



---

**JULIA OSBORNE CONSULTING LTD**

---

*BECAUSE CHEMICALS COUNT*

---

**STATEMENT OF QUALIFICATIONS  
FOR CHEMICAL REGULATORY  
COMPLIANCE ISSUES**

**Willowgrove, Burnham Road  
Mundon  
Maldon  
Essex CM9 6NT  
UK**

**Tel: +44 (0)1621 742286**

# Statement of Qualifications for chemical Regulatory Compliance issues

**Julia Osborne Consulting Ltd – My Aim:**

**“To help the chemical industry to comply with regulations”**

Chemicals count in modern life. Our life has always revolved around the use of chemicals; from the first minerals daubed as paints on the skin of prehistoric man to the advanced polymers and alloys that put man on the moon, chemicals touch every part of our lives. However, as modern life continues to put burdens on our planet, the responsible use of chemicals becomes ever more important and the pressures on industry to conform to necessary regulations ever more costly and difficult to meet. Industry cannot afford to get compliance wrong.

With more than 15 years work in the chemical compliance sector (12 of which were spent as a regulator), I, Julia Osborne, can help your company meet its compliance obligations.

## **Introduction**

The chemical sector is watched constantly, and not only by the regulator. The media, the public, competitors, and ‘green’ NGOs, to name a few, all claim a right to scrutinise a chemical company’s business. Despite the recent attempt by the EU to rationalise chemical regulations with the introduction of the Registration, Evaluation and Authorisation and Restriction of Chemicals regulations (REACH), the industry still doesn’t have an easy job.

REACH is supposed to make things consistent, to level the so called ‘playing field’. However, despite 400 pages of text the regulation seems deliberately woolly and open to interpretation. The European Chemicals Agency (ECHA) refuses to advise the industry on the specifics that need to be covered, and the national regulators apply the same rules. This means that it has been left to the industry to justify what it needs to register and what it doesn’t. How many companies in the industry have the in-house expertise to make these sorts of decisions? Although there is intent to make the legislation consistent, every country has its own enforcement legislation which allows the potential for

inconsistency for companies with locations across the EU and further afield. In addition, despite encompassing and superseding many different chemical registration policies, REACH has still left several different schemes which fall outside REACH and require additional compliance.

Therefore, the industry is left with a scheme requiring 'creative interpretation'. It has no clear boundaries and the regulator will expect companies to provide scientifically admissible evidence to support any decisions made to comply with any aspect of the regulation. Many small companies do not have this expertise and are at risk of failing to comply with the regulations. They face seemingly unarguable decisions made by Substance Information Exchange forums (SIEFs) and consortiums and are being actively encouraged to use sophisticated online IT systems at great expense which may not be needed to make their submissions under REACH.

Then there are the regulations that REACH didn't supersede i.e. the Globally Harmonised System of Classification and Labelling, Health and Safety legislation, Industrial Pollution Prevention and Control (IPPC) regulations. International Marine Organisation rules for transport, and all the rules and regulations which govern 'wastes'. There remain the rules and regulations which still impact specialist industries such as the use of chemicals by the offshore exploration and production industries, the manufacture and use of pesticides, biocides and drugs as well as all the chemical regulations which exist outside of the European Union and REACH.

Is it any wonder that some companies worry about what legislation they are going to be asked to comply with next?

### **Experience**

For 12 years I worked for the Centre of the Environment, Fisheries and Aquaculture Science (CEFAS) and was responsible for the day to day running of the UK's Offshore Chemical Notification Scheme (OCNS). During this time the legislation went through a number of changes, many of which I was directly involved in:

- Initially I worked with one of the first OCNS schemes – the so called 'Old OCNS' when company participation was voluntary and the data set was open to a large amount of interpretation.

- This was superseded by the 'Revised OCNS'; a scheme in which the dataset was considerably more defined (though still product based), and the industry actively signed up to participate in rather than be seen as not complying with good 'green working ethics'.
- Then finally I was actively involved in the implementation of the Oslo and Paris Commission's (OSPARCOM) Harmonised Offshore Chemical Notification Format (HOCNF) which required statutory compliance by the industry. This included the move to substance based toxicity testing; a decision which had differing impacts on the industry depending on the nature of the individual business and number of chemicals in their formulation range.

I was a member of the international team that developed the Chemical Hazard and Risk Management model (CHARM) and I specifically worked on the drilling algorithms. Following completion of the model I was a long term member of the CHARM Implementation Network, a group which oversaw the model's integration into the regulations. I was an active tester of the algorithms before the model's final release to the industry

I was running the OCNS at CEFAS as regulations gradually tightened on the industry and this historical perspective provides much needed insight into current working practices. I developed many of the systems that are still used today to transfer necessary confidential data between the various parties and I developed a complete understanding of the concerns and needs of the industry to protect its commercially sensitive data.

As part of my work at CEFAS I developed the database that was used for over 15 years to run the OCNS schemes and formed the basis of the system that the UK regulator still uses today to handle the HOCNF data. I helped CEFAS become the first regulator to tie a country's HOCNF data sets into the CHARM model; I am considered an international expert in using and understanding the model.

My experience in deploying and developing chemical regulations is against a practical background in analytical chemistry. For 7 years I worked on the analysis of trace levels of novel pollutants in marine samples specialising in the analysis of hydrocarbons, organo-tins and surfactants using most standard analytical techniques (GC-FID, GC-FPD, GCMS, HPLC, IR, UV-Vis spectrometry, AA etc.). I led sampling trips and worked aboard research vessels, sampling and analysing and gained practical

experience in deploying the toxicity and biodegradation studies used in the HOCNF dataset.

Following CEFAS I was a consultant for the large international consultancy group AMEC, I worked in a number of areas including:

- providing a lead for AMEC in working on REACH business development across the EU;
- providing a full consultancy and application service for the various OSPAR wide country specific HOCNF application schemes;
- managing several submissions under the Industrial Pollution Prevention and Control (IPPC) regulations, and
- authoring several expert reports to support various regulations, including one to support a successful application for a UK chemical patent.

Whether you are looking for a full support service to handle your company's chemical regulation portfolio, or just need an ad-hoc telephone service from someone who knows how regulators think, why not speak to me and see what I can do to help?

### **Project examples**

**UK Government, Offshore Chemicals Regulator** – I have 12 years experience of the control and running of the UK's Offshore Chemical Notification Scheme (OCNS) which controls the hazard and risk assessment and use of chemicals by the offshore oil and gas sectors. This included running the scheme whilst it was voluntary and overseeing the introduction of statutory controls in the industry across the OSPAR sector. I developed and built the Access database which was used for around 15 years to run the UK OCNS scheme and store all the chemical and eco-toxicity data on the products. The concept of this system is still used to run the UK scheme today. I also worked on the committee which developed the mathematical Chemical Hazard and Risk Management (CHARM) model used to support the hazard and risk assessments of offshore chemicals across OSPAR. During my time as a regulator, notifications were provided on over 3,000 chemical products comprising over 8,000 chemical components. This process included the assessment of their chemical and ecotoxicological (mostly persistence, bioaccumulation and toxicity) datasets (most carried out to standard OECD protocols)

submitted on a Harmonised Offshore Chemical Notification Format (HOCNF) as well as a practical grounding in many of the (mostly OECD) methods used to generate these.

I represented UK Government on several occasions at the meetings of National Contact points and was a UK Government representative on the CHARM Implementation network which discussed issues related to the OSPAR wide classifications of offshore chemicals.

**Confidential Clients; Submission of chemicals to OSPAR Offshore Chemicals Regulators** – The majority of my clients require advice on the completion of the HOCNF dataset and submission to the various regulators which control the chemicals used in the North Sea. I routinely assist with the scheduling and assessment of the eco-toxicity studies necessary to support these submissions as well as completing the necessary paperwork. In the case of some USA based clients, I manage the submission of their entire portfolio of HOCNF notified chemicals in the North Sea sector.

**Confidential Clients; Submission of chemicals to OSPAR Offshore Chemicals Regulators** – Whilst with AMEC I provided consultancy services for various clients to submit chemicals on HOCNF forms to the various offshore regulators across OSPAR. This included project management, liaising with the appropriate regulator, organising appropriate eco-toxicity testing, verifying the results obtained, generating the application and subsequently submitting it to the relevant authority.

**Confidential Clients, UK** – Whilst with AMEC I reviewed literature data to assess its suitability to support offshore chemical notifications to various offshore regulators. I reduced the burden on the client by identifying suitable data for inclusion in the HOCNF document.

**Confidential Client, UK** – Whilst with AMEC I performed data collation and final submission of HOCNF to CEFAS for selected products. The client was required to resubmit their products to CEFAS due to the expiration of their previous certification, which had been made using product-based toxicity data. Since the original submission, OSPAR had changed the HOCNF submission criteria to require that all new and recertified products

should now be supported by substance-based eco-toxicity tests. My work with the client determined the most cost-effective testing regime for the formulations. Under the previous scheme the products had enjoyed Gold UK OCNS classification; however, it soon became clear that substance-based testing results had the potential to change this to something less favourable. I ran various scenarios through the Chemical Hazard and Risk Management Model (CHARM) to develop a formulation with the best chance of securing the coveted GOLD rating when submitted. Finally, I managed the testing and made the submissions to the UK OCNS scheme and achieved the desired outcome. As part of the submission process, I identified a problem with the newly introduced 'fish limit test,' which resulted in the UK regulator proposing changes to OSPAR which led to improvements to the test. The final product was successfully notified to parallel schemes in Holland, Denmark and Norway

**Confidential Client, USA** – Whilst with AMEC I performed data validation against OCNS requirements, product testing, and final HOCNF submissions to OSPAR countries for various proppant products. Proppants are by their very nature difficult to test with regard to HOCNF requirements. Following successfully negotiating the testing that would be required with the regulators, I arranged testing of, and notified a number of the client's proppants to, the various statutory OSPAR HOCNF schemes. In addition, I provided ongoing EU-based support for documentation requests following these successful submissions.

**Confidential Client UK** – The client had developed a novel reservoir performance enhancer and was looking to introduce the product into the UK E&P industry. Whilst with AMEC I was contracted to provide full support to this application: negotiating required testing with the regulator, commissioning and managing the testing process, assessing the likely categorisation and making final submissions to the UK application scheme.

**Confidential Client UK - Data Review, Report and Re-submissions of the client's products to the Dutch Offshore Chemical Regulation Scheme, with a view to securing a more favorable categorisation; UK** – The client had products notified with the Dutch offshore chemical regulation scheme, but due to a perception that these submissions were incomplete the products

had poor categorisation and this was affecting sales. Whilst at AMEC I reviewed the existing datasets against Dutch requirements and provided a report on the potential to improve the categorisation. As a result of my recommendations I updated and re-wrote the applications and re-submitted them to the Dutch regulator. Following lengthy negotiations with the regulator relating to application protocols, and a change in the Dutch application process at the time of the submissions, both products were accepted and upgraded to the best classification in the Dutch scheme.

**Confidential Clients; UK** – Whilst at AMEC I advised on chemical substitution within formulations to achieve favourable notifications and subsequent favourable product rankings to OSPAR Offshore Chemicals Regulators. As part of this process I carried out preliminary assessments of existing chemical and ecotoxicity data generated to support offshore chemical notifications which identified the poorly performing chemicals within formulations. I then worked with companies' formulation experts to replace poorly performing chemicals with environmentally better options of similar technical performance to achieve the best possible classification for their offshore E&P products.

**Confidential Client, UK** – Whilst at AMEC I authored an 'Expert Report' to the UK Patent Office supporting the client's claim that the use of a specific substance constituted a novel approach to environmentally sound product development in the design of a new hydraulic fluid. The patent was subsequently granted.

**Confidential Clients, UK** – Whilst at AMEC I often carried out hazard and risk assessments using the CHARM model. Because it is a requirement that OSPAR offshore chemical regulators use the mathematical CHARM model to inform their product assessments it is in a company's interest to achieve favourable environmental assessments for their products. I have developed an Excel version of the written CHARM model which allows me to predict final CHARM rankings (which guide the product ranking system particularly in the UK) and I can use this to inform the chemical substitution process to gain favourable environmental assessments within a formulation.

**Julia Osborne**

**Julia Osborne Consulting Limited**

**'Willowgrove' Burnham Road**

**Mundon**

**Maldon**

**Essex CM9 6NT**

**Tel/Fax: 01621 742286**

**Business Mobile: 07905 262169**

**Email: [Julia.osborne@juliaosborneconsulting.com](mailto:Julia.osborne@juliaosborneconsulting.com)**

**Web: [www.juliaosborneconsulting.com](http://www.juliaosborneconsulting.com)**