Brussels, 12th February 2018

Background

This paper addresses the issue of the validity of the petroleum industry's current datasets in its REACH Registrations dossiers regarding human health. The **sector believes it is paramount regulators accept this dataset so further work can go on in increasing the understanding of its substances for the Evaluation phase of REACH according to a feasible and pragmatic approach**.

The petroleum industry has been collecting data on its products and substances before REACH started as part of its long history and has now collected a large data set. Much of this historical data was used to meet the first Registration phase of REACH. This data shows that there are a large number of substance identities whose compositions overlap to such an extent it makes sense to group them in categories of products with similar chemical composition and chemical hazard. As a result of this substance grouping, using 'read-across' of certain data from one substance to another has been an effective way of reducing testing requirements.

The petroleum industry's substances are widely used as a variety of different products by consumers and industry, across the economy. Our nearly 200 substances, across 18 categories, represent thousands of registrations and registrant companies. The industry works hard to support of all of REACH's goals, including the safe use of substances and reducing animal testing. For example, we modified the standard test for mutagenicity[1], only testing an aromatic portion, to avoid false negatives which the standard test returns for our products.

For over a year now, the petroleum industry has been involved with the PetCo working group, collaborating with experts from ECHA, the European Commission and Member States, in order to develop a work plan to address dossier data gaps and set up the approach for the Evaluation phase of REACH. These discussions have been highly productive so far, and the petroleum industry wishes to keep on this positive and efficient collaboration to achieve the objectives of the SVHC Roadmap and REACH.

The issue and FuelsEurope's position

FuelsEurope have been made aware that some stakeholders are questioning the historical data of human health provided in Registration dossiers, and that the sector could have to start from the beginning with data generation. This would mean that instead of an incremental work plan, an approach is enforced that entails extensive testing on all substances. **We believe this approach is disproportionate and unnecessary. Indeed, such an approach could put delivery of REACH at risk; such testing may not be feasible in terms of required resources and time span.**

Whilst there are some improvements needed, we strongly advise against throwing out the historical data from the basis for substance evaluation. The industry's goal is to meet the REACH requirements, but we believe this can be done with a minimum of in vivo[2] tests, by applying a number of strategies including use of historical data and read across between substances.

FuelsEurope firmly believes the **industry approach is feasible, faster, involves fewer animals for testing, is more affordable for registrants, and consistent with the REACH text and process**. The work plan is not set in stone, but setting out the right basis is fundamentally important. Such an approach will generate high quality and relevant data across all our categories of petroleum substances on a relatively short timeframe,

[1] The Ames test for mutagenicity
[2] Animal-based tests

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while developing a more sustainable approach to human health risk assessment of petroleum substances for the short to long-term future. The industry approach will generate solid data in a way that:

- Takes less time, and puts less constraints on Europe's laboratories, and delivers the REACH goals faster
- Uses read across and looks at categories rather than examining every item in the long array of overlapping Petroleum Substances
- Requires less animal testing, potentially saving thousands of animals from unnecessary tests
- Is more affordable for registrants of petroleum substances (which are not all large multinationals), sharing REACH costs through the SIEF system

For example, over 100 laboratory years and hundreds of thousands of animals[3] would be required to fulfil ECHA's requirements in the extreme case, if higher-tier testing were required for many substances. With the Industry approach, where weight of evidence, optimised in vivo tests, read across supported by CAT APP[4] are proposed in the tiered approach, time can be reduced to 5 years testing for all categories and 10 times less animals would be killed.

Going forward, the industry also wants recognition within the REACH framework of data developed by innovative new approach methodologies, such as CAT-APP. Here, in vitro[5] tests are used to show when certain substances are similar, so that data based on tests on one substances can be 'read-across' to other ones, avoiding the repetition of testing and the related additional animals required. There are several ways of accepting such new methods, eventually formalised through guidance or regulatory updates, to account for these developments, which could occur in the mid-term, according to REACH's stated goals of innovation and avoiding unnecessary animal testing.

Details of issue/industry response

Here, the sector will address the main challenges to the dataset and explain why such challenges are not legitimate reasons to throw out all the data. An approach must be kept in mind that recognises all the main considerations and objectives of REACH, as expressed in the recitals. These include the avoiding of unnecessary animal testing and promoting competitiveness.

Taking a pragmatic approach to REACH, focused on the safe use of substances, rather than satisfying academic interests by building up unnecessarily extensive datasets, better serve the needs of wider society and the economy. This industry is a responsible one, and takes a conservative approach to safety and risk management, but does not believe the detailed molecular investigation is necessary to the extent that some stakeholders have suggested.

Issue 1: chosen exposure routes

Regarding route of exposure, the reason the sector carried out tests based on dermal (skin) and inhalation exposure was the "most appropriate route of administration, having regard to the likely route of human exposure", according to Annex VIII to Annex X. Rejecting such data on the basis that oral exposure is REACH's default- method neglects that safe handling of substances is the regulation's concern. There is no blanket mandate for oral testing.

Issue 2: accordance with modern testing standards

[3] 4 high tiered tests, on 4 substances being worst case in each category, is 8 years of test per category and for 18 categories ends up with more than 100 years of tests.

[4] CAT APP, or category approach, is a process of testing the biological responses of cells in order to group substances by similarity of response and read across deep test data for between such substances

[5] Alternative, non-animal based tests

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Some stakeholders expressed concern that our data is based on tests not done according to currently-recognised methods. The datasets were based on tests according to methods which have since been expanded and updated. The industry believes that the findings, from tests which met the standards of the time, are still valid now. If a study is fit for its purpose under REACH, despite not being under current standards, then its use should be allowed, as according to Annex XI.

If test results are rejected, there should be scientific reasons for doing so. We ask for allowing data from tests used as references in other legislation. We ask not to be required a test update for the sake of an update, in line with the REACH goal of reducing unnecessary animal testing.

Issue 3: justification for read-across

The petroleum Industry believes that the criteria for 'reading across' are met: the substances in a category are composed largely of the same chemical compounds, but in differing proportions, therefore meeting the read across requirement according to Annex XI. Within the categories a worst case approach has been applied: results of tests with the most hazardous substances within a category have been given prevalence. Looking to the future, innovative techniques such as the CAT APP program will demonstrate a pattern of similarity of biological response, further supporting our read across as per Annex XI.

Issue 4: composition of test material and representativeness in the dossiers

There is adequate data on the substances tested to show they are representative of the substances covered by our dossiers, given the variability at a molecular level that is a characteristic of UVCBs. The petroleum industry position is that authorities should accept a weight of evidence approach indicating that the compositions of refinery products were similar in the past to present products. This follows the similarity of crude oil (based on crude assays and acknowledging the different component distributions in different crudes), refinery processes, and product specifications.

The petroleum industry's approach

The petroleum industry recognises uncertainty, and appreciates the proposed workplan may evolve as testing begins and findings are uncovered. However, the industry plans to **follow an informed testing strategy** and a tiered approach, making decisions on potential further animal testing based on data as they become available. The workplan will enrich the dossiers, making it easier for regulators to understand our substances for evaluation, further supporting our historical data and use of non-standard studies when applied, as well as further developing and incorporating animal testing alternatives.

Conclusion

To summarise, **the petroleum industry requests that further work go ahead on the basis that the existing data on human health is valid**, and that additional tests can refer to this. Starting from scratch would set back an ambitious, realistic and productive plan, which saves on unnecessary animal testing. The petroleum industry's proposed workplan is much more focused than a plan based on complete overhaul and extensive tests on every substance. Recognition of the validity of the existing dataset could allowing the sector to follow its proposed workplan, concentrating on those substances that matter the most and speeding up deliver of REACH. Going forward, innovative techniques such as CAT-APP can further increase the data industry has in a more efficient way.

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FuelsEurope, the voice of the European petroleum refining industry

FuelsEurope represents with the EU institutions the interest of 42 companies operating refineries in the EU. Members account for almost 100% of EU petroleum refining capacity and more than 75% of EU motor fuel retail sales.
FuelsEurope aims to promote economically and environmentally sustainable refining, supply and use of petroleum products in the EU, by providing input and expert advice to the EU institutions, Member State Governments and the wider community and thus contributing in a constructive and pro-active way to the development and implementation of EU policies and regulations.

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