

## Development of a Protocol that Allows Safe Consumption of the Hypoallergenic Apple Cultivar Santana

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### Abstract

The apple (*Malus ×domestica*) cultivar Santana was shown to have a low allergenicity in a previously reported clinical trial. A protocol was developed to validate these results outside a clinical setting and to market the Santana as a hypoallergenic apple for large-scale consumption. This protocol was designed to ensure safe consumption of the Santana by consumers suffering from apple allergy. We tested the protocol in a pilot in 100 supermarket stores and evaluated in an internet-based survey with 295 respondents. Forty-one percent of the consumers with an apple allergy did not have an allergic reaction to the Santana. Only five percent of the allergic consumers that tried the Santana reported a strong allergic reaction. In concordance with this, the majority (78%) of the mild apple allergic consumers appreciated the Santana. The developed protocol is considered suitable for safe consumption of the Santana providing that information about the possibility of having an allergic reaction among consumers with a mild apple allergy is added to the label.

### INTRODUCTION

About 2% of the population in Northern and Central Europe suffers from allergy to apple (Kootstra et al., 2007). The majority of these people suffer from a type of food allergy called oral allergy syndrome (OAS; Ortolani et al., 1988). The primary measure to deal with this allergy is to avoid eating fresh apples (Kootstra et al., 2007). This limits their normal dietary intake, which is not an ideal situation because apples contribute to a well-balanced and a healthy diet.

Products that have a reduced allergenicity are called hypoallergenic. Consumption of such products results in a reduced allergic reaction or no allergic reaction in part of the consumers that react to the allergenic counterparts. The Dutch apple cultivar Santana was identified as hypoallergenic in a screening test among 21 apple cultivars using the prick to prick method and in a small-scale Double Blind Placebo Controlled Food Challenge (Bolhaar et al., 2005). Kootstra et al. (2007) confirmed these results in an open challenge and found that eight out of fifteen (53%) apple allergic patients did not develop any allergy complaints to the Santana. This differed significantly from the number of subjects who reacted to the apple cultivars Topaz (7%) and Golden Delicious (7%). In addition, four out of seven individuals that did react to the Santana experienced symptoms that were less severe than after consumption of the other two cultivars. Seventy-three percent of the test subjects stated that they would eat the Santana apple in the future.

This study examines whether the Santana is suitable for marketing and consumption by apple allergic consumers using a special protocol.

### MATERIALS AND METHODS

A protocol was developed to ensure that the Santana was made available for consumers with apple allergy in a medical, legal, logistic and commercial warranted way.

The protocol was established in cooperation with the Dutch Food Allergy Foundation and with scientists in the field of allergy. The protocol was put in practice in

cooperation with the Dutch supermarket chain Albert Heijn.

The information leaflet that was enclosed with the product redirected consumers to an internet page that provided additional information on apple allergy. The consumers were then prompted to fill in a survey. The survey included items on the severity of the apple allergy in general, the occurrence of an allergic reaction to the Santana, the severity of the symptoms in case an allergic reaction had occurred, the appreciation of the Santana, the use of allergy medication after eating Santana, and the consultation of a family doctor/allergologist before eating the Santana.

## **RESULTS AND DISCUSSION**

### **The Protocol**

The following measures were included in the protocol:

1. Measures to prevent mixing of the Santana with other apple cultivars. Mixing should be prevented throughout the production chain in order to avoid exposure of apple allergic consumers to cultivars which do induce an allergic reaction. The following steps were taken: exclusion of Santana orchards with pollinators in the Santana rows, storage in separate storage houses and packaging of the Santana prior to the shipment to selling in the stores. Special instructions were given to the workers involved to avoid mixing with other apples.
2. Measures to restrict consumption of the Santana to consumers with a mild apple allergy. Previous studies showed that the Santana is not allergenic to part of the apple allergic consumers. Others with an apple allergy are still expected to have an allergic reaction to the Santana. Therefore, people who suffer from a severe allergic reaction to apples and who experience swelling responses or worse were strongly advised not to try the Santana. The package of the Santana read on the label: “suitable for people with a mild apple allergy; first read the enclosed information leaflet”.
3. Measures to minimize the consequences of having an allergic reaction to the Santana (restriction to mild was considered insufficient to guarantee the absence or a sufficient reduction of all allergic reactions). Some patients with a mild apple allergy will still have an allergic reaction to the Santana. Therefore, an extra safety precaution was required to minimize the consequences of an allergic reaction: the enclosed information leaflet, included an appeal to follow a safe testing procedure. This step-wise procedure was described on the leaflet and could be carried out by consumers themselves at home.

### **Consumer Survey**

The survey was completed by 295 consumers with an apple allergy who had all tried the Santana. The results in Table 1 show that the majority of these respondents classified themselves as having a mild or moderate apple allergy.

Information about the reaction to the Santana is presented in Table 2. The most important observations are:

1. The percentage of consumers who could eat the Santana without having an allergic reaction was highest in the “mild” apple allergy class (52%).
2. The percentage of consumers who could eat the Santana without having an allergic reaction in the “moderate” and “severe” classes were lower (35 to 32%).
3. The majority (78 to 84%) of the consumers in all apple allergy classes appreciated (score 5-7) the Santana.
4. Experiencing an allergic reaction or not, had a large influence on appreciation. All consumers that had no allergic reaction to the Santana appreciated the Santana.

The severity of the allergic reaction to the Santana among the consumers that did experience an allergic reaction was generally mild. Only five percent of the consumers reported having a strong allergic reaction, while four percent of the consumers used allergy medication after consumption of the Santana. Three percent of the respondents consulted a family doctor before eating the Santana.

The protocol covered the measurements that could be taken in terms of product responsibility on the part of the retailer especially the avoidance of severe allergic reactions occurring . Some consumers with a severe allergy did, however, try the Santana. Consumers have their own responsibilities to act on the suggestions that were provided with the product.

## CONCLUSIONS

The results from the sales pilot indicated that the applied protocol was suitable to allow safe consumption of the Santana by apple allergic consumers. The majority of these consumers appreciated the Santana, although a considerable number of them still had a mild allergic reaction to the Santana. The step-wise testing protocol minimizes the consequences of these reactions. Information about the possibility of the occurrence of an allergic reaction in individuals that have a mild apple allergy should be added to the information label, as omitting this information may raise false expectations.

## ACKNOWLEDGEMENTS

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## Tables

Table 1. Number of respondents in the consumer survey, divided according to the self-reported severity of the allergic reaction to apple in general.

Classification apple allergy	Description <sup>1</sup>	Number of respondents	Percentage (%)
Mild	Itching and irritation	77	26
Moderate	Slight swelling	187	63
Severe	Severe swelling and shortness of breath	31	11
Very severe <sup>2</sup>	Life threatening symptoms	0	0

<sup>1</sup> Reference to mouth, lips, tongue, nose, eyes and throat

<sup>2</sup> The application of this protocol is restricted to the Netherlands, Belgium and Luxemburg. In these North-West European countries, most people who suffer from apple allergy have a relative mild form of allergy. The allergy class “very severe” is expected to be extremely rare among apple allergic consumers in these countries. In contrast, a type of apple allergy that is caused by lipid transfer proteins may result in very severe symptoms in southern Europe (Pastorello et al., 1999).

Table 2. Appreciation of the Santana by respondents with an apple allergy. Numbers in the table are percentages.

Allergic reaction to the Santana	Appreciation of the Santana by consumers <sup>2</sup>	Classification apple allergy <sup>1</sup>		
		Mild (%)	Moderate (%)	Severe (%)
No	1-4	0	0	0
No	5-7	52	35	32
Yes	1-4	22	17	16
Yes	5-7	26	48	52
Total	1-4	22	17	16
Total	5-7	78	83	84

<sup>1</sup> According to the classification in Table 1

<sup>2</sup> Scale 1 to 7 with “1” labeled as “no appreciation at all” and “7” labeled as “high appreciation”