



ANNUAL REPORT

2021



working together for safer colorants

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PREFACE

Dear friends of ETAD,



We all have had a year with online meetings, working from home and a demanding business environment. Unfortunately, we also could not meet personally at the general assembly. Nevertheless, the strong support from ETAD was of great help.

The Basel office was able to address its vast network formed by authorities, brands, labels and organizations, which is a great benefit for all member companies.

Again, we have seen that there are many different stakeholders in our industry and ETAD is a sought-after partner because of its scientific expertise and professional networking, based on the know-how of its member companies.

Additionally, activities of national authorities have become more and more important, with today's decisions of a national authority often having a severe impact on our complex supply chains. For a single company it is nearly impossible to monitor all the technical and legal requirements alone; having ETAD informing us about new developments and coordinating our common actions has been especially relevant last year in topics like PCBs or the restriction of sensitizers.

In the bigger picture, the actual development of the pandemic gives an optimistic view of a more relaxed future, which is my wish to all ETAD companies. I would like to end by thanking all ETAD members, Committee participants and the Basel staff for keeping all projects running, for sharing all the relevant information and for being on our side.

Stefan Ehrenberg

Dear all,

With a little bit of luck, I will be able to see at least some of you in person at this year's General Assembly. However, despite the pandemic and the online-only possibilities to meet I can confidently say that also in 2021 our work together (for safer colorants) has been quite constant and fruitful. I thank you for all your contributions throughout another untypical year!

In 2021, we have been especially focused on several projects and on far-reaching issues, which will mostly continue in 2022; our industry is under scrutiny from many different angles, and we will have to keep working through all our channels on the advocacy for our products.

More than ever, we will need to get involved in many high-level discussions on topics of potential big impact on our products. It is sometimes a difficult balance between ETAD's cornerstone of providing solid scientific evidence and facing political agendas which seem to overlook sound science.

Fortunately, there also still are discussion partners who are interested in finding solutions to current issues based on scientific arguments. In any case, there will be for sure plenty of opportunities in 2022 to engage ourselves in such discussions.

My last words in this introduction go to the Basel team, Heidi, Stefka and Gecheng, as well as to our accountant Reto, to thank them for their support in all the small and big activities which make ETAD work.



Pierfrancesco Fois

47th Ordinary General Assembly

The 47th Ordinary General Assembly of ETAD was held as a web meeting on May 21, 2021. The President, Dr. Mehmet Şener, opened the proceedings by welcoming the attendees. Out of the current ETAD membership of 34 companies, 24 were represented by proxy; of the current total vote entitlement of 78 votes, 67 votes were represented at the meeting (86%).

The participants approved unanimously the minutes of the 46th Ordinary General Assembly 2020 as well as the Annual Report 2020.

The Treasurer Mr. Roentgen presented the summary of the financial report for 2020 which had been sent to all member companies. In 2020, total income was SFr. 1'089'000 compared with total expenditure of SFr. 792'000, resulting in a profit of SFr. 144'000. Mr. Roentgen underlined how the actual profit was notably above the budgeted one, even though the actual income had been below the prevision: this very positive result was due both to the changes in the ETAD staff during the year 2020 and to a careful administration of the resources. This financial report was approved unanimously, as well as the appointment of PriceWaterhouseCoopers AG as auditors for the 2022 accounts.

Before the election of the new Board, upon demand by Dr. Fois, the Assembly granted the members of the Board the release for 2020 with no votes against and no abstentions.

The new Board:

Dr. Stefan Ehrenberg (president)
Dr. Ulrich Veith (vice president)
Mr. Georg Roentgen (treasurer)
Dr. Felix Grimm
Dr. Yoshitaka Koshiro
Ms. Carole Mislin
Dr. Mehmet Emre Şener
Mr. Jashvant Sevak

As is customary, the Board proposal for its composition for 2021/2022 was presented to the Assembly. There were no additional nominations in response to the invitation by ETAD Legal Counsel, Dr. Olano.

The Board was elected unanimously with a new President and a new Vice-President.

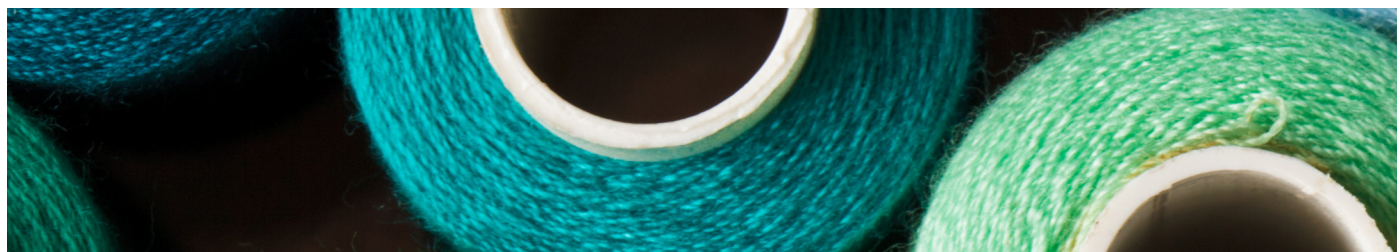
Dr. Fois presented to the Assembly ETAD's highlights for 2020 and main goals for 2021. The main highlight in 2020 was the unchanged commitment of ETAD members to the association, which allowed to continue the association's work without interruptions.

ETAD is involved in many long-term activities which were already in focus in 2020 but will also continue to be so in 2021: among others, the advocacy on the sensitiser proposal, the internal analytical projects, the different projects and discussions with national authorities and the new effects of the nano debate on colourants. Additionally, special attention needs to be given, as also underlined by the Board, to the extensive plan for regulatory changes in the EU known as "Green Deal". In particular, the specific "Textile Strategy" included in this far-reaching plan will require a dedicated activity from ETAD.

Dr. Roentgen presented the Board proposal for the Budget 2021, foreseeing a total profit of SFr. 41'000 and, reflecting the increase in activity on new projects, including a substantially enhanced investment on this item. The Budget 2021 was approved unanimously. No change in the membership fees was proposed for the current year.

Dr. Şener announced that the next General Assembly and committees' meetings would take place in Freiburg, Germany in May 2022. Dr. Şener thanked all the participants to the GA, as well as the ETAD staff for their work during the year and the preparation of the online meeting. He then congratulated the newly elected Board and particularly the new President, to whom he gave the floor for the closing remarks.

Dr. Ehrenberg, reflecting on the association objectives presented during the Assembly, emphasized the importance of ETAD's work and the necessity for all companies to keep working together: there are more and more all-encompassing developments which need a joined effort and a good coordination.



OUR LATEST NUMBERS

Membership

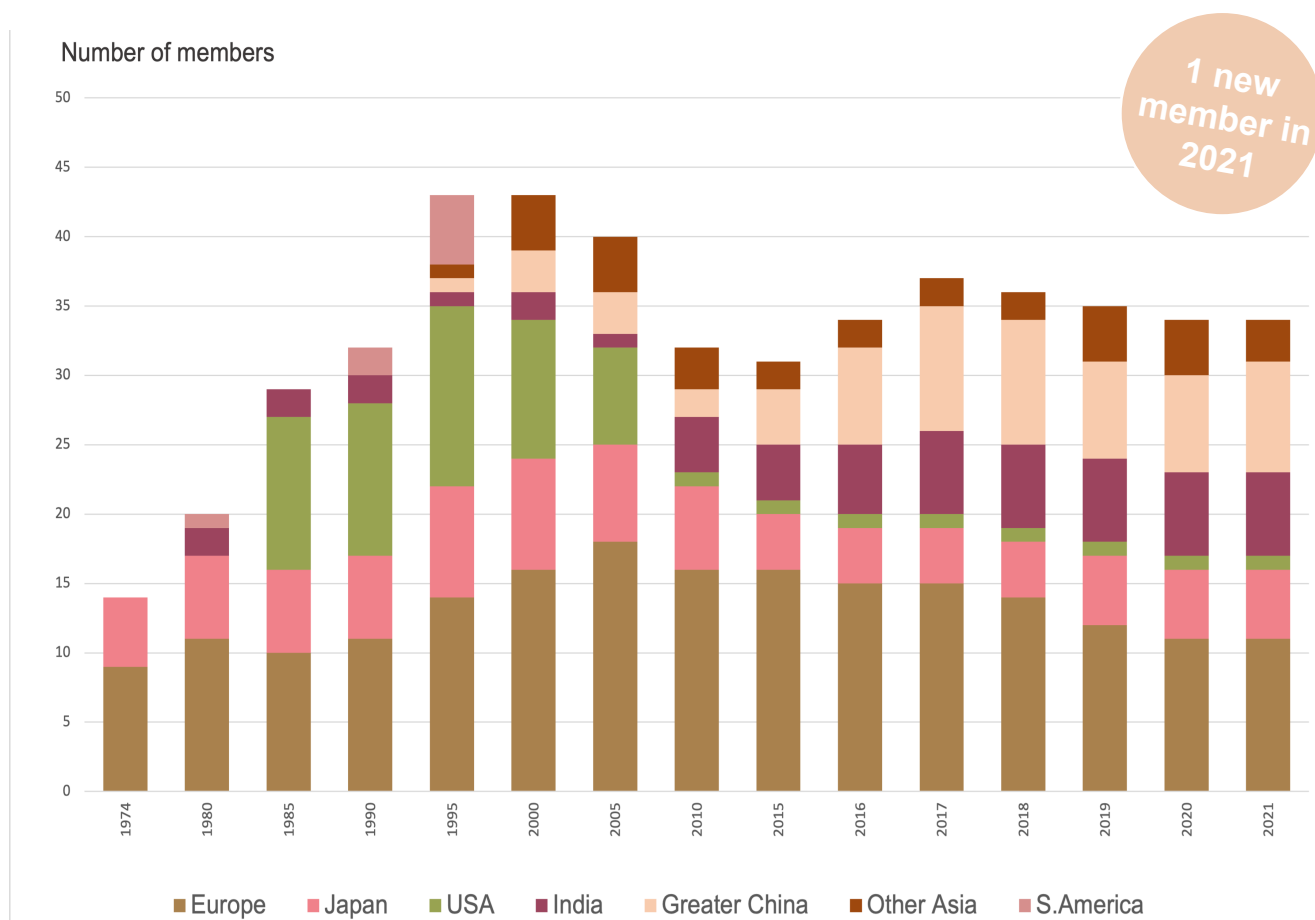


Fig. 1 – Growth and changing regional composition of the ETAD membership

In 2021, ETAD welcomed the company Anshan Hifichem as a new member. Additionally, the member company BASF Colors and Effects became part of Sun Chemical, also already an ETAD member. Finally, due to non-compliance with its member obligations, the company Thai Ambica had to leave ETAD.

Finances

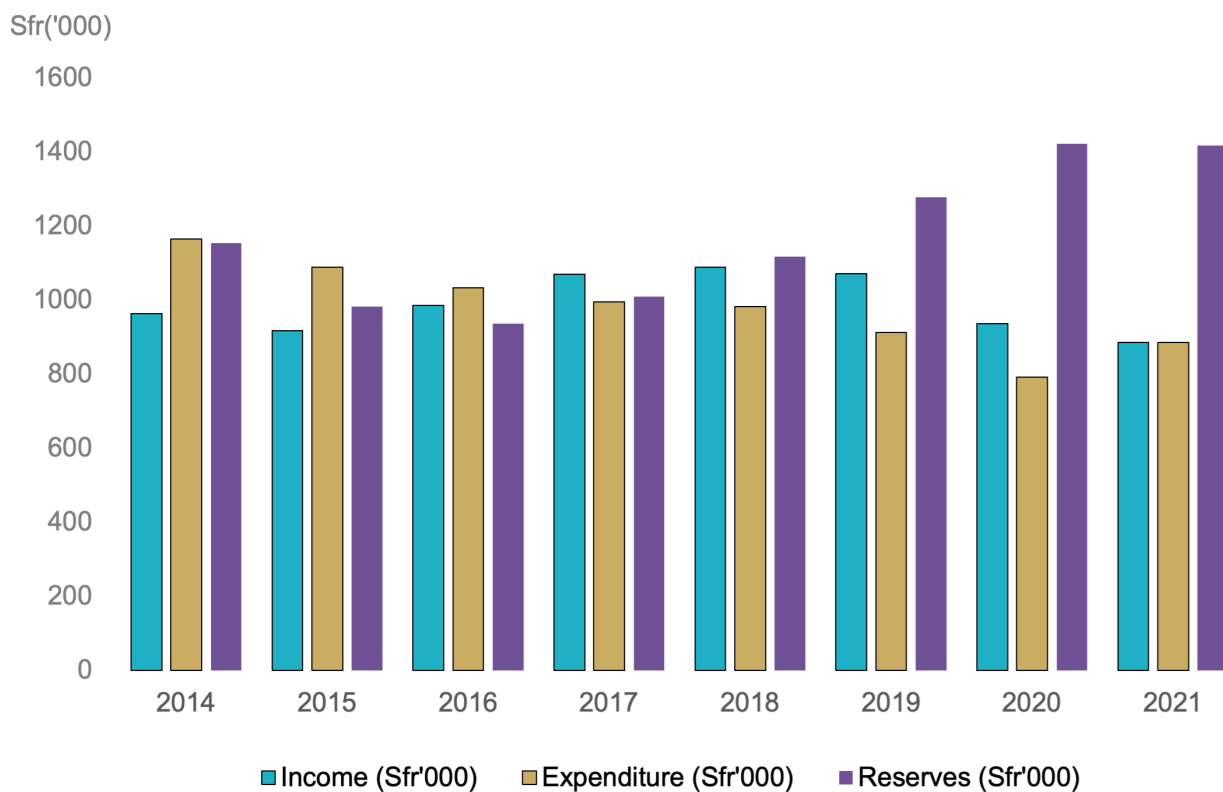
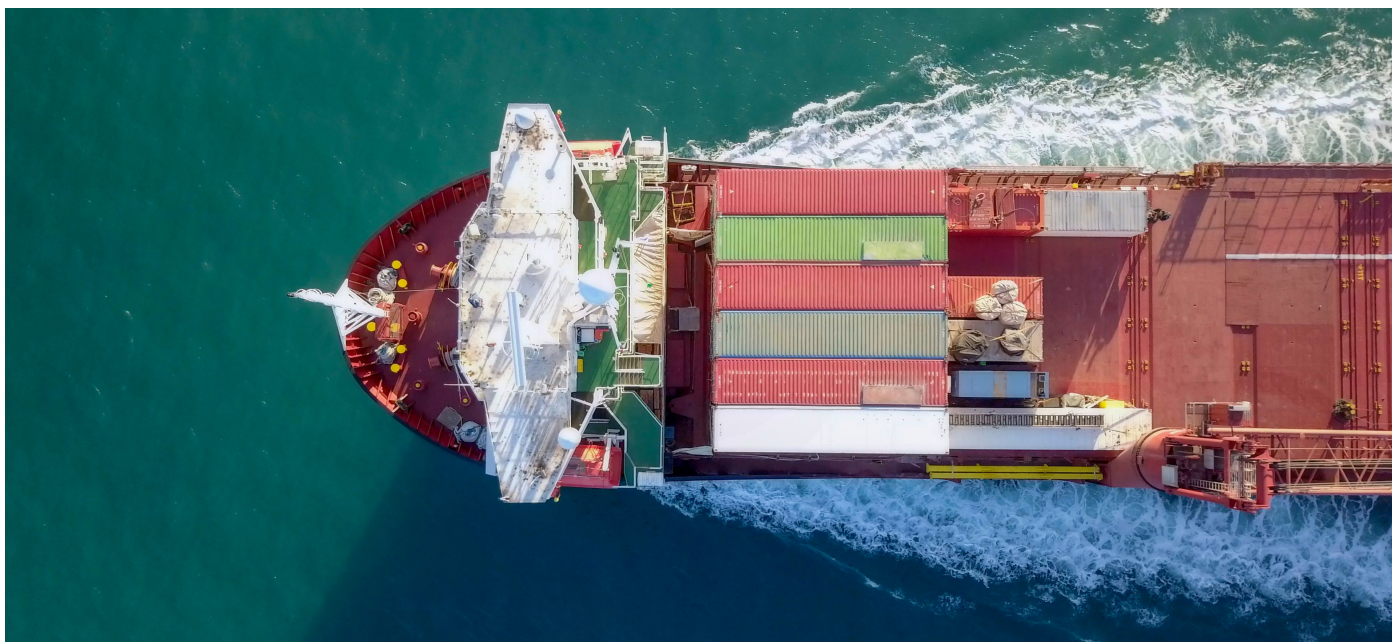


Fig. 2 – Summary of income / expenditure 2000 – 2020

ETAD is a non-profit association. The operating expenses are recovered mainly by means of payments by the ETAD members. In 2021, total income was SFr. 885'053 compared with total expenditure of SFr. 885'053, resulting in a profit of SFr. 18.





ETAD COMMITTEES

Sector Committees

Dyes Operating Committee (DOC) and Pigments Operating Committee (POC)

The DOC and the POC address, respectively, global dye and pigment issues, in particular considering their impact on the whole value chain and deciding on corresponding actions.

Key activity areas:

- Representation of member company interests in colourant-related topics
- Development of scientific data on possible health and environmental effects of colorants
- Cooperation with authorities, brands/retailers, consumers associations and issuers of standards
- Harmonization of regulatory requirements worldwide which affect colourants manufacturing and applications
- Publication of informative material on dyes/pigments

Regulatory Affairs Committee (RAC)

The RAC is ETAD's monitoring committee as regards worldwide regulatory changes, corresponding compliance and practical impact on colourants.

Key activities areas:

- Monitoring and reporting on worldwide developments of chemical control regulations
- Ensuring awareness of new regulatory requirements affecting colorants among member companies
- Providing advice on interpretation of the regulatory requirements
- Constant updating of the ETAD Guidance Document

Regional Committees

ETAD North America (ETAD NA)

ETAD North America furthers the efforts of the North American dye manufacturing industry as an authoritative information source on properties of organic dyes.

Key activity areas:

- Input on draft regulations
- Education and training in all phases of handling dyes
- Collaboration with the US government on exposure reduction projects
- Research on the safety and biological behavior of dyes
- Cooperative research with industry, government, and academia on environmental fate and impact of dyes

Chinese Operating Committee (ChOC)

The ChOC is the reference for all ETAD member companies on colorant-related issues concerning ecology, health and safety arising in China.

Key activity areas:

- Collaboration with the China Dyestuff Industry Association
- Distribution of information on topics affecting non-Chinese members importing or manufacturing in China
- Cooperation with Chinese authorities on environmental fate and impact of colorants
- Enhancement awareness of ETAD among new potential members

Indian Operating Committee (IOC)

The IOC focusses on interaction with the Indian government, particularly stressing the regulatory aspect and playing an active role in deciding and framing policy.

Key activity areas:

- Establish links with Indian national and regional authorities to be involved in the process of chemical legislation
- Inform members about regulatory developments and organize coordinated response
- Collaborate with national groups and associations
- Assistance to member companies on product safety issues and regulations

Japanese Operating Committee (JOC)

The JOC addresses colorant issues relating to environmental and health in Japan, and regularly updates ETAD on specific Asian colorant-related activities.

Key activity areas:

- Monitoring of Asian colorant-related regulatory developments
- Encouraging the scientific understanding of the possible health and environmental effects of colorants
- Development of management systems for potentially hazardous substances
- Cooperation with customers associations of the textile dyeing and printing industries

Taiwanese Operating Committee (TOC)

The TOC focuses on collaboration with Taiwanese regulatory bodies in all policy and legislation-making processes which impact the local colorant industry.

Key activity areas:

- Cooperate with Taiwanese national authorities in the creation of chemical legislation
- Inform members about regulatory developments and organize coordinated response
- Collaborate with the Taiwanese Dye and Pigments Manufacturers Association
- Assist member companies on product safety issues and regulations





PROJECTS

Development of ETAD Method 231: Determination of Cr(VI) traces in water-soluble and water-insoluble dyes

In 2021 the analytical expert team worked intensively on the finalization of the procedure for the determination of Cr(VI) impurities in chromium complex dyes.

In the final draft, the UV-VIS and the IC/PDA detection methods are provided as equal possibilities for the determination, depending on the laboratory equipment. Three ETAD companies performed internal analyses of identical contaminated Acid Black 60 samples and could obtain reliable results with both detection procedures.

The experts agreed that before adopting the method it will be important to perform some additional measurements with different dyes and to confirm that the filtration procedure could be performed correctly also by laboratories having less experience with chromium dyes.

Development of a procedure for measurements of free Co(II) in cobalt complex dyes

In 2021, ETAD and the member companies restarted the work on the development of an analytical procedure for determining Co(II) impurities in Co-complex dyes. Previous experiments of ETAD companies were based on extraction of Co-complex dyes and analysis of the eluate through differential pulse polarography (DPP), which did not apply to all cobalt complex dyes and did not achieve a satisfactory differentiation between Co(II) and Co(III).

For the new method development, the analytical experts are working together with an external analytical laboratory on a procedure proposal including extraction and HPLC measurements on Co(II)- and Co(III)-complexes with appropriate complexing agents, including masking ligands.

The new method should be general and ideally valid for all market-relevant Co-complex dyes. Additionally, the detection limit of the method has to be very low and compliant with the regulatory limits.

Azo dyes and their cleavage products

Beginning of 2021, ETAD forwarded to BfR the infosheets for the dyes in the 100-1000 tonnage band and advocated for a weight-of-evidence approach, also considering the information on amines. The BfR indicates that they are positive to the dyes-based approach and would work on some grouping in case further tests are required. The infosheets data will be checked by the authority through a special tool due to limited capacities.

Regarding the next stage of the project, ETAD and TEGEWA decided on a possible strategy for the low tonnage band dyes. For the data evaluation the dyes were divided into two sub-groups: 1-10 tonnes/year and 10-100 tonnes/year. 23 dyes were selected, and the available data were summarized.

In parallel, ETAD and an external consultant on toxicology worked on a list with 21 priority aromatic amines distributed by the BfR. Although the list is still not final it was being taken as a basis for the data collection and evaluation. ETAD will continue to underline the weight-of-evidence approach, especially considering the information on dyes and amines together.

Migration of dyes from textiles

11 ETAD/TEGEWA member companies prepared for the German BfR 84 dye samples (crude dyes or formulations of reactive and disperse dyes) and 74 dyed and printed fabrics of different types and qualities.

All samples were anonymised by ETAD and forwarded to authority until the beginning of 2021, including general dyeing procedures.

Since receiving the dyes and textile samples, the BfR is working on a procedure for migration measuring.

The following aspects play an important role:

1. Comparison of different extraction methods (sweat simulants, but also water-solvent mixtures);
2. Quantitative detection of dyes in the eluate;
3. Possibilities for detection of possible cleavage products from the reduction of dyes in the extraction eluate.

The first results from this method development are expected for the end of 2022.

Safety of aromatic amides in food contact materials

In collaboration with the German association VDL, ETAD was discussing the presence and safety of some aromatic amides which have been identified by German authorities as residual impurities in food contact materials.

These aromatic amides come from organic pigments, and it has to be determined in particular, whether they might be metabolized to carcinogenic aromatic amines.

Following the investigation by the German authorities, ETAD and VdL commissioned a preliminary report the university of Würzburg. It showed that there is some cleavage of the amide bond, but only to a minor extent.

On this basis, it can be demonstrated that most of the findings reported by BfR report are of no concern. The BfR is willing to adapt its statement, depending on the final report, but demands a micronucleus test for N-(2,4-dimethylphenyl)acetamide (NDPA).

It was agreed to commissions a micronucleus test in vitro (human lymphocytes). The cost for this study was shared between ETAD and VdL.

In December 2021, the final report on the possibility of amide cleavage in printed food contact materials was sent to ETAD und VdL, confirming that, in gastric juice simulant, very limited cleavage to aromatic amines occurs. Additional, first results from the in-vitro micronucleus test in human lymphocytes of N-(2,4-dimethylphenyl)acetamide are already available: no genotoxicity from the amide was observed under the test conditions. More complete results will follow in 2022.





REGULATORY HIGHLIGHTS

Europe

Nanomaterials

In its ongoing check of nano-related information in submitted dossiers, ECHA continued requesting additional specific studies, including, e.g., in vivo inhalation toxicity, for the nano form of the pigments. The waiving arguments in dossiers submitted in the past are no longer accepted. As regards information on the nanosized components of organic pigments, TEM analysis is the main way to obtain these data, but additional characterisation through other data such as dustiness also needs to be submitted.

In 2021, the European Commission performed the planned review of its Recommendation on the definition of nanomaterial. A targeted online stakeholder consultation was carried out to update, test and verify the preliminary findings of this comprehensive review, gathering further evidence and feedback from a wide range of stakeholders who have a role in application of the harmonized regulatory definition of nanomaterial in the EU. The online consultation closed on 30 June 2021.

Probably due to precautionary over-nominating, many dyes were listed in the French nano inventory and are now available through the database of the EU Nano Observatory, even though they were not reported in REACH as nanomaterials. ECHA had no way of verifying the reliability of these data before publishing the EUON nano list, and did not state clearly enough that the inclusion of items into the list does not include any evaluation of the reasons for “nano declaration”.

EU Green Deal and related initiatives

As part of the Chemicals Strategy for Sustainability, discussions continued on the pre-defined “essential use” criteria, which the European Commission suggested to be used by authorities to take regulatory decisions on chemicals with most hazardous properties (starting with CMRs, endocrine disruptors, PBT/vP/vB and considering extension to chemicals affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ).

Several EU trade bodies have dismissed this approach, claiming that it may lead to regrettable substitutions in non-essential uses, and instead advocate a case-by-case approach.

A public consultation on the EU's strategy for sustainable textiles closed in August 2021.

A revision to the Toy Safety Directive also falls under the commitments of the chemical strategy for sustainability. This will consider the extension of the currently applicable ban on CMRs to include endocrine-disruptors as well as substances that are persistent and bioaccumulative.

Positive lists may also be established. In addition, it may be required that information on chemical compositions be communicated in the supply chain, in a similar way to cosmetics and food products.

Drinking Water

The revised EU Directive came into force in 2021.

ECHA started to compile lists of chemicals, compositions or constituents that can be safely used in materials coming into contact with drinking water.

ECHA intention of restricting sensitizers in textile/Leather

The final SEAC opinion, published in 2020, included the proposal of using the Master List (added as reference in the restriction proposal) and not all substances with a harmonised classification as H317 as well as to remove Disperse Violet 93, Disperse Blue 291 and Disperse Yellow 64 from the proposed restriction.

This opinion was aligned with the comments submitted by the colorant industry to the previous RAC and SEAC draft opinions. In 2021, DG Grow and DG Env worked on the preparation of a draft proposal for the restriction to be presented to the European Commission, expected for the beginning of 2022.

Microplastics

The European Commission requested ECHA to prepare a restriction dossier concerning the use of intentionally added microplastics to consumer or professional use products. The Commission will soon assess ECHA's submission and reflect on the most appropriate measures.

ECHA's proposal foresees a ban on microplastics between 100 nm and 5mm. This may be relevant for pigment master batches and, for the textile industry, the secondary microplastics (non-intentional release) from synthetic fibers will also become important. A call for evidence will be open for feedback until 18 January 2022.

REACH and CLP updates

ECHA clarified that the chemical safety assessment does not allow registrants to omit submitting standard information on degradation. Also, for mutagenicity, a combined comet assay and micronucleus test may be required for substances registered under Annex VII with a positive Ames test.

ECHA has called for comments and evidence on cobalt and inorganic cobalt compounds to support its recommendations on occupational limit values. It must be remembered that some current tests do not adequately differentiate between Co(II) as found in inorganic salts and Co(III) as used in dyestuffs.

A request for the harmonized classification of Reactive Black 5 as respiratory and skin sensitiser has been announced.

The latest proposed definition for perfluoro-substances (PFAS) includes now molecules with a single -CF₃ group. This could impact some dyes and organic pigments.

REACH Reform

Two comprehensive inception impact assessments were launched concerning a revision of the REACH Regulation and a revision of EU legislation on CLP. For REACH, a revision of the registration requirements will be considered.

For CLP, several options are under consideration including new CLP classes such as endocrine disruption, PBT and vPvB. Authority opinions on persistent mobile toxic (PMT) and very persistent very mobile (vPvM) have also been voiced.

Persistent Organic Pollutants

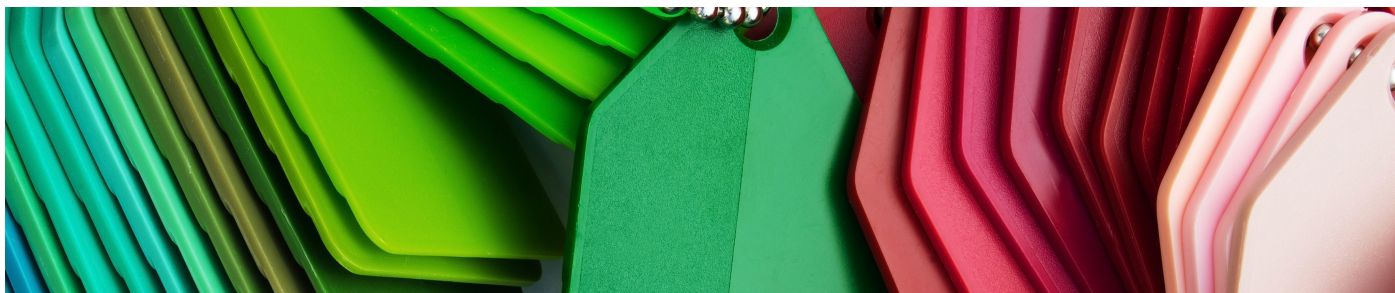
Annex 1 of the EU's persistent organic pollutants (POPs) Regulation was amended to set a lower limit value of 5mg/kg for pentachlorophenol, salts and esters in substances, mixtures or articles.

Germany

WHC classification of pigments

The German authorities UBA and BMU have re-assigned Pigment Yellow 12, Pigment Yellow 13 and Pigment Yellow 83 to "No Water Hazard" class, formerly known as Water Hazard Class 0 (WGK-0).

Theoretically, the successful argumentation provided by the industry for these three cases may be applicable for other pigments in the same class.



UK

The European Commission refused to grant REACH data access to the UK during the Brexit trade negotiations due to the UK's refusal for regulatory alignment. Companies will therefore need to establish whether they have sufficient rights to refer to data in their UK dossiers.

Importers and downstream users supplying in Great Britain are encouraged to voluntarily submit information on hazardous mixtures to the National Poison Information Service via the SDS. In Northern Ireland, chemicals placed on the market must comply with the EU CLP Regulation.

Certain harmful substances in tattoo inks and permanent make-up could be restricted under UK following a call for evidence by the HSE.

An independent biocides regulatory regime is now in operation. Consolidated versions of the GB biocides laws are not currently available though most aspects of EU BPR are expected to continue in the same way.

The UK government is to consult on an extension to UK REACH deadlines, potentially of 2 years.

Turkey

The KKDIK registration phase officially started on 1 January 2021. The authorities released a tool where each participant can see who the lead registrant, or lead registrant candidate, is. There is a requirement that potential lead registrants should contact all pre-registrants before declaring their position. Registration of all tonnages is due by 31 December 2023.

Turkey also communicated the update of its cosmetics products Regulation to harmonise with EU rules.

Russia and Eurasian Economic Union

The Russian Ministry of Industry and Trade (MINPROMTORG) published the final version of its chemicals inventory, as the Eurasian Economic Union (EAEU).

Companies that did not meet the August deadline but can prove their chemical was used on the EAEU market before then, are expected to have until 2 June 2023 to notify, in order to avoid the new substance notification procedure.

The exact date of entry into force of the Eurasian technical regulation on the safety of chemical products is unknown but is not expected to be before November 2022 due to continuing disagreements between EAEU member states.

The requirement for registrants under the technical Regulation to create a chemical safety passport for new chemicals on the day the legal text comes into force could be a problem since no transition periods are envisaged. It is also expected that registrants will be required to disclose the full composition of their chemical products during the registration submission process. Companies will not need to register existing chemicals or mixtures containing existing chemicals.

India

The Food Safety and Standards Authority of India (FSSAI) consulted on plans to establish a 60 mg/kg migration limit for pigments and colourants used in plastic food contact materials. This would change the 2018 stipulation that drinking water bottles must be colourless.

China

The final revised version of the Inventory of Existing Cosmetic Ingredients in China was published. Non-listed substances will be considered as new and require registration. The revised inventory also adds maximum use concentrations in wash-off and leave-on cosmetics.

China's National Health Commission approved 19 new substances for use in food contact materials, including additional use approvals for Solvent Red 135 and Pigment Violet 15.

South Korea

South Korea's Ministry for Employment and Labour published revised standards for material safety data sheets. Grace periods were defined for existing products (Jan 2022 for >1000t, Jan 2023 for >100t, Jan 2024 for >10t and Jan 2025 for >1t) though not for new products.

A partial amendment to K-REACH expanded the definition of existing substances to include isomers of an existing substance, hydrates or anhydrides of an existing substance and reaction products consisting of two or more existing substances.

The authorities also clarified that the K-REACH government support programme will not apply to only representatives (ORs) acting on behalf of overseas manufacturers. K-REACH registrations are required between 2024 and 2030 depending on tonnage.

Substances were also added to the existing restricted/prohibited chemicals lists in line with obligations under the UN's Stockholm Convention on persistent organic pollutants (POPs).

Japan

Japan will now only accept 'new chemical' notifications via the National Institute of Technology and Evaluation's (NITE) website. For the small-quantity notification of new chemicals (under 1t) a complete application schedule (from January 2022 to January 2023) was published, both for the simple notification and for the request of specific permits.. Manufactures or importers of new chemicals are now obliged to apply for notification prior to manufacture or import.

Thailand

Thailand's Ministry of Industry has added 153 hazardous substances to the list of chemicals companies must report every six months, if handling volumes over 100kg. The substances are mostly those listed under the Rotterdam, Minamata, or Stockholm Conventions, or the Montreal Protocol.

Thailand's Ministry of Public Health published a notification that lists and sets restrictions for 158 substances that can be used as colouring agents in cosmetics. The notification adds purity restrictions for the pigment carbon black, both in normal and nano form. Companies may also use colouring agents that are authorised for use in cosmetics by the US Food and Drug Administration.

Vietnam

The nomination process for the Vietnam chemical inventory ended in 2021. VINACHEMIA will place those deemed to be existing chemicals on the National Chemical Inventory.

Substances were also added substances to the existing restricted/prohibited chemicals lists in line with obligations under the UN's Stockholm Convention on persistent organic pollutants (POPs).

Taiwan

The previous deadlines for the registration of the 106 PEC substances were; 31st December 2021 (>100t) and 31st December 2022 (>1t). The PEC registration (≥ 1 t/y) deadline will now be extended till 31 December 2023. Due to the extension of the deadline, the nomination of the second batch of PECs is not on EPA's current agenda. The same regulation amendment also extends the valid period for the new chemical substance registration approval period to five years regardless of registration type.

Australia

Australia has approved the establishment of a national public register of industrial chemicals, categorised according to the level of concern they present to the environment.

USA

The final risk evaluation for Pigment Violet 29 published on and concluded that the colorant presented unreasonable risks to workers from 10 out of 14 conditions of use. The EPA rejected the argument that pigments are only available as agglomerates and not the primary particle, which presents risks for further pigment evaluations. Pigment Red 52, Pigment Yellow 65 and Pigment Yellow 8 remain on the TSCA workplan.





Nanomaterials

ETAD's companies continued their participation on the different discussions on nanomaterials, as well as with their internal activities.

Dustiness of nanomaterial

The testing of dustiness of nanomaterials according to different methods continued in 2022, since these measurements are required to describe nanoforms. The majority of pigments tested belong to the category "low dustiness" (under 50 mg/kg). However, individual tests results differ greatly (big standard deviations) and are not comparable. Therefore, ETAD collected available dustiness data to assess the possibility of developing an aligned reference for the testing.

Dyes in nanomaterial inventories and in the general nano debate

ETAD analysed colorants registered as nanomaterials through the connection of the REACH page with the EUON. Around 180 substances were identified, including 55 dyes – 15 acid dyes, 40 solvent dyes and some other dyes. ETAD found out that most of the dyes are registered in the French nano inventory but were not reported in REACH as nanomaterials.

ETAD met with the authorities, where it was clarified that EUON only has an "aggregation role" regarding the collecting of information on the nano materials. The Observatory does not have the possibility to check in detail the information from the different sources, on which basis the substances have been reported.

ETAD asked that the differentiation between EUON notification and REACH-registered substances is made clear, as well as that REACH dossiers updates are the references. It also should be clarified that EUON has no possibility to check the appropriateness of the notifications.

The presence of dyes in the European Observatory on Nanomaterials has been commented publicly and has been followed up by ECHA's statement that solubility is not to be seen as an excluding parameter for the identification of a substance as nanomaterials (in the current argumentation, the dyes are dissolved in the final application medium and in this case the "nanotoxicity" arguments would not be valid).

Therefore, ETAD decided to start collecting existing data on dyes from its member companies in order to be able to answer possible future inquiries from the authorities.

EU Restriction proposal for sensitizers in textile/leather

After the publication of the final opinion of the Socio-Economical Assessment Committee, the European Commission has to prepare a draft of the official restriction text. ETAD and TEGEWA continued their activities towards the national authorities in order to influence their opinion on the restriction proposal. The main goal is to avoid the automatic dynamic link to the CLP classification and the possibility for this to be used as a decision tool on restrictions and bans of dyes.

Furthermore, a position paper with EURATEX, ACEA, AFIRM and others interested parties is in preparation with the main goal to avoid a general approach of the dynamic link to become a bad precedent for future regulatory proposals.

Following the multi-stakeholder webinar organised in April 2021 by the industry coalition ETAD is member of, a practical proposal from the industry on the possible implementation of a different mechanism than the "dynamic link" was provided to the European Commission representative. However, according to our internal information, the current proposal under discussion will only adopt our suggestion on the derogation for the three disperse dyes relevant for the market. It is not clear when the Commission draft will be ready (first expectation was end of 2021).

EU Green Deal

CLP revision

ETAD provided its comments to the Targeted Stakeholder Survey of the CLP revision, based on the one prepared within Eurocolour and, among other points, underlined the relevant issues of some of the proposed changes: loss of alignment with the GHS, confusion between hazard-related and risk-related impact, and the general additional burden for both authorities and various actors in the value chain (without any substantial improvement in consumer safety).



Application of mixture rules for MOCS

During the CARACAL meeting in June 2021 a “thought starter” concerning the definition of the MOCS (substances containing more than one constituent), was announced. This definition includes:

- substances of unknown or variable composition, complex reaction products or of biological materials (UVCBs)
- other substances with more than one component (i.e., monoconstituent substances with impurity(ies), and multiconstituent substances with or without impurities).

For these substances, a component-based approach, like for CMR endpoints, should take precedence to test data for their classification for biodegradation and bioaccumulation endpoints.

ETAD already contributed to an Eurocolour position paper to this proposal: the approach is very debatable, and the definition will affect practically all chemicals in REACH. In case some of these endpoints were considered, the companies would have to change almost all of their dossiers.

Communication on Green Deal initiatives

ETAD gave input to different papers containing general comments published through Eurocolour:

- Position on the EU Sustainable Product Initiative
- Position on the introduction of new hazard classes in CLP (October 2021)
- Position Paper on MOCS concept (August 2021)
- Position on Green Deal and on the Chemicals Strategy for Sustainability (August 2021)

ETAD also participated in the preparation of back-up documents for a possible discussion on the “essential use” concept:

- A position paper on essential uses
- A detailed list of specific essential uses

Reactive Black 5 – dossier update and effect on CLP harmonisation proposal

Reactive Black 5 had been proposed in 2020 for harmonized classification, but the process did not advanced since June 2020. In the meantime, following its REACH dossier evaluation by the authorities, the description of Reactive Black 5 was changed to UVCB.

A new request for the harmonized classification of Reactive Black 5 was started by Germany in 2021.

The harmonized classification is targeting the hazard phrases H334 and H317 (respiratory and skin sensitizing). ETAD is following this request regarding the effect on the parallel discussion on the skin sensitizer proposal.

vPvM / PMT substances

The combined endpoints of substances which are very persistent and very mobile (vPvM) or persistent, mobile and toxic (PMT) are becoming more and more relevant. Since the mobility will be the new criterion that has to be considered in this assessment, ETAD carried out a first screening on 104 REACH-registered dyes, in the 10 to 1000 tonnage band. Criteria proposed by regulatory bodies were used, which showed the necessity to analyze in detail the available information and if necessary improve it.

ZDHC

Also in 2021, ETAD continued its work in ZDHC, where the association is one of the administrators of the Chemical Supplier Advisory Group, which provides the consolidated input from these stakeholders. The most relevant activities in 2021 covered in particular:

- The general update of ZDHC’s MRSL: the MRSL Council started the revision of all substances, their limits and test methods; the Council is composed by representatives of six different stakeholders’ groups;
- The chemical companies also provided their input to the revision of the Conformance guidance;
- The discussions on the proper approach for the goal of a “sustainable chemistry”: The chemical industry has developed an alternative approach to the current screening methodologies and is looking for an alignment of the two approaches or, at least, for acceptance from the brands of the equivalence of the two systems;
- In the Solvent Task Team, ETAD is working with other ZDHC experts on a specific approach for dealing with solvents used during the manufacturing of textile and leather.

PFAS restriction proposal

The EU has started a consultation on PFAS, using as definition:

$X-(CF_2)_n-X'$ with $n \geq 1$ and X, X' not being H (thus including $X-CF_3$) meaning fluorinated substances that contain at least one aliphatic carbon atom that is both, saturated and fully fluorinated, i.e. any chemical with at least one perfluorinated methyl group ($-CF_3$) or at least one perfluorinated methylene group ($-CF_2-$).

Some colorants (both pigments and dyes) will fall under the definition, and ETAD started a first evaluation. There is no clear evidence that the affected colorants could be compared with the PFAS of concern, but based on the existing information, in some cases only a screening assessment could be done.

ETAD started a communication with the national authorities active in this discussion for typical colorants applications, providing the general feedback that no clear evidence of PFAS-like concerns was found was communicated. ETAD's goal is to show that the dyes should be evaluated separately, because they do not clearly show the same concerns as the PFAS.

New limit for pentachlorophenol in (EU) 2019/1021 (POP Ordinance)

In December 2020, the European Commission adopted an amendment to Annex I of the EU's persistent organic pollutants (POPs) Regulation that sets a lower limit value of 5mg/kg (0.0005% by weight) for pentachlorophenol and its salts and esters (an unintentional trace contaminant limit).

Following the amendment, ETAD updated its limit for PCP in dyes and aligned it with the new official one (5 ppm). This change was immediately communicated to all members as well as externally. As a consequence, the limit for TeCP had to be specified. DOC proposed a 5 ppm limit as well; and the proposal was distributed for approval to all ETAD companies, which did not communicate any objections.

An updated limit list and an update version of the Guidance to ETAD Members are in preparation.

ECHA's incorrect identification of dyes cleaving to carcinogenic amines

As a tool for clarifying Entry 43 (Azocolourants and Azodyes) of Annex XVII of REACH, ECHA created a webpage listing incorrect substances as azodyes potentially cleaving to carcinogenic aromatic amines. However, a check performed by ETAD upon information from its member companies showed that about 80 items out of 172 listed were incorrect, with most of them not cleaving to any of the known carcinogenic aromatic amines. ETAD communicated to ECHA about this issue, stressing the presence on the list of REACH-registered colourants, for which the mistake might have an important commercial impact. ECHA answered in May and confirmed that there are indeed errors in the listing of substances under this entry. ETAD checked the new list regularly and, in December 2021, only two unproblematic entries had remained.

PCB position paper

In 2021, PCBs remained one of the busy topics for POC, which has been active in this area to cope with the changing regulatory challenges in the field of POPs. One of the major efforts was the publication of a position paper on the ETAD website on 15 June 2021. The position paper, entitled "ETAD Position on the Presence of Unintentional Trace PCBs in Some Organic Pigments in the Context Regulation (EU) 2019/1021 (POPs recast Regulation)" has been well received by sister associations such as VdMi, VdL and CPMA.

Furthermore, meetings together with VdL and the German competent authorities UBA and BME were scheduled to take place in early 2022, to explain ETAD's position on unintentional trace PCBs in organic pigments.

In a nutshell, ETAD's position can be considered to be threefold: (1) "Zero-PCBs" is not feasible, when chlorine atoms are present as part of the chromophore, in a raw material or in some form in the production process, e.g., as part of a solvent. (2) ETAD recommends a limit value of 50 ppm, with a long-term goal of reducing the limit to 25 ppm over an agreed period. (3) An appropriate test method should be accompanied with the proposed limit value. In this context, ETAD recommends the method ISO 787-28:2019 or its European equivalent DIN EN 787-28:2020-12.

Taiwan evaluation of suspected CMR dyes

The evaluation of the dyes suspected to be CMR continued during 2021. Unofficially, the Taiwanese authorities confirmed that the information provided by ETAD, at least for the most relevant substances on the list, should be enough to prove they are not CMRs. The official announcement was expected to be published before the end of 2021.

Discussion with AFIRM on their method for chlorophenols

Chinese as well as Indian ETAD member companies reported several cases of false positives for 3-chlorophenol when testing for other chlorophenols using the AFIRM method. ETAD discussed the possible reasons for these results with AFIRM. Following internal discussions with its experts, AFIRM proposed the new DIN 50009:2021 method for chlorophenols, which should be adopted for the 2022 AFIRM RSL update. It was agreed that it is a good solution, since it already includes a suitable extraction process. Additionally, it includes all chlorophenols and even warns about possible false positives and how to verify them. It is, therefore, quite a complete and useful reference for all involved parties. ETAD will inform the companies once the method is officially adopted.

PARTNERS

National authorities

BAG	Swiss Federal Office for Public Health
BfR	German Federal Institute for Risk Assessment
BIS	Bureau of Indian Standards
BLV	Swiss Federal Food Safety and Veterinary Office
Danish EPA	Environmental Protection Agency
EC	European Commission
ECCC	Environment and Climate Change Canada
Health Canada	
JRC	Joint Research Center - European Commission
KemI	Swedish Chemical Agency
METI	Japanese Ministry of Economy, Trade and Industry
OSHA	Taiwanese Occupational Safety and Health Administration
UBA	German Federal Institute for the Environment
UNEP	United Nation Environment Programme
US EPA	United States Environmental Protection Agency

Other associations

ADIF	Asia Dyestuff Industry Federation
Cefic	European Chemical Industry Council
CDIA	China Dyestuff Industry Association
CPMA	Color Pigments Manufacturers Association
EuPIA	European Printing Ink Association
Euratex	European Apparel and Textile Confederation
Eurocolour	European Association of Pigments Manufacturers
ICC	Indian Chemical Council
JDICA	Japan Dyestuff and Industrial Chemical Association
SDC	British Society of Dyers and Colourists
SOCMA	Society of Chemical Manufacturers and Affiliates
TDPIA	Taiwan Dyestuffs and Pigment Industrial Association
TEGEWA	German Association of producers of textile, paper, leather and fur auxiliaries and colourants, and other auxiliaries

Standard issuers

AFIRM	Apparel and Footwear International RSL Management
ISO	International Organization for Standardization
CEN	European Committee for Standardization
SNV	Swiss Association for Standardization
GOTS	Global Organic Textile Standard
ZDHC	Zero Discharge of Hazardous Chemicals Group
SAC	Sustainable Apparel Coalition
Bluesign	
EU Ecolabel	
C&A	
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* These lists give membership as in April 2022

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