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Allergen Content and in vivo Allergenic Activity of House Dust Mite Extracts

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Dear Editors

In the paper of Casset et al. [1], we have recently shown that commercially available extracts from the house dust mite *Dermatophagoides pteronyssinus* from different European manufacturers differed considerably regarding their amount of the major allergens, Der p 1 and Der p 2, and often lacked other important allergens (e.g. Der p 5, Der p 7, Der p 10 and Der p 21). Because of this, some extracts failed to diagnose certain house dust mite-allergic patients.

The two different batches of *D. pteronyssinus* extracts from Stallergènes used in this study showed a good batch-to-batch consistency, but contained only low levels of Der p 1 and Der p 2. The other tested mite allergens, Der p 5, Der p 7, Der p 10 and Der p 21, could not be detected in the two batches (table 1). As a consequence, the Stallergènes extract failed to diagnose 2 house dust mite-allergic patients [1].

Moingeon et al. [2] present in their ‘Letter to the Editor’ the quality checks which are routinely performed to guarantee pharmaceutical-grade quality of their mite extracts. Using immunoblotting with allergen-specific antibodies, the authors showed that the source materials contained the most important house dust mite allergens, including those which we tested in our study. This is in agreement with our study and the study by Batard et al. [3], which both showed that raw house dust mite extracts contained the most important allergens. However, table 1 of the ‘Letter to the Editor’ by Moingeon et al. [2] indicates that only the source material is tested for the presence of the allergens known so far, whereas the finished products used for diagnosis and immunotherapy of house dust mite-allergic patients are only tested for the content of the major allergens, Der p 1 and 2. We showed in our study that these final house dust mite extracts from Stallergènes lacked some of the most important allergens (table 1) [1]. Certain allergens might be lost during the production of the final extract as a result of the proteolytic activity of the extract or other manufacturing processes.

The finished products from Stallergènes are tested for their allergenic activity in comparison to an in-house reference standard. This test ensures a good batch-to-batch consistency of the

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extracts which was also seen in our study (table 1) [1]. However, in-house reference standards are not suitable for a comparison of extracts from different companies and are the reason for the differences seen in skin prick tests between extracts from different manufacturers [1].

In summary, the quality control steps performed by Stallergènes during the manufacture of house dust mite extracts for diagnosis and immunotherapy may ensure some degree of batch-to-batch consistency of their extracts but they do not ensure the presence of all important mite allergens in the extracts. As a consequence, the extracts may fail in diagnostic tests and give suboptimal results in clinical trials. An improvement of the situation can only be expected from the use of defined recombinant allergens.

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Table 1

Concentrations of Der p 1 and Der p 2 and content of Der p 5, 7, 10 and 21 in two different batches of *D. pteronyssinus* extracts from Stallergènes

	Der p 1 concentration μg ml^{-1}	Der p 2 concentration μg ml^{-1}	Der p 5	Der p 7	Der p 10	Der p 21
Batch 1	8.8	3.7	–	–	–	–
Batch 2	14.0	4.3	–	–	–	–