Kontroll av subcontractors

Jukka Salo, Flygteknisk Inspektör

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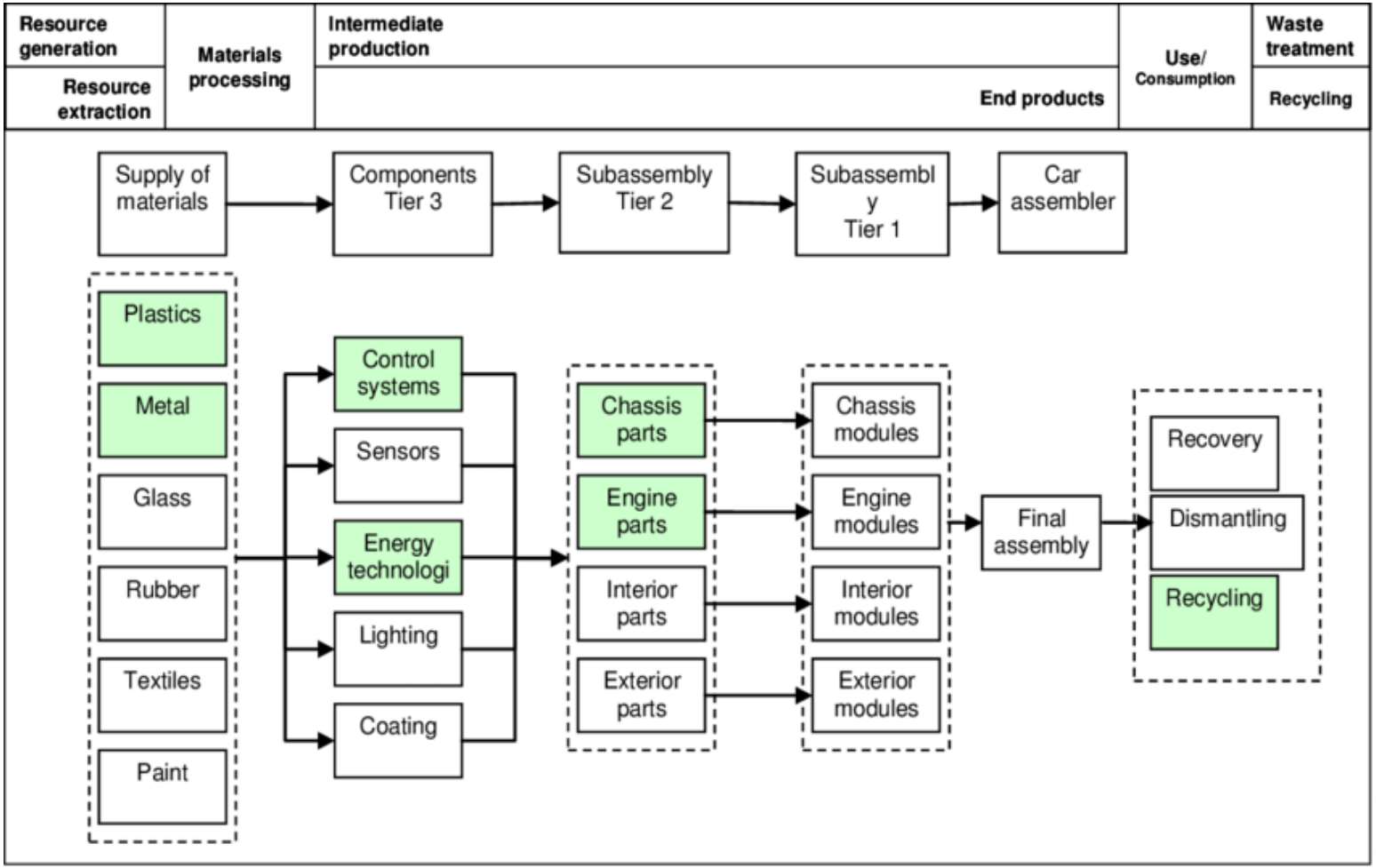

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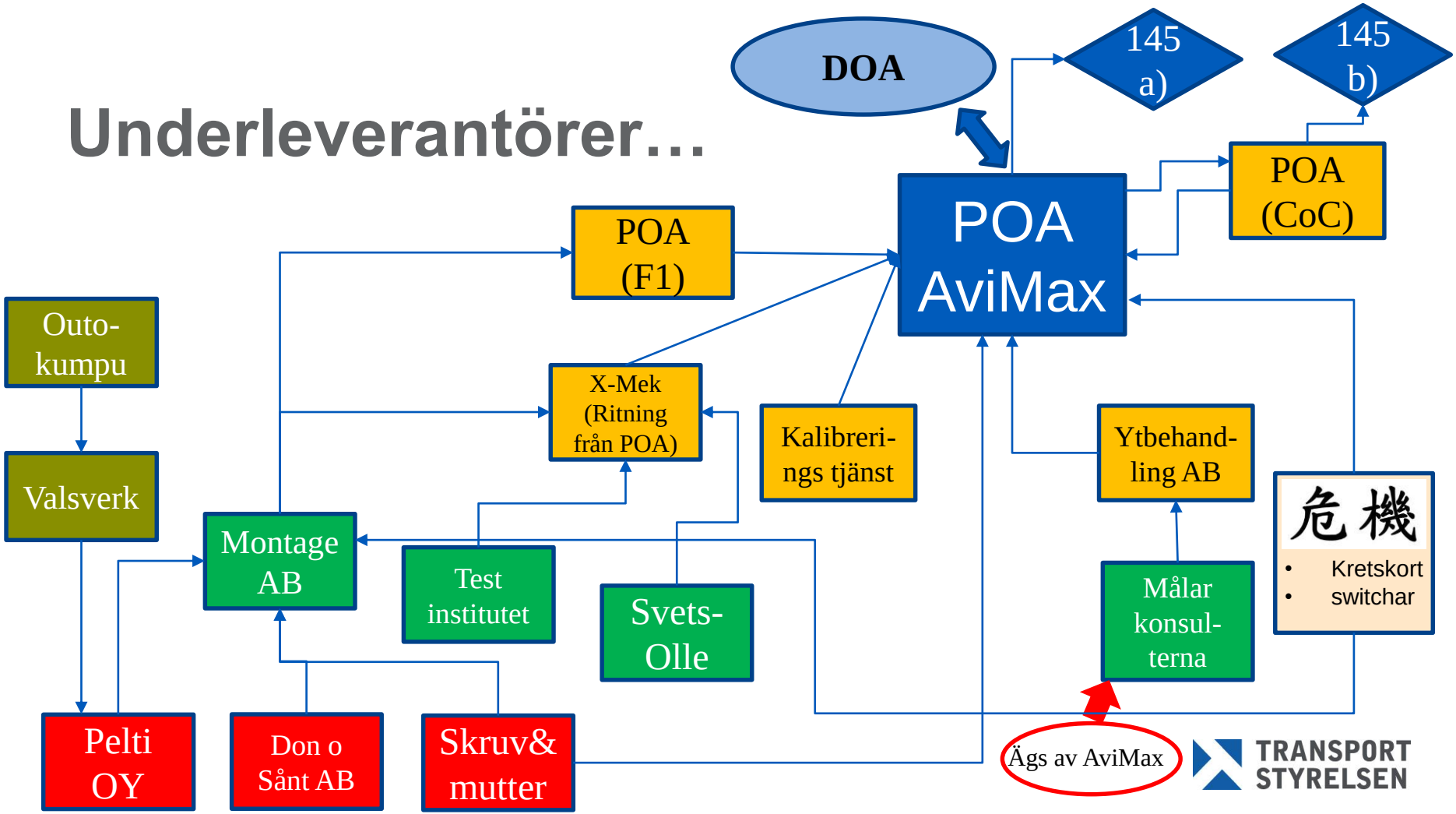
Underleverantörer…



Dilemma…

- *“We use 150 suppliers … from some of them we are ordering 75 buttons a year, some of them 25 special embroidery yarns. With that size orders, we can’t go in and ask things about their business, they would say, ‘Why? Go away, you are wasting our time’.”*

Travelling Textiles

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Vad säger regelverket…

21.A.139 Quality System

(ii) vendor and subcontractor assessment audit and control;

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GM No 2 to 21.A.139(a) Quality System - Conformity of supplied parts or appliances

- …the quality system needs an organisational structure and procedures to adequately control suppliers.
- Control can be based upon use of the following techniques;

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GM No 2 to 21.A.139(a) Quality System - Conformity of supplied parts or appliances

- **Qualification and auditing** of supplier’s quality system
- **Evaluation of suppliers capability** in performing all manufacturing activities, inspections and tests necessary
- **first article inspection**, including destruction if necessary,
- **incoming inspections and test**s of supplied parts or appliances

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GM No 2 to 21.A.139(a) Quality System - Conformity of supplied parts or appliances

- **identification of incoming documentation** and data relevant to the showing of conformity to be included in the certification documents,
- **a vendor rating system**
- **any additional work, tests or inspection** which may be needed for parts or appliances which are to be delivered as spare parts and which are not subjected to the checks normally provided by subsequent production or inspection stages.

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GM No 2 to 21.A.139(a) Quality System - Conformity of supplied parts or appliances

The POA holder may rely on inspection/tests performed by supplier if it can establish that:

- personnel responsible in charge of these tasks satisfy the competency standards of the POA quality system,
- quality measurements are clearly identified,
- the records or reports showing evidence of conformity are available for review and audit.

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GM No 2 to 21.A.139(a) Quality System - Conformity of supplied parts or appliances

- For the purpose of showing conformity, a POA holder can rely upon documentation for parts or appliances released under a suppliers 21.A.163 privileges (POA).
- A supplier who does not hold a POA is considered as a sub-contractor under the direct control of the POA quality system.
- The POA holder retains direct responsibility for inspections/tests carried out either at its own facilities or at suppliers facilities

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21.A.157 Investigations

- The arrangements should allow the competent authority to make investigations that include the complete production organisation including **partners, sub-contractors and suppliers**, whether they are in the State of the applicant or not.
- **…visits not only at the organisations own facilities but also at subcontractors, partners or suppliers.**

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21.A.159 Duration and continued validity

(a) A production organisation approval shall be issued for an unlimited duration. It shall remain valid unless:

- 2. the competent authority is prevented by the holder or any of its **partners or subcontractors** to perform the investigations in accordance with point 21.A.157; or

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21.A.165 Obligations of the holder

The holder of a production organisation approval shall:

- establish an archiving system incorporating requirements imposed on **its partners, suppliers and subcontractors**, ensuring conservation of the data used to justify conformity of the products, parts or appliances. Such data shall be held at the disposal of the competent authority and be retained in order to provide the information necessary to ensure the continuing airworthiness of the products, parts or appliances;

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GM 21.A.165(d) and (h) Obligations of the holder – Recording and archiving system

- Ensure that the recording and record-keeping system used by the **partners, supplier and subcontractors** meet the objective of conformity of the product, part or appliance with the same level of confidence as for their own manufacture.
- They should define in each case who is to retain the record data (organisation or partner, supplier or sub-contractor). They should also define method for surveillance of the recording/record keeping system of the **partners, suppliers or sub-contractors**

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GM No 3 to 21.B.220(c) Procedures for investigation – POA applications received from organisations with facilities/partners/ suppliers/sub-contractors located in a third country

- 3) in accordance with competent authority procedure, assess the necessary level of surveillance to be exercised by the production organisation on **partners / suppliers / sub-contractors** and check the audit plan of the production organisation against this level.

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Vilken nivå skall man ha kontroll på?

Det viktiga är att POA; (Beskrivet i POE)

- Känner att man har kontrollen, som om det var in-house
- Har ett system för kontrollen
- Systemet medger flexibilitet
- Systemet bygger på en klassning som följd av
  -komplexiteten av underleverantörens leverans
  -underleverantörens organisation
- Säkrar att underleverantören kan auditeras
- I SMS tänk – riskanalyser vid byte/ny underleverantör

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NPA 2019-05, 21.A.139 c) 3

- (3) establish, implement and maintain a safety risk management process that includes:
- (i) hazard identification **in all domains of the organisation and its production activities**, resulting from analysis of the occurrences collected according to point 21.A.3A; and
- (ii) safety risk assessment and mitigation;

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NI vet bäst vad som är VIKTIGT för att säkra kvalitén i ER produkt!

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Five tips for Conducting a Supplier Audit

- For pharmaceutical manufacturers, there are primarily **two reasons** to conduct a supplier audit: the quality management system **(QMS) requires it, or there's a problem.**
- Conducting supplier audits is an essential and well-established tool for identifying, eliminating and preventing quality problems in a supplier's products, processes or management system before the problems spread.

Källa: Pharma Manufacturing

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One: REVIEW BEFORE YOU GO

- review both parties' expectations and responsibilities as laid out in the quality agreement.
- past audit reports,
- company history using the supplier's product,
- current product specification,
- importance of the product to the company,
- whether the product has ever failed,
- alternative manufacturers qualified,

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REVIEW BEFORE YOU GO

- interviews with in-house personnel about the supplier and the product.
- deviations and non-conformances,
- regulatory certifications,
- corrective actions,
- change controls,
- return rates,
- raw material chain of custody,
- batching process
- production records,
- complaint history.

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Two: CONSIDER THE DIGITAL FOOTPRINT

- Beyond the typically prescribed audit-preparation tasks, the audit team should probe the supplier’s active and passive digital footprint, including social media channels and online reviews.

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Three: DON'T UNDERESTIMATE CUSTOMER COMPLAINTS

- During an audit, it’s important that you ask to see the customer complaints on products you currently purchase from the supplier.
- A pattern of missing ship dates often indicates a failing manufacturing process is affecting the supplier’s quality.

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Four: BE AWARE OF SUPPLIERS OUTSOURCING

- As companies add more vendors, materials and components to their business, maintaining visibility throughout the supply chain becomes more challenging.
- A supplier having its own suppliers adds another level that blurs visibility in a supplier’s activities.
- Before and during supplier audits, you should review the chain of custody documents.
- If a supplier is outsourcing parts of its process, it’s important that you are notified of that fact and that you ensure the supplier has quality agreements with organizations from which the supplier sources.
- In general, suppliers should be willing to reveal their subcontractors

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Five: STAY VIGILANT AND ON TRACK

- Knowing the right questions to ask is a powerful component during an audit, and as such, the auditor shouldn't be afraid to ask bold and even uncomfortable questions during an audit. Such questions might be:
  "What's your worst deviation this year?"
  "Can you show me a failure and how you fixed it?"
  "What aren't you showing me?"
- The supplier should feel that, despite the uncomfortable questions or observations, you're there to help to identify process, training or documentation issues affecting the supplier's quality metrics and help guide the supplier to an improved state of quality.

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STAY VIGILANT AND ON TRACK

- Not every auditee may be forthcoming and transparent.
- If it seems like a supplier is being evasive during an audit, they probably are.
- If the supplier is not providing clear answers or certain quality-related documents, it may be a deliberate attempt to hide quality issues.
- If the supplier is aggressively leading you down certain paths during a tour, they may be trying to divert your attention from process problems like deviations, out-of-specification or failed lots.

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FINALY

- Remember that, when it comes to conducting audits, **you're working with people** and not just assessing processes and documents. While it's important to review these things during an audit, it's equally important to actively listen to the supplier, read and understand situations, and stay focused on achieving objectives.

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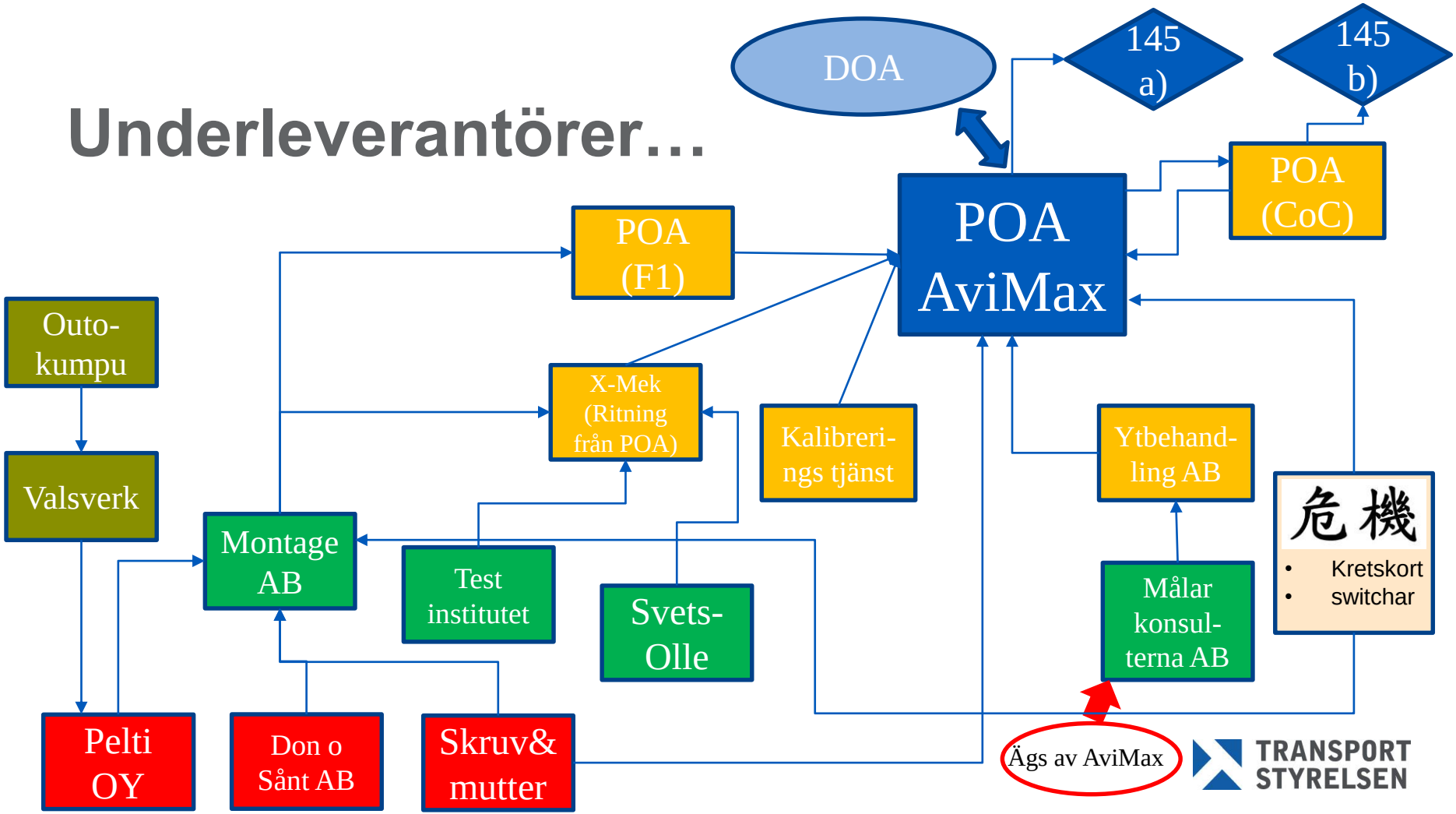
Underleverantörer…



Frågor?

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