

**TELECONFERENCE WITH PPE INDUSTRY ON  
COVID-19  
BRIEFING**

**Tuesday 10 March 2020**

**Brussels**

# 1. Steering note


## Description of the agenda, the topics to be discussed and the context

The teleconference will take place on Tuesday 10 of March from 11:00 to 12:00.

The teleconference is planned to be private with senior management of Personal Protective Equipment manufacturers and suppliers operating in the European Union.


Commissioner Breton will chair the meeting. He will open the meeting and after introductory remarks he will give the floor to the CEOs of PPE companies to discuss the issue on COVID-19.

The teleconference takes place at a moment where the supply of Personal Protective Equipment (PPE), mainly masks, is under particular strain.



A European procurement procedure for personal protective equipment is ongoing under the Joint Procurement Agreement for medical countermeasures.

20 EU MS joined this joint procurement procedure that was launched on 28 February 2020. The companies will have until 9 March to submit their offers. The Public Procurement Committee will assess these offers by April and the contracts are expected to be signed in the course of April. The joint procurement asks for



The letter of invitation for the conference call contained the following 4 questions:

1. Has your company taken steps to increase the supply of personal protective equipment, which is in particularly high demand, such as disposable facemasks?
2. Have you identified any bottlenecks, including of a regulatory nature, which restrict your company's ability to increase the supply of adequate personal protective equipment?
3. Do you believe that there are any specific support measures that could be put in place by the European Commission to support the various actors along the supply chain of personal protective equipment?

4. What has been your company's reaction to the significant increase in the demand for personal protective equipment? According to your observations, is the increase in demand being channelled via your usual commercial channels or are you also being solicited by new prospective clients?

## **2. Objectives**

The objectives of the meeting are:

- 1) To obtain information on the current state of the market for Personal Protective Equipment in the European Union.
- 2) To identify any remaining bottlenecks in the supply of Personal Protective Equipment in the European Union.
- 3) Take stock of request from the companies on where the European Commission can help.

## **3. Key messages and Speaking points**

The Commission is aware that at the moment, the supply chain for PPE products and in particular of surgical and FFP type masks is under severe strain.

This constraint is due to the exponential growth of the demand, and the restriction of exports of such equipment from China, which used to account for a significant share of the global market.

The Commission is also aware that most of your companies have already taken the relevant steps to either increase your manufacturing capacity, to relocate manufacturing facilities or to diversify suppliers.

We welcome these measures and we would like to encourage you to pursue them.

I am confident that the European industry, which you represent, has the capacity to respond to the current challenge posed by the rapid spread of the virus in the EU.

I also interpret the fact that you have responded positively to my invitation as a sign of your willingness to take on this challenge. My plea to you today would be to act swiftly.

We all see that the wider spread of the virus induces panic. This panic puts additional strain on a supply chain, which is already stretched thin on two fronts:

1. Citizens are rushing to buy PPE (face masks in particular), which creates additional demand alongside your usual supply channels.

2. Some Member States have introduced restrictions on the export of certain types of PPE, which have a direct impact both on the manufacturing but also on the distribution of PPE.

The Commission is committed to deploy all the tools at its disposal to fight against this further spread of panic.

In particular, the Commission is working on guidance for the Member States who intend to adopt measures to mitigate the risks related to the COVID-19 virus crisis. The purpose of the guidance is to recall some relevant legal provisions and common objectives to be pursued also at EU level, in order to support all Member States in their current efforts.

The overall message is that any national measure should respect the spirit of synergy and solidarity which would make the containment of the virus as effective and as extended as possible at both national and cross-border level.

Finally, we are working closely with the Ministries of Health to identify and coordinate the needs for PPE in each Member State and region.

From an industrial perspective, I am convinced that the only way to bring an effective and timely response to the threat is to work together.

I know that a number of Member States have already reached out to the respective PPE economic operators on their territories in order to discuss the need to improve cooperation and the possible support measures.

The reason for calling today's meeting is to complement and further deepen this cooperation and elevate it at EU level.

I know that a number of your companies have manufacturing facilities or distribution centres located in different Member States. Others among you have suppliers located in two or more different Member States. Therefore, I believe that only EU wide solutions could be effective enough to meet the needs of companies such as yours who operate on a wider EU market.

Thus, I look forward to further discussing the points raised in my invitation. I am grateful for the initial elements of response that most of you have provided. I would welcome any further comments on your side with a particular focus on the biggest challenges that you identify today as well as the possible support measures that you would expect from the side of the Commission.

Any other issues:

- a. In addition to the mouth masks: Is the industry aware of any shortages for testing kits?
- b. DG Sante is also looking into launching another joint procurement for ventilators, which could be raised today as well.
- c. The deadline for application of the EU Joint Procurement ends this morning. The representative of DG Sante might be able to provide an update.

#### **4. Defensives on issues raised by the industry in response to the invitation**

*Q: What is the European Commission doing against Member State decisions to restrict the trade of personal protective equipment?*

- The Commission is preparing a guidance document on restriction to export of protective equipment and is in a constructive dialogue with the national authorities in view of ensuring that public health needs in all Member States continue to be addressed.
- The national measures should be assessed under Article 36 of the TFEU, which allows restrictions of the free movement of goods. This provision allows Member States to temporarily restrict, under certain conditions, the sales of products to other Member States, for instance to ensure the protection of health and life of humans. It is for the Member States, within certain limits, to decide the level of protection they wish to afford to their population.
- Additionally, national measures have to be notified under directive 1535/2015.
- In the spirit of EU solidarity, we favour a collective and coordinated approach to meet the health needs of the EU citizens, and in particular to ensure adequate supplies where most needed in the public health services of the Member States.
- The Commission understands the need of Member States to take actions in order to protect public health. At the same time, the Commission supports European-wide solutions that protect EU citizens on an equal footing without unnecessarily hampering the free movement of goods in the internal market and without creating or aggravating shortages or risk of shortages.

*Q: What is the Commission's view on third country measures that restrict the export of personal protective equipment?*

- The European Commission is concerned by any measure that prevents the arrival of vital equipment to the health professionals and patients in need.
- We are monitoring the situation and exploring the possibility to react as necessary.

*Q: What is the Commission doing to address the general disruption in the global supply chains caused by the Corona health crisis?*

- The Commission is carefully monitoring the situation, and gathering intelligence from industry and respective trade associations. This is not only the case for the Personal Protective Equipment industry but all other industries.
- On the basis of the information collected, we will explore the need to adopt possible support measure that would ensure that there is enough appropriate equipment in the EU.
- As such, could we ask that you provide us for precise information on materials and other resources that are in short supply.

*Q: Today, healthcare services and institutions appear much focussed on single-use mouth masks. However, there exists also re-usable mouth protection devices. What is the Commission doing to promote re-usable mouth protection devices.*

- The Commission encourages healthcare services and professionals to consider all appropriate equipment that can help to contain the disease.
- We would be happy to receive ideas on any concrete actions that could be undertaken to raise awareness on the possibility of re-usable mouth protection equipment.

*Q: Around the world, different regulatory frameworks and requirements exist for Personal Protective Equipment. This in turn limits and shapes the global supply and manufacturing base of these PPE products. What measures could be taken to alleviate such burden?*

- The PPE Regulation does not foresee any derogations to the requirements to affix the CE marking, or to any of the other obligations, imposed upon the manufacturers.
- However, the PPE Regulation makes a distinction between formal non-compliances, such as the absence of CE-marking, and more substantive non-compliances. The enforcement of formal non-compliances is organised in such a way that Member States are only required to prohibit the placing on the market once non-compliance persists.
- In this context, we could imagine that national market surveillance authorities may make use of this flexibility in the enforcement of the legal obligations.
- Finally, there are some treaty provision under the TFEU, such as TFEU 114(8), that may allow for adapted measures by the Commission. However, these need to further be investigated.

*Q: What is the Commission doing to promote a multilateral response that ensures the supply of PPE across the world and within the EU? For example, by having an agreed priority list for supply to healthcare professionals?*

- The Commission is supporting 20 EU Member States to jointly procure personal protective equipment for healthcare workers for the care of patients with suspected or confirmed novel coronavirus (COVID-19) under the Joint Procurement Agreement for medical countermeasures.

- By pooling needs and increasing volumes to be procured, the Agreement improves Member States' preparedness, ensures equal treatment, guarantees more balanced prices and shows a high level of solidarity between EU Member States agreeing to share a limited availability of personal protective equipment in the context of the ongoing COVID-19 outbreak.
- It allows for a greater exchange of best practices and pooling of expertise, and ensures equal access to all participating Member States.

## 5. Background

**Please note that the Background section comes straight from the Background section provided for the EPSCO Health Council meeting of last Friday. Therefore, the content of this section is not specifically adapted to the current Teleconference.**

### **Availability of stocks of personal protective equipment (PPE)**

Since the outbreak of the crisis, the Commission has been in continuous contact with manufacturers and distributors of PPE products designed to protect against biological hazards. These include in particular: disposable face masks, re-usable face masks, coveralls, gloves and skin care products. The aim has been to gather intelligence on available stocks, manufacturing capacity and evolution of demand.

On the basis of the information gathered we can conclude that disposable FFP2 and FFP3-type masks, as well as surgical masks are the products where shortage is mostly felt.<sup>1</sup> The supply chains of other PPE product such as protective goggles, gowns or gloves are less impacted as the increase in demand is less drastic. A contributing factor to this discrepancy in the demand between the different types of PPE products lies with the fact that a high number of private citizens have rushed to buy face masks. The unexpected/unusual demand from consumers has thus added on top of the already high demand from the usual supply channels (e.g. healthcare providers, emergency responders etc.).

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<sup>1</sup> FFP-type masks are items of PPE are tight fitting masks, designed to create a facial seal. Designed to filter the air breathed in, the FFP-type masks can serve to protect healthy individuals from becoming infected with the coronavirus, which is mainly spread by means of small droplets in the air.

There are three classes of FFP-type masks:

**Respirator Standard Filter Capacity (removes x% of of all particles that are 0.3 microns or larger)**

FFP1	80%
FFP2	94%
FFP3	99.95%

Conversely, surgical masks fall within the scope of the Regulation Medical Devices. They are loose fitting, covering the nose and mouth and designed for one way protection, to capture bodily fluid leaving the wearer. Thus surgical masks may be used to avoid the further spread of the virus by infected persons but not to protect healthy individuals from becoming infected.

With respect to **production capacity in Europe**, the following trends seem to emerge:

Manufacturers who have been producing PPE under license in China have seen their Chinese sub-contractors **capacity totally requisitioned by the Chinese** authorities at the beginning of February. This has caused temporary restrictions in their respective total manufacturing capacities. The same is applicable to distributors, who have been relying on suppliers with manufacturing facilities in China.

As a result, existing manufacturers have deployed efforts to increase the output of their existing production lines or to open new production lines.

- [REDACTED] has a current production capacity of [REDACTED]. The company has ordered machines and is working to increase its manufacturing capacity to [REDACTED].
- [REDACTED] was historically relying on Chinese sub-contractors for a significant share of its production. Currently, the company is working to launch a manufacturing line in CZ, expected to be operational by May. The expected output capacity of the CZ line would be around [REDACTED]. Furthermore, the company has found a sub-contractor in Israel albeit with lower output capacity ([REDACTED]).
- [REDACTED] has also increased capacity [REDACTED] manufacturing facilities. According to available intel, the company has also launched a production line in [REDACTED] as well.
- [REDACTED] has manufacturing facilities in the [REDACTED] and a distribution centre in [REDACTED]. Following the adoption of the DE restrictive measure, [REDACTED] indicated that it will no longer send shipments to its [REDACTED] in order to avoid them getting blocked. This will however have an impact on the availability of PPE in other regions, potentially including in Northern Italy.

**Existing distributors**, which were historically relying on Chinese sub-contractors have also been looking for new suppliers.

- [REDACTED] is now working with [REDACTED] a manufacturer based in Poland. [REDACTED] seems to currently have significant manufacturing capacity but it's currently facing overwhelming demand.
- [REDACTED] has been working with [REDACTED] but seem to have now also diversified suppliers and is also buying from [REDACTED] based near Milan).

**New entrants** seem to be entering the market. Our initial assessment points to an absence of major regulatory bottlenecks as well as the absence of any major non-regulatory barriers to entry/capacity increase (c.f. Section 4 below for further details). This would explain the emerging trend of new market players, which seem to enter the market.



- Available intel suggests that there has been contacts between the Member States' authorities in BE and IT and textile industry companies in view of the launch of possible new manufacturing lines.
- Similarly, a [REDACTED] has started the production of protective masks at the [REDACTED] manufacturing plant, as part of the HU government's action plan to tackle the virus.
- A new manufacturer of face masks has also started production recently in NO, highly praised by the national authorities.

### **Joint Procurement Agreement**

The overall framework for any joint procurement procedure is the overarching Joint Procurement Agreement (JPA). This is a framework, which lays down common rules for the practical organization of joint procurement procedures of medical countermeasures for cross-border health threats, like diagnostic kits and services, laboratory services, medication, vaccines, antivirals-treatments, medical devices and other goods and services, decontamination kits, masks and protective equipment.

The Agreement adopted in 2014 is so far signed by 25 Member States and the UK. Poland and Finland have not signed. Sweden joined the JPA last Friday, the 28th February 2020.

For non-signatories of the JPA, any participation in future joint procurements is possible but would necessitate becoming signatories of the JPA first. The UK, currently a third party, may not participate in any new procurement procedures

Two procurement procedures are currently ongoing: one for pandemic influenza vaccines and one for personal protective equipment.

#### **Joint procurement for personal protective equipment - 2020**

In line with Council Conclusions of the Health Ministers Council on 13 February, a procurement procedure for personal protective equipment is ongoing under the Joint Procurement Agreement for medical countermeasures.

20 EU MS joined this joint procurement procedure that was launched on 28 February 2020. (Austria, Belgium, Cyprus, Czechia, Germany, Estonia, Spain, Greece, Croatia, Hungary, Ireland, Italy, Luxembourg, Latvia, Malta, the Netherlands, Romania, Slovakia, Sweden and Slovenia. France is not among the MS who expressed interest in the procedure.)

The companies will have until 9 March to submit their offers. The Public Procurement Committee will assess these offers by April and the contracts are expected to be signed in the course of April. [REDACTED] –

#### **Further Joint Procurements**

It is possible to launch further joint procurements, if the need arises.

Concerns about the potential strain on access to medicines were raised in the last months. The press reported on Tuesday 3 March about suspension of exports to the EU

of basic medicines (paracetamol, hormones, and antibiotics) due to delays of active pharmaceutical ingredients from China.

As such, just like with the joint procurement of the personal protective equipment, any additional joint procurements would also be subject to availabilities on the market.

Nonetheless, the mechanism is there and allows for the procurement for medical counter measures for serious cross-border threats to health, including COVID-19.

The Commission has been asking countries to provide information on any additional needs already, but could specifically enquire with Member States about the need to begin additional joint procurements. A particular need could be for example on respiratory equipment for treatment of coronavirus patients.

### **Regulatory/non regulatory bottlenecks**

DG GROW assessed whether there may be any regulatory obstacles to increase in PPE production.

Their conclusion is that the possible increase of production of PPE would not lead to an increase in the administrative burden for the manufacturers. In particular, in the case of manufacturers that are already producing such items of PPE, one could expect that no particular impact on their ability to ramp up the production would stem from the regulatory requirements. Also there wouldn't seem to be no significant regulatory barriers/bottlenecks to the possible entry of new prospective manufacturers of PPE, which may be foreseen at this stage.

To our knowledge there are no major non-regulatory barriers to entry/capacity increase.

### **EU wide export restrictions under Regulation 2015/479**

By Regulation 2015/479, the Commission may adopt measures, such as quantitative restriction on exports, in order to prevent or remedy critical situations caused by a shortage of essential products on the EU market and where Union interest calls for immediate intervention.

This Regulation was only exceptionally used in the 70s/80s in order to restrict exports of steel scrap, but since then the situation has changed, the EU does no longer apply quantitative restrictions and the EU usually opposes export restrictions in the international trade context. In any event, the Regulation was never used in order to address considerations of public health, including in the context of the SARS outbreak.

████████████████████ in order to enquire whether this Regulation could be used to restrict exports of protective equipment, and we believe it could indeed be used in order to address the exceptional current circumstances.

**From a procedural point of view**, Regulation 2015/479 offers two possibilities: measures (in the form of a Commission decision under a normal procedure or urgency measures).

- Under a normal procedure option, the Commission can adopt measures under examination procedure, after having consulted MS. The Commission proposal should be submitted to MSs two weeks in advance of the Consultation Committee. If the act concerns the protection of health or safety of humans, a positive QMV of MS is required<sup>2</sup>.
- In case of emergency (Article 5), the Commission can, on its own initiative or at the request of a Member State, take restrictive measures for a limited time period, by invoking an urgency procedure. These measures can only take the form of subjecting exports to a prior authorisation<sup>3</sup>. This is therefore not an export ban but an export authorisation. They can be adopted by the Commission before consulting MSs. The duration of such emergency measures is however limited to a maximum period of 6 weeks, during which the Commission should decide whether to adopt appropriate measures as described above under a normal procedure. If the emergency procedure is taken at the request of the MS(s), the Commission should decide within five working days. No time limits are set out in the Regulation in case of the own-initiative action.

**In terms of substance**, the Commission act should demonstrate that there is, at EU level, the existence or the possibility of a critical situation it caused by a shortage of products. The justification could follow the one made [REDACTED] in its own export restriction decision adopted on the 4 March 2020, albeit at an overall EU level: an indication of an expected sudden increase of the demand for protective products, which could only be satisfied if the EU production remains domestically available, considering export restrictions applied by other third countries.

The regulation would have to identify the products subject to the authorisation / restriction with a sufficient level of precision to allow the Member States and their customs offices to implement it.

**From a political point of view**, the decision to restrict import at EU level is a balance of interest between public health considerations and avoiding a patchwork of different measures taken by individual MS. If a political decision is taken that the Commission should provide for a framework to restrict EU exports in this particular case, there are arguments to act both at the request of the MS or ex-officio under the urgency procedure. In communication terms, it would be important to insist on the terminology (ie. making exports of protective equipment subject to a prior authorisation vs an export ban). We would suggest to leave the modalities of granting these authorisations to MSs, so they can still modulate the measures in terms of specific products (e.g. the French measures covers only face masks while the German measure covers a wider range of protective equipment) or individual situations (i.e. domestic spread of the virus).

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<sup>2</sup> Regulation 182/2011, Article 5(4)a.

<sup>3</sup> The Commission should specify the modalities of the authorisation.

## ANNEX I: Additional information received in response to Commissioner Breton's questions

### Question 1: What steps have you undertaken to increase the supply of personal protective equipment?

[REDACTED]

- [REDACTED] is deeply engaged in the effort to protect and allocate scarce PPE.

[REDACTED]

- Increased capacity by 50% on disposable face masks (FFP).

[REDACTED]

- [REDACTED] manufactures Corona masks and has the possibility to rapidly increase the production if orders increase. The most sales are in Asia. Not many enquires come from within the EU.

[REDACTED]

- [REDACTED] is not directly involved in the manufacturing of disposable facemasks, but more on protective garments including coveralls [REDACTED]
- In January, [REDACTED] to create both upside capacity as well as multi-source solutions.

[REDACTED]

- Due to the export restrictions out of China, [REDACTED] is working on replacement products called [REDACTED] that will be produced by March 25–30, 2020.
- They will contain a revolutionary layer of fabric with [REDACTED] which deactivates all viruses and bacteria with a 99.9% efficiency.
- Moreover, these products can be reused and they will not become biohazardous material.

[REDACTED]

- Since the end of January, the production of half facemasks has been doubled. Securing the sourcing of their components and increasing the staff for the production of the products are the main concerns for the company.

[REDACTED]

- They only manufacture chemical suits. The company tries to increase the production, to deliver in the field of disposal (e.g. asbestos and other hazardous waste) restoration and cleaning.

[REDACTED]

- Focus on the hospital market and more specific the CSSD (Central Sterilization Service/Supply Department) in the hospitals.
- Increase in demand for masks FFP1+FFP2 from Dutch hospitals.

**Question 2: What are the bottlenecks, including of a regulatory nature, that restrict company's ability to increase the supply of adequate personal protective equipment?**

[REDACTED]

- There are serious bottlenecks to supply from Asia.
- The most urgent and impactful bottlenecks are the new orders published in France and Germany that restrict the normal supply of PPE within the EU.

[REDACTED]

[REDACTED]

- Restrictions by Germany make it impossible to deliver FFP2 and FFP3 products within the EU.

[REDACTED]

- Reusable masks: WHO and other respected organisations have gone out with information only stating that N95/FFP2/3 masks protect. Since [REDACTED] manufactures masks conforming to much higher standards (EN12942 TM3P), people responsible for purchasing safety equipment, do not see our products as an option.

[REDACTED]

- PPE regulations around the world have distinct differences, which shape the makeup of our global capacity.

[REDACTED]

- Mask production capacities and mask stock in China are under restriction to be exported out of China [REDACTED] is working on replacement products, which will contain a revolutionary layer of fabric with [REDACTED] which deactivates all viruses and bacteria with a 99.9% efficiency.

[REDACTED]

- The biggest bottle neck is the amount production staff connected to the production of half masks. Over time the component could be an issue.

[REDACTED]

- Ban of exports is not clear if it is also valid for reusable suits.

**Question 3: What specific support measures could the European Commission put in place to support the various actors along the supply chain of personal protective equipment?**

[REDACTED]

- Urgently and quickly prevail upon the health ministries across Europe, and particularly in Germany and France, to rescind their orders restricting trade within the EU.
- Develop a cohesive joint multilateral European Union response to safeguard the supply of healthcare institutions across Europe. This would include deployment of a robust and effective campaign against misuse and unreasonable purchases, which is among the root causes of the current supply shortages.

[REDACTED]

- Apart from the belief that export restrictions within Europe do not help we do not see any specific steps.

[REDACTED]

- Commission to inform all purchasing bodies the ladder in which respiratory protection equipment is classified and also publicise information about the cost savings of going reusable.

[REDACTED]

- The Commission to help provide recognition of equivalent performance standards.

- The Commission to prioritise demand among member states according to the need.
- Strategic collaboration between the EU and key industry players for future pandemic crises.

[REDACTED]

- The Commission to urgently and quickly prevail upon the health ministries across Europe, and particularly in France, to rescind their orders restricting trade within the EU.

**Question 4: Is the increase in demand channelled via your usual commercial channels or are you also being solicited by new prospective clients?**

[REDACTED]

- [REDACTED] blocked access to our PPE from all new customers. Historic customers are very carefully allocated quantities at a ratio of their historic purchases.

[REDACTED]

- The demand is overwhelming – we have reserved a part of our capacity for the health sector. A central distribution center in Europe would surely help.

[REDACTED]

- We are currently building new production lines to support EU, and taking different approaches to protect our staff. In regards to new clients, we have nearly no clients within the EU, almost everything we manufacture goes to Asia.

[REDACTED]

- Prioritisation of orders and work with government agencies around the world to finalise the response to the Commissions recent tender for PPE.

[REDACTED]

- [REDACTED] only supplies the existing and approved distributors.

[REDACTED]

- Main reason of increase of demand was that other suppliers (e.g. [REDACTED]) were not able to do so in the Netherlands.

## ANNEX II: List of confirmed participants

### Video-conference/conference call with CEO's on State of play of the PPE supply chain in the context of the coronavirus threat – 10/3 at 11 am – Salle S5 BERL

[REDACTED] (Belgium) - [REDACTED], Chief Commercial Officer EMEA / APAC

[REDACTED] (Germany) - [REDACTED]

[REDACTED] (The Netherlands) - [REDACTED] Group President [REDACTED]

[REDACTED] (Denmark) - [REDACTED] CEO

[REDACTED] (Belgium) - [REDACTED] **Vice President**, Government Relations

[REDACTED] (France), [REDACTED] Directeur des Operations EMEA

[REDACTED] (USA) - [REDACTED] Global Business Leader (USA)

[REDACTED] (France) – Vice-President

[REDACTED] (Norway) - [REDACTED], Supply Chain Manager

[REDACTED] France & Belgium) – [REDACTED], Directeur de Division

[REDACTED] (Italy), [REDACTED], CEO

[REDACTED] (Belgium) – [REDACTED], Head of Corporate Corporations

[REDACTED] (Sweden) – [REDACTED], Sales Manager Central Europe

[REDACTED] (Germany) – [REDACTED] Joint Managing Directors

[REDACTED] (Czech Republic) – Roman Zima, CEO

### CABINET Members + DG

[REDACTED] (Cabinet Kyriakides) +

[REDACTED] (Cabinet Janez LENARČIČ) + [REDACTED] (DG ECHO)

DG GROW : [REDACTED]