EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Health, Consumers and Reference Materials
Chemical Safety and Alternative Methods Unit
EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)

Summary Record
Joint PARERE-ESTAF Meeting
28-29 November 2017, Ispra, Italy

The joint meeting of PARERE and ESTAF was held on 28-29 November 2017 (the agenda is included in Annex I).

Welcome and Introductory Session

Highlights from the past year were presented by EURL ECVAM and these included:

- communication, dissemination and educational activities undertaken since the last meeting
- the recently published recommendation on the use of non-animal approaches for skin sensitisation testing
- the IATA case studies project under the OCED Working Party on Hazard Assessment and activities related to the Strategy Document on Toxicokinetics
- updates on the outcome of the 29th meeting of the Working Group of National Coordinators of the OECD Test Guidelines Programme
- the call to EU-NETVAL members for participation in the validation study of *in vitro* methods for the detection of thyroid disruptors
- the draft of the OECD Guidance Document on Good *In Vitro* Method Practices (GIVIMP)
- the involvement of EURL ECVAM in the GHS classification criteria for non-animal methods
- the recent development of VICH guidelines for the reduction of animal tests for quality control of veterinary vaccines
- the recent translated version in Portuguese of the EURL ECVAM Search Guide

More details are available in the EURL ECVAM 2017 Status Report.

Introduction to workshop: Better knowledge sharing for advancing alternative approaches

Effective knowledge sharing is fundamental to achieving 3Rs (replacement, reduction, refinement) impact in every field where animals are used for scientific purposes. During 2016, the JRC's EURL ECVAM conducted a study to review the availability of 3Rs related knowledge and how it is currently

shared between sources and end-users. The key findings of the study[1] were presented at the European Commission's conference on "Non-animal Approaches – the way forward" (Dec 2016)[2] and are as follows:

- Existing knowledge sources need to be better **coordinated**. There is a vast amount of 3Rs relevant content, but it needs to be better managed. This could be achieved, for example, through better networking between leading knowledge providers.

- The **outreach** of existing knowledge sources need to be greater to increase the beneficiaries and to enhance translation across sectors and communities.

- **Education and training** opportunities relating to the 3Rs need to be increased and improved and aimed primarily at 3 key target groups: school-goers (teens), undergraduates and young professionals. More teaching resources should also be made freely available for educators.

- How 3Rs knowledge is **communicated** and shared needs to be better considered. Although there are many examples of good practice, in general people require more guidance on how to access knowledge and more trust in the content.

The purpose of this workshop was to build on the results of this study by exploring the status of 3Rs relevant knowledge sources and sharing practices in three specific areas, namely:

- **Research**: basic and applied research in academia and industry

- **Education and Training**: teaching of 3Rs in schools, universities and professional environments

- **Regulatory Testing**: toxicological hazard assessment of chemicals across industrial sectors

The workshop included the exploration of:

- Success stories – notable initiatives and solutions which have had impact; what are the ingredients for success?

- Primary channels of knowledge sharing – common means of knowledge sharing today.

- Opportunities and proposed solutions for better knowledge sharing.

Experts in each of the three areas were invited to give plenary talks to inform the discussions which took place in breakout groups dedicated to each of the three areas. The outcome of these groups is summarised below.

Research

The research breakout group was underpinned by the understanding that basic research operates under very different principles to regulatory and toxicology/safety testing science. The motivations and indeed the goals of basic researchers may differ significantly from those of regulators and educators and this has to be taken into account. In addition, it was acknowledged that scientists involved in basic research are unlikely to have experience or knowhow of regulation, validation, IATA, or of the OECD test guidelines. Consequently, there are opportunities to bridge gaps which

[1] JRC Science for Policy Report from Holley et al. (2016) Accelerating progress in the Replacement, Reduction and Refinement of animal testing through better knowledge sharing.

[2] http://ec.europa.eu/environment/chemicals/lab_animals/3r/scientific_conference_non_animal_approaches_en.htm

should be considered in reaching out to develop and share knowledge sources with all stakeholder groups. However, it is incredibly important to reach academic researchers, given the data shown in the plenary sessions that indicated that animal used in basic research remains the biggest use of animals for scientific purposes[3]. Furthermore, there is an increasing list of retractions of scientific papers on account of animal welfare issues (http://retractionwatch.com/?s=animal).

Case studies used in the plenary session included an example of how to develop "the best stem-cell derived liver model" as a vital part of knowledge sharing; clearly demonstrating the scientific and biological relevance of, and applications for, humanised *in vitro* models. Although perfect liver models from human cells do not yet exist, models that allow specific toxicity assessments are increasingly being improved, such that there is pharmaceutical interest to work with academic researchers and biotechnologists to further develop 3D cell/organ models for drug discovery. By extension such models, if validated, will have a place in toxicological screening. At a different level, the OECD initiatives, IATA and AOP, can also be considered as success stories, but would need to be clearly directed at basic research applications, and it was felt that this may be more efficient through targeted, face-to-face conference presentations and possibly via **disease-focused workshops** for researchers from basic to clinical disciplines, where a 3Rs focus or dedicated session on non-animal methods could be included. In some domains this has been driven and supported by the EU Directive on animal use for scientific purposes. Better reporting and institutional management of ethical issues promote improved practice.

Publication of written case studies and their use as knowledge sources was considered as an important element in engaging the basic research community. Dedicated journals such as, but not limited to, Nature Protocols, are working to highlight the fundamental importance of ensuring that research is reliable, robust and reproducible. This is a step towards discovery plus validation and could be used beyond this, to inform regulators. Selected case studies could be illustrative of more mechanistic approaches that show how non-animal methods can offer improvements over *in vivo* models, and all should be based on solid, scientific evidence of the successes of *in vitro* method application, demonstrating that *in vitro* (and other non-animal) methods are often less expensive, can provide results faster or even provide better answers to specific questions than *in vivo* models can. There was an appreciation within the breakout group that *in vitro* methods may not always outperform animal models, and that the usefulness of animal models in certain disease areas should not be neglected in order to build trust, ensure transparency and create knowledge bridges spanning *in vitro* (non-animal) and *in vivo* (animal) methods. However, whilst it may be possible to identify 'good' examples of animal models, their weaknesses should also be acknowledged and frank discussion of their continued advantage/applicability is necessary. It is not sufficient to perpetuate the use of an animal model because of the value of the historical data generated from it. In contrast, it may be advantageous to use the example of the ban on the use of animals in cosmetics testing in Europe. For many this is seen as a successful precedent for replacing animals, and is well understood by many stakeholder groups, including MEPs, NGOs, regulators and scientists.

Communication is key for knowledge sharing to all groups and should be developed into a network that reaches beyond basic researchers. Efforts to improve 3Rs knowledge sharing in research must reach beyond universities and basic researchers and the overall consensus was that it should include journal editors, publishers, funders, clinical researchers, regulators, politicians, and society at large. Promoting the 3Rs in basic research from the viewpoint of making public health more cost-effective and public-funded research more impactful may have more traction than the ethical arguments against animal use, and may better engage the wider society, including politicians. For basic research into a particular disease, it was considered that direct communication with, and input from, the

[3]Seventh Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0859&from=EN

specific patient groups, alongside the relevant researchers, would be welcome. Such conversations may be possible via presentation or attendance at specific disease-focused conferences, where the advantages of the non-animal methods, beyond any ethical reasoning, could be explored more fully with the relevant stakeholders. Similarly, a structured debate could be facilitated by social media including blogs which are widely used by patient groups.

Currently, the main communication channels for reaching basic researchers are through specific funding calls or in face-to-face training on the 3Rs and this could be widened; the **creation of data-sharing platforms** was proposed as one example of how to engage disparate groups. If the deposition of non-animal methods in a searchable database[4] could be encouraged, this may facilitate the more widespread use of non-animal methods, enable application beyond the method's original intention and could be used by the National Committees, and more locally by Research Ethics Committees along with Animal Welfare Boards (AWB) institutionally, as a resource for project evaluators to discover non-animal methods and to appreciate the breadth of their potential applications. Thus, the institutional Ethics Committees and also AWBs could act together as an important conduit for raising awareness of new methods, and that extension of the AWB to include experts in non-animal methods (the **3Rs ambassadors**) would be an advantage.

It was felt that basic researchers are likely to be open to new methods, but may adhere to established techniques in their labs, and it could be very useful to **incentivise the wider use of 3Rs** and non-animal methods. This could take the form of formal prizes, or recognition of researchers who make significant 3Rs advances- currently a few of these exist, including NC3Rs, EPAA, Lush, but expansion of their remit may help to engage more basic researchers.

It was strongly recommended that **communication networks are open and inclusive** and are composed of experts in *in vivo* and *in vitro* science in order to facilitate frank and open discussions that acknowledge the failures and successes of both approaches. The breakout session explored how knowledge sharing is more than access to information (although this is important[5]) but increased access to information needs to result in **increased confidence**. Various levels of confidence were discussed, with the overall message that increased confidence in the utility of the non-animal methods and their ability to produce appropriate, powerful data are likely to enhance the uptake of the non-animal methods in basic research. Demonstrative reproducibility of non-animal methods is crucial here and may require global harmonisation of basic research methods, in a manner similar to validation. Researchers using non-animal methods need to feel encouraged to reach out beyond the 'niche' alternative journals (such as Altex) to enhance their visibility beyond the non-animal field, and this may require a change of mindset of journal editors and reviewers to be more accepting and less judgemental of non-animal methods. In fact, the focus should be put on the research using animals, and when submitting new work the authors should justify why such study would not be possible using alternatives, as an extension of the ARRIVE guidelines. It was thought that the Directive 2010/63/EU may be able to provide a framework to share information on alternative methods that arise from independent analyses of the JRC, and are disseminated to basic researchers who may not be aware of such advances, through specific training modules of ETPLAS, for example.

Funding agencies could play a pivotal role in facilitating 3Rs research, as it was recognised that for basic researchers, the motivation to change to non-animal methods could be strongly influenced by availability of funding (ring-fenced for non-animal projects/programmes of work). However, this goes beyond funding agencies in isolation, and would require co-ordinated efforts from the funding agencies together with the competent authorities, research institutions, publishers, and institutional ethics review boards (each can be used to increase awareness of 3Rs research). In terms of

[4]Please check the Inventory of the 3Rs knowledge sources.

[5]JRC Science for Policy Report from Holley et al. (2016) Accelerating progress in the Replacement, Reduction and Refinement of animal testing through better knowledge sharing.

increasing awareness, the possible role of expert advisors and **3Rs ambassadors** (such as is expected by NC3Rs grant holders in the UK) was explored. It was envisaged that 3Rs ambassadors would act at local levels, partaking in 3Rs training, providing informed input on alternative, non-animal methods during project review by ethical committees, understanding IATA and OECD TG, and disseminating knowledge of alternative methods and refined approaches more widely within the research environment.

Education and Training

Education and training are fundamental to driving progress in the development and uptake of the 3Rs. However, the current provision is not well defined and there are apparent differences in the levels of coverage and content between and within the Member States (MS). There are many opportunities to improve the delivery and access to 3Rs relevant education and training as discussed by the working group along with the potential benefits and challenges.

Bringing the 3Rs more into the public field of vision is certainly important for driving change, and addressing more general education is a way to do this, but how can this be achieved? Education falls under Member State competence as defined by the TFEU[6] (Treaty of the Functioning of the European Union). However Article 6 of the TFEU also states "*The Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States. The areas of such action shall, at European level, be: (..)(e) education, vocational training, youth and sport;"*.

A **top-down** and **bottom-up approach** could be conducted in parallel in a harmonised way to avoid overlapping efforts and a waste of scarce resources. From the top-down perspective, it is important to understand how the 3Rs could fit into the education system in each MS, and work with individual ministries for education and research to have this discussion. The bottom-up approach would be trying to work with the educators at the chalk-face, so to speak, the teachers in the schools and universities who could envisage ways to bring the 3Rs into their lessons (biology/ chemistry as well as philosophy/ethics). Educators are busy professionals and there would need to be a concerted effort to provide the time and resources for the training necessary to deliver lessons in this area. It is important of course to consider here the different levels and obstacles in school and university.

In any case **a network of educators**, across education levels (professional, university and high school) and within each MS, who could share ideas and resources for 3Rs, would be beneficial. In terms of **providing resources for educators**, a repository would be a good support, where teachers/educators could go to search for and download ready-made resources, which could be delivered directly or tailored to suit the particular audience. Resources could be for example i) teaching slide-packages in different languages for different audiences, ii) online courses/webinars to watch together with the educator iii) videos or even, iv) a "3Rs Bus" which comes to the schools/universities on request. Such repositories, with search and filter functions, already exist for teachers in other subject areas and are highly popular (for example, https://www.teachitscience.co.uk/ and https://www.tes.com/teaching-resources). The ideal situation would be to plug into existing repositories for 3Rs teaching material.

As a starting point, **a review of education and training resources with 3Rs relevance** could indicate key providers who could potentially participate in the establishment of a 3Rs education and training repository. Making the theme of the 3Rs a shared investment between educators from a range of backgrounds would be an ideal situation, however this may require incentives. **Motivations or incentives** could be the desire for better science, interest in new technologies, the need to stay up

[6] http://eur-lex.europa.eu/resource.html?uri=cellar:2bf140bf-a3f8-4ab2-b506-fd71826e6da6.0023.02/DOC_2&format=PDF

to date for employment prospects, credits for university courses, or, more simply, curiosity and the thirst for new knowledge.

As refinement and replacement approaches and technologies increase, so could the awareness of them, possibly precipitating the much-needed mind-shift necessary to promote their uptake and use. How to bring the 3Rs into the state school system is certainly a conversation worth having and **pilot projects** could be run for example in MS which gave the most support to the European Citizen Initiative "Stop Vivisection"[7]. Identifying the key actors who could initiate this dialogue and would be the next step if this were to be considered a viable route.

The benefits to teach the 3Rs at **high school level** are many: students are exposed to the 3Rs at a very young age and it should grow with them. A successful initiative which was given as an example is "Der Blaue Hund", which is an interactive program developed by practical veterinarians, paediatricians, ethologists, psychologists, educators and employees of the Art Academy Ghent which teaches children how to behave towards dogs. Aimed at very young children, it could be taken as a starting point to develop materials for this young audience.

At **university level**, it is apparent that there should be greater awareness of the 3Rs, particularly for those students following an undergraduate life science course. Exposure to the concept of the 3Rs even at this stage could not only furnish the next generation of regulators, research scientists and risk assessors with the skills to promote alternatives, but also will encourage early career scientists to intelligently question the validity of scientific knowledge which is based on the animal model.

Educating the professionals and teaching the regulators is crucial. Professionals (e.g. for toxicologists, the European Register Toxicologist-ERT) must provide proof of training to achieve or keep the qualification, this also holds for other fields of science and ethics. Thus education and training on all 3Rs should also be included in the continuous education courses in each national professional program. Regulators need to be informed about the role and impact of alternatives. The Joint Research Centre could play a crucial role in coordinating this knowledge, with the aims of sharing experience of using scientific evidence for policy making, providing information and material as well as a hub to share information, and not only for professionals but also for people from a variety of backgrounds.

Ultimately, **there needs to be a strong economic support for any education and training initiatives**, and this could also come from the private sector in addition to public funding. Involvement of key networks in knowledge sharing ventures with educators could be explored. Experts from industry could have ambassadorial roles in this context, with the potential for mutual benefits. Further dissemination could be implemented during open days at **primary** and **secondary schools**, as well as promoting and funding grants for best projects even through European institutions like the European Committee of the Regions[8].

Regulatory Testing

Knowledge sharing in the area of alternative methods and regulatory testing already takes place through for example symposia, conferences and publications. However, it is hard to keep track of all new developments and there are still significant knowledge gaps identified and much scope for improvement of knowledge sharing. Knowledge referred to in this context was understood to concern methods, strategies, success stories, interpretation criteria and possibly further elements to be explored and determined. As a result there is insufficient application or even reflection on the appropriate use of alternative approaches to animal testing, within the regulatory context of diverse sectors.

[7] http://www.stopvivisection.eu/
[8] http://cor.europa.eu/en/Pages/home.aspx

A need was identified in particular for regulators (e.g., legislators, higher management, risk assessors in Member States, European Agencies or committees) on the state of science through **education and training**, in order to increase general awareness and perspectives for future use of new approach methods (NAMs), and to allow regulators to engage with new alternative method developments. **All risk assessors should receive training on the available methods and strategies.** A good example of available training on the experimental aspects of alternative methods are the courses given by CAAT Academy (now Altertox Academy) or by EU-NETVAL. However, training should not only be limited to the knowledge of the test, but clarity should be additionally given on strategies/tiered approaches applicable within each sector.

Knowledge sharing of alternative methods by means of **guidance documents**, such as those prepared by ECHA for REACH and DG ENV for Directive 2010/63, provide a transparent knowledge-sharing tool, and regular updates to regulatory guidance documents are important. Terminology must be properly defined and clarified, for example 'hazard' and 'risk' can be confused terms. The differences in the various regulatory frameworks should be taken into consideration, what is said in general does not necessarily apply under specific legislation.

Alternative methods for regulatory use have business risks. In fact, more conservative regulators or industry scientists may prefer the 'easy choice' of the animal test to avoid failure within registration processes which consequently would have a high impact on the success of a product ('box ticking'). **Regulations should move away from 'data requirements'** (i.e., a list of required studies) **and more towards 'endpoint requirements'.** This would allow for flexibility in the methods used and improve chances of regulatory success using a combination of alternative methods rather than the traditional animal approach. In addition, in order to achieve a more effective use of alternative methods in the regulatory context, advice needs to be given to companies at an early stage of the authorisation process, and early involvement of regulators in scientific projects is important to get the buy-in on the most useful strategies. The question at a very early stage in the authorisation process is whether these proposed alternative methods or strategies can be accepted for regulatory purposes. The regulators themselves could provide advice to method developers through a 'consultation' service. In this context protocols could also be shared in a safe-harbour environment (a safe-harbour is a neutral place where data is deposited in full confidentiality). In certain regulated industries, such as pharma, animal welfare bodies established within the agencies working with the requirements of Directive 2010/63/EU on the protection of animals used for scientific purposes must play a role. They need to be aware of the alternatives, and advise staff accordingly, in order to avoid approving obsolete/unnecessary testing.

The interagency ECHA-EFSA-EMA project on common data submission forms across sectors may provide a unique opportunity to build metrics to track the use of alternative methods (e.g., the pharmaceutical sector currently provides a different format to other agencies, EFSA is looking into using IUCLID). Scientific committees such as the Scientific Committee on Consumer Safety (SCCS) should be included in this type of **across sector collaboration** having the largest experience by far in terms of regulatory use of alternative methods.

Regulators should **share knowledge of regulatory accepted cases**, by for example publishing success stories, as this information has a huge value for preparation of future dossiers as does retrospective analysis on the value of existing tests. Likewise, regulators and industry consortia counting for all sectors should exchange knowledge on alternatives. The European Partnership for Alternative Approaches to Animal Testing (EPAA) platform is an example of industry working together with the regulators across sectors covering cosmetics, pharmaceuticals, chemicals etc.

Communication between agencies should be facilitated for methods, tiered strategies and interpretation approaches and hazard and safety assessments which are very different across sectors and have become siloed with little exchange of data and misalignment of definitions and

protection goals, for example there is a lot of untapped knowledge in the cosmetics sector which uses only alternative methods. Better knowledge sharing is needed also under the umbrella of the EU Agencies Network on Scientific Advice (EU-ANSA) which brings together all EU regulatory agencies. A positive example of how close collaboration between regulator and industry can address the key question of what is acceptable in a dossier is that of the EMA J3Rs WG (Joint 3Rs working group). **Scientific advice** is given to companies when requested by two specific EMA scientific advice working parties (human and veterinary SAWPs). Companies can get advice also for specific 3Rs topics. The advice is free for small medicines entities (SME companies).

There could be regulatory data sharing sessions to capture international requirements by endpoint for example through the International Cooperation on Alternative Test Methods (ICATM). **Exchange of data** from retrospective analysis or prospective studies between industry and regulators provides an opportunity to give confidence on the use of alternative methods for regulatory purposes. The data is used to assess the value of a new method vs a reference method currently in use. Any confidentiality issues in data exchange could be addressed through a 'safe-harbour' model.

The OECD is a key player in any effort for **global and international harmonisation** and knowledge sharing. At OECD level it was considered important to harmonise testing strategies – and e.g., within the context of the UN GHS there should be regular harmonisation discussions.

Case studies for the use of alternative methods should be put forward in collaboration between regulators, industry and academia. This is being done to some extent in the OECD Working Party on Hazard Assessment (IATA case studies group). This should be followed up by OECD harmonised Integrated Approaches to Testing and Assessment (IATA) development embracing also defined approaches which are more fixed and easier to harmonise than IATA. In addition, it was considered important to delete obsolete data/information requirements. Industry should put together the evidence to propose the deletion of obsolete requirements and give examples. Furthermore, improvements could be made in the area of medical devices: where information could be shared on amendments of ISO standards with new *in vitro* methods with a good exchange between the key actors: ISO ↔ OECD ↔ ICH. Better communication and harmonisation is needed, feeding into and between these bodies as this area is disconnected from the alternative discussion.

It was put forward that industry should dare to submit data obtained with alternative methods with a robust reasoning behind it even if not yet accepted. There are examples where plant protection products were approved without fulfilling certain data requirements, and as a follow up, experience with real-case dossiers of positive and negative outcomes could be shared with different regulators to describe how alternative approaches were used and how interactions between industry and regulators could be improved in this context.

Finally, **stakeholder engagement** and **sociological aspects** should be considered by tackling societal/NGOs barriers in accepting alternatives for safety assessment, for example risk communication avoiding zero risk expectations and balancing the perception of uncertainties of current versus future methods, also in the area of food safety where *in vivo* based testing is considered more 'conservative'. By means of a sociological approach (analysing and changing attitudes of the population), promote acceptance of alternative methods and approaches at a broader population level, and help to foster a climate of change and innovation.

Annex I – Agenda

JRC Mission
As the science and knowledge service of the European Commission, the Joint Research Centre's mission is to support EU policies with independent evidence throughout the whole policy cycle.

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Agenda

Joint meeting of the Preliminary Assessment of Regulatory Relevance network (PARERE) and the ECVAM Stakeholder Forum (ESTAF)

JRC Ispra

28-29th November 2017

The European Commission's science and knowledge service
Joint Research Centre

Joint Research Centre

Joint meeting of the Preliminary Assessment of Regulatory Relevance network (PARERE) and the ECVAM Stakeholder Forum (ESTAF)

1st day: Tuesday 28th November 2017

Building 58 Auditorium

14:00-14:15	**Welcome and Introduction** *Elke Anklam (Director - Health, Consumers and Reference Materials)* *Maurice Whelan (Head of Unit - Chemical Safety and Alternative Methods)*
14:15-15:00	**Flash presentations on EURL ECVAM highlights** *EURL ECVAM*
15:00-15:30	**Question and Answer session for all**
15:30-15:45	Coffee break
15:45-18:15	**Plenary presentations on knowledge sharing for:**
15:45-16:30	**Research** *Catherine Verfaillie (University of Leuven)* *Lindsay Marshall (Humane Society International)*
16:30-17:15	**Education and Training** *François Busquet (Altertox)* *Annemarie Lang and Laura Behm (ReThink3R)*
17:15-18:00	**Regulatory Testing** *Marco Corvaro (Dow AgroSciences)* *Karin Kilian (DG Environment)*
18:00-18:15	**Working instructions for the breakout groups**
18:30	Departure
19:00	Aperitivo and dinner – *Hotel Conca Azzurra, Ranco*

JRC Ispra, 28-29th November 2017

2nd day: Wednesday 29th November 2017

Breakout rooms: Building 58, rooms 12a and 12b; Building 101, rooms 2002 and 2302

09:00-11:00	**Break out groups for discussion of the topics** **Research** *(Facilitators: Sofia Batista Leite and Francesca Pistollato, EURL ECVAM)* **Education and Training** *(Facilitators: Adelaide Dura and Tracey Holley, EURL ECVAM)* **Regulatory Testing** *(Facilitators: Sandra Coecke, Valérie Zuang and Andrew Worth, EURL ECVAM)* **Building 58 Auditorium**
11:00-11:30	Coffee break
11:30-12:30	**Reporting back and discussions on how to move forward**
12:30-13:00	**Wrap up**
13:00	Light buffet lunch and departures