SINCE 1987

connecting & business
government & society

Our expertise at your service

Anticipate regulatory developments through active monitoring of files and substances

Prepare Socio-Economic Analysis

Prepare Analysis of Alternatives

Train your regulatory teams

Represent your interests to the authorities

Meglena Mihova - Managing Partner

- 20 years of experience in European Affairs
- Expertise in REACH & CLH since 2001
- Experience in socio-economic analysis and analysis of alternatives

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- Expert in delegated and implementing acts
- Expertise on environmental, food, pharmaceutical and cosmetic issues
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- Focus on Chemical and Sustainability policies
- Strategic policy support in the cosmetic sectors
- Advice for cosmetics producers on Chemicals Strategy for Sustainability, microplastics and various chemical dossiers

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Who we are

EPPA is a specialist management consultancy established in 1987 that assists clients in managing alignment between business, European Union institutions and governments, while considering also research and technology developments and social-cultural shifts.

We are a multi-disciplinary and multi-cultural consultancy with a unique and successful approach that focuses on creating a constructive dialogue with policy-makers.

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Our monitoring services

We can help you anticipate regulatory developments thanks to a proactive monitoring of legislative processes and substances

On the basis of a mapping of relevant legislative and regulatory topics and/or relevant substances for your company / association, EPPA offers to prepare a **weekly or monthly tailor-made monitoring report.** The objective of the Monitor is to gather early intelligence about the trends and priorities of Member States, Commission and ECHA regarding identification, assessment and ban of substances, as well as the development of policies and legislations from the high-level political Strategies to concrete legislative initiatives (Regulations, Directives) and secondary legislation (implementing acts, delegated acts).

Examples of broad themes that may impact your products and substances:

- Political priorities concerning (SVHC, Nanomaterials, Endocrine disruptors, Sensitizers, Essential use, Combined effects…) both in high-level EU strategic policies (Chemical Strategy for Sustainability, Zero-Pollution Action Plan, Circular Economy Action Plan…) and in Member States' national programmes.
- New legislative initiatives and revisions of existing pieces of legislation (REACH, CLP, Cosmetics Regulation, Packaging and Packaging Waste Directive, Single Use Plastic Directive…) as well as secondary legislation adopted under them.
- Recent regulatory developments under REACH with focus on substances: updates of Registry of intentions, revisions of the Candidate list, evaluation of substances (CoRAP), process of priority sub-stances identification, assessment of SVHC with a view of their inclusion in the Authorisation (XIV) and Restriction (XVII) Annexes.

EPPA has a team of consultants who can offer you the following services:

- Preparing a summary of the key developments to have a one-glance overview of issues impacting your files and substances
- Getting early intelligence on relevant Member States, Commission and ECHA
- Actively reporting on the process (political, legislative and regulatory processes and substance assessment / authorisation / restriction processes)
- Advising on process and timing: preparing regulatory timeline for different processes to clearly identify next steps and recommendations on the best way forward
- Analysing the regulatory and business impact of potential developments
- Identify opportunities to participated in consultation processes at the level of the Commission (on new legislative or regulatory initiatives (roadmaps, public consultations, draft delegated or implementing act)) and of ECHA (REACH and CLP processes) and how to participate in the process.

Socio-Economic Analysis (SEA)

A strong tool to support your business cases by anticipating impacts of changes in EU legislations

The ongoing better regulation policy of the EU Commission, in which evidence and impact assessment play a key role in the design phase and in the political decision-making phase, makes the SEA a must-have. EPPA's economic consultants conduct Socio-Economic Analysis (SEAs) in numerous regulatory and policy areas. An SEA serves as an evaluation tool that analyses – from the societal perspective - costs and benefits of policy makers' decisions. It is a very flexible approach that can be applied in the ex-ante assessment of any political decision, and in various legal contexts.

Examples in which the SEA can support your case:

- Registration, Evaluation, Authorisation and Restriction of chemicals (REACH): The SEA is a key document when applying for authorisation. EPPA has successfully supported clients with SEA for their authorisation application and provided to its clients SEAs for shaping the scope of Restrictions during the public consultations.
- Biocidal Product Regulation (BPR): EPPA has prepared SEAs for active substances falling under exclusion criteria.
- Trade: EPPA has assisted companies to set up SEAs to support them in Anti-Dumping cases.
- Harmonised classification and labelling (CLH): EPPA has supported companies with a SEA to facilitate decisions on timing and scope.

EPPA has a team of economists who can offer you the following services:

- Conduct supply chain surveys and analyse the relevant markets.
- Draft the SEA report, tailored to your own specific case which implies:
  a) Identification of the likely stakeholders' responses to the specific policy option that is being considered
  b) Qualitative and quantitative assessments of social and economic impacts expected to occur as a result of the policy option being assessed
  c) Monetization of health and environmental impacts
  d) Analysing sources of uncertainties by conducting sensitivity analysis. In drafting SEA, EPPA economists work closely with chemists and toxicologists.
- EPPA can defend the conclusions from the SEA before the EU and national competent authorities.

With more than three decades experience working with EU institutions, member state governments, and private sector stakeholders, EPPA assists its clients to anticipate changes in different legislations and drafts the SEA in support of their cases. Thorough analysis and close collaboration with our clients are the milestones of our SEA service.

Analysis of Alternatives

The core justification for any application for defending your substances under REACH

Understanding the AoA

The core aim of the REACH regulation is to obtain the substitution of Substances of Very High Concern (SVHC) by others deemed less hazardous. The authorisation process is there to allow for continued use of hazardous substances when the applicant has no alternative. This could be because the alternatives are technically not feasible for the use in question or because a longer phase-out or substitution period is required. The same principle applies in the framework of a restriction process under REACH.

EPPA has long experience in European substance control legislation and the absence of alternatives is always a pre-requisite for any exception to be considered from a substance ban. Generally the applicant has all the information available because the hazard characteristics of the substance are well known. Company sustainability and general environmental and occupational health objectives tend to place a premium on phasing out of an SVHC. Therefore the raw data required to draft an AoA is generally available inside a company and the work required is merely to place this in the format required by the institutions and complement it with recent research.

An Analysis of Alternatives should describe the following aspects:

- Company purely internal information
  - Technical necessity of the use of the SVHC (metrics for analysing alternatives)
  - Research and development performed into finding alternatives including alternative methods of synthesis or process
  - Substitution plan with mile stones where feasible
- Partially external information
  - Potential alternatives need to be assessed on
    - Technical feasibility
    - Availability
    - Toxicological comparison
    - Economic viability
  - From the above the “least bad” solution needs to be chosen including a complete halt of the production but not exclusively a complete halt of the production.

With more than three decades experience working with EU institutions, Member state governments, and private sector stakeholders, EPPA assists its clients to anticipate changes in different legislations and drafts the AoA in support of their cases. Thorough analysis and close collaboration with our clients are the milestones of our AoA service.

EPPA’s AoA service

EPPA - with its team of multi-disciplinary experts can offer you the following services:

- Conduct supply chain surveys and analyse the relevant technologies that could serve as an alternative to your current SVHC use
- Draft the AoA report, tailored to your own specific case and this implies:
  - Compliance with the ECHA required formats
  - Ensure externally validated completeness of analysis of alternatives as well as the defence of that AoA against NGO or competitor claims
  - Work with the applicant on a viable and defensible substitution plan
  - Place the business context of the applicant into the bureaucratic context of the application for authorisation
- Management of the application for authorisation or restriction dossier end-to-end including the other required documents CSR and SEA
- Defend the conclusions from the SEA before the EU and national competent authorities.

Practical success when working with EPPA on an AoA

These are some examples of dossiers where the AoA prepared by EPPA was important part of the success:

- As a part of the authorisation application - for a company which uses diarsenic trioxide (carcinogen 1a) in gold electroplating process. An essential point in this dossier was that all alternative methods had to be kept confidential due to the extreme sensitivity of the manufacturing pro-cess. The client was granted the authorisation for 7 years.
- For a company, which uses trichloroethylene (carcinogen 1b) as a processing aid in the manufacture of beta-cyclodextrin. The client was granted a 12-year authorisation, being the longest review period. The difficulty in the AoA here was that the application involved enzymatic chemistry which is to a large degree empirical and it is therefore much harder to justify why a potential alternative does not work.
- For a company involved in the manufacture of glass but which had suffered a catastrophic set-back in substation, EPPA was able to show that whilst the failed process had yielded a method to introduce an alternative, it was no longer practically feasible to introduce this alternative in the short term.
- For a company involved in the production of upstream raw materials for electronics, the AoA was particularly challenging due to the existence of alternatives but which could nevertheless not be sold to customers due to pre-existing contractual and quality commitments.

The above are just an outline of the type of challenges that writing an analysis of alternatives represents. Generally all the knowledge is available inside the company but it needs to be placed into a con-text that complies with the conditions of the REACH Regulation as well as being understandable by persons who are at best modestly technical and at worst dogmatically inclined against allowing any exceptions to substance bans.

Courses & Training

EPPA has a branch specializing in training and coaching. This training centre - **European Training Institute** - offers training to professionals who directly or indirectly have to act at European level and who therefore need a good understanding of decision-making processes at political, regulatory and scientific level.

We offer both general courses open to the public and tailor-made courses that allow exploring specific subjects and files. Our training courses cover the European decision-making process in all its dimensions, advocacy and communication strategies in fields such as chemicals, cosmetics, and the environment.

All the training and coaching sessions delivered by ETI are hands-on and operational, geared at delivering maximum added value to participants in their day-to-day activities. They are delivered by top lecturers who are EU Public Affairs practitioners and dispose of recognised pedagogic skills.

The sessions are fully interactive allowing participants to ask all the questions they wish. Our tailor-made courses are prepared according to the field of activity of the association, company, individual.

For regulatory teams, we have developed specific and tailor-made programs:

- Discover the decision-making process in Brussels
- Understand the apparatus of European regulatory decisions
- Communicate efficiently with European decision-makers
- Interact with stakeholders and civil society

Please feel free to browse our website (www.e-t-i.eu) or contact Vicky Marissen (vicky.marissen@eppa.com) for further information on the courses mentioned above and/or for the development of a customized course or coaching according to your needs.

Harmonized Classification of Active Substances in Europe

Reinforcing the industry positions on harmonized classification of substances under CLP Regulation

The EU's Classification, Labelling, and Packaging Regulation (EC) No 1272/2008 (CLP Regulation) is well-meant but can pose a significant regulatory challenge to the future of your business. EPPA provides political and regulatory advocacy with the objective to facilitate appropriate harmonized classification that prevents jeopardizing certain future commercial uses of the active substances in the EU and abroad.

Examples in which regulatory advocacy can support your case:

- Harmonized classification processes for pesticidal active substances approved under Regulation (EC) 1107/2009. EPPA helped numerous agro-chemical companies achieving milder classifications and even a unique re-classification of a cut-off classified substance towards less adverse classification.
- Classification of chemicals authorised under REACH: With the help of dedicated socio-economic analysis and regulatory advocacy in the Member States, EPPA successfully prevented a number of adverse classification proposals.
- Classification of biocides authorised under Biocidal Product Regulation (BPR): EPPA facilitated many scientifically more appropriate classifications for important biocides in Europe.

EPPA has a team of skilled regulatory and policy consultants who can support you with the following services:

- Crafting dedicated strategy applying specifics of your case to political and socio-economic realities
- Strengthening of your scientific dossier with the help of a large network of independent experts
- Building a consistent socio-economic and risk-benefit narrative of your case to mobilize impacted Member States
- Addressing the right officials at appropriate levels, with your messaging in the right materials, at each stage
- Covering the majority of Member States' competent authorities with dedicated outreach with regulatory and scientific arguments supporting your case

With more than three decades of experience, having worked on dozens of active substances with EU institutions, Member States' governments, and private sector stakeholders, EPPA assists its clients to facilitate adverse effects of CLP Regulation and proposes and implements unique strategies in support of clients' cases.

Attentive listening, dedicated experienced team, thorough quantitative and qualitative analysis, and close collaboration are the milestones of our service to the many satisfied clients ranging from large multinationals to family-owned niches.