



# Interview with CONCAWE's Technical Coordinator for Health Sciences



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**Gary Minsavage**  
**provides his**  
**perspective on**  
**CONCAWE's research**  
**and the importance of**  
**health sciences for**  
**our industry.**  
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**G**ary Minsavage became CONCAWE's Technical Coordinator for Health Sciences in 2008 and returned in early May to his home company, ExxonMobil Biomedical Sciences, Inc. The CONCAWE Review departs from its usual format to interview Gary on his Brussels assignment and his return to the United States.

Q: Gary, what did you enjoy most about your Brussels assignment?

A: *I enjoyed the wide range of interesting projects and especially contacts with the technical experts I had the pleasure of working with for three years. This was an outstanding opportunity to use my knowledge as a health scientist on problems of critical importance to the European refining industry. I suppose I should say something about the pizza, Belgian beer and chocolates, and although they are very good, there is no doubt that raising our young daughter in Brussels and the birth of our second 'Belgian' daughter were very special events for my wife and me during our Brussels stay.*

Q: Why is CONCAWE doing research in the health sciences area?

A: *When CONCAWE was formed in 1963, its charter anticipated that research would focus on 'environment, health, and safety in refining and distribution'. In the early years, many of the health sciences that we rely on today were still being developed so the focus of work was mostly aimed at the occupational health of refinery workers, including toxicology studies and surveys of occupational exposures to hazardous substances. This work provided opportunities for CONCAWE to work with key international organisations within the United Nations and with European institutions involved in environmental and occupational health.*

*Over the past decade, EU legislation has increasingly focused on environmental impacts on public health and CONCAWE has contributed research in several areas, especially in air quality through the CAFE (Clean Air for Europe) programme and, more recently, through the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals—EC Regulation No. 1907/2006) programme. CONCAWE has devel-*

*oped a strong 'Health Management Group' to address these EU initiatives, with member company experts in occupational hygiene, exposure science, toxicology, epidemiology and other areas.*

*Today, a thorough understanding of the potential health effects associated with the production, distribution and use of petroleum substances is still the main focus of CONCAWE's health programme. Health sciences are harnessed to address these issues including the management of health and safety at work, the effects of air pollution on public health, and consumer safety related to the use of petroleum products. Our health programme also relies on leveraged projects and expert contractors in order to complement expertise from our member companies.*

Q: What do these different areas of health science contribute to your research?

A: *This is an important question so I would like to provide a few fundamentals on the major health sciences areas that we rely on:*

- **Occupational hygiene** includes the recognition, evaluation, and control of environmental stressors on human health which, in a work setting, could result in worker injury, illness or physical impairment. For our industry, this includes effects on the well-being of workers and on members of the public due to the manufacturing or environmental exposure to petroleum products.
- **Exposure science** identifies and characterises 'real world' contacts with toxic materials and their uptake in the human body causing acute or chronic health effects. Exposure studies are vital for preventing incidents and ensure that accountable and cost-effective policies result from a thorough understanding of exposure profiles in the population.
- **Toxicology** is the study of adverse effects on human health, for example the potential impact on people exposed to gasoline vapours.
- **Epidemiology** is the study of complex patterns of human health, illness and associated factors in the population. Statistics are very important in this area, for example to assess the risk that workers involved in the manufacturing or distribution of a petroleum product could develop a specific illness.



- **Occupational medicine** ensures that the best available health advice is provided to organisations and individuals so that the highest standards of occupational health and safety can be achieved and maintained. An example here might be providing first aid advice to emergency responders to accidental gasoline spills.

Q: Why is an understanding of the health effects associated with the manufacture, distribution and use of petroleum substances still important today?

A: You will not be surprised to hear that many petroleum substances are classified as hazardous to human health. For example, fuels, including gas oils, gasolines, kerosines and heavy fuel oils, represent the largest production volume for our industry and are classified as hazardous to human health with classifications ranging from skin irritants to carcinogens.

Understanding the uses, hazards, exposures and therefore risks to human health ensures that appropriate measures can be developed that enable the safe use of these substances. Achieving this outcome requires all of the areas of expertise that I mentioned previously. In addition, the development of advanced analytical techniques and genetic analysis are changing the way we study and understand human health effects. These approaches are important today for assessing the impact on human health from exposure to bitumen, benzene, particulates and ozone, for example. Importantly, regulatory-based health risk assessments have evolved, and will continue to do so (e.g. REACH).

Q: What was CONCAWE's goal in the REACH process?

A: REACH replaced a number of directives regulating existing chemicals and the introduction of new substances to the market. The core part of REACH is the registration of chemical substances with risk assessments related to human health and environmental impacts. Since the majority of petroleum substances met the REACH criteria for registration, our products could not be manufactured or imported after 2010 if they had not been successfully registered. In essence, successfully completing the risk assessments and REACH registration process provided a 'licence to operate' for petro-

leum substances and, without this 'licence', refining and importing operations could theoretically have been stopped. Fortunately, such drastic measures were not needed because CONCAWE's parts of the REACH dossiers and registrations by manufacturers/importers were completed on schedule. In the end, the European refining industry accounted for approximately 18% of all REACH registrations that were submitted to the European Chemicals Agency (ECHA) by the December 2010 deadline. ECHA is the EU agency responsible for managing the technical and administrative parts of the REACH system.

Q: What did the preparation of a REACH dossier actually involve?

A: Petroleum substances, except for sulphur and some petroleum gases, are recognised by REACH as 'substances of unknown or variable composition, complex reaction products or biological materials' (UVCBs). The complex and variable nature of UVCBs makes it challenging to assess their intrinsic hazardous properties and associated risks. For this reason, CONCAWE first had to develop methodologies including read-across, trend analysis, data sharing and toxicity-prediction approaches, that would help us to complete the required assessments. Although there had been a lot of previous work, some data gaps were identified, especially associated with reprotoxicity testing because this area has not historically been a focus of regulation.

To address the REACH requirements, CONCAWE's toxicologists developed a consistent approach to hazard assessment for all petroleum categories and substances. We also developed REACH-required 'derived no-effect levels' (DNELs) for petroleum substances based on available data. This obviously relied heavily on CONCAWE's data from decades of previous research. Health hazard assessments and DNEL recommendations were based on an extensive database on petroleum substances, and the toxicology team developed the final hazard classifications and recommendations needed for the REACH dossiers (see CONCAWE Report 11/10). To the extent that guidance was available from ECHA, the approaches we developed were aligned with their guidance.



CONCAWE's team of occupational hygienists and exposure scientists also simplified exposure scenarios and developed an approach to consolidate different uses of petroleum substances. To do this, the team used exposure data and models for the hundreds of different potential uses for petroleum substances identified through the REACH process. Many of these approaches were also used by other industry sectors to complete their own REACH dossiers. This was a substantial effort, estimated to be thirty to forty person-years of work by our toxicologists, occupational hygienists and exposure scientists.

Q: That does sound like a lot of work!

A: It was a mammoth task, certainly the largest single project that has ever been completed by CONCAWE. Our health sciences teams contributed significantly to the REACH process in terms of technical input, breadth of information and sheer people-power—what we call 'sweat equity'.

Let me give you an example. CONCAWE ultimately prepared 22 different REACH dossiers covering 576 petroleum substances grouped into 'categories'. If we were to look at just one of these dossiers submitted to ECHA in 2010, say for 'low boiling point naphthas (gasolines)', the dossier had a number of different required parts.

The core of the REACH dossier, the Chemical Safety Report (CSR), was about 600 pages for the gasoline dossier and summarised an even more detailed assessment contained in the IUCLID (International Uniform Chemical Information Database) data file, also required by REACH. About half of each CSR was devoted to health hazard assessments and exposure scenarios that were themselves based on literally hundreds of previously completed research studies. These studies could often run into several hundred pages and each study required review, assessment and entry into IUCLID. The rest of the CSR included information on classification and labelling, physico-chemical information, environmental hazard assessment, and risk characterisation.

In a post-REACH registration world, this detailed information will be communicated between producers and purchasers by means of a new

extended Safety Data Sheet (SDS). Creating the extended SDS is the responsibility of each producer but the information that it contains must be consistent with the CSR developed by CONCAWE.

Before REACH, an SDS was about 8 pages long. After REACH, an extended SDS can be as long as 100 pages if the producer is selling into markets involving all of the uses that were assessed in the CSR.

Q: What do you think was the benefit of all this work?

A: For the petroleum substances (excluding petroleum gases) that were finally registered by CONCAWE member companies and importers, 90% are classified as hazardous to human health to some degree, ranging from skin irritants to carcinogens. It is important to say that CONCAWE's historical hazard recommendations regarding the safe handling and use of petroleum products were not significantly changed by the REACH assessment process. We believe that this reflects well on our industry's past commitment to risk assessment and the development of safe use advice.

Still, as painful as the process was, it must be said that our industry and its supply chain have benefited from the REACH process. Through REACH, we have (1) assessed an extensive database of health-related information, (2) gained a more complete understanding of how petroleum substances are used and not used, (3) applied a thorough and systematic approach to risk characterisation, and (4) developed common approaches to minimise risk associated with petroleum substances and their uses.

Q: Does this mean that REACH work is now completely finished?

A: Although the common parts of the REACH dossiers have been submitted, we believe that REACH will continue to be an integral part of CONCAWE's work on health and petroleum products for a long time, probably at least until 2018. The REACH dossiers will be kept up to date, new ECHA Guidance will be addressed, queries from Member States will be answered, and new data from our industry and other sources will be added. In the meantime, we are developing technical methodologies and engaging with other stakeholders to clarify the hazards and risk assessments for UVCB substances.



Q: Clearly REACH was a major activity for you and for CONCAWE during your assignment. Did other work in health sciences take a back seat?

A: *Fortunately, no.*

*While our health experts were occupied with REACH, we still found time for a significant research programme on health and petroleum substances. Many of these projects were leveraged through multi-sponsor, multi-year projects being carried out by others. For example, we have projects under way with academic, private and national technical organisations including the University of Utrecht, Fraunhofer's Institute for Toxicology and Experimental Medicine, the Boston-based Health Effects Institute, VITO (at the Flemish Institute in Belgium), and RIVM in The Netherlands.*

*From 2008 to 2011, CONCAWE either sponsored or co-sponsored health sciences projects that resulted in 13 major publications. Six were published in peer-reviewed journals while seven were or will be published as CONCAWE reports<sup>1</sup>. These reports focused on important health-related issues: the contribution of diesel exhaust exposure to lung cancer risk in workers; an assessment of the relationship between benzene exposure and Non-Hodgkin's Lymphoma (NHL); a health assessment of refinery and maintenance activities associated with the use of heavy fuel oils; and an assessment of carcinogenic risk to asphalt workers exposed to bitumen fumes.*

*Health effects due to benzene exposure have been studied for more than 50 years. Key questions remain, however, regarding the lymphohematopoietic (LH) cancer subtypes that may be induced by low-level exposure to benzene. CONCAWE is coordinating work with the US API, CEFIC Aromatic Producers Association, and the Canadian Petroleum Products Institute that will be one of the most technically advanced and thorough studies assessing the relationship between benzene exposure and specific disease types and subtypes. This multi-year, multi-investigator study, known as the 'Benzene Pooled Analysis', will update, then combine or 'pool' existing benzene case-control studies to produce a robust database on disease states and benzene exposures. These*

*data are expected to affect updates to Occupational Exposure Limits (OELs) and Environmental Quality Standards (EQS) under the Water Framework Directive.*

*We are also engaged in critical reviews of the health impact of air pollution, especially related to industry operations and the use of petroleum substances. Where possible, we leverage our activities with other organizations to fill key knowledge gaps that will be important for the 2013 Air Quality Directive Review.*

Q: Where will CONCAWE's health sciences be going in the future?

A: *The success of CONCAWE's health sciences activities began with a focus on effective approaches for occupational health management and moved on to address broader environmental and human health issues. These included product safety and chemical risk assessment (e.g. REACH), vehicle emissions regulations, and ambient air quality standards. In these areas, many underlying scientific questions are still unresolved and new issues continue to emerge. CONCAWE's role is to work with scientific collaborators, regulators and other stakeholders to complete needed research to address these questions. To do this, we will continue to commission high-quality reviews and research from our own budget.*

*Fortunately, my replacement has already been named so the work in this area will continue with very little interruption. Arlean Rohde, seconded from ExxonMobil Chemical Company, arrived in Brussels this summer and the handover process is already under way.*

Q: So, what did you enjoy most about your Brussels assignment?

A: *Exploring the parks and forest with my family was very enjoyable. Riding my bike to work was also great ... and necessary to counteract the effects of the wonderful pizza, Belgian beer and chocolates!*

<sup>1</sup> See CONCAWE Reports 5/08, 5/09, 5/10, 8/10 and 4/11, available on the CONCAWE website ([www.concawe.org](http://www.concawe.org))