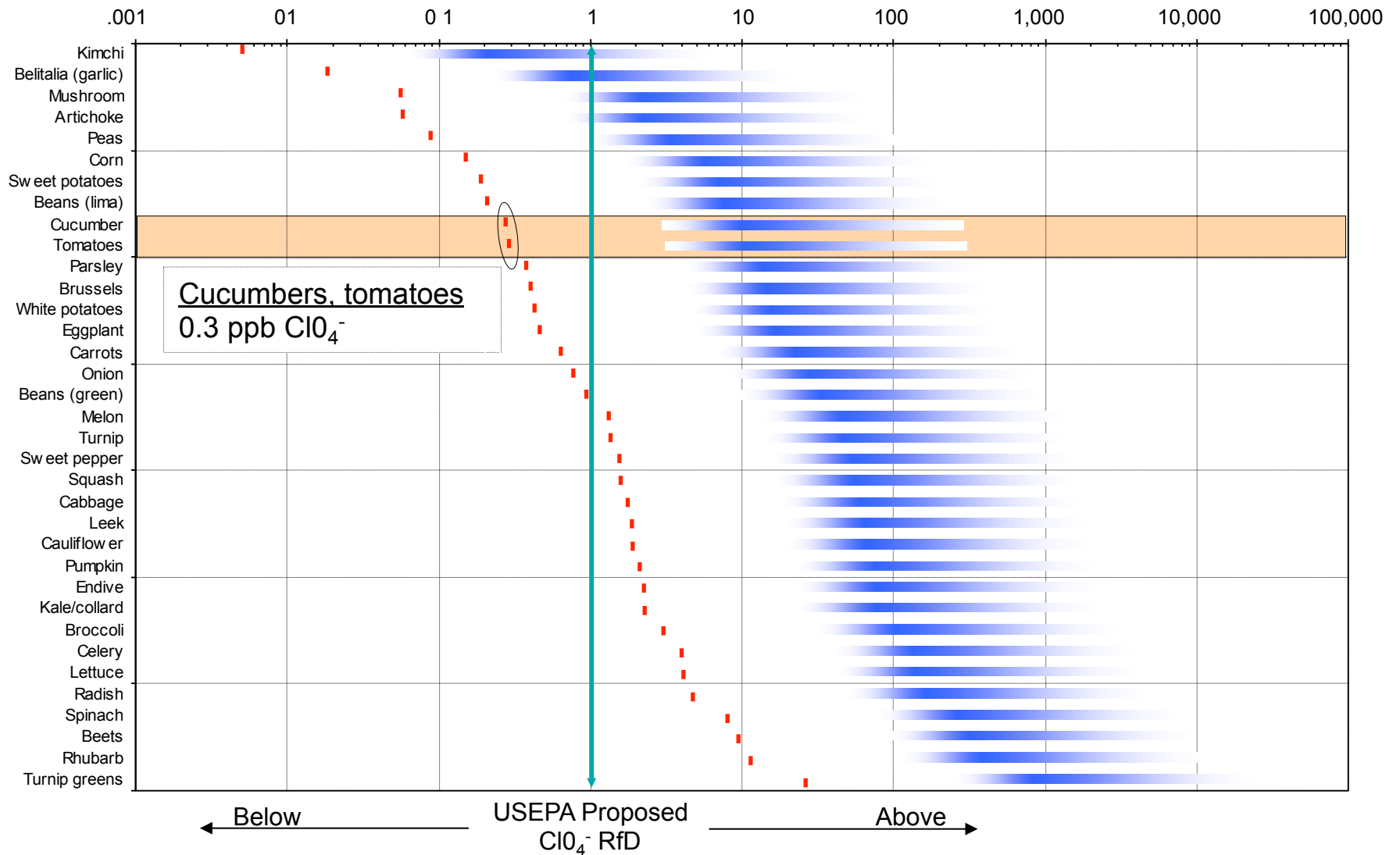
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Nitrate MCL PER Scenario



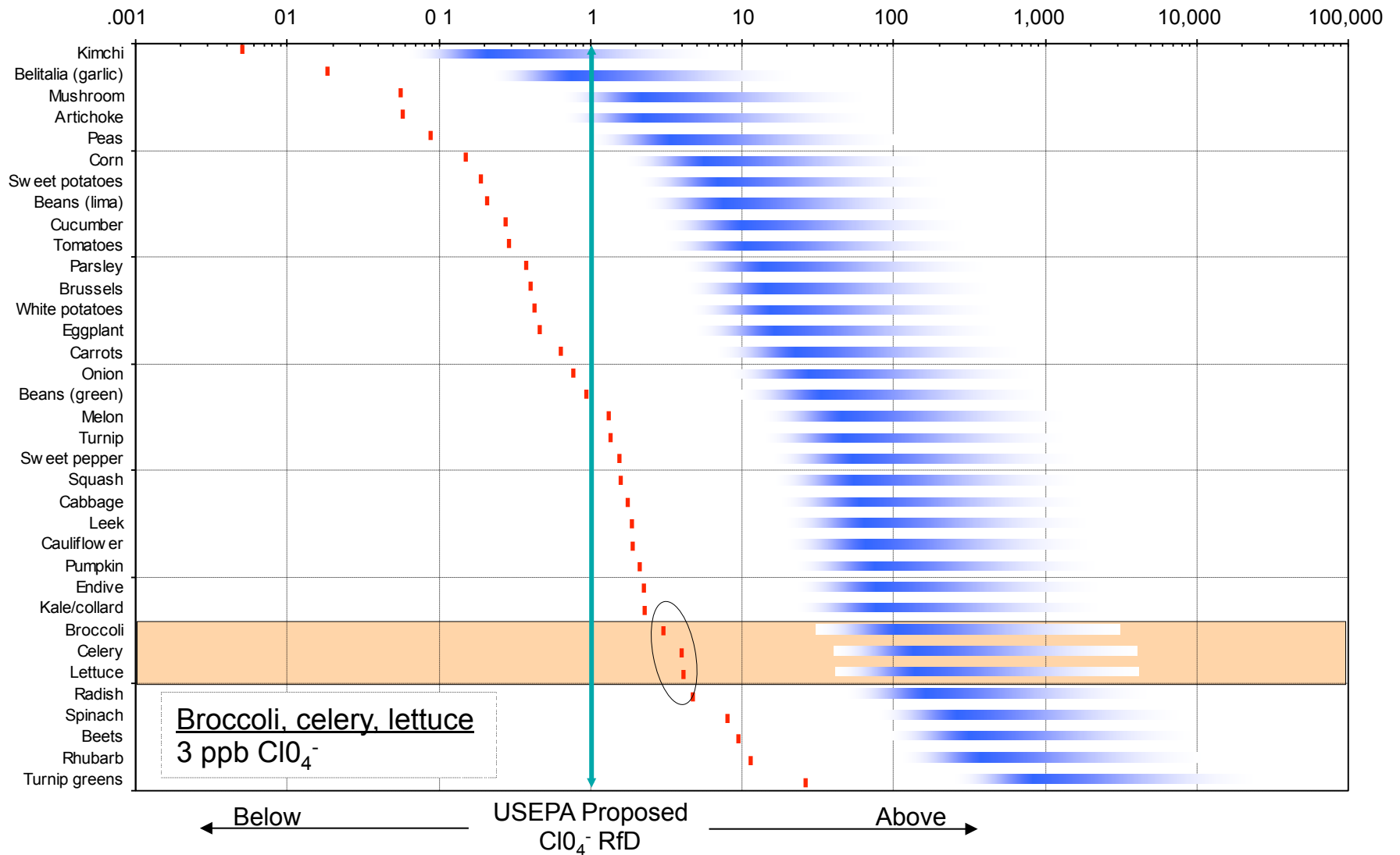
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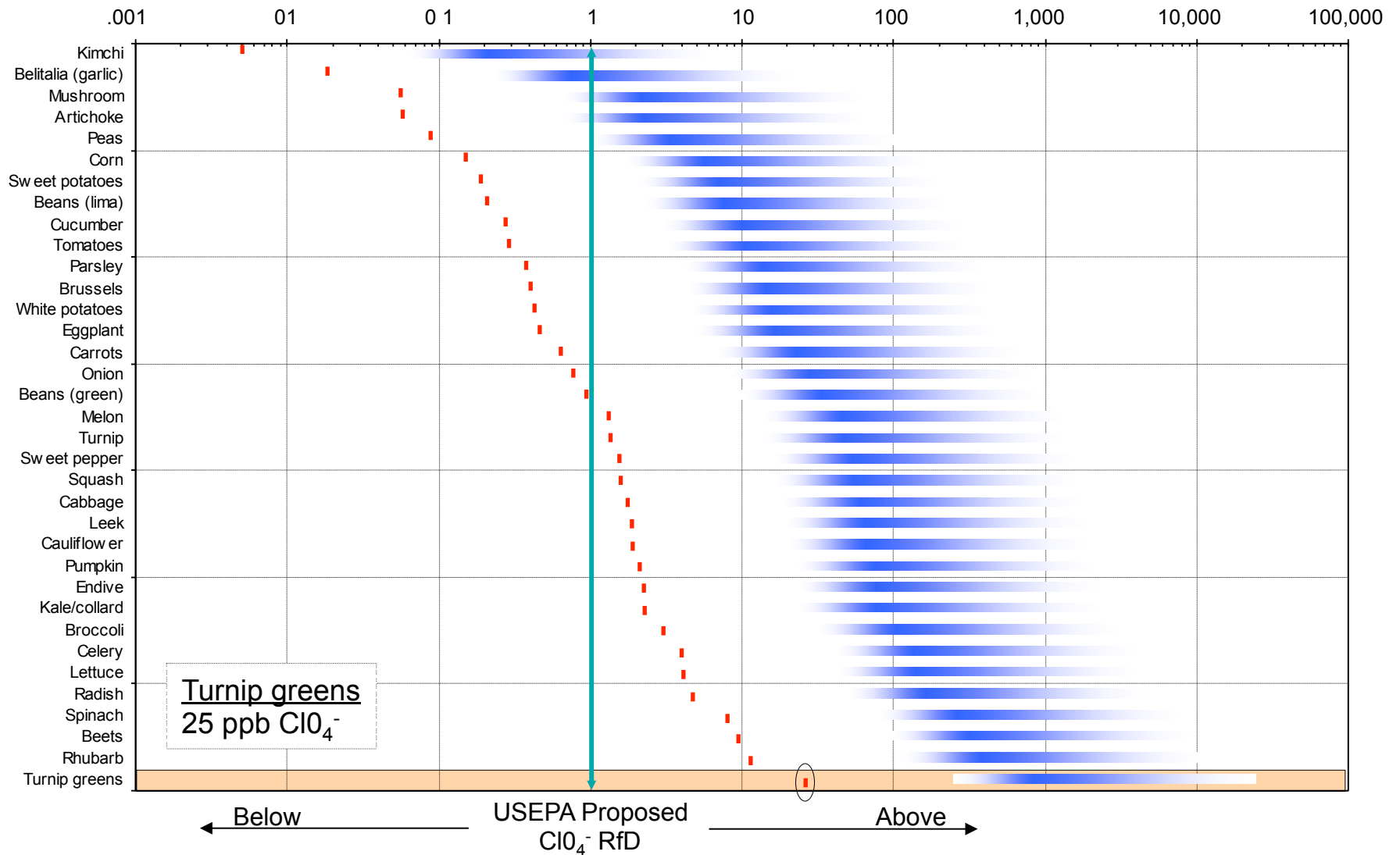
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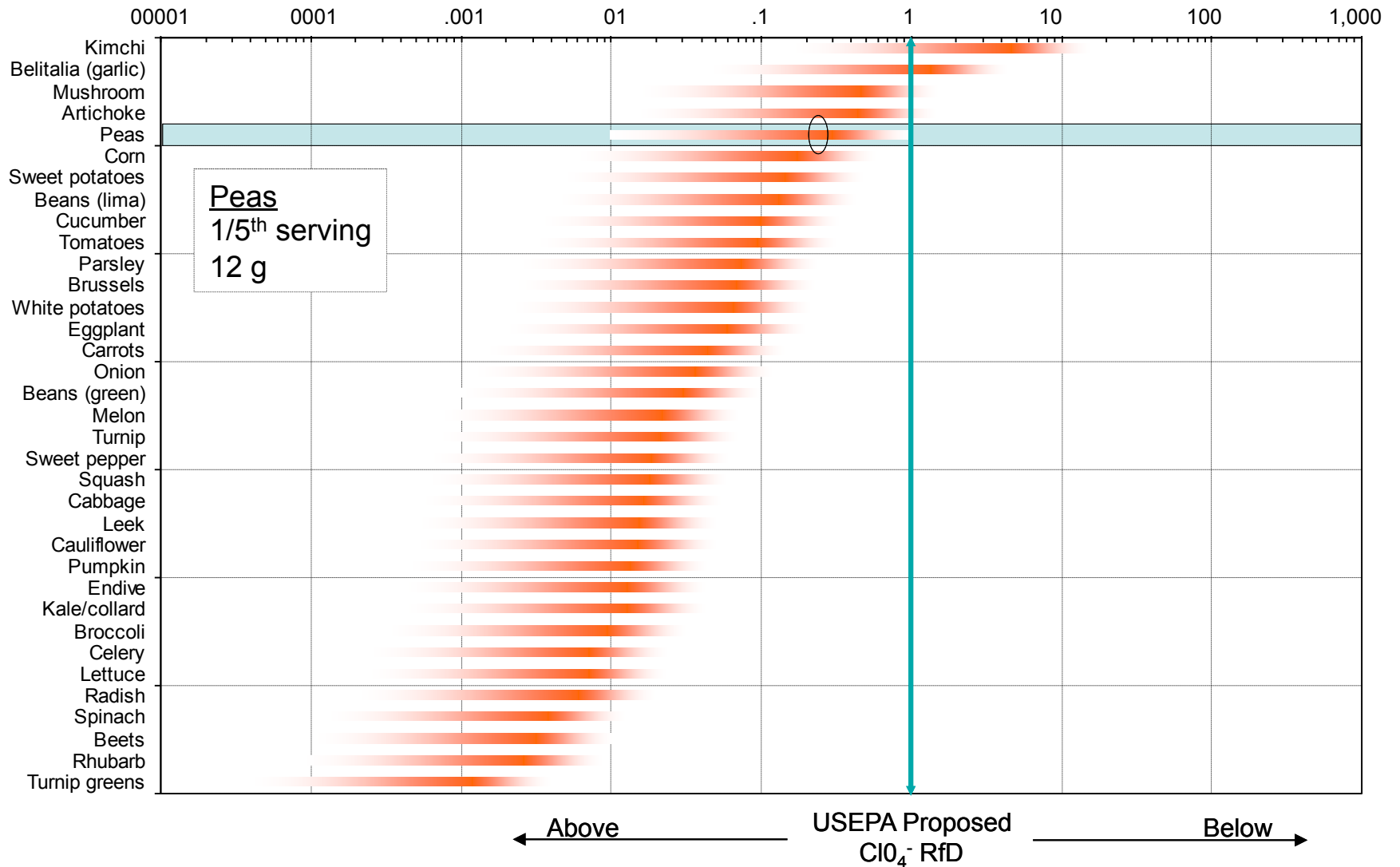
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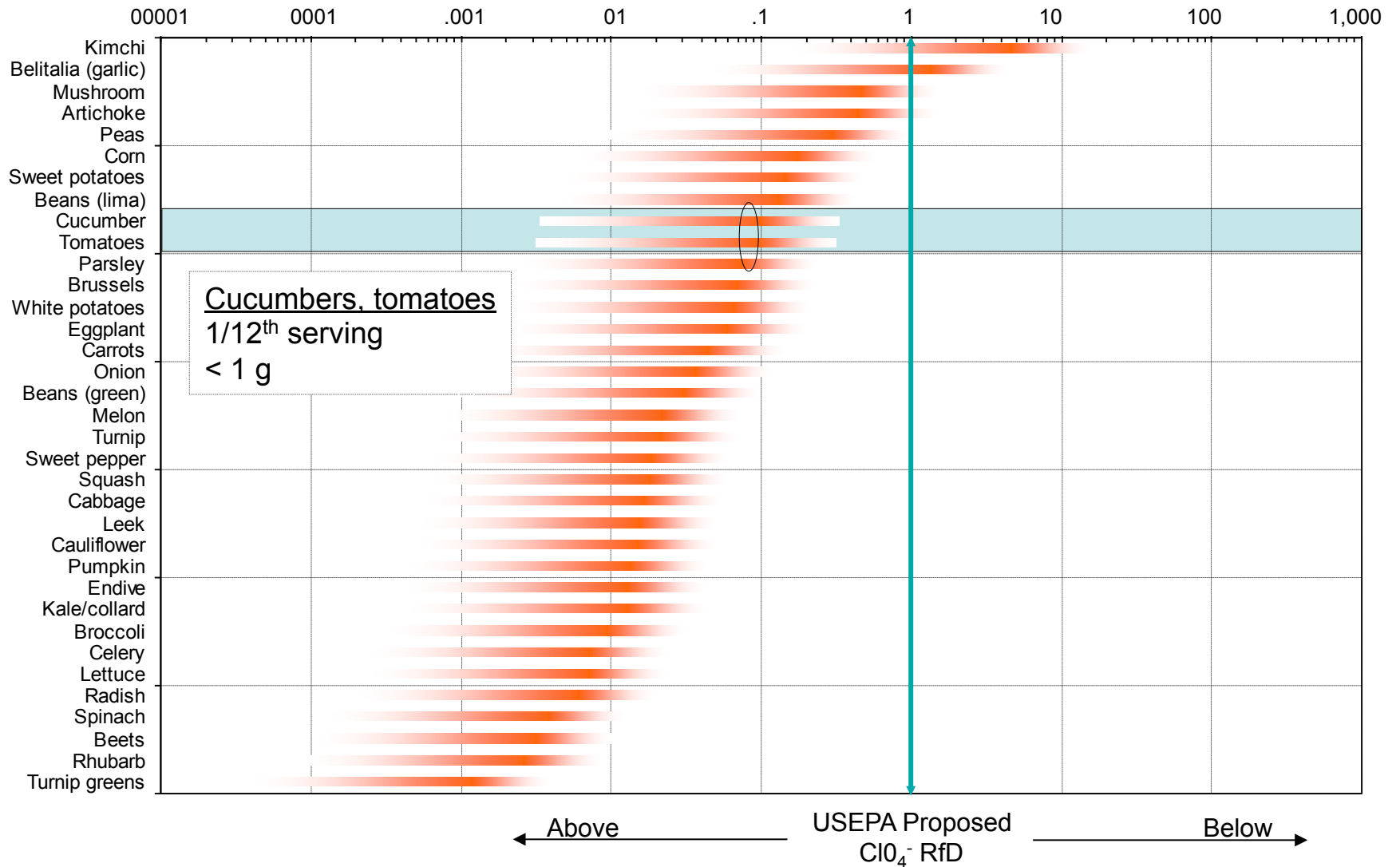
Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Best Professional Judgment PER Scenario



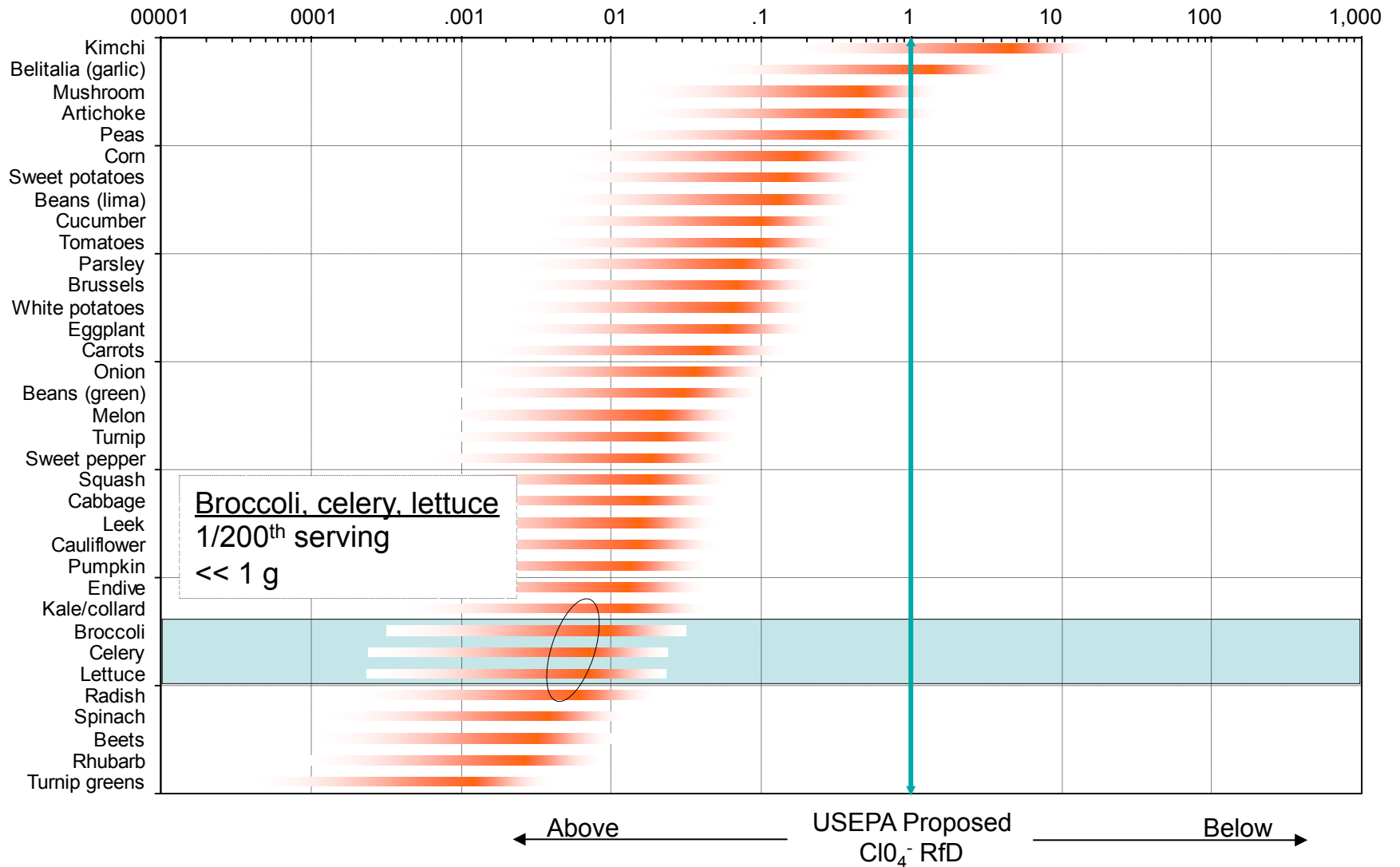
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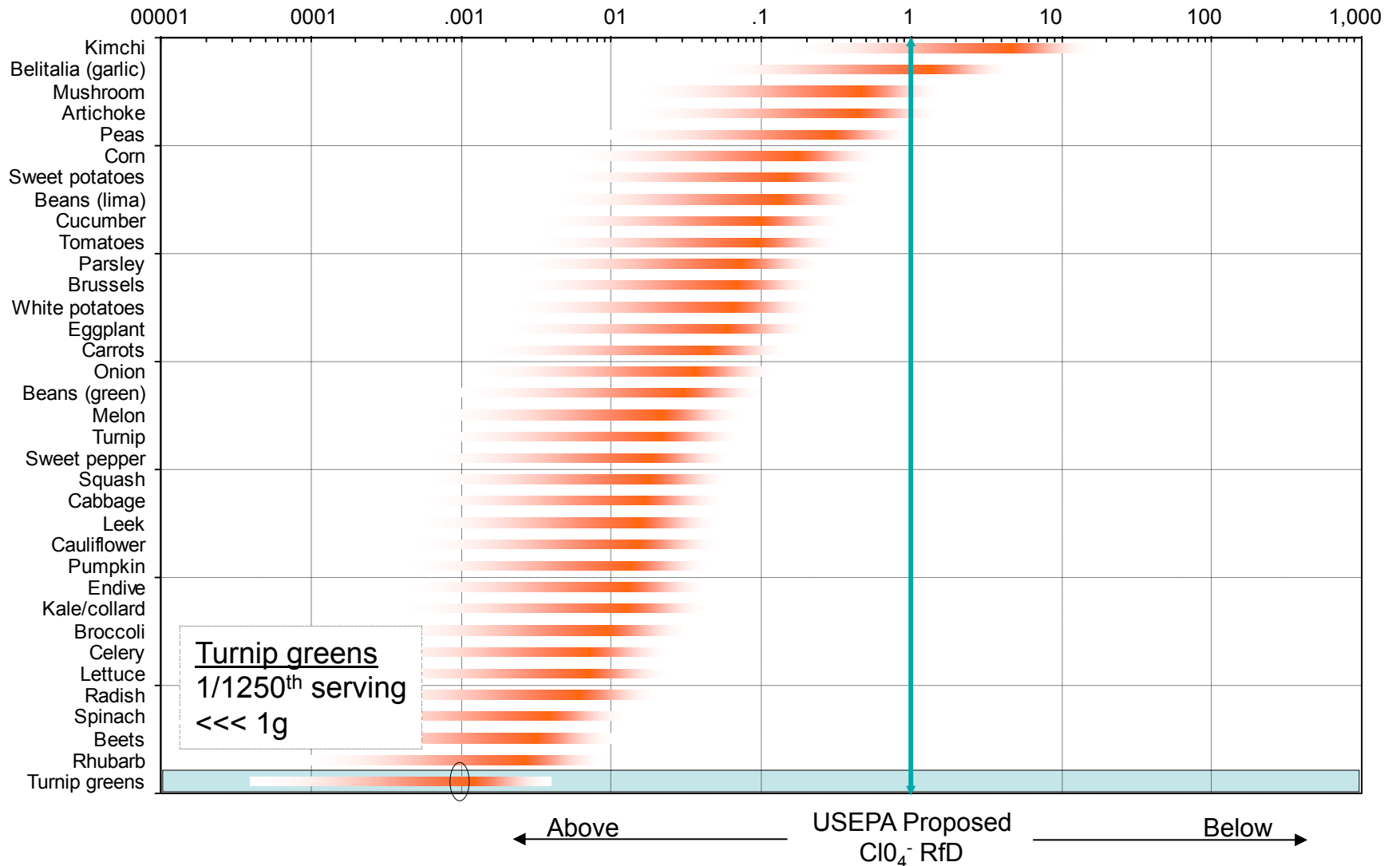
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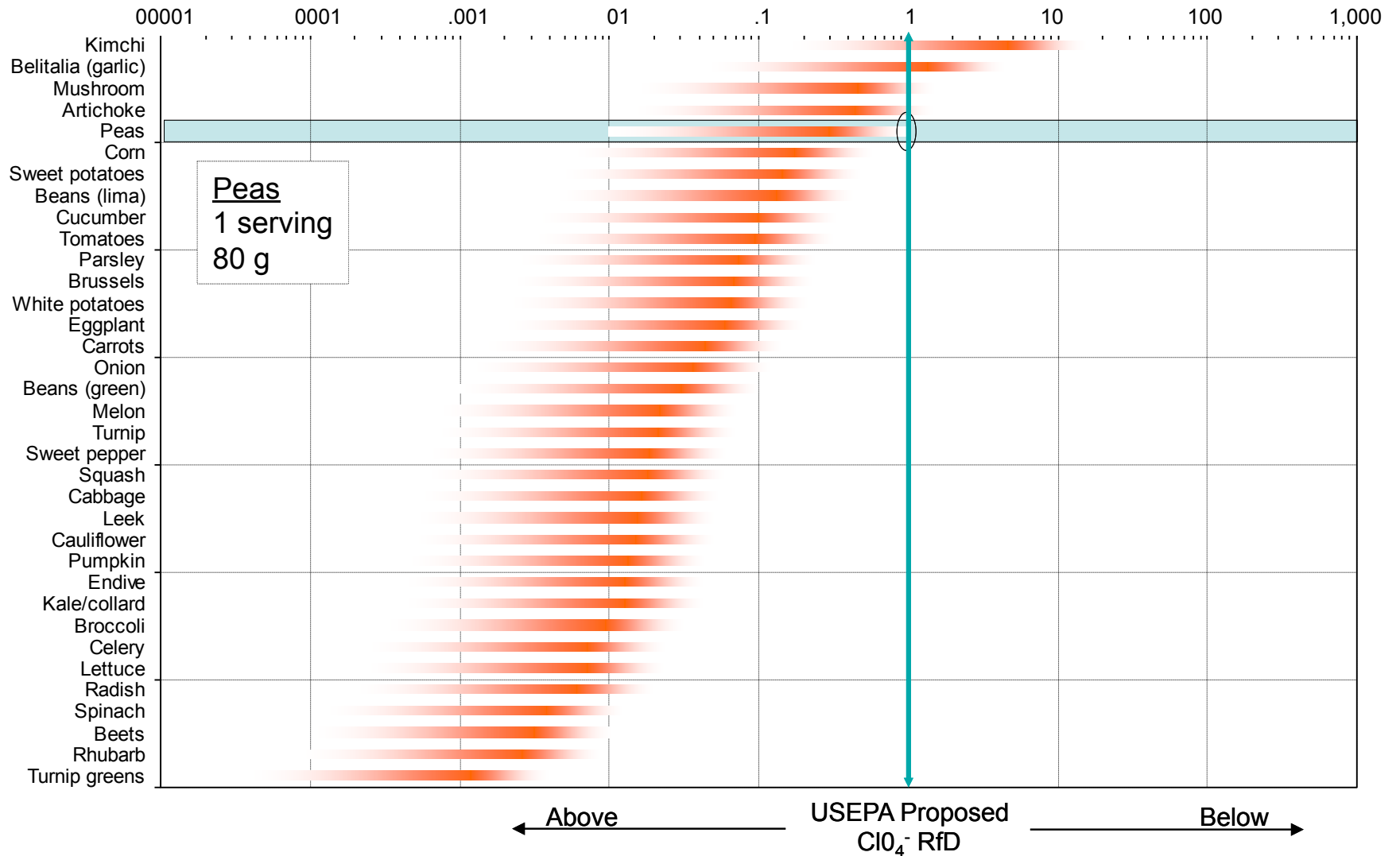
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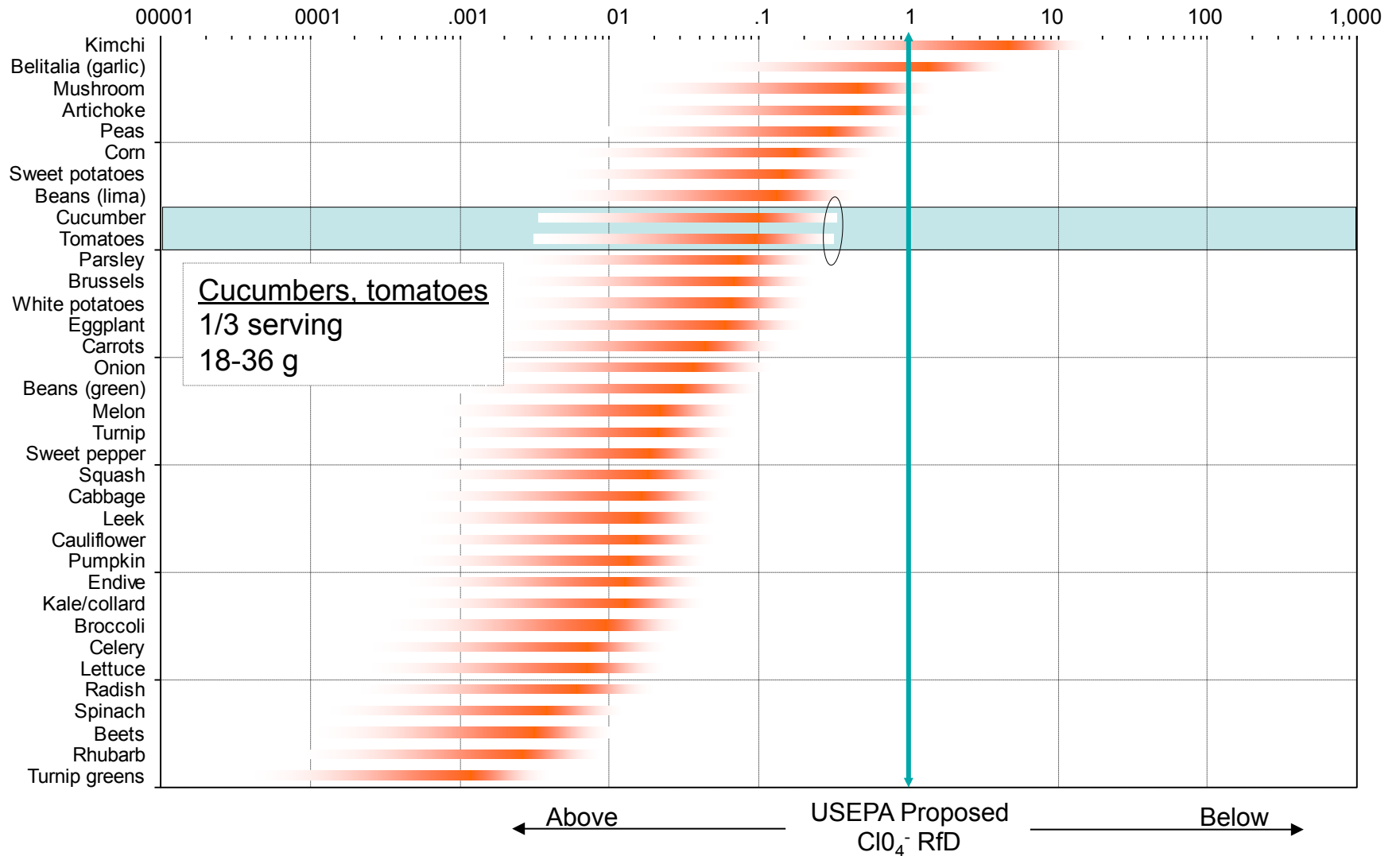
Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Maximum Plausible PER Scenario



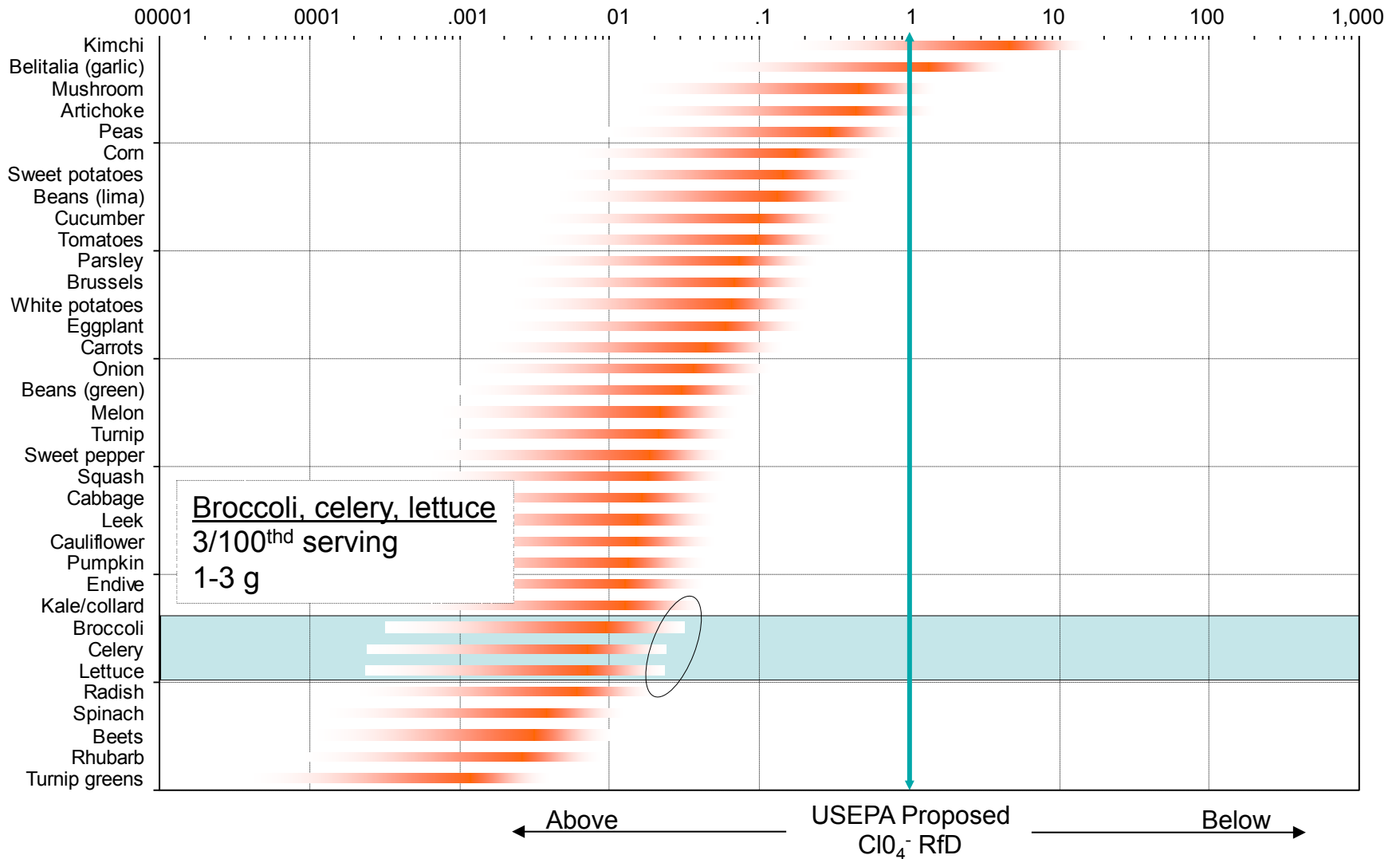
Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Maximum Plausible PER Scenario



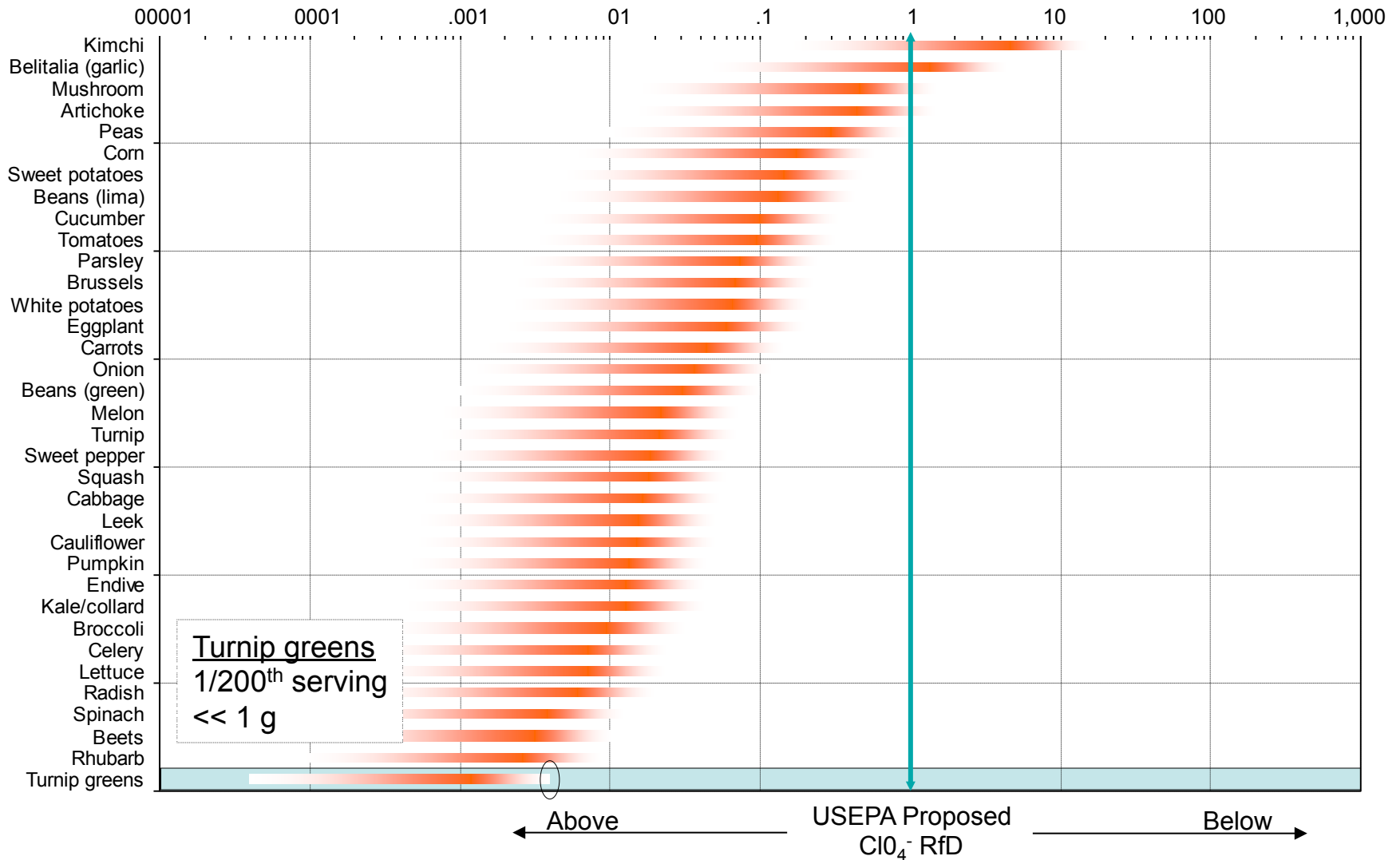
Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Maximum Plausible PER Scenario



Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Maximum Plausible PER Scenario

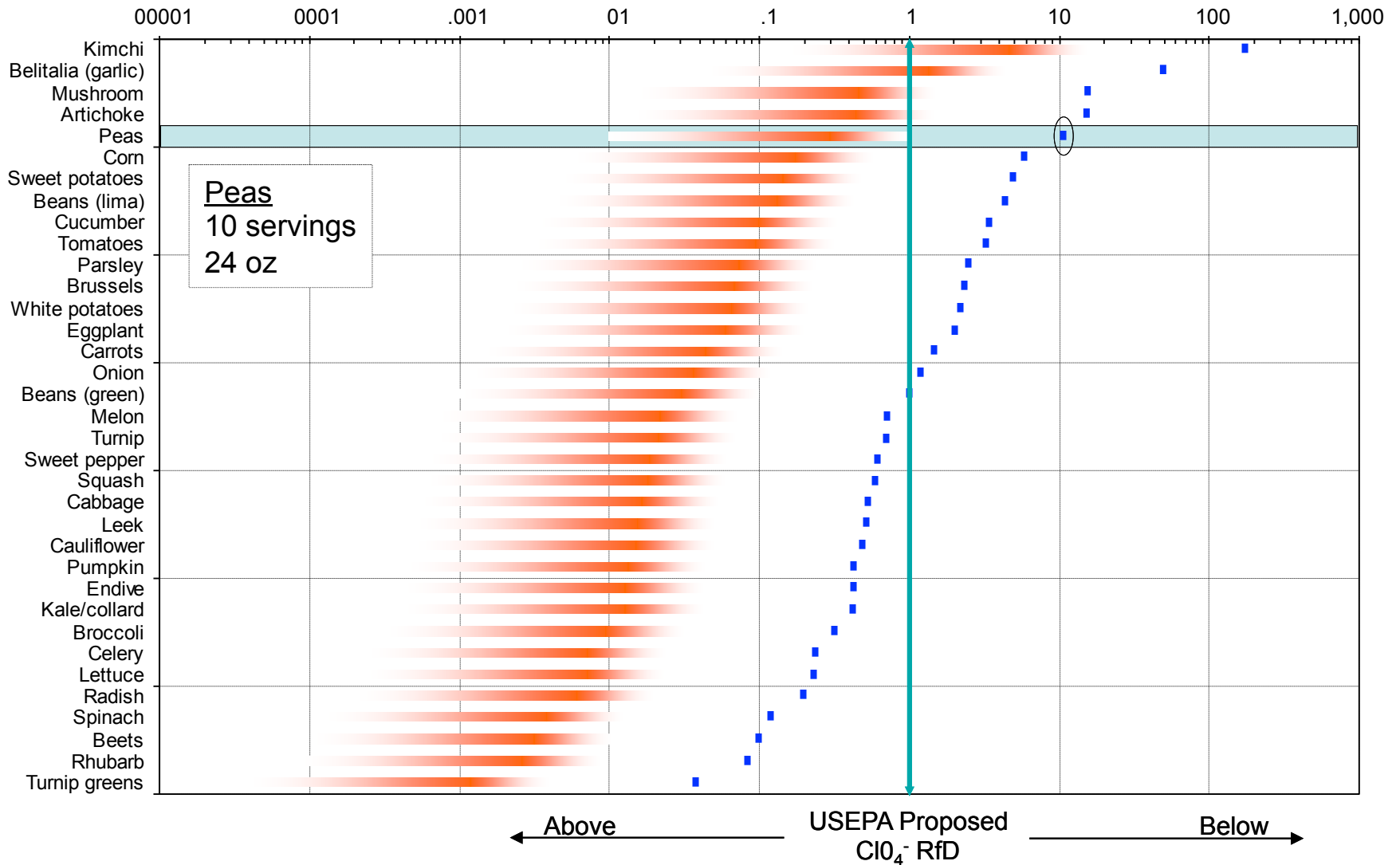


Maximum “Safe” Number of Servings— Nitrate MCL PER Scenario

- Stripe graphs illustrate results
 - Blue hash marks apply
 - Values decrease exponentially to the left
 - Some vegetable consumption causes more IUI than allowed by USEPA proposed perchlorate RfD
 - For some items, consumption is okay
 - Peas below 10 servings (24 oz)
 - For many items, consumption is marginal
 - Cucumbers, tomatoes below 3 servings (6/13 oz)
 - For some items, consumption must be eliminated
 - Broccoli below 1/3rd serving (1 oz/30 g)
 - Lettuce below 1/4th serving (1 oz/30 g)
 - Celery below 1/4th serving (3/4 oz/23 g)
 - Turnip greens below 1/20th serving (1/6 oz/5 g)
-

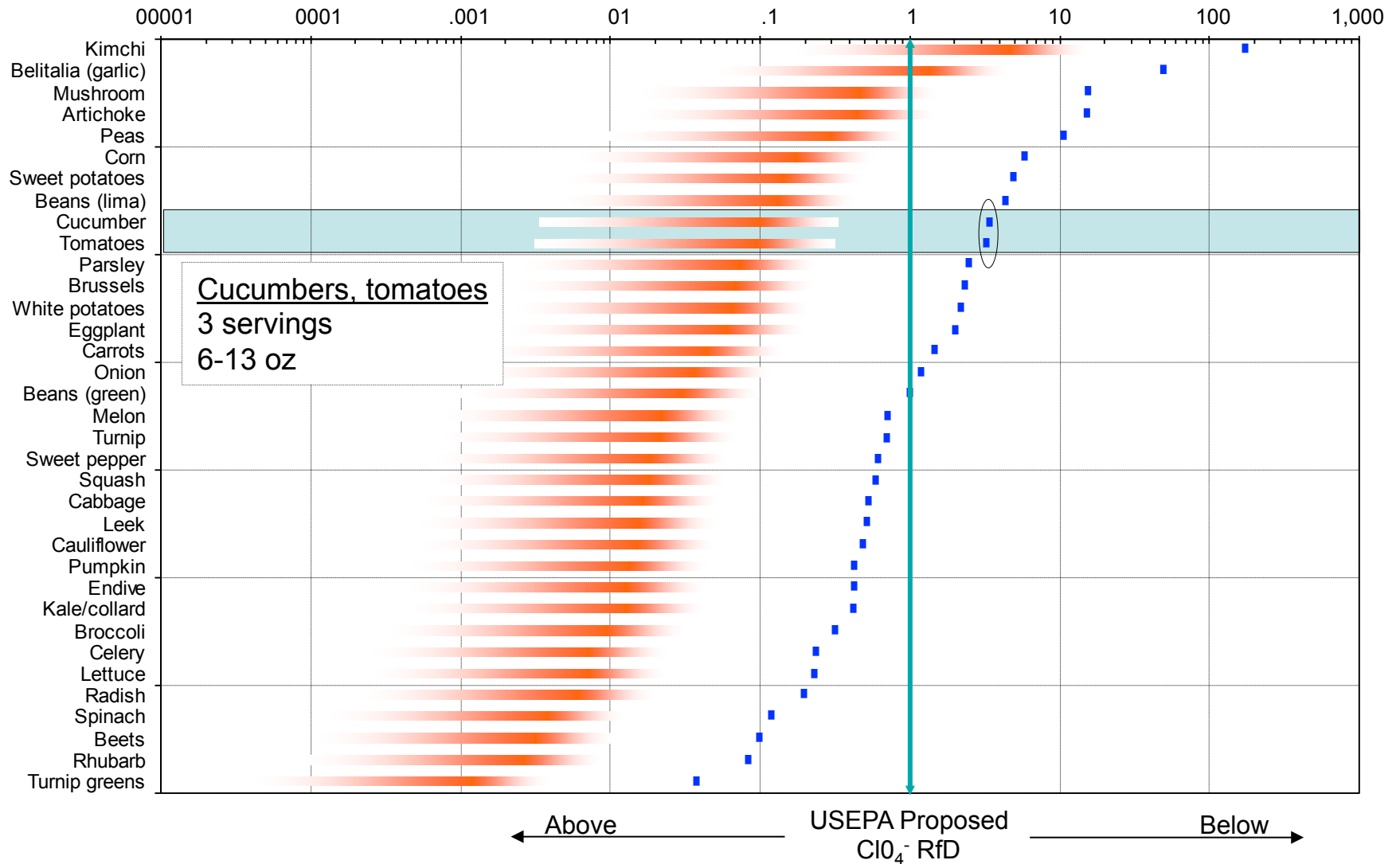
Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Nitrate MCL PER Scenario



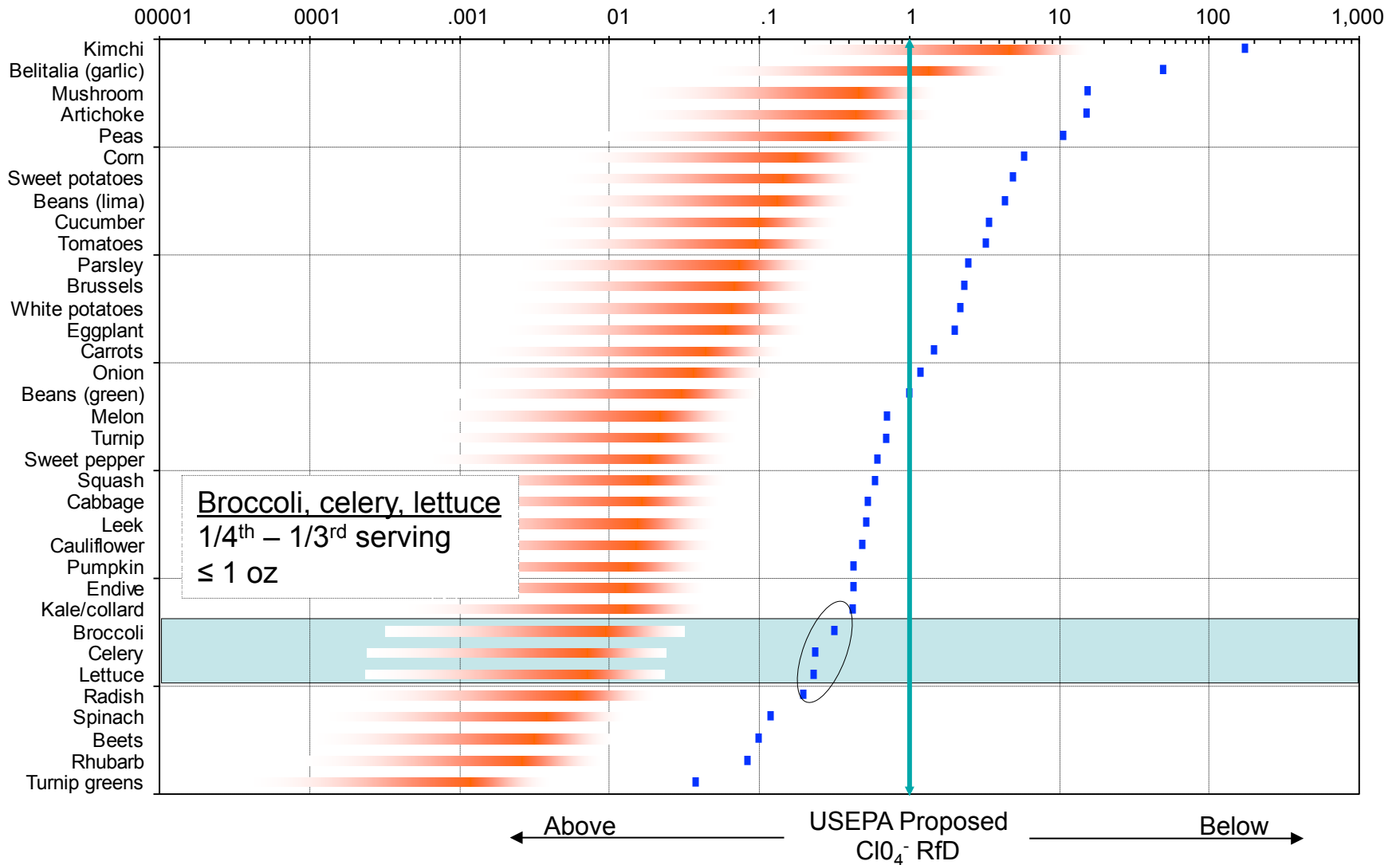
Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Nitrate MCL PER Scenario



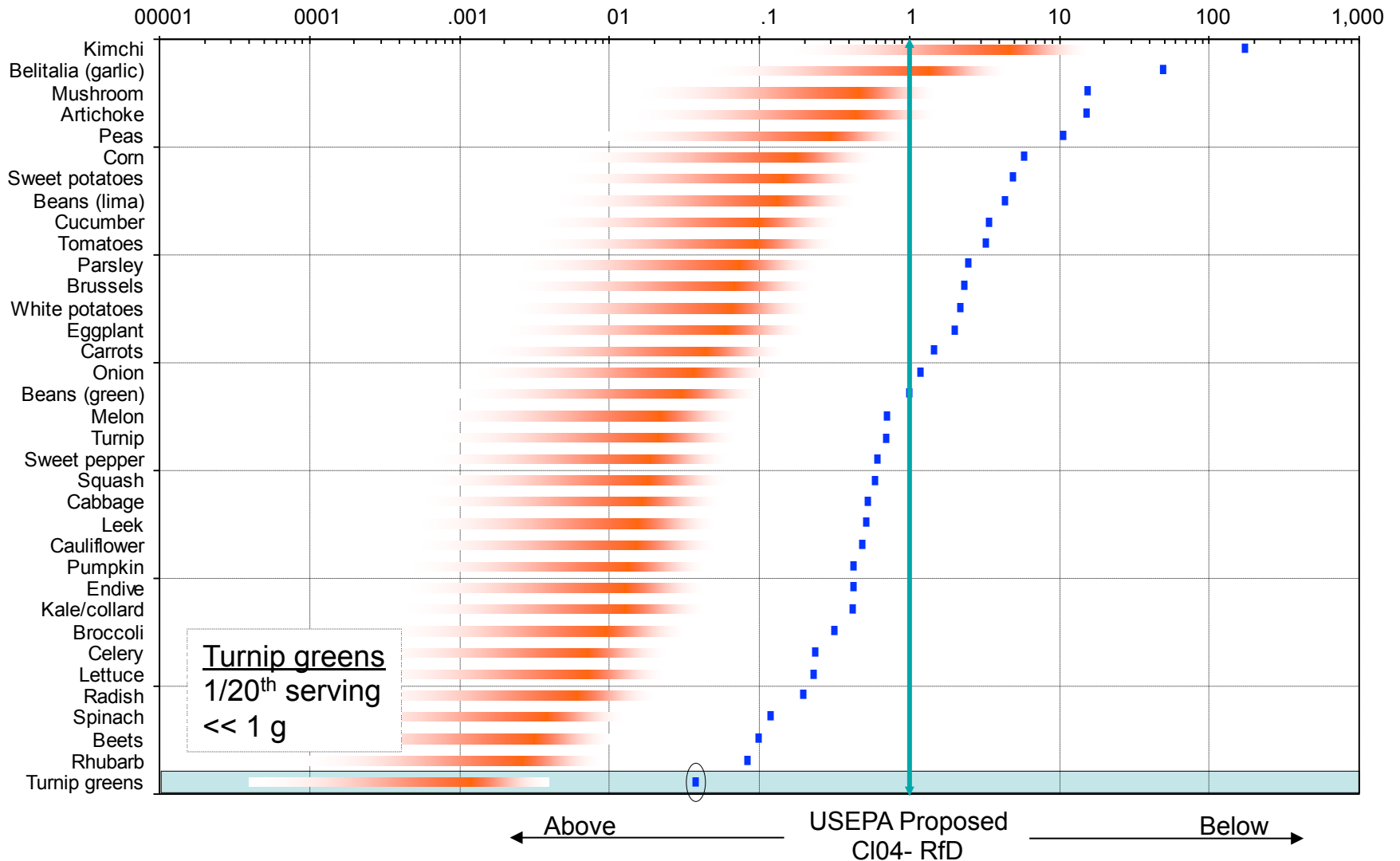
Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Nitrate MCL PER Scenario



Maximum Servings of Vegetables Permitted to Avoid Exceeding 1 ppb Perchlorate-Equivalent in Drinking Water

Nitrate MCL PER Scenario



Implications for Risk Communication: “Safe” or “Unsafe”?

- The level of exposure always matters
 - Regulatory authorities are charged with determining what’s “safe”
 - Inconsistent with the assessment of risk...
 - Risk rises with exposure or dose
 - ...but consistent with what people want to know
 - Reinforced by dichotomous risk indicators such as RfD
 - Setting RfD for perchlorate will produce a dichotomous risk message
 - “Safe”
 - “Unsafe”
-

USEPA Risk Communication Message:

Dairy and Processed Meats

- Very few are “safe”
 - They are “safe” only under high PER scenarios
- Most are “unsafe”
 - The true PER doesn't matter

Perchlorate-equivalent exposure in ppb, per serving
 Green = “safe” Red = “unsafe”

PER Value	10	30	100	300	1000
Bacon (peameal)	10.	4.	1.	.4	.1
Bacon (smoked)	40.	10.	4.	1.	.4
Milk	60.	20.	6.	2.	.6
Sausage (German)	90.	30.	9.	3.	.9
Bacon (unsmoked side)	100.	30.	10.	3.	1.
Sausage (Ukrainian Polish)	100.	30.	10.	3.	1.
Bacon (unsmoked back)	100.	40.	10.	4.	1.
Sausage (summer)	200.	60.	20.	6.	2.
Pepperoni (beef)	200.	60.	20.	6.	2.
Beef (pickled)	300.	90.	30.	9.	3.
Beef (canned corned)	300.	100.	30.	10.	3.
Beef (corned brisket)	300.	100.	30.	10.	3.
Ham	400.	100.	40.	10.	4.
Ham (smoked)	500.	200.	50.	20.	5.
Beef (corned)	500.	200.	50.	20.	5.
Ham (cured)	3,000.	1,000.	300.	100.	30.
Beef (cured corned)	3,000.	1,000.	300.	100.	30.

USEPA Risk Communication Message:

Vegetables

- Most are unsafe
- True PER does not matter

Perchlorate-equivalent exposure in ppb, per serving
 Green = "safe" Red = "unsafe"

PER Value	10	30	100	300	1000
Corn	200.	60.	20.	6.	2.
Sweet potatoes	200.	70.	20.	7.	2.
Beans (lima)	200.	80.	20.	8.	2.
Cucumber	300.	100.	30.	10.	3.
Tomatoes	300.	100.	30.	10.	3.
Parsley	400.	100.	40.	10.	4.
Brussels sprouts	400.	100.	40.	10.	4.
White potatoes	500.	200.	50.	20.	5.
Eggplant	500.	200.	50.	20.	5.
Carrots	700.	200.	70.	20.	7.
Onion	800.	300.	80.	30.	8.
Beans (green)	1,000.	300.	100.	30.	10.
Melon	1,000.	500.	100.	50.	10.
Turnip	1,000.	500.	100.	50.	10.
Sweet pepper	2,000.	500.	200.	50.	20.

Implications for USEPA Risk Assessments for Nitrates and Perchlorate

- At least one of the following is true
 - USEPA's nitrate risk assessment is wrong
 - USEPA's perchlorate risk assessment implicitly predicts IUI at nitrate levels below methemoglobinemia
 - The nitrate risk assessment is not protective against IUI, or IUI is not an adverse effect
 - USEPA's perchlorate risk assessment is wrong
 - IUI occurs at nitrate exposure levels above methemoglobinemia
 - The perchlorate risk assessment severely underestimates the level of perchlorate exposure that may cause IUI
-

Implications for USEPA's Nitrate Risk Assessment

- If USEPA's nitrate risk assessment is scientifically valid, then:
 - Consumption of common foods is safe
 - Preventing IUI is not a public health concern
 - IUI is not an adverse effect
 - Results can't be reconciled to perchlorate risk assessment
-

Implications for USEPA's Perchlorate Risk Assessment

- If USEPA's perchlorate risk assessment is scientifically valid, then:
 - Common foods cause much more IUI than perchlorate at environmental exposure levels
 - Consumption of these foods is not safe
 - IUI from nitrates should be endemic and readily detectable in the general population
 - Results can't be reconciled to nitrate risk assessment
-

USEPA “Provisional” Reference Dose:

Risk Communication

Message

- Provisional RfD is 32 ppb DWEL
- All PER/food pairs < 32 ppb are “safe”
- 43% still “unsafe”

Perchlorate-equivalent exposure in ppb, per serving
Green = “safe” Red = “unsafe”

PER Value	10	30	100	300	1000
Bacon (peameal)	10.	4.	1.	.4	.1
Bacon (smoked)	40.	10.	4.	1.	.4
Milk	60.	20.	6.	2.	.6
Sausage (German)	90.	30.	9.	3.	.9
Bacon (unsmoked side)	100.	30.	10.	3.	1.
Sausage (Ukranian Polish)	100.	30.	10.	3.	1.
Bacon (unsmoked back)	100.	40.	10.	4.	1.
Sausage (summer)	200.	60.	20.	6.	2.
Pepperoni (beef)	200.	60.	20.	6.	2.
Beef (pickled)	300.	90.	30.	9.	3.
Beef (canned corned)	300.	100.	30.	10.	3.
Beef (corned brisket)	300.	100.	30.	10.	3.
Ham	400.	100.	40.	10.	4.
Ham (smoked)	500.	200.	50.	20.	5.
Beef (corned)	500.	200.	50.	20.	5.
Ham (cured)	3,000.	1,000.	300.	100.	30.
Beef (cured corned)	3,000.	1,000.	300.	100.	30.

USEPA “Provisional” Reference Dose:

Vegetables

- 15 moderate-nitrate vegetables are mixed
- 57% of values are “unsafe”

Perchlorate-equivalent exposure in ppb, per serving
 Green = “safe”
 Red = “unsafe”

PER Value	10	30	100	300	1000
Corn	200.	60.	20.	6.	2.
Sweet potatoes	200.	70.	20.	7.	2.
Beans (lima)	200.	80.	20.	8.	2.
Cucumber	300.	100.	30.	10.	3.
Tomatoes	300.	100.	30.	10.	3.
Parsley	400.	100.	40.	10.	4.
Brussels sprouts	400.	100.	40.	10.	4.
White potatoes	500.	200.	50.	20.	5.
Eggplant	500.	200.	50.	20.	5.
Carrots	700.	200.	70.	20.	7.
Onion	800.	300.	80.	30.	8.
Beans (green)	1,000.	300.	100.	30.	10.
Melon	1,000.	500.	100.	50.	10.
Turnip	1,000.	500.	100.	50.	10.
Sweet pepper	2,000.	500.	200.	50.	20.

USEPA “Provisional” Reference Dose:

Vegetables

- 15 high-nitrate vegetables “unsafe” under almost all conditions
- 90% of values are “unsafe”

Perchlorate-equivalent exposure in ppb, per serving
 Green = “safe”
 Red = “unsafe”

PER Value	10	30	100	300	1000
Squash	2,000.	600.	200.	60.	20.
Cabbage	2,000.	600.	200.	60.	20.
Leek	2,000.	700.	200.	70.	20.
Cauliflower	2,000.	700.	200.	70.	20.
Pumpkin	2,000.	800.	200.	80.	20.
Endive	2,000.	800.	200.	80.	20.
Kale/collard	2,000.	800.	200.	80.	20.
Broccoli	3,000.	1,000.	300.	100.	30.
Celery	4,000.	1,000.	400.	100.	40.
Lettuce	4,000.	1,000.	400.	100.	40.
Radish	5,000.	2,000.	500.	200.	50.
Spinach	8,000.	3,000.	800.	300.	80.
Beets	10,000.	3,000.	1,000.	300.	100.
Rhubarb	10,000.	4,000.	1,000.	400.	100.
Turnip greens	30,000.	8,000.	3,000.	800.	300.

Conclusion

- USEPA's proposed 1 ppb RfD/DWEL significantly understates the safe exposure level for perchlorate in drinking water
 - Common foods contain nitrate, which inhibits iodide uptake the same way as perchlorate
 - These foods are considered safe and healthful
 - These foods cannot be safe if perchlorate exposure hundreds of times lower is not safe
 - The true safe exposure level for perchlorate is much higher than USEPA's proposed RfD
-

Conclusion

- USEPA “provisional” RfD/DWEL of 32 ppb also understates the safe exposure level for perchlorate in drinking water
 - Single servings of many vegetables cause IUI greater than permitted under this RfD
 - These foods are considered safe and healthful
 - These foods cannot be safe if perchlorate exposure below 32 ppb equivalent is not safe
-

Conclusion

- How high is the true RfD/DWEL?
 - Two principles:
 1. Routine dietary IUI must not exceed it
 2. Single servings must always be “safe”
 - $PER = 10 \Rightarrow \geq 30,000$ ppb
 - $PER = 30 \Rightarrow \geq 8,000$ ppb
 - $PER = 100 \Rightarrow \geq 2,000$ ppb
 - $PER = 300 \Rightarrow \geq 800$ ppb
 - $PER = 1,000 \Rightarrow \geq 300$ ppb
 - Depends on PER, but RfD must exceed 300 ppb drinking water equivalent
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