

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

### 2nd Meeting

Date and Time: 17:30-20:30, September 3, 2011

Venue: Meeting Room of the Japanese Society of Allergology Office

Attendee: 8 committee members, 4 observers

Kayoko Matsunaga (Chair), Yoshiro Ikezawa, Yasuharu Itagaki, Atsuo Urisu, Shinichi Sugiura, Reiko Teshima, Yuma Fukutomi, Akiko Yagami

Absentee: Michiko Aihara, Zenichiro Kato, Reiko Kishikawa, Hiroyuki Tanaka, Michihiro Hide, Eishin Morita (presence by proxy)

Witness: Norio Takeda, Noriko Sakaki from Yuuka Co., Ltd. (sales company)

Observer: Masashi Nakamura (Fujita Health University); Katsuhiko Takano, Hitoshi Sasa, Mariko Sugiyama (Japan Cosmetic Industry Association)

### Minutes:

1. The chairperson explained the background for urgent convocation and the 2<sup>nd</sup> meeting agenda. Establishing diagnosis criteria for “Cha no Shizuku”-induced sensitization (causative substance, how to identify unmistakable, suspect or not suspect case) was chosen as a main topic in view of the briefing sessions to be held by the defense team organized to rescue “Cha no Shizuku” victims in the prefectures of Aichi, Osaka and Tokyo in the following week.  
Diagnosis rules of thumb posted by Dr. Fukutomi in the “Wheat Allergy Information Center” page of the Japanese Society of Allergology website shows that challenge test is not considered essential for diagnosis if a patient has a clinically unmistakable symptom of wheat-induced allergy. Diagnosis criteria for determining “Cha no Shizuku” soap induced disorder were explained based on the “Cha no Shizuku” soap-induced wheat allergy study report” by Fujita Health University Matsunaga Group, with Yuuka Co., Ltd. and the Japan Cosmetic Industry Association participating.
2. Study report by Mr. Nakamura and Dr. Yagami using the materials distributed  
Dot blot IgE antigen test revealed that Glupearl 19S-specific IgE antigens are observed only in the “Cha no Shizuku” soap-induced allergy patients. Gluten-specific IgE antigen level had no distinct difference between “Cha no Shizuku” patients and other wheat allergy patients. Molecular weight distribution of Glupearl 19S was similar to that of gluten, but 2D-PAGE results indicated that protein existed only in the acid region as to Glupearl 19S while gluten had little protein on the acid side.
  - The Japan Cosmetic Industry Association reported on the results of the research as to 6 types of cosmetics ingredients containing hydrolyzed wheat and hydrolyzed wheat protein (interim report 2).

- Number of cases as of August 26 reported by Yuuka Co., Ltd. :

- 1) Medical certificates: 50 (305 in cumulative total)
  - 2) Other sources: 163 (905 in cumulative total)
  - 3) Notification from healthcare professionals: 20 (136 in cumulative total)
- 1346 in the aggregate

- The Committee made following requests:

- 1) Yuuka Co., Ltd. should inform the public of the product recall via TV commercial. (There are still many patients who don't know about the "Cha no Shizuku" related allergy. Publication through TV commercial is considered effective.)

- 2) Cosmetics additives should be reviewed for safety.

The incidence in question accompanies immediate allergic reaction, which threatens life, and parties concerned are required to address the problem renewing awareness for safety. Epicutaneous application of a substance that is usually taken orally might have risk. Safety check with epidemiological study is considered necessary at the least. Is it possible for a certain processing method to generate an unknown antigen?

Material companies should be asked to participate in the next meeting so that material safety can be confirmed.

- 3) Yuuka Co., Ltd. and the Japan Cosmetic Industry Association are requested to report on material safety evaluation method and condition before and after usage, and also to cooperate with required research for hydrolyzed wheat used in not only "Cha no Shizuku" soap but other products.

### 3. Diagnostic method

As there was an opinion that disorders should be diagnosed depending on severity (positive, highly suspect or suspect case), it was discussed how to diagnose wheat allergy induced by "Cha no Shizuku" Glupearl 19S.

### 4. Safety evaluation in releasing cosmetics as products (immediate allergic reaction)

- Product safety consideration employed so far
- Possibility of unknown antigen generation, which has been rarely observed
- "Cha no Shizuku" production accompanying acid hydrolysis→It is difficult to identify antigen determinant

Glupearl 19S: Serum inhibition test (to study cross reactivity between Glupearl 19S and raw gluten)

## 5. Case collection

In addition to animal model research, human skin data is essential. It was discussed how to collect user information through IT system proposed by Dr. Sugiura (Yuuka is asking 1,200 patients who have notified to the Ministry of Health, Labor and Welfare to register in the system) as well as how to provide collected information to healthcare professionals and patients.

## 6. Future activity

As to diagnosis criteria, oral wheat allergy and “Cha no Shizuku” allergy were actively discussed, which did not come to a conclusion, and the discussion was tabled to the next meeting scheduled for September 6.

Patient rescue system will be continuously discussed for optimum realization of its purpose. As to safety research, it was suggested that a study group should be organized to report the results in the Committee. The committee is to act from the patients’ point of view as a neutral agent.

\*Diagnostic criteria agreed by the Committee on October 11 are posted on the Japanese Society of Allergology website.

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