

PRINTOUT
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HIGH COURT JUDGEMENT
handed down Tuesday, 28 April 2009

Case S36/2006

(2nd division)

Trade Association for the Soap, Perfume and Technical/Chemical Articles, as proxy for
Unilever Danmark AIS and

Procter & Gamble Danmark ApS

(Attorney Søren Stenderup Jensen)

vs.

The Environmental Protection Agency

(Junior Counsel to the Treasury, attorney Peter Bjerling)

A previous judgement has been made by the High Court of Eastern Denmark's 2nd division
on 10 November 2006.

Five judges have participated in the judgement: Poul Sørensen, Per Sørensen, Asbjørn
Jensen, Poul Søgård and Poul Dahl Jensen.

Claims

The appellant, the Trade Association for the Soap, Perfume and Technical/Chemical
Articles, as proxy for Unilever Danmark AIS and Procter & Gamble Danmark ApS has
repeated its claim.

The summonsed, the Environmental Protection Agency, has had its claim upheld in
principal and has repeated its claim.

Allegations

With particular regard to article 6, item 3, part 1, in the European Parliament and
Commission's directive 1999/45/EC of 31 May 1999 on mutual harmonisation of the laws
and administrative provisions of member states on classification, packaging and labelling
of dangerous preparations (preparations directive), the Trade Association states that the
District Court has made an incorrect interpretation as grounds for its judgement. The
provision should be understood such that it gives authority for both the upward
classification and downward classification of a preparation. Downward classification can
also occur on the basis of scientifically-based specific studies of individual cases (case
studies) and on statistically-justified experience.

The Environmental Protection Agency has in contradiction stipulated that it does not disagree with the Trade Association that article 6, item 3, part 1 of the preparation directive could theoretically lead to upward classification and downward classification of a preparation. However, downward classification could only occur if there was documentation for the same, in the form of epidemiological studies. The Association has not however referred to such studies. The Association has solely referred to scientifically-based specific studies of individual cases and statistically-supported experience in the form of data from toxic information departments, which in the opinion of the Environmental Protection Agency cannot form the basis for downward classification of the preparations. Neither is the material in question in the opinion of the Agency sufficient to prove that the toxicological effect on humans of the preparations shall be used as the basis for an exemption of the calculation rule in article 6, item 1, (a) of the preparation directive.

Supplementary case presentation

In an overview article entitled the "Human Experience File" published by the Association Internationale de la Savonnerie, de la Detergence et des Produits d'Entretien (AISE) in May 2000 on eye and skin accidents in household in the European countries, it was stated (English translation from Danish translation of the French):

GENERAL CONCLUSION

Data concerning exposure accidents available from toxicity centres, medical centres or manufacturers, are a means of evaluating a product's safety on the market. They give valuable information on the effects on health after an exposure accident. Even though most of the data concerns ingestion of products, there is also data on skin and eye contact.

On the background of a study performed in 1978 in 900 homes, it was estimated that there are 17 million eye accidents with consumer products per annum in the 19 million British homes! (Goulding et al 1978). Eye accidents with household products are therefore very frequent but can apparently be considered as a general inconvenience to our modern lifestyle without any long-lasting consequences to health and are therefore not reported. Compared with the total number of accidents in the home, the number of

accidents in which the eyes are exposed to detergents/cleaning agents is very low. The number of accidents has not risen in recent years.

Based on a review of data related to such accidents, performed by several toxicology centres in Europe and complaints from consumers received by product manufacturers, it can be concluded that such eye accidents lead to no or mild symptoms.

In those cases where the consumers have felt that the accident was so serious that they had to seek medical help, the treatment has been limited to rinsing the eye, and the doctor has not recommended further treatment.

In some cases, consumers have been referred to a GP or outpatient clinic for follow-up, but hospital admittance is very rare, as the symptoms are rarely deemed to be more than moderate.

In all cases, complete healing has been reported or is expected. In those studies where comparisons have been made with products that are classified as local irritants or corrosive, it has been shown that a larger percentage of the cases with eye accidents are referred to doctors or hospitals for the latter, than for non-classified household products."

In a report dated 14 March 2004 on "Accidents with textile detergents - an account based on data from the Accident Registry," written by Consultant Peter Jacobsen, Giftinformation (toxicology information office) Bispebjerg Hospital, it is stated that:

"... the analyses are a detailed review of data from the Accidents Register on Casualty Department patients treated at 5 Danish Casualty Departments between 1998 - 2001 due to accidents with textile detergents. The register was chosen as a source of information because no minor injuries with detergents can be presumed to have primarily been handled at Casualty Departments. Furthermore, the register is of very high quality.

The work was performed as part of an ongoing collaboration with companies, authorities and stakeholder organisations represented on the toxicology information office's contact panel. The Trade Association has paid for the excerpt from the register, whilst the analyses were performed as part of the toxicology information office's normal work.

Data documentation

The Accidents Register contains data on patients treated at the Casualty Departments of Esbjerg, Randers, Frederikssund, Glostrup and Herlev for injuries sustained from accidents. Registration is performed according to Nordisk Ulykkesklassifikation (Nordic accident classification) by specially-trained medical secretaries. The population covered by the register is the catchment area of the 5 Casualty Departments, which in 2001 covered 786,000 persons, equivalent to 14.7% of the population of Denmark.

The data consists of an excerpt from the register covering all persons registered with textile detergent as the cause of an accident to the eyes between 1998 – 2001. Apart from the exposure data, data was also collected on the circumstances of exposure, age and sex of the patients, type and location of the injury and the need for medical treatment after attendance at Casualty. A variable with description of the event together with consistency between the aforementioned data was used to validate the data.

The pathology of the injuries was not described in sufficient detail in the register to be able to determine the seriousness. Instead, conclusion with admission, outpatient check-ups or discharge are used as indicators of outcome. This parameter was then related to personal characteristics such as age and sex, and to data on product type, exposure route, exposure at work etc.

Results

35 cases of injuries due to textile detergents were found. Upon validation one case was excluded, such that only 34 were included in the analyses, equivalent to a rate of 1.08 injuries per 100,000 persons per year. Five accidents occurred with stain-removal agents, and 29 with actual textile detergents, roughly as many with liquid detergents and washing powders, table 1.

Table 1. Accidents with textile detergents registered in the Accidents Register between 1998-2001. Breakdown by type of detergent.

Type of detergent	Total (%)
Liquid	13 (38%)
Powder	15 (44%)
Unknown whether liquid or powder	1 (3%)
Stain removal agent	5 (15%)
Total	34 (100%)

Table 2 indicates that just under half of the patients were children, of which 4 were over 2 years old. Eye exposure was the exposure route in 25 (75%) cases. 8 children had also tasted the detergent and one adult had gone to Casualty from work, after getting liquid detergent powder on the skin.

No injury could be ascertained in 7 of the patients when examined, a further 3 were sent home without treatment. In 3 cases, a check-up by their GP or at the hospital was recommended, whilst 31 of the patients could be discharged from Casualty. None were admitted.

Table 2. Characteristics of accidents with textile detergents registered in the Accidents Register 1998-2001. Broken down by detergents and stain-removal agents.

	Detergents N = 29	Stain removal agents N = 5	Total N= 34
Age < 15	14	2	16
Exposure of	21	4	25
At work or	15	3	18
Injury	24	3	27
Check-ups	3		3

Eye injuries are defined independently in table 3. The group contained relatively fewer children than the overall material and more work-related injuries

(including working at home) and a slightly higher proportion with diagnosed injuries. All 3 patients to whom check-ups were recommended belonged to the group with eye injuries.

Table 3. Characteristics of eye injuries related to accidents with textile detergents, Accident Register data 1998-2001.

	Eye exposure N = 25
Age < 15 years	8
At work or at home	17
Injury diagnosed	22
Check-ups	3

The most notable result of the study is the few injuries with textile detergents - a total of 34. In the same 4 year period from 1998 to 2001 the Accidents Register recorded 843 injuries with cleaning and washing detergents, 2,728 with chemical affects, including from cleaning and washing detergents and a total of almost 390,000 accidents. The 34 cases therefore represent just 4% of the accidents with cleaning and washing detergents, and just over 1% of accidents due to chemical exposure.

The catchment areas for the Casualty Departments contributing to the Accidents Register account for approx. 15% of the population of Denmark. The 34 cases registered over 4 years therefore correspond to an estimated occurrence of accidents treated at Casualty Departments involving textile detergents throughout the country of 57 (95% illegible 40-81) cases per year, or between 0.8 and 1.5 injuries per 100,000 persons per year.

Eye injuries account for nearly 75% of the injuries which is probably due to the eye mucous membrane is the only surface which is sufficiently delicate that brief contact with washing powder can cause a significant reaction. The injuries included accidents during children's' play including some cases of ingestion, accidents at work and during work at home. In approx. 30% of cases there was no need for treatment at Casualty and over 90% could be sent home without subsequent medical checkups. The three cases in which checkups of eye injuries were recommended did not differ from the other cases: Accidents at home or work and a 2-year old child who had an accident with washing powder at home.

The basis for the analysis was several hundred thousand Casualty cases, and the statistic material is therefore solid. Incorrect registration of accidents with textile detergents as injuries from other products cannot be excluded. It does not however seem to occur to any great extent, as there were no grounds for accidents with textile detergents to be registered as accidents with cleaning agents upon validation of the overall excerpt of accidents with cleaning and washing detergents. The perceived high data quality is supported by the fact that only just over 3% of the total number of cases were excluded, because other accidents were registered as caused by cleaning and washing detergents.

The study via Casualty registration can be deemed to be the relevant level if looking for injuries which are not trivial, even tough supplementary data from other sources than Casualty admissions undoubtedly would have led to a larger number of cases. These will however primarily have been injuries which were exclusively treated in the home or perhaps by a GP, and therefore lesser injuries than those at Casualty.

It is unlikely that injuries with washing detergents lead to admission of patients. A search through the National Patient Register for such cases will therefore for this reason alone be futile. In addition is poor registration of the cause of accidents in the

National Patient Register which makes it less suited to analyses of this type. Treatment of eye injuries can also occur in eye outpatient departments and ophthalmologist practices. Investigation of this will require an ad hoc study, but given the modest number of accidents and their benign character according to Casualty records, it is deemed to be irrelevant. A specialist in chemical eye injuries could perhaps supplement assessment of the problem.

Conclusions

- Injuries requiring treatment after exposure to textile detergents are primarily eye injuries
- Injuries are rare and represent only a small element of Casualty-treated accidents with cleaning and washing detergents.
- To the extent the seriousness of the injury can be judged from register data, modest and in all probability temporary effects are involved
- Whether there are any accidents at all of a more serious nature can perhaps be established by asking an ophthalmologist specialising in chemical eye injuries

In a declaration dated 9 September 2004 from the central toxicology information department in Stockholm, it was stated (English translation from a Danish translation from the original Swedish).

"Declaration concerning the medical consequences of skin and eye exposure to washing detergents intended for household use.

Giftinformationscentralen (GIC) (central toxicology information department) receives around 800 enquiries annually concerning acute poisoning with such products. In general, they do not cause any or at the most minor ailments. Skin exposure is as a rule harmless. Eye exposure can lead to irritation symptoms, which disappear after eye rinsing. No permanent damage is expected. GIC receives around 4000 epicrisis copies from Swedish hospitals per year, and) in this material, which ranges over several decades, there are no cases of illness where such exposure had caused serious injury. Neither can cases of illness be found in the toxicological literature or international databases of illness caused by cleaning detergents on the skin or in the eyes causing recognisable injury."

Stockholm 2004-09-09

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- Micromedex Inc. Poisindex, vol 121, expires 2004/9
- GIF's consultation registrations and epicrisis collections"

In a declaration dated 15 November 2004 by professor in ophthalmopathy, Sven Erik Nilsson, Linköping University, it was stated (English translation from Danish translation from Swedish original)

“A statement to the court concerning possible danger of eye injuries from the use of washing detergents in the household.

The task concerns two questions posed. My statement is relatively long, but there is a summary at the end of each of the two sections.

1. What is my general impression of the danger of washing detergents causing injury to the eyes?

In my over 30 years as an ophthalmologist from trainee to professor/consultant, I have never personally once met a patient who had consulted the doctor because of ailments of the eyes due to washing detergents, neither due to splashes of liquid detergent nor granulated, e.g. via the fingers, or from rubbing the eyes. An enquiry to my colleagues at the University hospital's eye clinic in Linköping yielded only one who could ever remember having received such a patient. The ailment passed quickly (less than one day) and there were no permanent changes. The clinical experience of me and my colleagues is therefore that detergents used in the house do not represent any kind of serious risk of serious and permanent eye injury.

Everyone knows from their own experience that soap solutions which get in to the eyes when taking a shower can sting, which nevertheless passes quickly. Soap solutions do however cause increased production of tear fluid, which dilutes the solution. The surface of the eye reacts by expanding the outer membrane's blood vessels (red-eye) and stings and feels irritated. Even this is non-dangerous and heals without treatment, usually in less than a day. The reaction to splashed detergent in the eye or small amounts of granulate which could perhaps end up there is in principal identical but often more pronounced. What is involved then is very superficial chances of non-dangerous character which is temporary, and once again usually within one day. Deep injuries or internal inflammation do not occur. If the patient does consult a doctor at all, treatment usually consists of rinsing the eye and applying eye salve during consultation.

As an ophthalmologist with extensive experience of different eye injuries from industry or the home, you tend to be almost surprised when you become aware of an opinion from the Swedish Chemical Inspectorate that the handling of detergents in the home is perceived to be a danger of serious eye injuries, and that its packaging should be marked accordingly. This will involve gross exaggeration of the actual risk and severely reduce the respect for such marking when it really matters, e.g. on highly corrosive substances, such as sodium hydroxide in drain cleaner.

A statement from the consultant at GIF, Mark Personne, confirms to a great degree my own experience. GIF has received around 4000 epicrisis copies from Swedish hospitals per year for decades. This material does not contain a single case where exposure to detergents for household use has caused serious injuries to the skin or eyes. Why should the products then be marked as representing a serious danger of injury? The logic is difficult to see

Peter Jakobsson at the toxicology information centre occupational and environmental clinic, Bispebjerg Hospital in Denmark has concluded that eye injuries caused by cleaning and washing detergents are rare, and in all probability temporary, based on widely-based register of accidents. His expert advice is to consult an ophthalmologist on whether serious eye injuries are caused by such products at all.

According to a statement, the highly regarded and very experienced eye pathologist J.U. Prause, eye pathological institute at the University of Copenhagen and Copenhagen University Hospital's eye clinic could not remember a single case of permanent eye injury from detergents.

In summary, it is my belief that based on my many years' experience and that of my colleagues regarding the effects of different chemical substances on the eye, there is no need whatsoever to classify or specially mark detergents for household use as representing a risk of serious or permanent eye injuries. It is my firm belief that this would seriously reduce respect for the classification and marking of the substances and liquids, where this is needed. Examples of such products are strong alkalines (lye), such as the aforementioned drain cleaner containing sodium hydroxide, which is highly corrosive and can cause serious eye injuries. A layman seeing a warning against serious eye injuries on a common detergent pack can hardly be expected to be impressed by it, and can therefore lose respect for similar warnings on packages containing e.g. sodium hydroxide. It does not seem likely that the Chemical Inspection Authority has consulted ophthalmological expertise in adopting its position.

2. Is the methodology LVET (Low Volume Eye Test) on rabbits, which the chemical vendors use to predict the irritation potential (potential risk) of these products to the human eye, based on well-researched and documented scientific basis?

Background to my assessment:

According to EU Directives, tests to ascertain the risk of acute eye toxicity/irritation have to be performed according to a method based on the Draize test, which apparently involves applying 0.1 ml of the test substance on the lower eyelid of one eye of 9 rabbits, and leaving the other eye untreated as control. The eye is rinsed with 20 ml lukewarm water on three rabbits after 2 seconds and after 4 seconds on three other rabbits. No rinsing is performed at all on the other three rabbits. Follow-up is performed after 24, 48 and 72 hours and after 4 and 7 days. Apparently, the test has been exposed to criticism from researchers as misleading, as substances such as detergents cause significantly greater effects on the rabbit eye than on the human eye due to the rabbit blinking extremely rarely, and because their tear mechanism is less effective. Consequently, the potential risk to the human eye can be exaggerated. Furthermore, the dose of 0.1 ml (100 micro litres) is deemed to be unrealistically large. The same dose is used in the FHSA test (Federal Hazardous Substance Act), a modified Draize test.

On this background, a Low Volume Eye Test (LVET) was developed, in which only 0.01 ml (10 micro litre) solution is used (in some instance, solid detergent is used at a weight corresponding to 0.01 ml) and applied to the cornea instead of the inner eyelid - a

more realistic comparison to a splash in the eye from housework. Otherwise, the test is identical with the previously used test. The question now is whether LVET used on rabbits can be said to represent a relevant test for assessing the risk of detergent products to the human eye from a scientific point of view.

The following references apply to articles published in scientific journals:

Freeberg et al. (J Toxicol Ocul. Toxicol., 1986) compared the time to symptom freedom for telephone-reported eye accidents in humans with corresponding times for LVET and FSHA tests respectively on rabbits. (FSHA test and Draize test use the same volume, (0.1 ml)_) The telephone reports were received via freephone number at the University of Cincinnati Drug and Poison Information Centre over an 18 month period in the 1980s). 9 dry or liquid washing, cleaning and washing up detergents were tested. How relevant these products are in relation to those currently on the market, I have no means of assessing. The time to symptom freedom for the human subjects was on average 0.5 days, for LVET on rabbits, 6.8 days and for FSHA test on rabbits, 20.7 days. The conclusion was that LVET was closer to the effects on humans than the FSHA test, and the latter apparently exaggerated the effects on the human eye. A certain weakness is that the study cannot guarantee that the telephone-reported accidents are representative of the entire group with accidents.

Freeberg et al. (Food and Chemical Toxicology 1986) have carried out another study in which the effects of detergents on the human eye were compared with the effects on the rabbit eye in LVET and Draize tests respectively, however without subsequent rinsing in both cases. The concentrations were selected so that the effects would be moderate and temporary within 24-48 hours. Three different detergents were tested to a value of 8 (in one case, only 2) [i] the human eye and 8 [i] the rabbit eye. Time to symptom freedom, subjectively and objectively (examination by ophthalmologist) was on average for LVET 3.8 hours for humans and 22.8 hours for rabbits. For the Draize test, the corresponding times were 15.2 and 54.3 hours respectively. These results indicate that agreement between the effects on the human eye are better for LYET on rabbits than for the Draize test on rabbits. Once the results for detergents, soaps, shampoo and softeners are combined, correlation coefficients were calculated. The best at 0.72 was found for LVET on rabbits and the Draize test on humans, and the next-best, 0.66, for LVET on both humans and rabbits. No positive correlation was found for the Draize test on rabbits to either LVET or the Draize test on humans. This study seems to be adequately conducted and supports the claim that LVET in this context can be better than the Draize test. However, non-diluted solvents were not studied, and the test products' relevance in relation to current products cannot be assessed.

Roggebrand et al. (Food and Chemical Toxicology 2000) recently published a study on eye irritation in rabbits and humans. Similar-sized volumes of *diluted*, liquid detergents of the same type which have been on the market for some time were used, by applying a single application (under the upper eyelid on humans and some rabbits, and on the cornea for the other rabbits). The detergent contained 15% soap, 27% "non-ionic surfactant" and 12% "anionic surfactant". The volume selected was 3 micro litres (0.003 ml), which is less than the 10 micro litres (0.01 ml), applied for LVET. It would probably have been more interesting for the current problem if LVET volumes were used, but the lower volume was selected to reduce discomfort for the volunteer study subjects. In my opinion

the study was performed adequately, and despite the lower test volume, I believe that its results are relevant to my problem. It was also revealed that the products tested include some still on the market.

Changes in the eye in humans were assessed by an en ophthalmologist, whilst the changes in the eye in rabbits were assessed by one of the study scientists. The change which is of most significance and interest is injury to the cornea surface (epitél defect with colouring). This also healed quickly as a rule. In humans, the cornea injury healed within 24 hours in 9 cases out of 10, and the 10th within 48 hours. In rabbits however, cornea damage was found in all cases after 24 hours, in two cases after 48 hours and in one after 72 hours. Control on the 7th day showed normalisation.

A similar study of washing up detergents (4% "non-ionic surfactant" and 38% "anionic surfactant") was included in the study, but the volume was reduced to 1 micro litre, i.e. one tenth of the LVET volume. Ten volunteers and 6 rabbits were exposed. The result for the volunteers was very close to that for washing detergents. The cornea was normal or nearly normal in all cases after 24 hours. The rabbit's cornea however showed continued outer cornea injury after 24 hours, but all had normalised after 48 hours.

The study therefore seems to show that even a volume of diluted test substance which is lower than LVET will cause more pronounced changes to the rabbit eye than the human. This represents strong support for the Draize test, which also has a 10 times higher concentration than LVET and in accordance with the supplier's claim, being a less adequate test to predict potential risk for the human eye than LVET.

It is important to point out that no serious or permanent eye injuries were caused by washing or washing-up detergents, either in this study or in any of the others referred to above.

Conclusion: The question posed above was "Is the methodology LVET (Low Volume Eye Test) on rabbits, which the chemical vendors use to predict the irritation potential (potential risk) of these products to the human eye, based on well-researched and documented scientific basis?" After reviewing the scientific literature provided to me, I believe that I can answer the question with a "Yes". The most convincing argument for this is made by Roggebrand et al., which shows that even a lower volume of test substance than that used for LYET causes more pronounced changes to the rabbit eye than the human. Furthermore, I will point out that no serious or permanent injuries occurred in any of the studies referred to. This agrees well with the clinical experience of me and my colleagues, and there are absolutely no grounds to mark common detergents with a black cross as a warning against their irritative properties."

In a declaration dated 20 December 2004 by professor of Dermatology Christopher David Anderson, University Hospital in Linköping, it is claimed that (English translation from Danish from Swedish original):

"Linköping 04 12 20

Statement on Human Patch Test (HPT) as a method for assessing any risk associated with the use of detergents for washing clothes in the home.

Background

Exposure to detergents is a daily occurrence; tens of thousands of tons of detergents are used every year in Sweden. A large part of the population is used to and has a lot of experience in using textile detergents. The opinion is prevalent that washing clothes is a boring, necessary hardly dangerous part of everyday life. This statement and a previous statement on the matter arise from allegations by the Chemical Inspectorate that detergent products are insufficiently marked on their packaging with regard to the risk of injury to the skin (and eyes). The inspectorate wants an adjustment to the conventional methods or data from certain animal tests for classification and marking detergent products, which will entail stricter product marking compared to that which has been applicable to detergents over many years. The manufacturers have noted through their trade association, the association of the European detergent industry (A.I.S.E.) that there is a discrepancy between a classification based on the conventional method and/or on use of data from animal testing in accordance with the directives, compared with the actual, observed effects on humans. They have proposed a test procedure called the Human Patch Test (HPT). This statement comment on this test procedure and certain aspects of relevance to the underlying need and conditions for the procedure.

"Human Patch Test"

Information on this protocol is contained in publications and in the material supplied for this case. I have also taken part in several meetings at the European Contact Dermatitis Research Group in the 1980s and 90s, where the development of the method was documented. Basically, the protocol is a technique which abandons animal testing and takes the step up to the [biological] species which is the end-use of the products to be classified. This is a major advantage, as transfer of results between species should always be treated with a high degree of caution. Human research naturally entails new problems and we cannot completely replace animal testing and in vitro tests, which have been developed over decades. Even so, it is my definite belief that the results generated from tests on humans are relevant, and can give much valuable information on the "toxicity to humans" in a way posed in the directives concerning the issue of classification.

HPT is performed using the body of knowledge generated by the previous test procedure, and the clinical epicutane test as base. Guidance can be obtained here on suitable reference substances and test concentrations. Even during the development phase, it was known that there was both over- and under-classification (compared with consumer test results). Furthermore, HPT is only performed when corrosive substances have already been deselected by another method.

As described above, it is general knowledge that the risk of relatively severe irritant reactions in the classic epicutane test quite high: In addition to working on the selection of the "right" concentration, the HPT protocol also introduced another way of reducing the risk of unnecessarily severe reactions - application times are limited to max. 4 hours (against 48 in the epicutane test), and rising application times have been introduced (15 minutes, 30 minutes, 1 hour, 2 hours, 3 hours and 4 hours).

Reading the reactions focuses on redness and soreness - no stronger reactions are needed to decide if the test has achieved "positivity" with regard to classification. In the event of a positive reaction, the subject does not need to be tested at higher concentrations. In the study plan, a smaller group of subjects can be inserted before the main group, which reduced the number of subjects which may show an unexpected severe reaction. The risk of a severe reaction in the subjects is minimal. Testing is performed in groups for which the result of a substance is compared against a reference substance with a known degree of irritation. Testing has been performed with individual substances in published materials, but the mix of substances has been documented in internal materials, which is a big advantage.

It would be desirable to continue to work with the model and its adaptation from both manufacturer and authorities. My belief is that the published works on HPT on a scientifically convincing basis prove that there is a discrepancy for a large number of substances between a classification based on the conventional method and/or use of data from animal testing according to the directives and a classification based on human testing. I see no ethical problem with the continued use and development of HPT.

Conclusion

Everything indicates that many years of working with detergent products by the manufacturers and authorities has led to a situation in which direct skin injuries caused by daily use of detergents are rare, and of little consequence. As such, I believe that the proposed stricter warnings on packaging which this case concerns will be of little practical use. Furthermore, there is a risk of negative educational effects due to the reduced impact of warning symbols. I believe it is proven that with regard to the relevant detergent there is a discrepancy between the result of the animal testing performed according to the directive, and clinical reality. "Toxicity for humans/"human experience"). I must state what everyone in reality already knows - that the animal testing methods proposed in the directive are not performed with regard to their relevance for daily use of these products by people. Neither is Human Patch Testing a perfect method, but it can be performed on the correct [biological] species and highlights in a relevant way the same areas as the animal testing proposed in the directive. Human Patch Testing therefore represents a valuable method for product development and regulatory issues with clear relevance to "toxicity for humans". I conclude by saying that there is of course a lot of work with regard to use of tensides in all forms and patients with eczema. Critical to this work will however be a trigger mechanism, called "cumulative insult irritant contact dermatitis", the major cause of which is over-exposure to water! Neither the animal testing referred to in the directive, or Human Patch Testing are of strict direct relevance to this, the most common trigger mechanism, which combines such different aspects as individual susceptibility (e.g. atopic), skin barrier damage (e.g. constitutional dry skin or 'wet' work), cell damage (effect mechanisms for irritants at cellular level can vary) and the ability to repair. Neither are these issues addressed by the marking proposed by the Chemical Inspectorate."

In an internal report dated 20 April 2005, the Environmental Protection Agency, Chemicals, stated:

"Brief comments to [declaration fated 20 October 2004, by professor Marc Paye] on antagonism.

The Environmental Protection Agency agrees with Marc Paye PhD (...) that he has demonstrated a certain antagonism for mixtures of surface-active substances under the given trial conditions.

However, the Agency believes that it has not been proven that antagonism occurs in the specific products, and neither can the result be used for more than a general comment that antagonism always occurs in detergents.

The trial conditions differ in several areas from reality for exposure to detergents;

The study has not tested the specific detergents, but only a mix of selected substances which are contained in the detergents. The study has therefore not allowed for the specific products containing other irritants such as proteases, sodium carbonate, sulphuric acid and sodium silicate, in addition to the surface-active substances tested.

The surface-active substances have been tested at a concentration approx. 10 times lower than that they are found in detergents, which can make a difference to the degree of antagonism.

The study used protein breakdown as a measure of irritation. Given that protein breakdown is not the only mechanism behind irritation, nothing specific can be established on the degree of irritation based on this study.

Furthermore, the Ministry of the Environment believes that the results cannot be used as grounds for an exception to classification of the specific products, as the test is not intended for classification purposes."

For the consideration of the High Court, the trade association has obtained further expert declarations from October and December 2008 from professor Roland Niedner, Potsdam, which according to the association, has examined the 8 products currently covered by the Ministry's order of 27 February 2004. According to the information, the studies were performed in accordance with a model, which the German authorities recognise and accept in connection with classification of similar products. According to the model, an independent expert is given access to all the data concerning the product to perform a comparison of the product with trial protocols from other, comparable, classified products, and the inspection authority can request access to all the data concerning making of the product. According to Professor Roland Niedner's declarations, none of the products the case concerns have been classified and marked as dangerous according to the preparations directive.

In a report dated 24 February 2009 from the Environmental Protection Agency, the declarations were referred to as:

"... The German method submitted for assessing detergents is a totally unauthorised method in line with AISE guidelines, and has clearly been conceived to avoid classification according to EU rules. The actual method is based on an 'independent' expert comparing the company's product formulation with comparable product formulations which have been experimentally tested, and assessing whether the product formulation should be classified for local irritation on that basis.

So-called 'expert assessment' has been performed by Prof. Roland Niedner who has compared the relevant product formulations with similar formulations which have been experimentally tested. The Environmental Protection Agency has not performed detailed toxicological assessment of the relevance of these comparisons, but can state that the experimental studies used to test comparable products include Low Volume Eye Irritation Test and Human Irritation Patch Test. Neither of these tests is internationally recognised, as stated in the previous case documentation. They cannot therefore be used as scientific documentation for the lack of the products' local irritating properties. Furthermore, the pH value for several of the product formulations lies in the 10.5-10.9 range, which in itself could indicate eye irritation properties.

The Environmental Protection Agency find that the material submitted is neither relevant to the case, or provides further new knowledge of relevance to the case."

The High Court's grounds and result

As stated in the District Court's judgement, the parties agree that use of the calculation rule in item 6, part 1, (a) of the preparations directive, implies that the detergents in question should be classified and marked as local irritants in accordance with the Environmental Protection Agency's order.

The parties also agree that the preparation directive is based on assessment of a preparation's properties and not on assessment of risk.

According to the formulation of article 16 and the wording of item 3, part 1 of the article, this provision can be interpreted such that there is a possibility in principal for both upward classification and downward classification of a preparation in relation to the classification arrived at by using the calculation rule. Executive Order no. 329 of 16 May 2002 on the classification, packaging, marking, sale and storage of chemical substances and products must therefore be interpreted in accordance with the same.

The question hereafter is whether the material the trade association refers to as supporting downward classification in pursuance of article 6, item 3, part 1, is sufficient basis to modify the classification ordered.

The High Court finds that neither the scientific studies, including the Human Patch Test and Low Volume Eye Test the trade association refer to, or the expert declarations and statistical material from the Accidents Register which the association has presented in the case, can prove with the necessary certainty that the toxicological effects of detergents on humans are different from those which assessment according to the calculation rule would lead to.

With regard to article 6, item 3, part 3, the High Court subscribes to the grounds stated by the District Court, in that the material presented to the High Court cannot lead to another result, that neither has the trade association proved that use of the calculation rule due to antagonism can lead to such an over-assessment of the toxicological danger that the danger classification ordered should not be used.

In addition to the evaluation of evidence referred to, it should be noted that no independent expert has been appointed during the case to give a declaration on the toxicological effects on humans.

According to the evidence and in accordance with the provisions of article 6, item 3, parts 1 and 3 of the preparations directive, the Environmental Protection Agency has not been unjustified in ordering classification and marking of the detergents on the basis of the calculation rule in article 6, item 1, (a).

On these grounds, the High Court rules that there are no grounds to overturn the order as invalid as a result of the provisions in article 6, item 3 of the preparations directive.

Hereafter – and because the High Court in agreement with the District Court finds that the Environmental Protection Agency has not displayed rights-forfeiting passivity, made any administrative errors or shown untoward regard - the High Court finds that the Environmental Protection Agency is not guilty of allegations 1 and 3 made by the trade association.

With regard to the trade association's allegation 2, the allegation is deemed to be included to support allegations 1 and 3. The High Court therefore rules that allegation 2 is rejected.

Hereafter, the High Court upholds the judgement.

The Court therefore finds:

The District Court judgement is upheld.

On the matter of case costs for the High Court, the Trade Association for the Soap, Perfume and Technical/Chemical Articles, as proxy for Unilever Danmark AIS and Procter & Gamble Danmark ApS shall pay the sum of DKK 250,000 to the Environmental Protection Agency.

The costs awarded shall be paid within 14 days after the High Court's judgement and will be subject to interest in pursuance of § 8 a of the Interest on Late Payment Act.

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As confirmation of this written document.

The High Court, 28 April 2009.

Eva Henriette Plesner

Administrative Officer