AK EUROPA

Position Paper
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Consumers

Rules for New Genomic Techniques

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Executive Summary

Central demands of AK

- Freedom of choice for consumers and traceability along the entire value chain: Food and feed produced using new genomic techniques (NGT) must be labelled as genetically modified products to enable consumers and all users along the value chain to make an informed choice.

- Compliance with the precautionary principle: Prior to market authorisation, all food and feed produced with the aid of NGT must be checked for risks to human health and the environment.

- A specific Directive for „green claims" is currently being negotiated at EU level to avoid greenwashing. Information on the property conferred by the genetic modification under this Regulation is therefore obsolete.

- Organic farming, as well as GMO-free conventional food production, must not be endangered. Existing GMO legislation must therefore continue to apply to all NGT processes in the future.

- For all NGT plants, specific detection methods shall be provided by the developers and/or distributors. There must be no exceptions and no facilitations for the genetic engineering sector. Control and nature conservation authorities and other control bodies (e.g. certified organic control bodies), as well as organic farmers or non-GM primary producers in the vicinity of fields where NGT plants are cultivated, must be enabled to detect contamination with modified gene segments in their own products, if necessary. This can only be achieved if the specific detection methods are accessible to the authorities and the general public.

- Distributors must bear any costs for contamination in organic and GMO-free food production. These costs must not be passed on to consumers. For this purpose, liability rules in the sense of the polluter pays principle must be provided for.
- No far-reaching intervention rights via delegated acts for the Commission, such as changing the criteria for the „equivalence" of NGT category 1 plants. Before the Regulation enters into force, it must be clear what the Regulation should look like in order to have clarity for all stakeholders.

- The precautionary principle enshrined in EU law in the food sector must not be undermined. Sustainability and climate protection as well as adaptation efforts and changed conditions due to climate On the basis of the arguments presented, AK concludes that the current Commission proposal, which leads to deregulation in the field of NGT, must be rejected in its current form; it requires a fundamental and comprehensive revision. change must not lead to a weakening of the established precautionary principle.

- The safe, transparent application of NGT and freedom of choice for consumers and organic and/or GMO-free agriculture must be ensured in order to guarantee the potential of NGT methods for the benefit of consumers, producers and the environment.

- No patent on life: Analogous to conventional breeding, a regulation must be created according to which products of new genomic techniques are not patentable. This is the only way to reduce dependencies and avoid licence fees for seeds and harvested and processed products.

- Conclusion: With its proposal, the European Commission is pursuing the clear objective of facilitating the cultivation of NGT in the EU. On the basis of the arguments presented, AK concludes that the current Commission proposal, which leads to deregulation in the field of NGT, must be rejected in its current form; it requires a fundamental and comprehensive revision.

AK's position

Content of the draft

On 5 July 2023, the EU Commission published a proposal for a Regulation introducing new rules for plants produced with the help of new genomic techniques (NGT) (e.g. CRISPR/Cas gene scissors). In the course of deregulating established GMO legislation, the Commission divides „NGT plants" into two categories.

Category 1 NGT includes plants that also may occur naturally or could be produced by conventional breeding. They are considered equivalent to conventionally bred plants provided that a maximum of up to 20 different genetic modifications have been made per plant. NGT category 1 plants are exempt from the requirements of current GMO legislation. This means no risk assessment for human health and the environment, no labelling for consumers as a genetically modified organism (GMO) and an end to clear traceability to genetically modified source products along the food and/or feed chain (the general traceability requirements of the EU Basic Food Regulation remain unaffected, however). Only the seeds are to be labelled as NGT 1 and entered in a public database, the criteria for which have yet to be defined, in order to ensure transparency for breeders and farmers. Organic farming remains GMO-free, where GMO plants of category 1 NGT and category NGT 2 are prohibited. The Member State shall ensure the coexistence of GMO-free agriculture and GMO agriculture.

The most important facts in a nutshell

All NGT plants will continue to be considered genetic engineering in the future. However, according to the draft Regulation, in the case of NGT 1 there is no risk assessment for human health and the environment, no labelling for consumers as a genetically modified organism (GMO), no traceability of genetic engineering along the value chain and no detection methods required. A large proportion of all new GM plants will fall into NGT category 1.

Category 2 NGT plants continue to be regarded as GM plants and existing GMO law must be applied, including labelling as GMOs. However, simplifications are also foreseen. For example, there is a different form of risk assessment, and detection methods for the genetic modification can be waived with a justification. Furthermore, the characteristics of the genetic modification can be indicated on the product.

- In organic agriculture, the use of genetic engineering and thus also of NGT plants of both categories remains prohibited.
- The previous possibility of banning the cultivation of GM crops (opt-out) in the Member State is excluded for NGTs.
- Austria has so far been a pioneer in the European Union in GMO-free agriculture and food production. In no other EU Member State is the proportion of certified GMO-free food and organic products as high as in Austria. This form of GMO-free agriculture is therefore of great economic interest and will face enormous challenges, if not even be endangered, by the planned new rules.
- The Commission is given far-reaching rights of intervention, such as to change the criteria for the classification of category 1 NGT plants or the criteria for the characteristics of the genetic modification on the category 2 product.
- Patentability of seeds and plants as well as possible liability rules are not addressed in the EU proposal.

On the background of the planned draft

In its ruling of 18 July 2018, the European Court of Justice (ECJ) defined NGT methods such as the CRISPR/Cas gene scissors as genetically modified organisms (GMO) under EU GMO legislation. It justified this with the novelty of the procedures as well as potential dangers for human health and the environment. Therefore, in the sense of the precautionary principle, applicable EU GMO rules should also be applied to NGT. In practice, this means an authorization system for genetic engineering according to defined criteria of EU GMO law. There is a comprehensive risk assess-

ment needed before food and/or feed made from or containing genetically modified ingredients are authorized on the European market. The companies have to present a detection procedure for the genetic modification, and the information on the genetic modification has to be passed on along the chain and presented during controls to enable traceability and a control of the labelling from field to table. In addition, there is clear labelling as a genetically modified organism for consumers to guarantee freedom of choice.

The indication that e.g. genetically modified maize has been used must be made in the list of ingredients of the end product concerned in the case of packaged products. In the case of packaged foodstuffs without a list of ingredients, the reference must be made in connection with the designation of the foodstuff (e.g. „maize flour from genetically modified maize"). If foodstuffs containing ingredients from genetically modified source materials are sold unpackaged (e.g. bakery, restaurant), the information must be provided in the immediate vicinity of the product (e.g. information sign, menu card). Labelling must take place regardless of whether the genetic modification is (still) detectable in the end product, which is the case with most processed foods. Therefore, not only detection methods are relevant, but also the established GM-specific documentation requirements, which are now no longer provided for NGT. The labelling obligation also applies analogously to animal feed. It allows consumers and animal keepers to make an informed choice and to influence the market through their purchase decision. However, the exercise of „power with the help of the shopping basket" by consumers is not always possible, because meat, milk and eggs from animals fed with genetically modified feed do not have to be labelled. If you are not in favour of genetic engineering, you can only choose organic food and food certified as „produced without genetic engineering" or „without genetic engineering".

On 8 November 2019, the Ministers of Agriculture commissioned the EU Commission to carry out a comprehensive assessment of NGT in the light of the ECJ ruling. In April 2021, the EU Commission presented a study on NGT in which it concludes that existing EU rules for NGT are „not fit for purpose". The EU Commission then initiated an impact assessment with the aim of submitting a legislative proposal for the NGT methods, which include in particular the CRISPR/Cas gene scissors. AK participated in this legislative process and critically noted in all statements that in the sense of freedom of choice and the safety of consumers as well as the environment, existing EU GMO rules were also appropriate and proportionate for NGT and should therefore be maintained. However, the present proposal for a Regulation means a deviation from the established principle of precaution and clear consumer information, is a comprehensive deregulation of existing GMO rules and is rejected by AK.

On the main provisions of the proposed draft

1) Freedom of choice for consumers is being undermined

The present proposal provides in Article 5 that existing EU GMO legislation shall not apply to NGT 1 plants. This means that for a large part of all GM food and feed produced by NGT, there will be no labelling obligation, no risk assessment for human health and the environment, and no clear traceability from field to table, and existing EU GMO law will be undermined.

Consumers want to have the possibility to freely choose whether they buy genetically modified food or not. AK expressed this wish for freedom of choice in all its statements, events and letters to the Commission. A study commissioned by the Vienna Chamber of Labour and carried out by the Federal Environment Agency clearly shows the restrictions for consumers if the labelling obligation for food from or with ingredients produced by means of NGT is dropped. The freedom of choice for consumers who reject genetic engineering in food would disappear, as would their ability to influence the market through their purchasing behaviour.

In addition, established standards that exclude the use of genetically modified organisms, regardless of how the modification was carried out (old or new genetic methods), such as organic products or food certified as „produced without genetic engineering", would face new challenges. What is needed in any case are contamination limits, because food processing routes are closely intertwined. If the processors at the various intermediate stages do not know whether they are processing ingredients from NGT or not, they cannot take appropriate precautions against contamination. In the medium term, GMO-free food production with labels such as „organic" or „GMO-free" could disappear for consumers.

A recently published survey by the Vienna Chamber of Labour shows how important the issue of genetic engineering is for consumers: for 84% of consumers, GMO-free is an important criterion when buying food. When asked about the qualitative restrictions that consumers face in the course of price increases, the majority of respondents said that they would not want to do without GMO-free products. If finances are tight, organic products are most likely to be left out. Vegan, light products and convenience products are also more likely to be abandoned, while taste, GMO-free, animal welfare and climate protection are not.

Furthermore, an EU-wide study commissioned by the Greens in the European Parliament shows that 86% of European consumers would like to see genetically modified crops and 81% of food from animals labelled as GMOs. A survey conducted by the Austrian Retail Association together with the environmental organisation Global 2000 in 2022 as well as a recent survey by the Austrian platform "ARGE Gentechnik-frei" clearly show that about 90% of Austrian consumers would like to see GMO labelling also for new genomic techniques.

The draft's proposed exclusion of category 1 from the labelling obligation ignores consumers' desire for freedom of choice. Only NGT category 1 seed must be labelled in order to enable transparency for breeders and farmers. From the point of view of AK, this type of labelling is not far-reaching enough. It is not even foreseen that the information along the supply and processing chains up to the point of delivery is passed on to the end consumer, in order to at least establish a right of information for consumers in this respect.

AK is firmly and emphatically against this planned deregulation, rejects the deletion without replacement of the consumers' right to information and demands, following the judgement of the European Court of Justice, that NGT products are also to be regarded as genetically modified organisms and must therefore be subject to the EU legislation that has been in force in this respect for years. The exclusive labelling of seeds is by no means sufficient to guarantee clear information and freedom of choice for consumers. The omission of the obligation to pass on information along the processing chain ultimately even makes it impossible to provide reliable information when consumers ask for it.

2) Precautionary principle is ignored

The precautionary principle enshrined in the Treaties of the European Union is being flagrantly disregarded with this proposal for a Regulation. NGTs are relatively new techniques, which is why there is still hardly any experience with how these plants behave in the environment and what possible undesirable properties they may exhibit. In the interests of precaution, an authorisation procedure analogous to the existing GMO legislation would be indispensable, as is also demanded by critical scientists.

The proposed categorisation disregards the precautionary principle for plants in NGT category 1, i.e. to avoid environmental pollution and damage to human health. Considering that only 1.6% of the national research budget for NGTs is spent on safety research, it is not surprising that there is little scientific data on the long-term effects of plants produced with NGT methods. The fact that these could be considerable is also supported by the view of the German Federal Agency for Nature Conservation, according to which NGT poses the same risk as classical genetic engineering. The Federal Agency clearly emphasises that unintentional genomic changes can also occur through these new methods. Furthermore, the introduction of new traits into a plant always carries the risk of negative effects on ecosystems and biodiversity and subsequently also on food safety and food security.

Many studies have been conducted on the unintended and unforeseen consequences of the use of CRISPR/Cas, mainly in humans, but also in plants and animals. Recently, an effect of double-strand breaks in plants called „chromothripsis" has been observed, in which hundreds of genetic changes often occur at once when the CRISPR/Cas gene scissors are used. Sections of the genetic material can be swapped, twisted, recombined or lost altogether. It is still unclear how these changes can affect the organism itself, humans and the environment. In mammalian and human cells, this effect has been known for some time. It is therefore irresponsible to forego a comprehensive risk assessment for human health and the environment for NGT category 1 food and feed.

3) Unscientific definition for NGTs

The definition used to distinguish category 1 from category 2 in Annex 1 is essentially based on the number of modified base groups in the DNA strand of the plant. The behaviour of the plant that may be triggered later (long-term genetic changes, invasive behaviour, etc.) is not taken into account at all.

The European science network ENSSER calls the EU Commission's proposal scientifically unacceptable, because it abrogates the provisions of the precautionary principle and endangers the public and the environment. According to ENSSER, equating category 1 NGT plants with conventional breeding is a return to the controversial concept of „substantial equivalence", which was used in the first EU GMO legislation of the 1990s and discarded in the later, i.e. current legislation, as an unscientific and unreliable concept. This lack of scientific basis and evidence is most evident in the arbitrariness of the number of modifications or base pair insertions/substitutions that may be considered „equivalent", where equivalence clearly does not equate to safety.

4) Detection method required for all NGT plants

No detection methods are required for category 1 NGT plants, as they are equivalent to plants of conventional breeding. This means that in organic and GMO-free agriculture and food production, it is difficult or impos-

sible to detect contamination with category 1 NGT plants. In these alternative production methods, which are appreciated by consumers, the use of genetically modified organisms, whether obtained by old or new methods, is not permitted under the current rules. Therefore, in accordance with the polluter pays principle, the parties legally responsible for placing these plants on the market in the EU must bear any costs incurred in preventing contamination of organic or GMO-free production. They must also compensate for (possible) reduced marketing opportunities if products can no longer be marketed as organic or GMO-free. Corresponding liability rules in the legal act or accompanying rules are therefore necessary. Furthermore, the distributors must bear any costs for contamination in organic and GMO-free food production. It is not reasonable that consumers should have to bear these costs.

AK demands: For all NGT plants, the distributors must provide detection methods. This is the only way to prove possible contamination by NGT plants. In addition, liability rules according to the polluter pays principle must be provided for.

5) Organic farming and GMO-free food sector under pressure

GMO-free and organic food is becoming increasingly popular among consumers in Austria and Europe. The demand for these segments has been rising steadily for years. In Austria, the share of organic food sold in the retail sector is already 11.5%, and in 2022, almost 27% of agricultural land will be farmed organically. The national goal is to farm 35 % of agricultural land organically by 2035. According to "ARGE Gentechnik-frei", in Austria alone almost 2.5 billion euros are turned over in the conventional, but GMO-free food sector.

The proposal for a Regulation of the European Commission provides that the use of plants of both NGT categories is prohibited for organic farming (Article 5, paragraph 2). AK welcomes this ban, which protects the interests of consumers who expect organic food to be GMO-free. However, the proposal does not take sufficient account of the requirements necessary for GMO-free organic farming.

Seed of NGT category 1 shall be registered in a publicly accessible database and labelled as such. This enables organic farming and the GMO-free food industry to establish their own GMO-free value chain. For organic farming and the GMO-free food industry, however, this means further hurdles. The associated costs are ultimately borne by consumers. There will also be additional costs for all companies along the processing chain to avoid contamination. To ensure that these companies do not have to bear the costs or pass them on to consumers, liability and compensation rules based on the polluter pays principle are needed.

Even if organic farming and the GMO-free food industry manage to establish their own GMO-free value chain, there is still the question of what coexistence, i.e. rules for the coexistence of organic farming and conventional GMO farming, looks like. Organic farmers need to know what is being grown on the neighbouring field in order to avoid cross-contamination. If this information is not available, it will be difficult for organic farmers to avoid contamination from neighbouring fields. The EU Commission has not proposed any criteria for this. Rather, this responsibility is placed in the hands of the Member States. Both organic and conventionally certified GMO-free agriculture are facing obstacles to their successful business model, which must be avoided. Therefore, comprehensive labelling, traceability from field to table as well as detection methods for all NGT plants are necessary to ensure coexistence and thus the production of organic food and conventionally GMO-free food in the future, without additional burdens.

6) Voluntary indication of characteristics that have been changed by the NGT

Food and feed as well as all other products of NGT category 2 are, according to the proposal, to be labelled as genetically modified organisms in accordance with EU GMO legislation (Regulation (EC) No 1829/2003). In addition, producers will be given the option of supplementing the labelling of Category 2 NGT products as GMOs with information on the trait conferred by the genetic modification. In order to avoid misleading or confusing information, a proposal for such labelling should be included in the notification for consent or in the application for authorisation and should be specified in the consent or in the authorisation decision (recital 32, Article 23).
This allows producers of category 2 NGT products to add the property conferred by the genetic modification directly after the mention of „GMO", i.e. a kind of environmental statement that could compensate for a negative perception of GMOs by consumers. It is unclear which evaluation criteria are used for this type of labelling, because there are no legally established evaluation criteria according to which one could objectively assess such a statement.
A specific Directive for „green claims" are currently being negotiated at EU level (European Commission proposal for a Directive on substantiation and communication of explicit environmental claims of 22 March 2023) in order to avoid greenwashing. A separate regulation in this Regulation is therefore obsolete.

7) Facilitated approval procedure NGT products category 2

Furthermore, NGT products that fulfil sustainability-relevant characteristics according to Annex III (e.g. lower use of pesticides, resistance to plant diseases, better nutrient composition, etc.) are to be granted facilitations in the authorisation process without having to provide a justification. These facilitations cannot be justified from a scientific point of view. In addition, the authorities are called upon to support potential applicants in the authorisation procedure. Furthermore, with justification by the applicant, detection procedures can be waived. It seems as if the EU Commission is doing everything in its power to approve NGT products on the European market as soon as possible. AK rejects a simplified authorisation procedure, which is only provided for on the basis of alleged „sustainability claims" (Annex III) and without scientific justification.

NGT products of category 2 are clearly genetically modified organisms, only that NGT methods are used for this. AK takes a critical view of simplifications in the authorisation process and the possibility of not submitting detection methods with sufficient justification and rejects them.

8) NGT plants and Novel Food Regulation

For plants in NGT category 1, there is to be only one notification procedure in future, which determines whether the respective plants fall under NGT category 1 or not. Should it be determined in this procedure that the novel plant influences the nutritional value of food or the metabolism or contains harmless substances in food, the Novel Food Regulation is to be applied (recital 22).

An assessment of the safety of novel foods for human health, regardless of whether they replace or are added to other comparable foods, is welcomed in principle, and specific labelling can also be standardised on a case-by-case basis (e.g. warnings for certain population groups) via the diversions of authorisation through the Novel Food Regulation. Novel food testing and authorisation should in principle apply to all foods with or from NGT plants, if the comprehensive safety assessment and specific labelling via this legal act is to be omitted in future, with a few exceptions, in order to establish a minimum level of safety and information. However, the treatment of all NGT processes according to current EU GMO law is preferred. An environmental assessment is not standardised in the Novel Food Regulation.

It is also unclear what is meant by a „significantly changed composition and structure". A comprehensive EU-wide database on the composition of foods with regard to all nutrients, secondary health ingredients and antinutritive substances is currently lacking or only exists in rudimentary form. Reliable estimates of „significantly altered compositions and structures" therefore appear difficult and leave considerable room for interpretation in practice.

Would, for example, the „GABA tomato" already marketed in Japan fall under the Novel Food Regulation and would ketchup made from these tomatoes be a Novel Food? The GABA tomato is said to have an antihypertensive effect. This is due to the ingredient GABA (γ-aminobutyric acid), which is elevated in this tomato and can inhibit the transmission of certain stimuli in the central nervous system.

A significant disadvantage of an assessment according to Novel-Food would also be that no risks for the environment are examined and there is no consistent specific genetic engineering labelling (because it is too decisive in individual cases). With regard to environmental impacts, foodstuffs that are still capable of reproduction or contain parts that are capable of reproduction are particularly relevant. In the above example, ketchup would be irrelevant, but tomatoes per se would not. However, it is questionable whether a note that the tomato should not be disposed of in organic waste will be examined in the course of the Novel Food approval and, if so, whether it will be prescribed.

AK advocates - also in view of the „Better Regulation Initiative", which is to ensure that rules should not be spread over various different legal acts - that food and feed of NGT category 1 must undergo a comprehensive case-by-case risk assessment according to the established EU GMO law with regard to potential risks for human health and the environment before they are authorised on the European market and that the uniform labelling for all GMO products is maintained in the same form.

9) Genetic engineering cultivation bans also for NGT

The Commission proposal aims to guarantee the free movement of NGTs within the EU. Accordingly, the Member States are not to be able to prohibit or restrict the deliberate release or placing on the market of NGTs. This would mean that in future it would no longer be possible to prohibit the cultivation in Austria of plants produced with the NGT of categories 1 and 2. This would invalidate the „opt-out regulation of genetically modified plants" for Member States, which was intensively supported by Austria and adopted in 2015. This encroaches on the sovereignty of the Member States and is strictly rejected by AK.

AK demands to apply the possibility of the „opt-out regulation" for all food and feed produced with the help of NGT.

10) Far-reaching intervention rights of the EU Commission

The Commission can adapt the criteria for NGTs of category 1 (Annex 1) as well as the criteria for sustainability labelling for NGTs of category 2 (Annex 3) at any time via delegated acts (power to adopt rules). The Member States are involved via their national delegates, but the EU Commission ultimately decides without consulting the Member States and the European Parliament. The EU Commission thus creates the possibility for itself to expand or adapt the criteria for a large part of the NGTs as well as the „sustainability labelling" for Category 2 NGTs at will. The justification why a detection method cannot be developed is also placed in the hands of the EU Commission.

AK strictly rejects these far-reaching rights of intervention by the EU Commission. They elude parliamentary control and, with this Regulation, leave actors in the food chain in the dark about the extent to which changes will be made to categorisation and labelling. However, as these points are of decisive importance for the implementation of the proposal, these answers must already be available before a vote by the Member States and the Parliament.

11) Patents - many open questions

The proposal leaves open how to deal with NGT patents. The number of patent applications for the economically profitable use of technical innovations with NGT has risen considerably in recent years. For example, the company Corteva has already applied for 1,430 patents on new breeding methods and products worldwide. The German company Bayer, the second-largest player in the „patent race", has applied for 119 patents, as research by environmental and consumer organisations shows. These patents are not only for individual plants, but also for broad applications such as resistance to diseases. Not only the seeds, but also the harvested and processed products are part of the patent application. Thus, in the future, the farmer who grows a potato variety with a higher starch content, the baker who bakes bread from the flour of these potatoes, or the food industry that produces its products from this potato variety, up to and including the French fries on your plate, would have to pay royalties. Austrian plant breeding is largely carried out by small and medium-sized enterprises that do not have a large legal department to sift through the growing patent jungle. Patents increase the market power of those who apply for patents and lead to greater dependence on international corporations. Ultimately, this has negative consequences for the diversity of supply. In concrete terms, this means that corporations could obtain monopoly rights to important natural traits such as heat tolerance or resistance to a disease and thus exclude others from using them. Especially in times of climate crisis, however, it is all the more important that sufficient biodiversity is available that breeders can use for their work without restrictions. Moreover, patents on seeds are a threat to future food security. They not only restrict the freedom of choice of consumers and producers, but could also lead to an increase in food prices. Analogous to conventional breeding, a regulation must be created according to which NGT products are not patentable. This is the only way to reduce dependencies and avoid licence fees for seeds and harvested and processed products.

12) Extension of the approval of NGT plants

The approval of NGT plants of both categories shall be renewed after ten years. However, after this renewal, the authorisation is valid indefinitely. This also applies to plants in the NGT 2 category, which in themselves fall under current GMO law. In GMO law, renewal is obligatory every ten years. AK is against an unlimited renewal of the authorisation and demands a regular review - every 10 years - for all NGT plants.

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About us

The Austrian Federal Chamber of Labour (AK) is by law representing the interests of about 3.8 million employees and consumers in Austria. It acts for the interests of its members in fields of social-, educational-, economical-, and consumer issues both on the national and on the EU-level in Brussels. Furthermore, the Austrian Federal Chamber of Labour is a part of the Austrian social partnership. The Austrian Federal Chamber of Labour is registered at the EU Transparency Register under the number 23869471911-54.

The main objectives of the 1991 established AK EUROPA Office in Brussels are the representation of AK vis-à-vis the European Institutions and interest groups, the monitoring of EU policies and to transfer relevant Information from Brussels to Austria, as well as to lobby the in Austria developed expertise and positions of the Austrian Federal Chamber of Labour in Brussels.