

How Many Substances Are Illegally Listed in the Biennial Report on Carcinogens?

Richard B. Belzer PhD

Belzer@RegulatoryCheckbook.Org

(703) 780-1850

Society for Risk Analysis

2013 Annual Conference

Baltimore, MD

December 10, 2013



Criteria for RoC listing: 42 U.S.C. § 241(b)(4)

The Secretary shall publish a biennial report which contains—

(A) a list of all substances

(i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and

(ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying

(i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and

(ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance.

Criteria for RoC listing: 42 USC § 241(b)(4)

The Secretary shall publish a biennial report which contains—

(A) a list of all substances

(i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and

(ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying

(i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and

(ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance.

Criteria for RoC listing: 42 U.S.C. § 241(b)(4)

The Secretary shall publish a biennial report which contains—

(A) a list of all substances

(i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and

(ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying

(i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and

(ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance.

Criteria for RoC listing: 42 USC § 241(b)(4)

The Secretary shall publish a biennial report which contains—

(A) a list of all substances

(i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and

(ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying

(i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and

(ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance.

Assignment to 'known' category is nonscientific

- ① 'There is sufficient evidence of carcinogenicity from studies in humans, which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer'

Assignment to 'reasonably anticipated' category is nonscientific

- ③ 'Limited evidence of carcinogenicity from studies in humans'
- ③ 'Sufficient evidence of carcinogenicity from studies in experimental animals'
- ③ 'Less than sufficient evidence of carcinogenicity in humans or laboratory animals,' but a catchall provision applies

Assignments are based on policy preferences, not science

- ◎ ‘Sufficient evidence’, ‘limited evidence’, ‘convincing relevant information’ are not scientific terms (and are not defined by NTP)
- ◎ Decisions require a WoE scheme
 - NTP has never disclosed its WoE scheme
 - Evidence is ‘sufficient’, ‘limited’, or ‘convincing’ if NTP says it is
 - Causality is not assessed; it is assumed

Belzer RB. 2012. *The Report on Carcinogens: What Went Wrong and What Can Be Done to Fix It*. Washington, D.C.: Competitive Enterprise Institute.

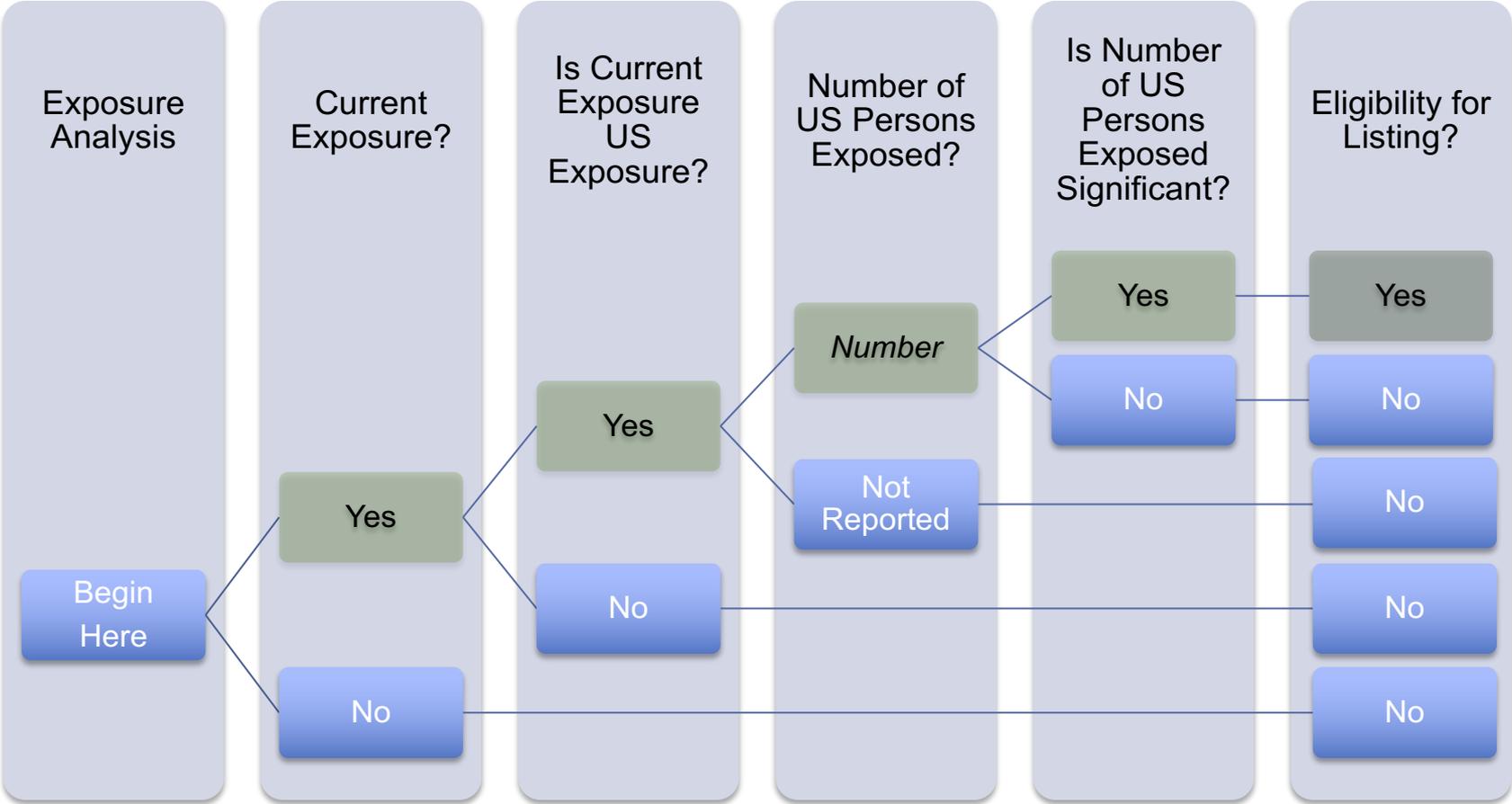
What about exposure?

- ③ § 241(b)(4)(A)(ii) requires that ‘a significant number of persons residing in the United States are exposed’ for listing
- ③ If listed, NTP must report ‘information concerning the nature of such exposure and the estimated number of persons exposed’
- ③ How does NTP comply?

A rational and transparent way to comply with § 241(b)(4)(A)(ii)

- ⊙ Define a *de minimis* cancer risk level
- ⊙ Estimate for each candidate substance the number of persons in the United States exposed above the *de minimis* cancer risk level
- ⊙ Determine if this number is ‘significant’

Exposure analysis logic tree



Exposure analysis logic tree simplified

	Significant Number of US Persons Currently Exposed	Not Significant Number of US Persons Currently Exposed
Below de minimis cancer risk level	Not eligible for listing	Not eligible for listing
Above de minimis cancer risk level	Eligible for listing	Not eligible for listing

Exposure information required for listed substances

- ◎ § 241(b)(4)(B): ‘information concerning the nature of such exposure and the estimated number of persons exposed’
 - Nature = exposure setting
 - Estimated number of (US?) persons
- ◎ Not a requirement for listing

How RoC exposure descriptions are generally organized

- ◎ Proxies in lieu of exposure
 - Pathways
 - Releases to the environment (e.g., TRI)
- ◎ Historical exposure
 - Occupational
 - Hazardous waste sites
 - Stocks (e.g., body burdens)

Data collection from 12th RoC

- ⊙ All RoC statements presumed to be true
- ⊙ No other sources consulted
- ⊙ Evidence of current exposure?
- ⊙ If yes, is current exposure to US persons?
- ⊙ If yes, how many US persons?
- ⊙ If US persons quantified, is this number 'significant'?

Evidence of current exposure?

- ◎ 'Exposure' is not defined in RoC; I use EPA IRIS definition
- ◎ Excluded: production volumes & releases, speculative statements
- ◎ Included: biological measurements & measured ambient concentrations
- ◎ 'Current' defined as 2000 and later
 - Actual date
 - Report publication date

If exposure = yes, is current exposure to US persons?

⊙ Includes:

- Specific reference to US persons
- Ubiquitous ambient concentrations

⊙ Excludes:

- Specific references to other countries
- Ambiguous geographical references

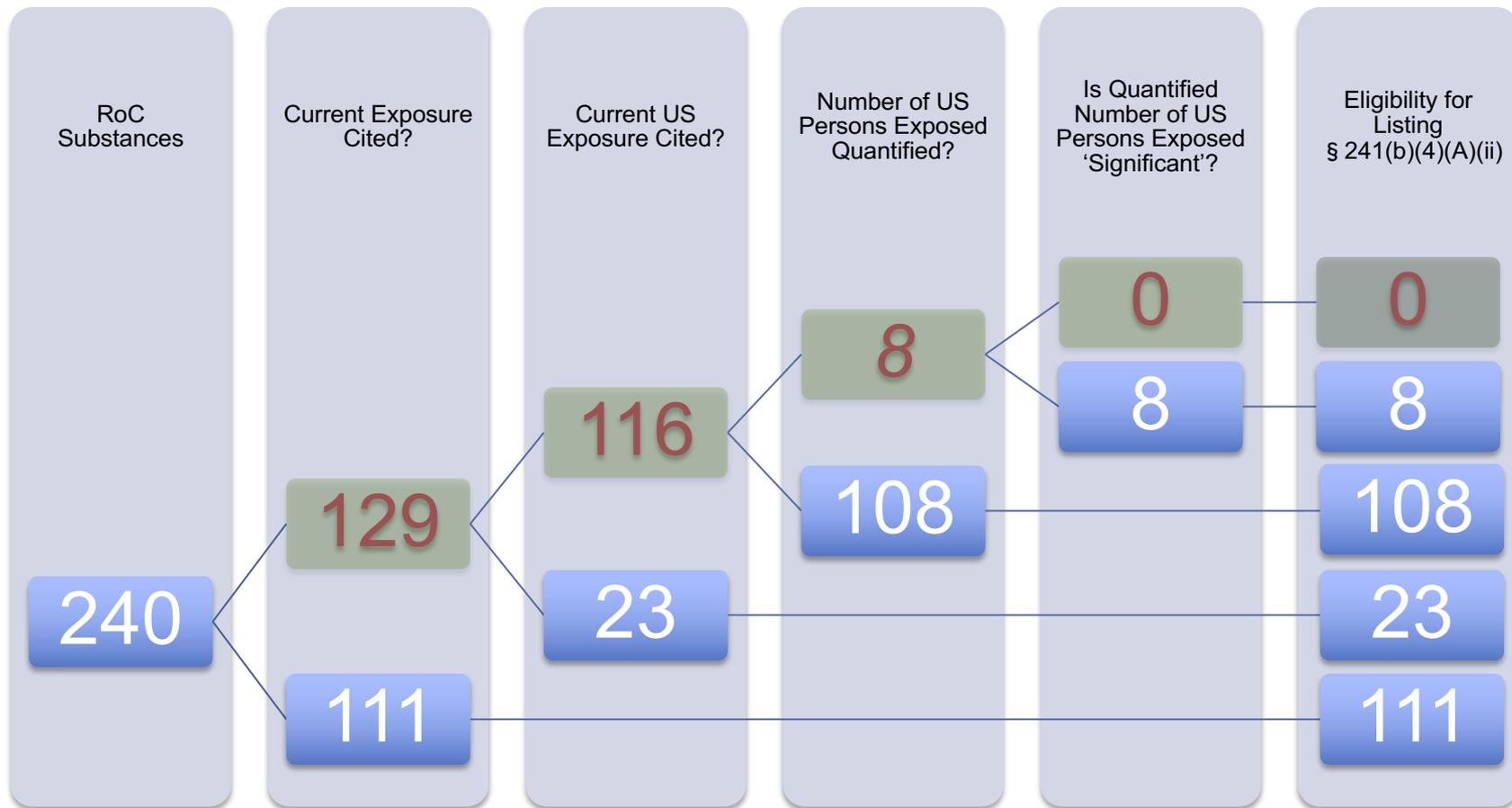
If US exposure = yes, how many US persons are exposed?

- ① Quantified values and applicable date included as reported

If US persons exposed are quantified, is this number 'significant'?

- ① Any explicit statement that a number of US persons exposed is 'significant' is accepted, whether or not the statement is supported

RoC data allocated by statutory exposure requirement



How does NTP comply with the statutory requirement in § 241(b)(4)(A)(ii)?

- ◎ Do listings define a *de minimis* cancer risk level?
 - Undefined; implicit *de minimis* cancer risk = 0
- ◎ Do listings include the number of US persons exposed above the *de minimis* risk level?
 - Cited for 8 of 240 substances (3.3%)
- ◎ Is the number of US persons ‘significant’?
 - ‘Significant’ is not defined
 - Minimum across 8 substances = 28k

Conclusion

- ◎ NTP is statutorily required to include US exposure metrics in listing determinations
 - All 240 substance profiles do not comply
 - 8 substance profiles are close to compliance, missing only the 'significance' determination
- ◎ NTP is statutorily required to include for all listed substances the number of persons exposed and the nature of their exposure
 - All 240 substance profiles do not comply