THANK YOU!

Our member company experts

Concawe communications team and assistants

ECHA for co-presenting

And all of you for joining us and actively participating today

[1] According to GDPR, if you do not want your name to be mentioned in the summary, please inform Concawe

Welcome!

Housekeeping

- **Use the chat during the presentations to raise your question and comments**
  - **After the presentations, we will run through these**
  - **If you wish to join in the discussion, raise your virtual hand**
  - **Discussions will not be recorded**

- **As we have over 100 participants, please**
  - **Mute your line and switch off your camera if you are not speaking**

- **After the workshop, the following will be made available:**
  - **Slides and recording of presentations**
  - **Short summary with main points discussed and suggested follow-ups on pathways explored[1]**

Looking forward to open and interesting discussions!

[1] According to GDPR, if you do not want your name to be mentioned in the summary, please inform Concawe

Online workshop on testing and assessment of petroleum UVCB substances

21 June 2021

PROGRAMME

10:00-10:15	**Welcome**
10:15-10:45	**Setting the scene** Background to petroleum UVCB substances and introduction to the practical challenges faced in testing and assessment of these substances which call for more tailored approaches to efficiently manage and progress their regulatory assessment.
10:45-12:45	**Challenge 1:** How to overcome the practical challenges for petroleum UVCB substances in delivering a testing program which takes into account animal welfare considerations and delivers required information within an acceptable timeframe while avoiding underestimation of human health hazards? - Short presentations to set the scene (2 x 15min) by ECHA and Concawe; - Open debate between all participants.
12:45-13:30	**Break**
13:30-15:30	**Challenge 2:** How to progress PBT assessment of petroleum UVCB substances in a scientifically sound, regulatory-acceptable and timely manner, with a testing program taking into account that state-of-the-art analytical techniques cannot identify all constituents? - Short presentations to set the scene (2 x 15min) by ECHA and Concawe; - Open debate between all participants.
15:30-16:00	**Pulling it all together** - Overall evaluation and identification of opportunities to assess remaining challenges and uncertainties; - Agree on a way forward towards a common understanding of the requirements to help progress the regulatory assessment of petroleum UVCB substances.

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Environmental Science for European Refining

Setting the Scene

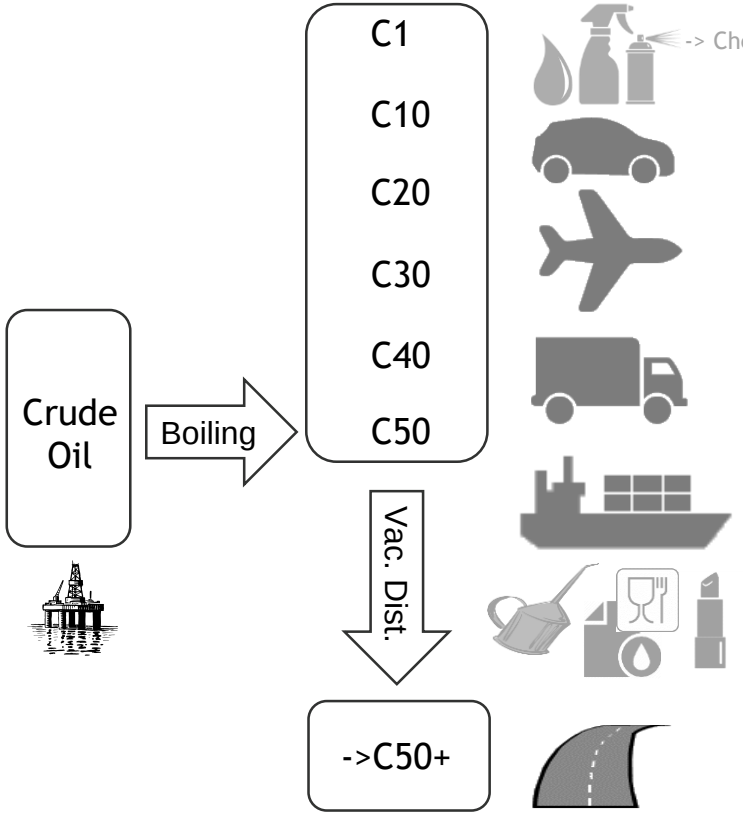
Online workshop on testing and assessment of petroleum UVCB substances

21st June 2021

Hans Ketelslegers

Carol Banner

Petroleum Substances are archetypical UVCB (1/2)



- 166 Petroleum Substances (PS)
- **hundreds to millions of HydroCarbon molecules** (isomers) per PS
- **UVCB**
  - **U**nknown or
  - **V**ariable composition,
  - **C**omplex reaction products,
  - **B**iological materials
- About 4,300 registrations
- REACH: Yearly cycle of comprehensive dossier updates
- CLP: PS are classified for their hazards[1]
- High volume on EU market, but non-fuel, widespread uses are about 2% of the total volume

https://www.fuelseurope.eu/knowledge/how-refining-works

[1] https://www.concawe.eu/publication/hazard-classification-and-labelling-of-petroleum-substances-in-the-european-economic-area-2020/

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Petroleum Substances are archetypical UVCB (2/2)

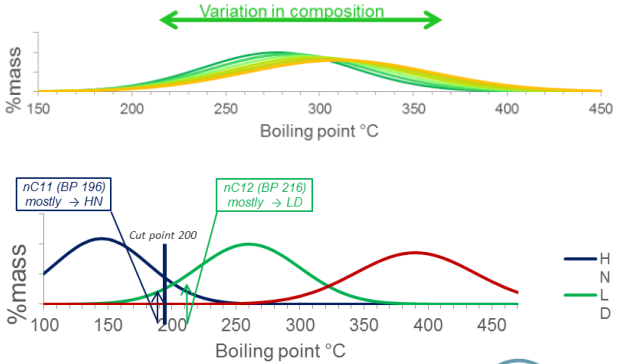
- Petroleum substances are UVCB
  - **Unknown** or
  - **V**ariable composition,
  - **C**omplex reaction products,
  - **B**iological materials

- Due to the high number of molecular hydrocarbon constituents,
  - Not all individually identified
  - But PS constituents are collectively characterized

C number	Boiling point °C (n-alkanes) (*)	Number of isomers (alkanes only!)
3	-42	1
4	-1	2
5	36	3
6	69	5
7	98	9
8	126	18
10	174	75
15	269	4 347
20	343	366 231
25	402	36 777 419
30	450	4 108 221 447
35	490	493 054 243 760
40	525	62 353 826 654 563

- Petroleum substances are UVCB
  - **U**nknown or
  - **Variable composition**,
  - **C**omplex reaction products,
  - **B**iological materials

- PS are variable in nature, but
  - Variability is limited to meet product specification
  - Petroleum substances form a continuum whereby physical-chemical properties overlap in the hydrocarbon space



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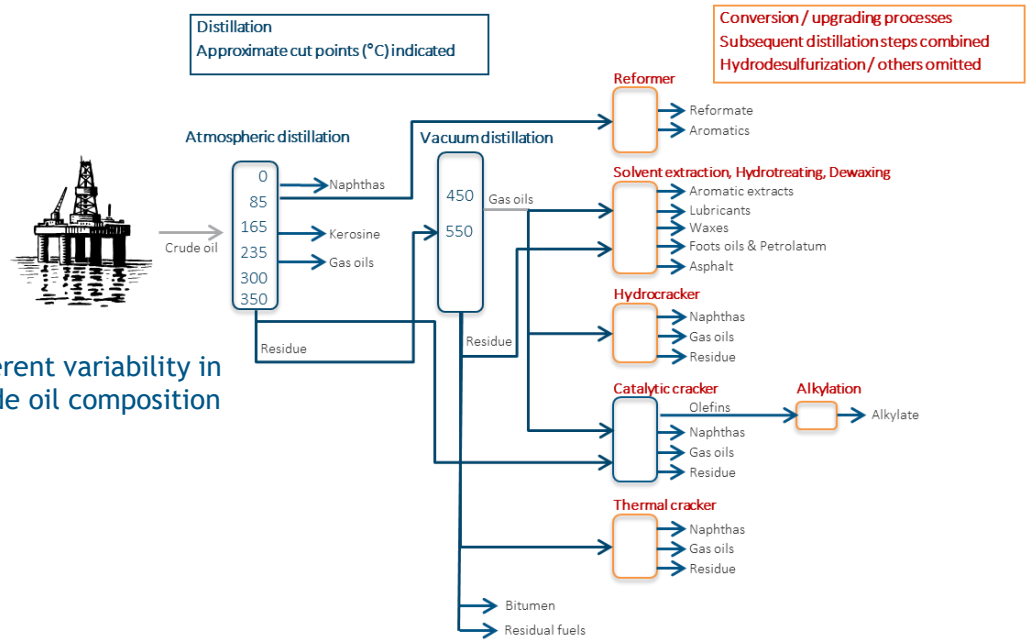
Substances grouped into categories based on boiling/carbon range and manufacturing process



Inherent variability in crude oil composition

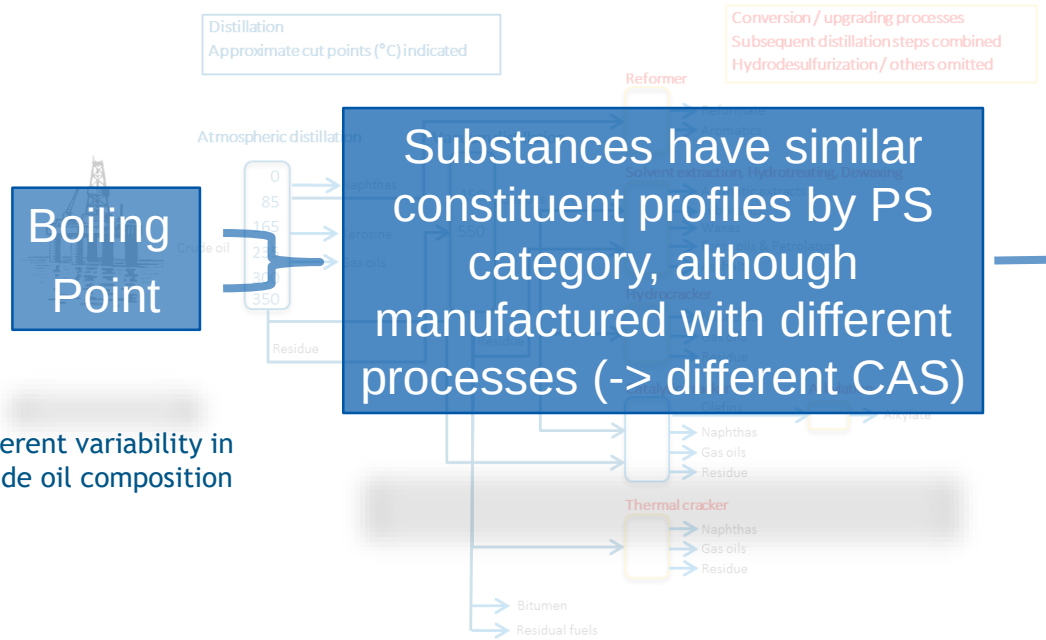
1. Low Boiling Point Naphthas (Gasolines)
2. Kerosines
3. **Straight-run Gas Oils**
4. Cracked Gas Oils
5. **Vacuum Gas Oils, Hydrocracked Gas Oils& Distillate Fuels**
6. **Other Gas Oils**
7. Heavy Fuel Oil Components
8. Unrefined / Acid Treated Oils
9. Other Lubricant Base Oils
10. Highly Refined Base Oils
11. Foots Oils
12. Paraffin and Hydrocarbon Waxes
13. Slack Wax
14. Petrolatum
15. Untreated Distillate Aromatic Extracts
16. Treated Distillate Aromatic Extracts
17. **Residual Aromatic Extracts**
18. **Bitumen**

In addition CONCAWE has prepared the joint parts of the Registration Dossier for the following stand-alone substances:

- MK1 diesel fuel (EC number 931-250-7),
- **Oxidised Asphalt (EC number 265-196-4)**
- Sulfur (EC number 231-722-6)

Examples of processes in refineries

Substances have similar toxicological hazards within these categories



Boiling Point

Substances have similar constituent profiles by PS category, although manufactured with different processes (-> different CAS)

Similar toxicological Hazard of the PS (-> different CAS) within these categories[1]

Inherent variability in crude oil composition

[1] https://www.concawe.eu/publication/hazard-classification-and-labelling-of-petroleum-substances-in-the-european-economic-area-2020/

Concawe analytical program

Substance identity and hazard assessment support

Registrant support on substance identity

Collation of registrant data to determine Substance Identity Profile

Industry standard methods, e.g. SIMDIS, ASTM D2007 (LCC) method
IP 391/ IP 548/ IP 436 (HPLC) methods

Guidance on recommended methods

Support for Human Health and Environmental hazard assessment support

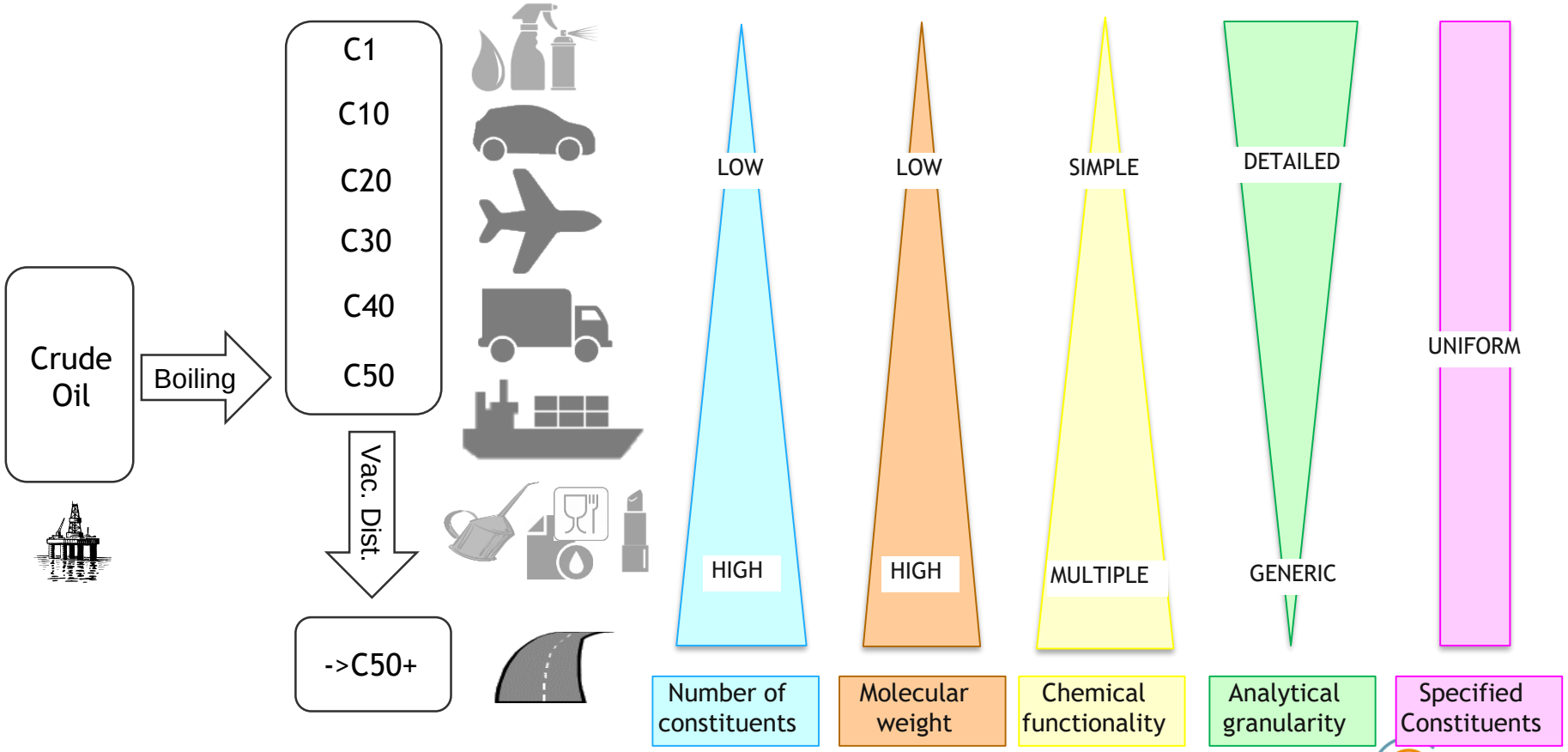
Fuller characterisation using wide range of non-standard analytical approaches

Concawe analytical database in numbers

17 analytical programs since 2003
20 analytical methods
565 constituents / constituent groups measured
958 samples analysed
219865 measured values

Example publication on substance characterization in the 2015 analytical program (further data is in Concawe dossiers or still to be published):
https://www.concawe.eu/wp-content/uploads/Concawe-Substance-Identification-Group-Analytical-Program-Report-Abridged-Version.pdf

Petroleum substance characterization



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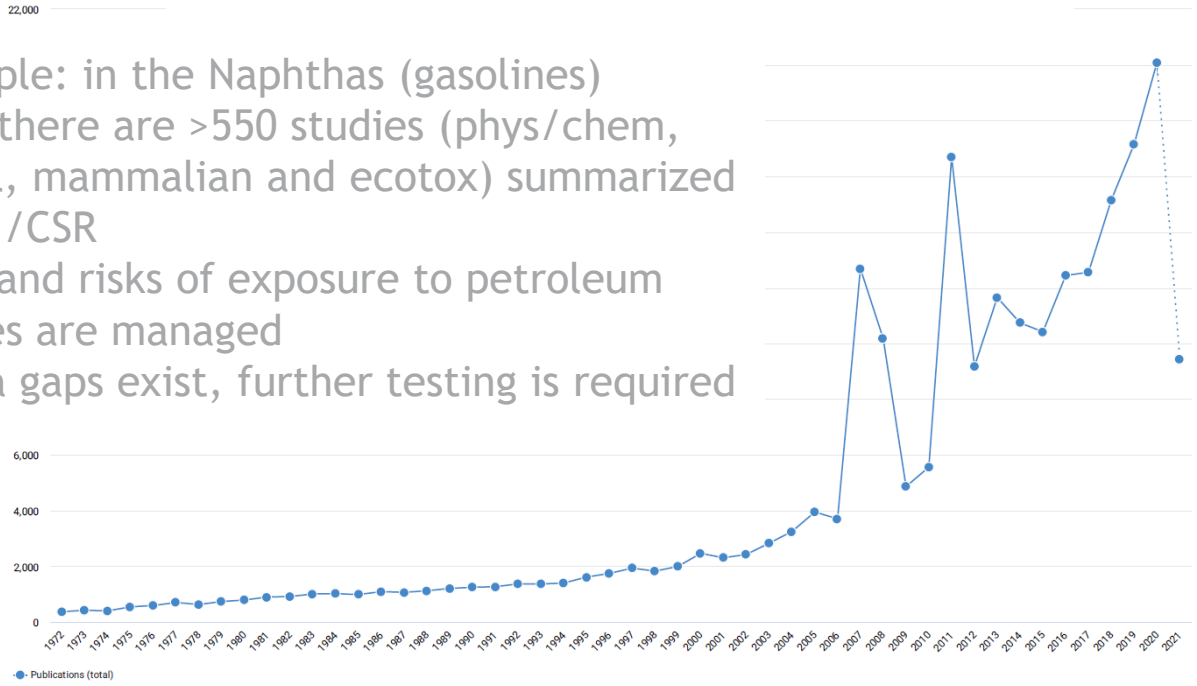
Petroleum substance toxicity well studied

Over 200k publications on petroleum toxicity over last 5 decades

- For example: in the Naphthas (gasolines) dossiers, there are >550 studies (phys/chem, analytical, mammalian and ecotox) summarized in IUCLID /CSR
- Hazards[1] and risks of exposure to petroleum substances are managed
- Still: data gaps exist, further testing is required



[1] https://www.concawe.eu/publication/hazard-classification-and-labelling-of-petroleum-substances-in-the-european-economic-area-2020/

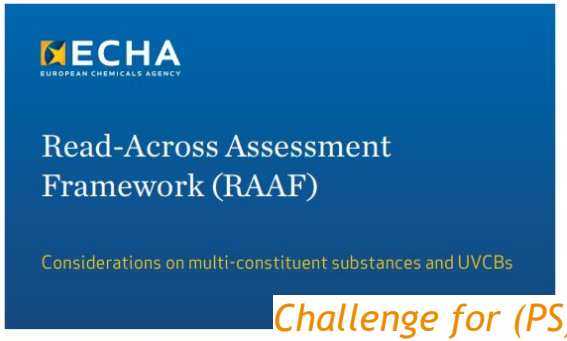
Mind and manage the gaps

Combining analytical and hazard data to maximize value of existing studies and testing strategies with read across

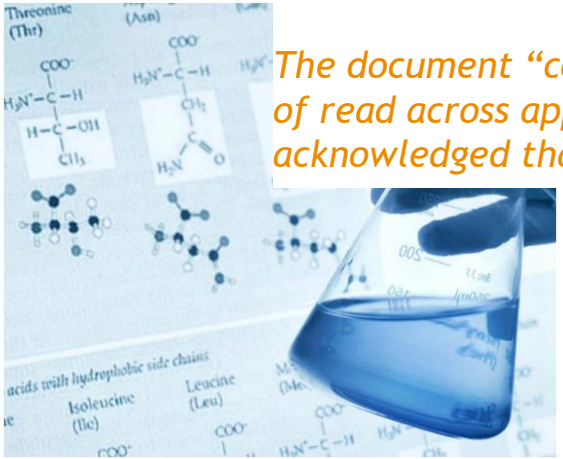
REACH ANNEX XI:

General rules for adaptation of the standard testing regime set out in Annexes vii to x

-> Grouping and read across Should be built on molecular / structural information: how to apply for substances containing hundreds to millions of molecules..?



Challenge for (PS) UVCB substances:



The document "confirmed the complexity of read across approaches for UVCBs" and acknowledged that "more work is needed"[1]

[1] https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf

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Summary

- ✓ Petroleum UVCB substance constituents are collectively characterized but not fully individually identified
- ✓ Although petroleum substances are variable in composition, this variability is limited to meet the product specifications
- ✓ Petroleum substances form a continuum of substances, based on their refining processes; neighboring streams overlap
- ✓ Substances grouped into categories based on boiling/carbon range and manufacturing process
- ✓ Within these petroleum substance categories, substances are expected to be similar in both analytical composition as well as their biological response
- ✓ However, for both human health and environmental assessments, fulfilling information requirements to prove grouping and read across is challenging for UVCB substances

Introduction to joint challenges

Challenge 1:

How to overcome the practical challenges for petroleum UVCB substances in delivering a testing program which takes into account animal welfare considerations and delivers required information within an acceptable timeframe while avoiding underestimation of human health hazards?

Challenge 2:

How to progress PBT assessment of petroleum UVCB substances in a scientifically sound, regulatory-acceptable and timely manner, with a testing program taking into account that state-of-the-art analytical techniques cannot identify all constituents?