

Meeting Report of the Special Committee for the Safety of Protein Hydrolysates in Cosmetics

3rd Meeting

Date and Time: 17:00-19:00, November 12, 2011;

Venue: Grand Prince Hotel New Takanawa

Attendee: 10 committee members, President of the Japanese Society of Allergology, 8 observers

Kayoko Matsunaga (Chair), Yasuharu Itagaki, Atsuo Urisu, Reiko Kishikawa, Shinichi Sugiura, Hiroyuki Tanaka, Reiko Teshima, Yuma Fukutomi, Akiko Yagami, Yuko Chinuku (new member), Kazuko Akiyama (President of the Japanese Society of Allergology)

Observer: Jun Shoji representing Mitsuru Sawa as a new member; Masashi Nakamura (Fujita Health University); Hitoshi Sasa, Mariko Sugiyama (Japan Cosmetic Industry Association)

Witness: Norio Sakaki from Yuuka Co., Ltd.

Material maker representative: Tetsuya Nakamura, Seiji Nagao, Takeaki Enatsu (Seiwa Kasei Co., Ltd.)

Refuser: Croda Japan, BASF Japan

Minutes:

Dr. Akiyama explained the set-up background and role of the Committee, referring to the importance of and expectation for the Committee.

1. Introduction of new committee members

As disorder in the periorbital area had been frequently reported in a series of applicable cases, Mitsuru Sawa and Atsuki Fukushima (recommended by the Japanese Ophthalmological Society) and Yuko Chinuki (a member of the research group), whose participation had been admitted by the Japanese Society of Allergology board of directors, were introduced.

2. Reaction from and support for the public after the diagnosis criteria announcement

Supplemental statement was made as to the skin prick test as a diagnosis criterion.

3. Report by participants

1) Yuuka Co., Ltd. presented the data collected from October 8 through 21.

Notification from customers: (1) Medical certificates: 39 (569 in cumulative total)

(2) Other sources: 21 (1,254 in cumulative total)

Notification from healthcare professionals: 12 (177 in cumulative total)

2) Japan Cosmetic Industry Association

(1) Cause investigation: The Association will, in 1 or 2 months, publicly solicit institutions, teams and researchers who can work on the theme of "Research on Causes for Systemic Allergy Induced by Hydrolyzed Wheat Powder".

(2) Measures to be taken: Establishing the system to promptly catch information of a certain cosmetics

(including quasi-drug/cosmetic) that has hazardous effects and also gather relative information such as other products that may cause similar problems.

3) Mr. Nakamura (Fujita Health University)

Mr. Nakamura reported on his research (the diagnosis by means of ELISA and the cross-reactivity with Gluperal 19S).

IgE antibody test by means of the dot blot immunoassay revealed that Gluperal 19S-specific IgE antigen is only observed in “Cha no Shizuku” soap-induced allergy patients and not found in other wheat allergy patients or healthy individuals. This testing technique is complex and difficult to standardize.

On the other hand, the ELISA method employed by Fujita Health University has high quantitative performance and throughput, which facilitates standardization. Dr. Teshima, Dr. Aihara, Dr.

Kishikawa, Dr. Chinuki and Dr. Hide are inspecting measures to achieve reproducibility between institutions. In some cases, the ELISA unit value went down after 1 month.

Cross reactivity was studied as to other hydrolyzed wheat powders to clarify what is problematic with Gluperal 19S and identify the disease development mechanism.

4. Material maker hearing

Only one company out of three was present.

Difference between Promois WG-SP® and Gluperal 19S® was explained by Seiwa Kasei. (① Safety test result was negative as to Promois WG, which was found in the U.S. in 2006 and in Japan in 1991, primary irritation was observed in the animal experiment) , ②Promois WG-SP® and Gluperal 19S® molecular weight comparison, ③Promois WG-SP® and Gluperal 19S® solubility comparison) .

5. General

It was agreed to ask Katayama Chemical Inc., which was not invited to the meeting, to participate in the hearing conducted on another occasion and also ask Croda, which declined to participate in the meeting, to provide information.

Dr. Fukutomi and Dr. Sugiura were asked to continually work on the establishment of patient registration system and the preparation of case report. Dr. Chinuki was asked to proceed with the Gluperal 19S quantification and the remission case consideration.