

• **News and Voices**

What must be done to prevent another humidifier disinfectant disaster?

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The humidifier disinfectant disaster (HDD) was not a simple poisoning accident by biocides, but a singular disaster in history created by chemicals in household products. This disaster was a result of the failure of a system for the management of chemical and product safety. Since the management authority for chemical usage safety is different from those for chemical safety in products, many blind areas for chemical safety management in products still remain. The 'Act on the Registration and Evaluation, etc. of Chemical Substances (ARECS)' or the new 'Biocidal Product Act' must not only address the blind areas in the management system for chemical and product safety, but also prevent a second HDD. To prevent another HDD, an integrated registration, evaluation, and management system for chemicals and consumer products must be incorporated into the 'ARECS' as an essential part for chemical safety in consumer products.

Keywords: Humidifier disinfectant disaster, Integrated registration, Evaluation, Management system of chemical and product safety, Chemical use safety, Chemical safety in products

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Introduction

The public has wondered why the humidifier disinfectant disaster (HDD) only occurred in South Korea (here after Korea). The issue of how a demand for humidifier disinfectant (HD) formed in Korea, how the product was released, and how it was distributed for over 20 years needs specialized analysis. This study intends to seek answers on issues that must be addressed regarding the HDD from the perspective of a chemical substance expert.

The first question that comes to mind is, "Why weren't we able to foresee the HD issue, figure it out in time, and properly handle the case?" Then it is natural to wonder, "Can we prevent the toxic HD or a similar product from entering the market under the current system?" Through analysis of the two questions above, this study ponders the answer to the question, "What must be done in order to prevent another HD incident?"

Diagnosis of the Causes of the Humidifier Disinfectant Incident

What were manufacturers, authorities, and relevant experts doing for the past 20 years when more than 1000 victims (100 of which were casualties) resulted from the release and distribution of the HD? Why weren't they able to identify defects in the product beforehand and deal with the issue in advance? These are questions asked by people who are first introduced to the HD case. We must clearly distinguish the causes of the accident—whether it was simply a lack of inhalation toxicity data, a systemic problem such as a blind area in management, an issue regarding policy intentions of the authorities, or an issue of professional capacity. Future forecast and prescription will differ depending on the cause.

Regarding the cause of the disaster, the following three potential causes are mentioned the most: (1) Since the HD issue was caused by a lack of information such as inhalation toxicity data,

it was impossible to predict such an accident with the level of technology at the time; (2) Because the authorities did not have the legal right to prevent the release of a company's product or the use of chemical substances for certain purposes, it was impossible to prevent the market release of the HD; (3) It was possible to predict the inhalation toxicity of the HD to some extent; therefore, although it was not subject to management, if the manufacturers and authorities had the will to do so, the market release of the product could have been prevented in many ways, even without any legal reform.

To explain point three further, when the HD was released into the market, there was no obligation to submit toxicity data during the process of product certification under the "Act on Quality Management and Safety Control of Industrial Products." Because the HD was not subject to management, the product was able to enter the market without any restrictions even though there was no inhalation toxicity data about it. However, even if the HD would have been subject to management, it could have been sold in the market with a Korea Certification (KC) mark attached if it had just met product safety standards and had obtained certification.

Even though the possibility of inhalation exposure was clearly stated in the hazard review data, in the case of poly(oxyalkylene guanidine) hydrochloride (PGH), a toxic HD, the chemical registration review group did not request submission of additional inhalation toxicity data in 2003; subsequently, PGH was classified as a common chemical substance, not a hazardous substance. In this case, a general regulation, which requires inhalation toxicity data when there is a possibility of inhalation exposure, was ignored. Eventually, the chemical registration assessment team of the National Institute of Environmental Research reversed the decision, designated PGH as a hazardous substance, and announced it in August of 2013 [1].

Therefore, we cannot assign the blame to manufacturers for failing to put together toxicity data regarding the HDs. At the time, no one had requested toxicity data from manufacturers and no one had assessed the danger of inhalation toxicity of the products before market release. It is regretful that the severe danger of the HD could have been identified if the inhalation toxicity data of PHMB (a similar substance to polyhexamethylene guanide phosphate (PHMG)—another HD) would have been used [2].

This leads us to consider the present day situation. Is it possible to prevent the release of a product with a serious defect like that of the toxic HDs? In cases where a product is subject to the list of product under the management according to the Act on Quality Management and Safety Control of Industrial Products, it can still be released without any obstacles if the product safety

standards are met through the autonomous safety certification system and a 'KC' mark is attached. The same goes for hazardous products list of concern according to the Act on the Registration and Evaluation, etc. of Chemical Substances (ARECS). Unless current product safety standards are exceeded, products can be freely released in the market without any product registration procedure. Unlike the Act on Quality Management and Safety Control of Industrial Products, ARECS does not even have a product registration system that can track the products released in the market.

If a product is not subject to management, there isn't really a way to take measures beforehand. In terms of managing the usage of chemical substance, it is possible to take some advance measures since the ARECS system stipulates that the safety of chemical substances which exceed 10 tons of usage annually must be reviewed beforehand through a risk assessment of their specific uses. However, chemical substances used in most consumer products are excluded from the risk assessment, except for substances that are coincidentally also used for industrial purposes. Therefore, just as in the past, even if inhalation toxicity data is produced, there is almost no possibility of preventing the release of products that may cause health damage (such as that of the HD) due to the inadequacy of the present system for chemical management.

While the HD was not regulated at the product level because it wasn't subject to management, an argument has been raised asserting that there would have been a big difference if a safety review were carried out on its chemical substances after receiving relevant toxicity data during the review process, and it could have been declared a hazardous substance and managed. If the HD had been classified as a hazardous substance due to inhalation toxicity data, would the relevant chemical substances still have been used as components of the HD? The answer is "yes." The same substances could have been used without any legal consequences. Products both subject to and not subject to management do not face any restriction for using hazardous substances if they meet product safety standards. And even if a chemical is classified as a hazardous substance, there are no legal means to restrict manufacturers from using the substances for the HD.

The same goes for the present situation. Today, ARECS stipulates that manufacturers must declare hazardous chemical substances used in a household chemical product if the annual usage amount exceeds one ton for a product or the content of the substance exceeds 0.1% of a product. However, it is estimated that chemical substances used in most household chemical products are not subject to declaration. Therefore, under ARECS, there is no other way to limit the use of hazardous

chemical substances in household chemical products than to set product safety standards. Then, is it possible for the government to identify the substances used in products subject to management before market release, and to manage those products by setting product safety standards? It is realistically not possible because there are no means to identify which chemical substances are used in which products and to what degree, and no means to assess the risk of the products.

Because the toxicity of the biocide was evident, the risk of inhaling the substance was logically predictable even if there was no inhalation toxicity data. The danger of inhalation exposure is mentioned in Material Safety Data Sheet. Yet, the HD, which used disinfectant components without any restriction in a product with a possibility of inhalation exposure, was released into the market. The Korean Agency for Technology and Standards, which was responsible for the safety management of the product at the time, initially refused requests from manufacturers to authorize KC mark since it deemed the product a disinfectant, not a cleaning product as subject to management, but did not take any measures toward ensuring the safety of the product and neglected the situation. Finally, the Korean Agency for Technology and Standards awarded the KC mark to Costco's Humidifier Clean Up product, which contained PHMG. The agency shouldn't have awarded it a KC mark, and instead should have designated the product as subject to management and prepared product safety standards. It were possible to apply those measures within the legal system at the time, if only the authorities had the will to carry them out. Therefore, the primary responsibility of the government for the HD incident lies in the hands of the Korean Agency for Technology and Standards, which was the principal agency responsible for the management of chemical substances in industrial products at the time and which directly received product certification requests from manufacturers.

The current policies of the Ministry of Trade, Industry and Energy and the Korean Agency for Technology and Standards have not drastically changed since the HD incident; only the problematic household chemical products were transferred over to the Ministry of Environment. It is difficult to simultaneously expect professionalism and responsibility regarding the safety management of products from departments that are responsible for supporting and promoting manufacturers under the name of industrial revitalization. It is no longer admissible to leave the lives and safety of citizens in the hands of agencies that are neither responsible nor professional. In order to prevent another HD incident, the entire workload of safety management of chemical substances must be fully transferred over to the Ministry of Environment and the Ministry of Food and Drug Safety.

Similar to the case of household chemical products, it is also

worrisome that the Korean Agency for Technology and Standards—a Ministry of Trade, Industry and Energy-affiliated organization—is in charge of safety management of chemical substances for industrial products (especially children's products). This is because the Korean Agency for Technology and Standards usually considers the safety management work as taking international regulation standards, and many cases have been reported in which manufacturers modify such standards to meet the level acceptable by manufacturers. For instance, international standards limit the use of six phthalates in products for children 3-years-old or younger, but a Special Act on Children's Product Safety in Korea allows the use of three phthalates without any limit on the content on the condition that the substances are declared. This example illustrates that the true intention of the Special Act on Children's Product Safety is not to specifically protect children, but to specifically protect Korean manufacturers from international competitors.

The Absence of Prevention Measures From the Government's Response to the Humidifier Disinfectant Disaster

Currently, HD is considered a "substance used as an additive to water within the humidifier for preventive purposes against microbe propagation and limescale," and is managed through a prior authorization method after being designated as a quasi-drug. The HD was designated as an item that needs prior authorization and must be subject to management after taking into account the form of the product (substance used as an additive to water within the humidifier) and its functional uses (prevention of microbe propagation and limescale). The functional use of the product (prevention of microbe propagation and limescale) provides indirect information on the kinds of functional materials that can be used. The form of the product (substance used as an additive to water within the humidifier) is a preliminary factor of product management in terms of determining the route and level of exposure. However, under the current management method, it is difficult to identify beforehand the release of products that add chemical substances to humidifier water for purposes other than to prevent limescale and microbe propagation. Moreover, such products could be excluded from being subject to quasi-drug authorization because of their different usage, and could be released without any restriction. For chemical substances used as an additive to the water within the humidifier, whatever its use, prior authorization must be received after reviewing the safety of the chemical substances used. Therefore, it is hard to say that other kinds of chemicals used as an additive to water within the humidifier is currently being properly man-

aged through its designation as a quasi-drug.

For many of the same reasons, similar issues arise when designating consumer products (e.g., household chemical products or children's products) as subjects of management. There is a need to identify the actual safety of the product type and to manage the product type by designating it as an item subject to management. For instance, aerosol-generating products such as humidifiers, sprays, and manual and mechanical injectors, must be managed as items subject to prior authorization, regardless of their different uses. Prior authorization is also needed for products used by children (a susceptible group), such as products children bite and suck on, powder/clay-type products, accessories, and children's cosmetics, all of which have a high level of exposure intensity and exposure time, and have a high frequency of use.

The same goes for household chemical products managed by ARECS today. This is because of a fundamental limitation in the current regulation system, which allows substances to be used without restriction, save for a few designated substances that are used in quantities less than the standard value. The current regulation system is a kind of negative regulation method in which the government, instead of the manufacturer, essentially takes responsibility for the proactive management of product defects. While the government prescribes product safety standards by law, the problem is how well such a regulation system will actually work. For this kind of regulation system to function properly, information about what substances and how much are being used, but the government doesn't have that information, and manufacturers do not reflect such information in their safety designs even if they have it. If the manufacturers cannot make their own decisions, they should entrust authorities to make decisions for them, but they are currently ignoring things, under the excuse that they are trade secrets. Ultimately, since the authorities do not possess information about substances and their quantity used in the products, the opportunity to identify product safety before market release disappears. In other words, it is a system in which no one can take responsibility for product safety before market release. This is the key point behind the meaning of "system inadequacy."

Basic information for chemical substance management through "registration of the uses of chemical substances" (providing the necessary information needed to prepare an exposure scenario for a preliminary risk assessment of the product) and "product registration" (including the substances used, the amount of substances used, and the product uses, etc.) must be secured by authorities in order to manage the chemical substance uses and the safety of the products. However, the current system does not ensure the minimum requirements for safety

management of chemical substances and products due to various constraints.

Agencies carry out safety management of chemical substances by self-assessing the uses verified for safety and registering them with the authorities. This is the fundamental background for the advancement of the European Union's REACH and Korea's ARECS. In the case of ARECS, such a registration process is applied to chemical substances in which more than one ton is used per manufacturer annually, and only to chemical products, excluding the articles (consumer products except for chemical products). However, most manufacturers do not use more than one ton of chemical substances annually for household chemical products or children's products. Properly identifying the kinds of substances used in products that may cause harm is difficult for manufacturers and authorities. Substances that have not been tested for inhalation toxicity are still being used in spray products. Ultimately, it is difficult to properly carry out management of chemical substance use for most consumer products.

Under the current management system, consumer products manufacturers determine whether chemical substances are used in consumer products, but authorities do not have enough legal power or means to identify the usage beforehand and to prevent the release of products when there is concern for harm. Therefore, the National Assembly must amend laws in order to create legal authority for the government to take responsibility on its own. It is realistic conditions for the government to carry out administrative responsibility that manufacturers must be given the legal duty to provide lists of chemical substances used in products and their content and other relevant information that may be needed regarding product functions, and the authorities must be given the power and means to recall products if there is a violation of regulations. It is no solution that the public just criticizes the rights and wrongs of the authorities.

In particular, the Special Act on Safety of Product for Children comprehensively stipulates safety management work regarding chemical substances used in children's products, which is essentially the same management system defined by the Act on Quality Management and Safety Control of Industrial Products. If products satisfy the safety requirements presented by the Korean Agency for Technology and Standards, they can use any chemical substance and be released without any restrictions. In particular, for children's products as with biocide products, a "registration and prior authorization system for children's products" is needed, which would allow only products whose safety is verified beforehand containing substances whose safety is identified. However, the Korean Agency for Technology and Standards doesn't seem to have the expertise to deal with the

management responsibility for children's products. The Korean Agency for Technology and Standards is currently completely dependent on the Ministry of Environment for preliminary risk assessments regarding actual children's products—it only determines whether the safety standards are met, through follow-up monitoring called a “product safety investigation.” Therefore, administrative responsibility for safety management of chemical substances in consumer products can only be made possible if the responsibility for safety management of chemical substances used in all consumer products—including children's products—is fully transferred over to the Ministry of Environment.

For consumer products that are known for their dangerousness (e.g., biocide products and spray products), a prior authorization system must be adopted immediately. For this, ARECS must be amended (adopting the consumer products registration system and imposing the responsibility of product risk assessment to consumer products manufacturers) and a separate legislation for biocide products must be advanced.

Measures to Prevent the Recurrence of a Humidifier Disinfectant Incident

The HD incident needs to be understood as having two aspects: an accident due to a biocide (the disinfectant) and a safety issue of a consumer product (the humidifier). Therefore, in order to prevent another HD incident, we need answers to questions such as, “How can we make safety management possible for biocides (e.g., the disinfectant) and biocide products?” and “How can we guarantee safety of chemical substances for consumer products that require special management, like that of the humidifier?” In addition, we need to tackle the issue of preventing the reckless use of chemical substances without inhalation toxicity data in products that require special care due to the possibility of inhalation exposure.

Conclusion

In conclusion, the only solution is to adopt a product registration and prior authorization system for “consumer products subject to special management,” such as that of the humidifier, and for “biocide products that contain biocides.”

Adopting a Product Registration and Prior Authorization System for Biocides and Biocide Products

First, there is already a systematic plan proposed for biocides and biocide products. Parts of the plan have already been implemented within the ARECS system. A separate legislation that

can play the role of the European Union's Biocidal Product Regulation is the most realistic plan. To prevent blind spots in the chemical management, the essence is to adopt a certification for all biocides by use, except for biocide products already managed by different laws, and to adopt a prior authorization system for biocide products.

For this, it is important to identify the actual distribution of biocides that have been pre-approved, which is only possible through the adoption of a prior authorization system with legal force. Manufacturers were asked to take countless surveys and provide material aid, but they only submitted questionable data from unknown sources. Unless there is a device to expel products from the market if, through a later survey, unregistered substances are detected in products subject to management, it is realistically impossible to understand the actual state of affairs. A realistic plan is to identify the usage of active biocide components through a product registration system. Trying to identify the actual condition of biocides without such a registration system is impossible. If the registration system does not immediately demonstrate its full functions, there is a need to temporarily report biocides whose domestic and foreign usages are identified, and to self-declare that other unreported substances are not used. This is a necessary measure so that manufacturers are held responsible from the registration of the product to its entry into the market.

The remaining issue is safety management of chemical substances used in household products that manufacturers claim are not biocides (active ingredients). There are substances that could cause harm when used in consumer products, even if they are not “active ingredients,” whose functional purposes (or uses) are disinfection, sterilization, and preservation. The most representative is waterproof coating material used on clothes and shoes for hiking, which is not a biocide in terms of its function, but could cause serious lung disease if used indoors without ventilation as a spray, since the substance can be inhaled [3]. Besides biocides, assessment of product safety through pre-registration is needed for products and chemical substances that may cause harm. However, it is over-regulation to designate all consumer products as products that need certification. There is a need to review a plan to adopt a registration system only for products identified as having the possibility to cause harm (e.g., humidifiers, spray products, and children's products that have a high exposure intensity) and designating products that could generate aerosol or products that need special management (e.g., children's products) as products that need prior authorization.

Preparing a Resolution for Management Blind Spots Regarding Consumer Products

The only method to resolve the blind spots of management is

to create a system to comprehensively manage chemical substances and consumer products, not to expand the number of products subject to management, which is a “mend the barn after the horse is stolen” kind of approach. By separating the management of chemicals in products from the management of chemical substances, neither the chemical substance use management nor the safety of consumer products can be guaranteed. The following are the only ways to prevent another HD (product), another Oxy Reckitt Benckiser (product manufacturer, downstream user), and another SK Chemical (chemical substance manufacturer, upstream supplier): safety assessments of chemical substance use, governmental certification of chemical substance safety for consumer products, imposition of the burden of proof on manufacturers, and a disciplinary compensation system.

First, the principal agent of safety management for chemical substances must be completely transferred over to the Ministry of Environment and the Ministry of Food and Drug Safety, out of the current dichotomized system of products in either the Ministry of Trade, Industry and Energy and the Ministry of Environment or the Ministry of Food and Drug Safety. The safety management agent for chemical substances used in consumer products must be clearly stipulated as the Ministry of Environment and the Ministry of Food and Drug Safety. In particular, a massive system reform is needed for the establishment of a comprehensive management system for chemical substances and products regarding children’s products. In order to achieve this, the physical safety management work must be left as is under the jurisdiction of the Special Act on Children’s Product Safety, and the chemical substance safety management work must be excluded. Instead, the chemical substance safety management of children’s products must be expanded and reorganized within the framework of the Environmental Health Act, which supervises all children’s environmental health issues. The adoption of a pre-registration and assessment system for the chemical substance use management of children’s products must also be advanced.

For the safety evaluation of each usage type in the chemical substance management system, the downstream user is responsible for delivering information on usage, quantity, and exposure conditions. If this responsibility is violated, a realistic penalty must be prescribed. That way, if chemical substances are used for unidentified purposes, the upstream supplier (the agent responsible for registering chemical substances) can be held accountable and tangible registration and assessment of chemical substances can be made possible. However, this regulation could exist in name only if the downstream user has the upper hand. If a substance is registered once, the downstream user has

the full responsibility to determine whether the substance is used in a safety-certified way or used in a different way from its registered exposure conditions. Along with considering a change in registration for changes in exposure condition as well as usage, an effective penalty must be made clear in case there is a violation of a change in registration.

Cases where chemical substances are used in the final products such as articles were excluded from registration and assessment under ARECS, due to trade secrets and other reasons. However, at least for consumer products, new regulations must be created in order to make registration assessment possible, with upstream suppliers and article manufacturers responsible for usage safety. ARECS must be transformed into an act that contains comprehensive regulations that manage the safety of chemical substances in consumer products, except for products that are managed under other individual laws. If it is realistically impossible to demand disclosure of information from downstream users, regulations must be amended so that instead of the current system of conducting a risk assessment by representative upstream suppliers, a risk assessment can be conducted after an exposure scenario is prepared through a self-evaluation by the downstream user. In other words, the choice must be made between a risk assessment carried out by upstream suppliers after collecting information about exposure scenario and exposure condition, or a risk assessment carried out by downstream users so that they can wield control over secretive information regarding their businesses. A few Korean conglomerates and associations are already disclosing whether or not they use harmful chemical substances in order to respond to the regulation systems of foreign countries (EU REACH, California Proposition 65). Such information should be disclosed in a suitable way and utilized for safety management of chemical substances in Korea.

Just as the registration and assessment of chemical substances is compulsory in principle, the registration and assessment of consumer products must also be fixed as a rule. Plans for a proactive management system and follow-up management and supervision must be proposed after properly classifying the scope in which the prior authorization system will be applied (biocide products, children’s products, spray products, recycled products) and the scope in which self-certification will be applied (other household chemical products). Just like the Act on the Registration and Evaluation, etc. of Chemical Substances, methods for the registration and assessment of existing and new consumer products must be proposed with a legal basis. Priorities must be set by considering product characteristics, such as usage (intensity of use, duration, and frequency), material, and form, for consumer products that may cause harm (e.g. household

chemical products, children's products, aerosol generators, indoor construction material and flooring material, plate lumber/furniture).

Prohibition of Substances of Unknown Inhalation Toxicity in Consumer Products That May Be Subject to Inhalation Exposure

The HD incident shows that a chemical substance with a toxicity so low that it was deemed safe to eat can cause tremendous consequences if inhaled. Therefore, using chemical substances whose inhalation toxicity is unidentified must be restricted or prohibited for consumer products with a strong possibility of inhalation exposure. Priorities for management must be set by evaluating the relative degree of inhalation exposure regarding the usage/material/form of all consumer products currently in use. The priority for spray products used as air fresheners, deodorants, disinfectants, sterilizers, insecticides, and anti-rust additives is a safety check regarding inhalation toxicity. For products that generate aerosol, a list of usable substances should be suggested after taking exposure intensity into account, and must be strictly managed so that the substances are only used after receiving prior authorization.

Currently, a total inspection is needed for identifying the usage of chemical substances that do not have inhalation toxicity data in products with a strong possibility of inhalation exposure. Manufacturers should be ordered to report information on raw materials used in products. Since there is a realistic possibility that manufacturers will not know the quantity and types of substances used by manufacturers, measures must be taken regarding this issue. In the future, a list of usable substances should be

suggested so that safety-certified products will be produced and distributed. Through an investigation of the functions of individual chemical substances, measures are needed to limit usage, unless the function is essential. If the function is essential, usage of alternative material should be induced through the support of alternative material assessment. An Integrated Testing Strategy must be prepared for efficient production of inhalation toxicity data.

Conflict of Interest

The author has no conflicts of interest associated with material presented in this paper.

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