Supplemental Information to article by Pirow et al. "Contact allergies from clothing textiles – is there a cause for growing concern?"

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Table S1: Chronology of efforts within the EU to restrict or regulate the use of skin-sensitising substances in clothing textiles.

Time	What happened?
early 1990s	A **panel of experts** in the predecessor institutions of today´s German Federal Institute for Risk Assessment (BfR) dealt intensively with concerns related to chemicals in clothing textiles which could pose a health risk to consumers (BfR 2012; Platzek et al. 2001; Platzek et al. 2002). **Eight allergenic disperse dyes** (Table S2) **should be banned or labelled**, at least in textile clothing in close contact with the body (Platzek et al. 2002).
1997	**The German Government sent a communication to the EC to propose union-wide measures** for the eight allergenic dyes (Platzek et al. 2002).
1999	A **study commissioned by the EC** concluded that garments with insufficient colour fastness containing the dyes in question pose a risk for skin sensitisation to some members of the population (WS Atkins International Ltd 1999). The study report concluded that **a restriction should be considered**. However, the health risks associated with proposed alternative dyes were unclear and the use of the dyes in question already declined. It was therefore suggested that it an **ecolabel-based approach might be more effective** to generate an incentive for the non-use of the dyes in question.
2000	In its opinion on the EC study report, the **CSTEE (2000)** concluded that the **limited data on the dyes in question** do not allow for a valid risk assessment. However, the committee noted that the **very limited available epidemiological evidence suggested that the risks for skin sensitisation are indeed low**. Overall, the CSTEE concluded that the proven sensitising potential of the dyes in question and the incidence of sensitization to them among the general population raised the concern **that such a risk may exist**.
since 1999	Establishment and revision of the criteria for awarding an **EU Ecolabel for textiles** (EC 1999; EC 2002; EC 2009; EC 2014), **including a ban on the use of certain potentially sensitising disperse dyes** (Table S3). The number of banned disperse dyes increased from initially eight dyes in 1999 to 21 substances in 2014. Since then (or even earlier), corresponding requirements regarding chemicals have also been established in the textile standards of many other **labels and quality seals** (KEMI 2013).
2011	Industry published the **Roadmap towards Zero Discharge of Hazardous Chemicals** ("ZDHC initiative"), which introduced an **MRSL** that also includes a ban on skin-sensitising disperse dyes (Table S4).
since mid-2000s	Because of these voluntary initiatives and the industry's self-commitment, **problematic disperse dyes and other sensitising chemicals have been found less frequently in clothing** (ANSES 2018; BVL 2008; BVL 2010; BVL 2019; Carlsson et al. 2022; Danish EPA 2014; KEMI 2014; Malinauskiene et al. 2012).
2012	In the context of the European Textile Labelling Regulation (EU) No. 1007/2011, the **EC commissioned a study** to investigate whether there is a causal link between allergic reactions and chemical substances used in textile products. The study report (RPS 2013) concluded that—because of **data gaps and uncertainties**—it is very difficult to draw a conclusion on whether there is a link between these substances remaining on finished textiles and ACD. A **prioritization of substances** used in textiles **according to their hazard classification and intentional use** (i.e. as dye or auxiliary) was proposed, as well as a **combination of non-regulatory voluntary action** (e.g. codes of conduct, standards) and **regulatory measures** under the relevant existing legal framework. Based on this study report, the EC (2013) expressed the expectation that future developments would focus on promoting research on alternative, non-allergenic substances, on exposure and risk assessment, on uncertainties regarding substances that can be released from finished textiles, and on limit values to protect against allergies. In addition, the substances identified in the study could be included in **ongoing activities (screening, prioritisation, risk management option analysis)** between ECHA and the Member States.
2013	**KEMI (2013)** published results of a government assignment **to develop a unified and coherent EU legislation on hazardous chemicals in textile clothing**, since voluntary efforts were not harmonised at EU level and there were several different pieces of EU legislation for textile products. The agency's overall recommendation was to regulate hazardous chemicals in textiles in the Textile Labelling Regulation. **ACD from exposure to skin sensitising substances in textile articles** was identified as one area for which **regulatory action was considered necessary**.
2016	**KEMI (2016) published an RMOA for skin sensitizers in textiles** and considered a **restriction under REACH**—involving a **complete ban on placing textile articles containing skin-sensitising substances** on the EU market—to be the best option The agency pointed out that more information on the prevalence and costs of textile-related ACD was needed to reach a final conclusion on **whether the health benefits of such a restriction outweigh the societal costs.**
2019	**KEMI & ANSES** submitted an **Annex XV dossier proposing a generic ban** on all substances with a harmonised classification as skin sensitizers and a further 24 disperse dyes **in textile and also leather, fur and hide articles** (ECHA 2019).

ANSES, French Agency for Food, Environmental and Occupational Health and Safety; BfR, German Federal Institute for Risk Assessment; CSTEE, European Scientific Committee on Toxicity, Ecotoxicity and the Environment; EC, European Commission; ECHA, European Chemicals Agency; MRSL, Manufacturing Restricted Substance List; RMOA, risk management option analysis.

Table S2: Disperse dyes with sensitising potential that should no longer be used in clothing textiles from the point of view of the former German Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV), the predecessor institution of the German Federal Institute for Risk Assessment (BfR) (Platzek et al. 2002).

Dye name	Colour Index Number	CAS number
C.I. Disperse Blue 1	64500	2475-45-8
C.I. Disperse Blue 35	–	12222-75-2
C.I. Disperse Blue 106	–	12223-01-7
C.I. Disperse Blue 124	–	61951-51-7
C.I. Disperse Orange 3	11005	730-40-5
C.I. Disperse Orange 37	–	12223-33-5
C.I. Disperse Yellow 3	11855	2832-40-8

Table S3: Potentially sensitising disperse dyes that, according to the award criteria for the EU Ecolabel for textile products established by the EU Commission's decisions (EC 1999; EC 2009; EC 2014), shall not be used for dyeing textiles.

Dye name	Decision 1999/178/EC	Decision 2002/371/EC	Decision 2009/567/EC	Decision 2014/350/EU
C.I. Disperse Blue 1				✓
C.I. Disperse Blue 3	✓	✓	✓	✓
C.I. Disperse Blue 7		✓	✓	✓
C.I. Disperse Blue 26		✓	✓	✓
C.I. Disperse Blue 35	✓	✓	✓	✓
C.I. Disperse Blue 102		✓	✓	✓
C.I. Disperse Blue 106	✓	✓	✓	✓
C.I. Disperse Blue 124	✓	✓	✓	✓
C.I. Disperse Brown 1			✓	✓
C.I. Disperse Orange 1		✓	✓	✓
C.I. Disperse Orange 3	✓	✓	✓	✓
C.I. Disperse Orange 37/76	✓			
C.I. Disperse Orange 37		✓	✓	✓
C.I. Disperse Orange 76		✓	✓	✓
C.I. Disperse Red 1	✓	✓	✓	✓
C.I. Disperse Red 11		✓	✓	✓
C.I. Disperse Red 17		✓	✓	✓
C.I. Disperse Yellow 1		✓	✓	✓
C.I. Disperse Yellow 3		✓		✓
C.I. Disperse Yellow 9		✓	✓	✓
C.I. Disperse Yellow 39		✓	✓	✓
C.I. Disperse Yellow 49		✓	✓	✓

Table S4: Disperse dyes suspected of causing allergic reactions, which — in accordance with the Manufacturing Restricted Substance List (MRSL) of the industry initiative "Roadmap towards Zero Discharge of Hazardous Chemicals" (ZDHC 2014) — shall no longer be used for dyeing textiles.

Dye name	CAS number
C.I. Disperse Blue 7	3179-90-6
C.I. Disperse Blue 26	3860-63-7
C.I. Disperse Blue 35	12222-75-2 56524-77-7
C.I. Disperse Blue 102	12222-97-8
C.I. Disperse Blue 106	12223-01-7
C.I. Disperse Blue 124	61951-51-7
C.I. Disperse Brown 1	23355-64-8
C.I. Disperse Orange 1	2581-69-3
C.I. Disperse Orange 3	730-40-5
C.I. Disperse Orange 37/59/76	13301-61-6
C.I. Disperse Red 1	2872-52-8
C.I. Disperse Red 11	2872-48-2
C.I. Disperse Red 17	3179-89-3
C.I. Disperse Yellow 1	119-15-3
C.I. Disperse Yellow 3	2832-40-8

Table S5: Allergens of the DKG leather and textile dye series (TDS) which were patch-tested in the study of Heratizadeh et al. (2017). Allergens indicated as *p*-amino compounds contain moieties in their chemical structure which are related to PPD or toluene-2,5-diamine.

Allergen	Colour Index	CAS number	Test concentration (%)	*p*-amino compound
p-Aminoazobenzene (PAAB)	CI 11000	60-09-3	1	yes
p-Phenylenediamine (PPD)	CI 76060	106-50-3	1	yes
Disperse Blue 3	CI 61505	2475-46-9	1	no
Disperse Blue 106		12223-01-7	0.3	yes
Disperse Blue 124		61951-51-7	0.3	yes
Disperse Orange 3	CI 11005	730-40-5	1	yes
Disperse Red 1	CI 11110	2872-52-8	1	yes
Disperse Red 11	CI 62015	2872-48-2	1	no
Disperse Red 17	CI 11210	3179-89-3	1	yes
Disperse Yellow 3	CI 11855	2832-40-8	1	yes
Disperse Yellow 9	CI 10375	6373-73-5	1	no
Acid Yellow 36	CI 13065	587-98-4	1	no
Bismarck Brown R	CI 21010	5421-66-9	0.5	no
Naphthol AS	CI 37505	92-77-3	1	no

Table S6: Composition of the textile dye mix (TDM) 6.6% (Isaksson et al. 2023).

Allergen	Colour Index	CAS number	Test concentration (%)	'*p*-amino' compound
Disperse Blue 35		12222-75-2	1	no
Disperse Blue 106		12223-01-7	0.3	yes
Disperse Blue 124		61951-51-7	0.3	yes
Disperse Orange 1	CI 11080	2581-69-3	1	no
Disperse Orange 3	CI 11005	730-40-5	1	yes
Disperse Red 1	CI 11110	2872-52-8	1	yes
Disperse Red 17	CI 11210	3179-89-3	1	yes
Disperse Yellow 3	CI 11855	2832-40-8	1	yes

Table S7: Proportion of positive reactions to the textile dye mix (TDM) 6.6% and *p*-phenylenediamine (PPD), observed in consecutive dermatitis patients across various studies. Also shown is the proportion of patients who were TDM-positive but PPD-negative. Italicised letter codes indicate countries where either TDM, PPD, or both were not tested. NR, not reported.

Study	Study period	Country	Number of patients tested	TDM-positive (%)	PPD-positive (%)	TDM-positive, but PPD-negative (%)
Ryberg et al. (2011)	2006 – 2008	SE, BE	2546	2.55	2.40	1.65
Ryberg et al. (2014)	2011	SE, DK, BE, FR, DE, CH, ES, PT, IT, US	2907	3.72	2.58	1.75
Ryberg et al. (2015)	2011	SE	2122	2.45	2.50	NR
Malinauskiene et al. (2017)	2010 – 2012	SE, LT	642	2.96	NR	NR
Isaksson et al. (2015)	2013	SE, DK, BE, DE, CA, US, IN, SG, UY	2493	3.61	3.61	1.40
Stenton et al. (2020)	2015 – 2017	SE	2250	2.40	2.62	1.07
Isaksson et al. (2023)	2020 – 2021	SE, LT	1481	3.58	2.84	1.96
Isaksson et al. (2025)	2020	SE, DK, NL, PT, HR, CA, IN, TH, SG, JP, UY	2951	4.30	3.29	2.13
Uter et al. (2021a)	2015 – 2018	*AT*, *CH*, *DE*, DK, ES, FI, IT, LT, NL, PL, PT, SI, UK	11996 – 37377	2.77	3.44	1.27
Uter et al. (2022)	2019 – 2020	*AT*, BE, *CH*, *DE*, ES, FI, *HU*, IT, LT, NL, PT, SI, UK	5403 – 11173	3.58	3.60	1.76
Uter et al. (2026)	2021 – 2022	*AT*, BE, *CH*, *DE*, ES, GR, *HU*, IT, LT, NL, *PL*, PT, SI, *UK*	6899 – 13563	3.79	3.85	2.35
Ipenburg (pers. com.) *	2015 – 2025	NL	8892	3.31	4.13	1.84
Stingeni et al. (2021)	2018 – 2019	IT	11697	1.50		1.21
Hernández-Fernández et al. (2021)	2019 – 2020	ES	1828	3.23	NR	NR
Hernández-Fernández et al. (2024)	2019 – 2022	ES	6099 – 6128	3.26	3.43	1.41
Kursawe Larsen et al. (2024)	2015 – 2023	DK	5495	2.33	NR	0.98
Zorko et al. (2026)	2020 – 2024	SI	380	4.74	4.21	0.79

* Data from consecutive dermatitis patients at Amsterdam University Medical Centers were provided by Norbert Ipenburg (personal communication, 14 October 2025)—one the co-authors of the study by Nijman et al. (2023)

Table S8: Description of the cases observed in the IVDK-ETAD research project (Wolfgang Uter, personal communication, October 2023).

Case No.	Description of the cases
1	Equivocal (not clearly positive) patch test reaction to a polyester/cotton clinic dress worn at work; a further analysis was not warranted.
2	Eczema of the fingers, for which the patch test with the leather and the wool lining of the suspected gloves were negative, so that a further analysis was not warranted.
3	Equivocal reaction to a pair of trousers that was already negative after three days, suggesting a mechanism other than contact allergy (e.g. irritant skin reaction).
4	Weak positive reaction to a textile strap of a cycling shoe that was inexplicably not followed up.

Table S9: Description of the cases observed in the ANSES biomedical study. 23 patients with contact dermatitis suspected of being related to 30 textile articles were investigated. In a few patients, more than one article per patient was implicated. Each patient-article relationship was considered a "case" in the study report (ANSES 2018; ANSES 2021). Following a methodology for investigating the causality between the dermatitis and exposure from textile clothing, the cases were grouped according to four situations.

Situation	**Number of patients and cases, and description of the cases**
The substance suspected by the physician (following a positive patch test) was detected and quantified in the article.	*2 cases, 2 patients* In the first case, nickel was detected in a concentration of 2.35 mg/kg in a synthetic fabric; patch tests with different parts of the article were negative. It was concluded that the patient's symptoms could be related to the presence of nickel detected in the article. In the second case involving a waistcoat made of coloured rabbit and groundhog hair, the patient's symptoms could be linked to the presence of DR17 (339 mg/kg) and DB106 (83 mg/kg); a patch test with the article was positive.
The initially suspected substance was not detected in the article, but the testing laboratory identified another substance.	*2 cases, 2 patients* In the first case, a knitted glove contained Disperse Orange 37/76 (9.53 mg/kg) that was positive in the subsequent supplementary patch test; patch testing with the article was negative. Study experts concluded that the patient's symptoms appeared to be linked to the glove material and the presence of Disperse Orange 37/76. In the second case, the clothing contained 3,3'-dimethoxybenzidine (72.87 mg/kg), benzidine (32.2 mg/kg), and cadmium (0.12 mg/kg); patch testing with the article was negative. Supplementary patch tests were not conducted with these substances. The study experts concluded that it was not possible to link the patient's symptoms to the detected substances.
The initially suspected substances were not detected in the article, and other substances were not detected.	*9 cases, 7 patients* A patch test with the article was performed in 8 cases and was negative in all except 2 cases. In 8 of the 9 cases, the patients' symptoms were judged to be unrelated to the article or to be caused by several exposure sources, external contamination, or a mechanism other than contact allergy (e.g. irritant skin reaction).
Other cases	*16 cases, 13 patients* In 6 cases involving 6 six patients, the symptoms were judged as unrelated to the article, but rather as result of external contamination of the article (e.g. by isothiazolinone-containing cosmetics and paints), or to be caused by a mechanism other than contact allergy (e.g. irritant skin reaction). In 10 cases involving 7 patients, it was not possible to conclude on the existence of a link between the patient's symptoms and the exposure from wearing the textile clothing, even though the patch test with the article was positive in all except 1 of 8 cases. This was because the substances originally suspected was not detected in the articles, and the substances found within the articles either yielded negative results in supplementary patch tests or were not tested on the patient.

Discussion of significantly deviating predictions in the verification of the CE-DUR approach

Patch test results for baseline series allergens in consecutive IVDK patients between 2007 and 2014 (Heratizadeh et al. 2017) were utilized to extrapolate sensitisation frequencies of a clinical population to the level of the general population. Table 1 shows the reaction frequencies to selected baseline allergens (metals, fragrances, preservatives, resins/glues, rubber additives, excipients) and the corresponding CE-DUR estimates for the 30-year prevalence (as approximations of lifetime prevalence) of contact sensitisation for the general population in Germany. These estimates were compared with point prevalences for the German subsample of the population-based cross-sectional study from the period 2008–2011 (Diepgen et al. 2016).

In nine of the 15 baseline allergens (Table 1), the 30-year prevalence estimate (medium-case scenario) fell within a two-fold range (0.5–2.0) of the mean point prevalence, in another five allergens within a three-fold range. Among the latter were fragrances (fragrance mix I, balsam of Peru) and preservatives (paraben mix) that are used in cosmetics and for which the 30-year prevalence exceeded the point prevalence by a factor of 2.1–3.0. For nickel and epoxy resin, the 30-year prevalence was 2.6–2.7-fold lower than the point prevalence. For *p-tert*-butylphenol formaldehyde resin (PTBP-FR), the 30-year prevalence of 0.2% (medium-case scenario) was eightfold lower than the mean of the point prevalence (1.6%).

Some of these larger deviations can be explained by the age dependence of sensitisation to specific allergens and the age distribution of the consecutive IVDK patients (72.4% were older than 40 years) (Heratizadeh et al. 2017). Nickel, which is present in many consumer products (Thierse and Luch 2019), exhibits a peak prevalence of sensitisation in the early 20s, with a progressive decline at older ages, as shown in a single-centre cohort of 45,110 patients at St John´s Institute of Dermatology (Guy´s and St Thomas NHS Foundation Trust, London) (Lynch et al. 2017). This could be explained by both age-related changes in immune function and exposure patterns (Lynch et al. 2017). In addition, people who are sensitised to nickel and suffer from dermatitis caused by jewellery often have recognised their allergen themselves and do not seek medical advice with subsequent patch testing to the same extent—if at all—as people with other sensitisations (Schnuch et al. 2002; Uter et al. 2021b). For the two fragrance allergens and the paraben mix, the prevalence of sensitisation increases with age (Lynch et al. 2017), and people of older age with skin problems are more likely to visit a dermatology clinic and undergo patch testing. This could explain why the 30-year prevalence is significantly higher (fragrance allergens, paraben mix) or lower (nickel) than the point prevalence.

Of the two resin allergens, PTBP-FR is used in adhesives for shoes and in leather goods (Aalto-Korte and Suuronen 2021). It had a wide range of applications, at least in the past, in glues for a large variety of products including artificial fingernails, adhesive tapes and labels, athletic tapes and medical devices (Aalto-Korte and Suuronen 2021; Goossens and Morren 2021). The very low 30-year prevalence, being eightfold lower than the point prevalence, might be explained by reduced exposure in the period 2007–2014 as compared to earlier, and a lower likelihood of seeking medical advice when smaller skin problems occur, e.g. through the use of (craft) glue, adhesive tapes or labels.

Overall, the 30-year prevalence estimates corresponded quite well with the point prevalences determined in a population-based cross-sectional study. Larger deviations could be linked to the age dependence of sensitisation to specific allergens, the age distribution of the patients visiting a dermatology clinic, decreasing time trends in allergen exposure and the healthcare-seeking behaviour depending on the severity and extent of the skin problems.

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