

### Criteria for allergy-friendly apples

#### Background

Apples have several allergens that cause symptoms in the mouth area within 5 to 10 minutes of ingestion and therefore cannot be eaten by people with an apple allergy. About 7.5 million people in Germany have developed IgE antibodies to the main allergen (Mal d 1) in apples and are sensitised as a result. At least 3.5 million of those people go on to develop allergy symptoms characteristic of oral allergy syndrome, some of which can be significant. There is no effective drug therapy for this allergy.

Apple allergy sufferers must therefore avoid apples altogether, eat cooked or baked apples, or look for varieties that contain fewer allergens and can therefore be described as allergy-friendly apple varieties.

It cannot be predicted just by identifying the allergens in an apple in a laboratory whether an apple can be eaten without triggering apple allergy symptoms; clinical testing is required for this.

A standardised clinical, oral provocation test is used to characterise a low-allergen, allergy-friendly apple or apple variety.

The results of such tests, which are conducted over a period of at least three years, will be used to determine whether the ECARF Seal of Quality can be granted for allergy-friendly apples.

However, complete safety from allergen exposure cannot be guaranteed even with a certified allergy-friendly apple.

#### 1. Test criteria

##### 1.1 Required product features

- The objective of clinical tests should be to identify any apple allergens in the given apple, in particular Mal d 1.
- In addition to the variety, other factors such as ripening or storage of the apple can influence allergenic potential. Moreover, people with an apple allergy have individual reactions. The tests must therefore be repeated over a period of several years, usually three years.
- After several years of use, we consider the oral provocation test (OPT) with the apple as standard for determining the tolerability of apple allergens. It is described in detail as follows:

##### 1.2 Measurements (oral provocation test)

Testing of an apple (apple variety from a harvest): In a test on at least 20 subjects, an apple variety is considered allergy-friendly if it has a cumulative tolerated dose of 140 g from one apple variety, which on average does not exceed a Total Symptom Score (TSS) of 2.5 and remains under 3 in any given subject.

Subjects are tested in a suitable room with a study nurse and a doctor (present or on standby).

The doctor and the study nurse will explain the test procedure again and answer any questions.

The apples used for testing are at room temperature, washed and will not shown whole to the test persons. Their name and origin will not be disclosed.

Nasal flow is measured and documented using the Positive Nasal Inspiratory Flow Test (PNIF) before the test and 15 minutes after the last ingestion of apple. Forced expiratory volume in one second (FEV1) measured by spirometry may also be determined if the subjects are asthmatic.

The subjects eat a pre-weighed amount of apple (peel and flesh cut from the top (stem) to bottom of the apple no more that 30 minutes before consumption) of:

- An initial 20 g,
- Another 40 g after 15 minutes,
- Another 80 g after an additional 15 minutes
- The rest of the weighed apple after an additional 15 minutes

Documentation of symptoms inside and/or outside the mouth according to a standard before the first piece of apple and before the next larger portion and 30 minutes after the last test dose. The symptoms after eating the apple are given a severity score based on a scale from 0 to 3.

- 0 = no symptoms
- 1 = mild symptoms
- 2 = noticeable symptoms
- 3 = severe symptoms

The severity levels are defined as follows:

- 0 = Complete absence of symptoms
- 1 = Symptom is present, not troublesome, easy to tolerate
- 2 = Symptom is perceived, troublesome but tolerable
- 3 = Symptom is difficult to tolerate and disrupts daily life

Provided that the subject is willing to continue, the test will be performed until symptoms of severity score 2 occur or the subject no longer wishes to consume another dose.

## 2. Quality control and complaint management

The producer has established a functioning system of quality control, which documents such information as the origin, harvesting and storage conditions of the apples. The following is also ensured:

- The apple producer's contact details, such as postal address, telephone number and/or email address.
- Complaints are handled and followed up in an appropriate manner by qualified and experienced personnel of the producer.