October 2014

Comment for answering to public consultation from ECHA concerning ECHA recommendation for Annex XIV consultation on boric acid and borates
Version du 03-10-2014

General comments on the recommendation to include the substance in Annex XIV

General part

Market has changed since 2009.

First of all, since the boric acid harmonized classification in 2009 as Toxic for Reproduction, Category 1B, some uses have been substituted. Moreover some mixtures have been modified in order to ensure that boric acid concentration is under the specific concentration limit. These evolutions are leading to some change within the market shares (less amount used by detergent industry getting smaller than the initial assessment of up to 26% of the total amount of borates used in Europe) and then of the related exposure. Relevancy of the 2005-to-2008 data, used for prioritization could therefore be challenged.

Prior to boric acid harmonized classification, the general rules for handling chemicals were applied when using boric acid. All specific measures which have been introduced and implemented since the classification (such as substitution, prevention and reduction of exposure as well as the protection of the employees) are therefore a maximum of 5 years old. Already now Europe faces a ban of boric acid by inclusion in annex XIV (or use has to be authorised). From the downstream user's perspective this timeline is not plausible, especially as there haven't been studies recently by the European public authorities on the effectiveness of the measures taken as well as any associated evidence of the remaining health risks of the affected employees as well as the environmental risk, which could justify the inclusion of boric acid in the Annex XIV. The study according to annex XV does not include these points from our point of view.

Uses outside of the authorization scope

Moreover some uses are outside of the authorization scope:

- depending on regulation on biocidal products (TP 8), cosmetics
- considered as intermediate for synthesis of other substances

These uses weights more than 60% of the amount used in Europe according to the 2009 « Annex XV Transitional report ».

A critical substance for the European economy

Otherwise, some uses are non substitutable, such as nutriment for certain crops or neutron absorbing capability for nuclear industry. A great number of authorization dossier should then been submitted. Borates are among the 20 critical substances for the European economy (Report on critical raw materials for the EU, Report of the Ad hoc Working Group on defining critical raw materials - May 2014). Substitution of such substances is moreover considered as tough (3rd most difficult substance to substitute among the 20 strategic substances) according to the Communication from the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee

of the Regions on the review of the list of critical raw materials for the EU and the implementation of the Raw Materials Initiative.

As a consequence, a shift would appear between REACH regulation of this substance and the market reality and needs.

Authorization seems therefore not to be the best way to manage the risks.

Nuclear part

Using boric acid in nuclear electric power plants is vital to control nuclear fission reactions and to ensure nuclear safety. Boric acid is used in all pressurised water nuclear reactors around the world (and to a lesser extend in boiling water nuclear power plants); no other chemical compound has the same characteristics required to replace boric acid for this use as expected in the authorization process. Boric acid is also used for its neutron absorbing capacities within the nuclear fuel cycle and during dismantling. Moreover boric acid is used in the glass for nuclear waste.

Boric acid releases are regulated and. most regulation requirements address concentration values in the environment.

In France, the use of boric acid in nuclear power plants is controlled by both chemical specifications and legal limits for discharges established by the French Nuclear Safety Authority (ASN).

This administrative independent regulatory body set up by law No. 2006-686 of June, 13 2006 pertaining to the transparency and safety of nuclear activities, is in charge of monitoring civil nuclear activities in France.

Managing the risk of using borates

Risks for workers are considered to be controlled by appropriate facility and equipment. Impact studies carried out as part of authorization requests for liquid discharge and water intakes on the one hand, and data from the environmental monitoring of sites on the other hand, demonstrate the lack of impact on the environment from boric acid liquid discharges due to the operation of nuclear power plants.

The health risk associated with controlled boric acid liquid discharge, based on current knowledge and methods tested by recognised scientific organizations, is not considered to be a concern.

- Managing the risk of using borates : workers protection

To manage the risk of boric acid exposure among employees working at the plants and to protect them, EDF, Areva and the CEA implement the actions required by the French Labor law:

1. Risk assessment : following the French Labor Law, chemical risk assessment at the work place under normal condition is performed, recorded and updated annually in the sole occupational risk assessment document (the assessment at the CEA is carried out as per a methodological UIC guidance – DT80)

2. Use of collective protective equipment in order to minimize the workers exposure (e.g. : fume cupboard[1], BAG, etc)
3. Personal protective equipment recommended in the supplier's safety data sheet must be worn, particularly the FPP3 protective mask (Particle Filtration Mask).
4. Exposure tracking
5. Training at the workstation according to all the phases of use of these products
6. Periodical exposure measures for workers and comparison with available limit values.

Moreover, organizational methods are implemented at EDF nuclear sites to prevent dispersion of materials. In 2009, buildings reconstruction was decided by EDF in order to handle boric acid in closed room.

When an operation involves an atmospheric dispersion risk, handling takes place under an air extractor. For material testing, boric acid is supplied as a liquid or as a powder – research on the use of solid pellets – to reduce inhalation levels has been unsuccessful. Workers wear personal protection equipment. After testing, fluid is cleaned through a resin.

- <u>Managing the environmental risk</u>

The boron element does not exist by itself in the environment but is naturally abundant combined with other common elements, such as oxygen to make boric acid.

- Boric acid occurs naturally in water. The concentration of this substance in sea water ranges from 4 to 5mg/L. The maximum concentration in added boric acid in effluents after mixing, accounts for a few percent of the natural background noise; it is of the same order of magnitude as the natural fluctuations of boric acid concentration in the environment.

- Boric acid also occurs naturally in soil. Boric acid concentration in soil ranges from 0,002 to 0,1 mg/g.

- Boric acid content in plants and particularly in vegetables is very high (from 0,025 to 0,5 mg/g).

➢ *Managing the risks of effluent discharge from nuclear power plants*

Effluent discharges containing boric acid are strictly regulated and controlled by the ASN. Managing the source and treating effluents (recycling, evaporation, and demineralisation) allow to limit the flows and concentrations of boric acid liquid discharges into the surrounding environment.

Some boric acid is discharged as a liquid; the rest is concentrated into solid waste. Most of the concentrates is incinerated with other burnable waste (Centraco facility of SOCODEI cie, an EDF Group subsidiary specialized in conditioning and treatment of industrial radioactive

1 A small ventilated enclosure with depression that draw air into the room and spewing outside using a fan. it is intended to protect operators on the risk of inhaling dangerous products.

waste and effluents); the remainder part is directly cemented in concrete blocks by the nuclear power plants. All waste packages containing boron are disposed of in the ANDRA (the National Radioactive Waste Management Agency) surface repository storage CSFMA (Low Level Waste/Intermediate Level Waste).

Steps for improving the effluents management and reducing them at the source have helped reducing boric acid in liquid discharges by a factor of more than 2 over the last 15 years.

- *Managing the risk for nuclear sites*

Impact studies have been carried out for nuclear sites located either by rivers or by the sea sides, according to a methodological approach for evaluating the environmental impact of the liquid chemical discharges.

In France, there is no regulatory limit for boric acid concentration in surface waters, apart from that defined in the order of January, 11, 2007 on the quality limits and references for raw water and water intended for human consumption (quality limit for "fresh surface water used to produce water intended for human consumption");

An ecotoxicological approach has been carried out for boric acid, supplemented by a risk index calculation.
The cumulated chronic risk index (taking account of concentrations upstream from power plants), calculated according to the methodology recognized and presented in regulatory and recognized files, are less than 1 (between 0.01 and 0.4 according to sites), which shows that chronic boric acid liquid discharges from nuclear power plants does not present a chronic risk for the environment.
The calculated cumulated acute risk index are also less than 1 (between 0.01 and 0.1 according to sites) which shows that boric acid liquid discharges from EDF nuclear sites does not present an acute risk for the environment.

Regarding the sea, boric acid is among the main constituents of marine waters; it is therefore naturally present in the aquatic environment.
The maximum concentration in added boric acid after mixing accounts for a few percent of the natural background noise; it is of the same order of magnitude as the natural fluctuations of boric acid concentration in the environment.

Use of ecotoxicity data obtained in the laboratory, as part of an evaluation carried out by the ecotoxicological approach, does not seem relevant given the natural levels of boric acid concentrations found in marine waters, of about ten milligrams per litre of boron, with species acclimatized to these high concentrations. Hydroecological monitoring performed around each nuclear site moreover has never demonstrated a significant influence of boric acid liquid discharges from the site on the marine ecosystem. Consequently, the boric acid liquid discharges produced by nuclear sites by the sea have no impact on the marine ecosystem.

In conclusion, impact studies carried out as part of authorization requests for liquid discharge and water intakes on the one hand, and data from the environmental monitoring of sites on the

other hand, demonstrate the absence of impact on the environment from boric acid liquid discharges due to the operation of nuclear power plants.

- *Managing the public health risk*

An evaluation of the health risk of boric acid liquid discharges from nuclear plants was conducted by EDF based on the quantitative evaluation of health risks (Quantitative Health Risk Assessment - EQRS), in compliance with recommendations (INERIS 2003 guide) from the French National Institute for Industrial Environment and Risks.

The INERIS is a French public institution under administrative control of the Ministry of Ecology, Sustainable Development, and Energy (MEDDE). Its mission is to conduct studies and researches that can help to prevent risks that economic activities impose upon the safety of people and goods.

Boric acid is a threshold substance: its effect only occurs beyond a dose threshold, and its severity increases with the dose. It is considered therefore to have no effect if the level of boric acid is below this threshold dose, called the Toxicity Reference Value (VTR).

For threshold effects, the risk indicator is the HQ, hazard quotient (or risk index) which is the ratio between the daily exposure dose and the Toxicity Reference Value (VTR).

When the HQ is lower than 1, the risk of a toxic effect is unlikely. When the HQ exceeds 1, the occurrence of a toxic effect cannot be ruled out, and a second, more independent evaluation must be conducted by re-examining all of the hypotheses, data and parameters used.
The Toxicity Reference Values (VTR) used to characterize the potentially toxic effects of boric acid (dose-effect relationship) are based on the critical analysis of toxicology, epidemiology, and clinical information established by international bodies (WHO) or national institutions (US-EPA and US-ATSDR in the United States (US Agency for Toxic Substances and Disease Registry), the RIVM in the Netherlands (The National Institute for Public Health and the Environment), Health Canada, etc.).
Evaluations of the health risk of boric acid liquid discharge from nuclear power plants show that the hazard quotient related to chronic exposure or acute exposure from ingestion is still lower than 1.
Consequently, the health risk associated with boric acid liquid discharge, based on current knowledge and methods tested by recognised scientific organizations, is not considered to be a concern.

Comments on the proposed dates:

Nuclear industry requires investments which can be granted only with regulatory guarantees for a period of nominal life of power plants and even farther by considering decommissioning. The principle of a limited duration authorization, even renewable, is not bearable for such investments.

A RMO study is absolutely necessary before adding this group of substances whose uses affect so many industrial sectors, taken into account the unsuccessful substitution attempts.